INDEPENDENT REVIEW GROUP ON

RETENTION OF ORGANS AT POST-MORTEM

Final Report

NOVEMBER 2001
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Final report of the Independent Review Group on the
Retention of Organs at Post-Mortem
A copy of the main documents received by the Review Group during the course of its work, including transcripts of oral sessions, can be viewed on the Review Group’s website at www.show.scot.nhs.uk/scotorgrev.

A copy of the material is also available for public viewing at the Scottish Executive Library, located at Saughton House, Broomhouse Drive, Edinburgh. Those wishing to consult this material should telephone 0131-224 4552 to arrange an appointment. A list of the material, and a copy of it, can also be made available on request from the Scottish Executive Health Department, Area 2W (S), St Andrew’s House (telephone 0131-244 3194).
INTRODUCTION

1 The independent Review Group on the Retention of Organs at Post-Mortem is chaired by Professor Sheila McLean, Professor of Law and Ethics in Medicine at Glasgow University. The membership of the Review Group, which is shown at Appendix 1, was designed to reflect a range of expertise and incorporated medical professionals, and experts in legal and ethical issues. The independence of the Group was maintained through its predominantly non-NHS membership. The Review Group was established in September 2000 by Susan Deacon MPS, the Minister for Health and Community Care. Its remit was as follows:

To review previous post-mortem practice in Scotland, in particular in relation to organ retention, and current documentation on consent and guidance, taking account of developments across the UK; to develop a Code of Practice for Scotland with particular emphasis on issues of informed consent and the most effective mechanism for keeping that Code of Practice under review; and to clarify current legal issues with a view to making recommendations.

2 Phase 1 was essentially about helping families come to terms with the consequences of past practice, by restoring to them as much as possible the control of which they felt they had been robbed, particularly in relation to children. It made recommendations for dealing with the problems of the past, and we know from the parents’ support groups that in many cases these arrangements are proving effective. Phase 1 was very much about helping individuals. Phase 2 has been undertaken in the interests of the public good. Phase 2 is about the future; about moving forward from the uncertain legal basis which has underpinned hospital post-mortem practice since 1961, towards the identification of a sound legal system which recognises the strong impulse towards altruism and concern for others which motivates so many people. The creation of such a system will also help the hospital staff who need to discuss the possibility of a hospital post-mortem with those who, in life, were closest to the deceased.

3 A preliminary report was published in February 2001, and specifically reviewed past practices, making recommendations for change. The full report can be found at Appendix 2 to this document, and is also available on the Review Group’s website at http://www.show.scot.nhs.uk/scotorgrev, as is this report, along with a summary of our main recommendations.
From February 2001, the Review Group embarked on the second phase of its work. This entailed considering current legal provisions and making recommendations for change. It also involved the further development of an information leaflet and form of authorisation which can be found at Appendix 3. The remit of the Review Group allowed it to make wide-ranging investigations into the current law in respect of all aspects of this subject and this is reflected in the wide range of issues which it has considered and commented on. The Review Group held seven meetings during Phase 2. Its method of working was to identify the issues that needed to be addressed, picking up on the concerns expressed by families and health professionals about the current legal framework. Each of these topics formed the subject of a position paper written by the member or members of the Group with the greatest expertise in that subject. Each paper reviewed the state of the law in relation to that issue and outlined any ambiguities or deficiencies, as well as offering proposals for legislative change where appropriate. Following discussion by the Review Group, the essential points are included in this report. The Review Group has adopted a radical approach, made easier by the comparative lack of existing legal provision in many of the areas it investigated.

Once the Review Group’s recommendations had been clarified, a meeting was held with parents’ support groups on 15 October 2001, in order to explain to them the way in which the Review Group’s thinking had been evolving and to test the degree to which it satisfied their need to be sure that there could be no recurrence of past practice. Those who attended the meeting appeared to be satisfied with the thinking outlined.

PAPERS

Papers were produced by members of the Review Group on the following subjects:

- Research Ethics Committees: Problems, Principles and Proposals
- Parents, Children and Consent
- Critiques of Research Ethics Committees
- Role of Research Ethics Committees in Monitoring Research Undertaken on Tissue Removed at Post-Mortem
- Organs, Tissue Blocks and Slides
- Distinction between Organs and Tissue Blocks or Slides
- Confidentiality after Death
- Ownership and Commercialisation

- Human Tissues: Commercial Uses
- Family Rights and Decision-Making
- Is There An Intellectual Distinction Between Organs, and Tissue Blocks and Slides?
- Discussion paper on Research
- Stillbirths and Abortion
- Use of Retained Material/Research
- Disposal of Human Organs and Tissue Blocks: A Property Model?
- Property Rights
- The Defence Post-Mortem Examination
- Concepts of Consent, Permission and Control
- Who Has the Right to Consent to a Post-Mortem.

7 A wide range of other documents on similar matters, both from the United Kingdom and elsewhere, was consulted during the course of the work on Phase 2 of the Review Group’s remit.

8 In addition, there are a number of issues, which we describe as cognate issues, which – although not central to the work of the Group – we nonetheless regard as being of importance and worthy of further consideration by the Scottish Executive. A note of these can be found at Appendix 4. As this part of our work was heavily dominated by legal and ethical issues, the membership of the Review Group was modified.

9 In the course of the second phase, a number of initiatives have taken place to follow through our preliminary recommendations. These are highlighted below.

IMPLEMENTATION OF RECOMMENDATIONS FROM PHASE 1

10 Phase 1 of the Review Group’s work resulted in a series of recommendations and included a Code of Practice designed to ensure that, in future, hospital post-mortem examinations would take place, and organs retained from such examinations, only with the specific agreement of the relatives. Our recommendations were designed to ensure that the role of relatives, particularly of parents, is recognised and respected, helping to restore a climate of mutual confidence between relatives and hospital staff. We also underlined the role of the hospital post-mortem as part of the continuum of patient care.

11 The Review Group was pleased that the Scottish Executive gave a commitment, on publication of the report, to implement all of these
recommendations, and considerable work has been done since the report of Phase 1 was published on 6 February 2001 to take these forward.

12 As recommended by the Review Group, all NHS Trusts in Scotland have nominated a member of staff with a sound understanding of the issues, and the necessary sensitivity, to act as a liaison officer for inquiries from bereaved families. It has been made clear to Trusts that they are expected to provide as much information as they possibly can, as speedily and as sensitively as possible, when contacted by relatives. They have also been advised to follow the example of Yorkhill Hospital in meeting the burial or cremation costs where organs have been retained without proper consent.

13 The Clinical Standards Board for Scotland is currently drawing up national standards for hospital post-mortem practice across Scotland. These cover the main areas concerning: the general quality of the post-mortem examination, communication with relatives, storage, handling and disposal and record-keeping and audit. In keeping with the Board's constitution, there is strong non-NHS representation on the group drafting the standards which will also be subject to wide consultation before they are published. Once the draft standards have been published, the Board will hold public meetings to make sure the standards have general support. Once the standards have been finalised, groups of peer reviewers, again with a strong non-NHS component, will visit hospitals to determine whether or not the standards are being met. This is a core part of the work of NHSScotland, and the standards are mandatory: every hospital undertaking post-mortem examinations will be obliged to work to those standards. The Review Group is anxious to ensure there is consistency between the standards and its information leaflet, and will offer comments on the draft standards to ensure that this aim is met. The Review Group also understands that the work of the Board does not extend to post-mortem examinations carried out on the instructions of the Procurator Fiscal, but feels very strongly that those examinations should be performed to the same standard as hospital post-mortem examinations, and hopes the Board will find some way of conveying that message to the Lord Advocate.

14 The Review Group recognised the need for independent validation of the data provided by the Trusts on organs currently retained in Scottish hospitals. The Scottish Executive has invited Audit Scotland to undertake this work. The Review Group welcomes this decision. As this is a type of project which Audit Scotland has never undertaken before, and it has had no involvement in the organ retention issue, it is able to bring to bear exactly the sort of independence which the Review Group had in mind. Apart from validating the number of organs now held by Trusts, Audit Scotland's report will list the reasons for retention of currently held organs and provide a breakdown by child and adult of the total number of hospital and Procurator Fiscal post-
mortality examinations since 1948. Audit Scotland is also reviewing the systems which identify all currently held organs, tissues, blocks and slides. This will allow all Trusts to benefit from best practice in record-keeping, and will help them to respond as efficiently and effectively as possible to inquiries from families. Before publishing the report on their work, which is expected at the end of January 2002, Audit Scotland will share the results with the Review Group, and with parents’ support groups.

One of the main messages which came from bereaved relatives during the first phase of our work was the need for consistency of approach to this very sensitive subject across the country as a whole. We recommended, therefore, that a standard information leaflet and form should be drawn up for use across Scotland. These documents can be found at Appendix 3. The production of these has proved one of the more difficult tasks which the Review Group has had to undertake. The fundamental problem is that for so long as hospital post-mortem examinations are governed by the Human Tissue Act 1961, there is no option but to try to find a way of making its provisions work, even while taking account of the problems which the legislation has generated in the past. These problems are described in some detail in the main report which follows. Because the revised leaflet and form are in many ways a radical departure from anything which has been used before, the Review Group wishes them to be subject to widespread consultation amongst both support groups and health professionals. It also believes that it would be helpful to pilot their use in a particular Trust in order to assess their effectiveness, and looks to the Scottish Executive to arrange this. The Review Group is particularly concerned to ensure that the leaflet and form give the information they need to relatives who wish to know, while protecting the position of those who do not want to be made aware of all the details.

It also became evident during our scrutiny of past practice that there is a need for fundamental changes in the culture in NHS Scotland with regard to the whole process of discussing with relatives the possibility of a hospital post-mortem examination. The Review Group was encouraged by the decision of the Minister for Health and Community Care to ask the Chief Medical Officer to take forward this recommendation. He has been working with the Deans of Scotland’s Medical Schools and with the Medical Directors of Trusts to bring about the necessary changes, particularly the development of new teaching and training programmes. These should take account of the new national form, as its completion will require a high degree of sensitivity towards the attitude of the relatives. We hope that the design of the form will also help to guide health professionals through the complexities and sensitivities surrounding the hospital post-mortem examination. The role of
family support groups as a teaching resource should be explored. The Review Group is also aware that the Scottish Executive is considering the nature of the bereavement support provided by NHSScotland as part of its response to the final report from the Bristol Royal Infirmary inquiry.

17 The issue of research involving organs, tissue blocks and slides retained under past practice is dealt with in paragraphs 47-50 and 121-123.

18 The recommendations of the Review Group with regard Procurator Fiscal post-mortem examinations were formally referred to the Lord Advocate by the Minister for Health and Community Care on 9 May 2001. The Lord Advocate replied on 13 June 2001 indicating that the recommendations had been considered by his officials and that revised guidance would be issued to Procurators Fiscal to take the recommendations forward. In tandem with this, the Procurator Fiscal’s office in Glasgow has implemented a joint scheme with the Department of Forensic Medicine and Science at the University of Glasgow to set up ‘Next of Kin Interview Clinics’. The purpose of these clinics is to allow an opportunity for interviews to be conducted with the relatives of deceased persons on whom a post-mortem examination has been carried out on behalf of the Procurator Fiscal. The interviews are conducted by the pathologist responsible for the post-mortem examination, and the Procurator Fiscal to whom the death was reported. Schemes such as these embody the sensitivities that we espouse and we support the expansion of these clinics throughout Scotland.

19 We know that many parents have been distressed at the thought that the publicity, sometimes sensational and inaccurate, which the issue of organ retention has attracted, may have had an adverse effect on the number of organs becoming available for transplantation. We too have been concerned at the apparent confusion between the issues of organ retention at post-mortem examination and organ donation for transplantation purposes. We have therefore been encouraged to discover from UK Transplant that the adverse publicity appears, so far, to have had no damaging effect on organ donor numbers. In framing our recommendations for amendments to the existing legislation, we have been very mindful of the fact that the 1961 Act also forms the legal basis for the donation of organs for transplantation. We would be extremely concerned were the implementation of any of our recommendations to impact adversely on organ transplantation programmes, in particular the work of transplant co-ordinators who approach relatives about the possibility of donation taking place. Some of the issues we touch on, particularly the weight to be given to the wishes of the deceased, as opposed to their surviving relatives, are central to the process of seeking agreement to organ
donation. Organ donation is outwith our remit, but we suggest that the Scottish Executive, in implementing any changes to existing legislation as a result of this report, will need to think very carefully about whether it should also be looking at the legislative basis for organ donation, and suggest this is something the Scottish Transplant Group could be asked to investigate. Any revision of the 1961 Act must take this into account and ensure that a clear structure also exists in respect of organ transplantation, either by way of a clarified combined Act or by way of a stand-alone statute dealing with transplantation. The Review Group is aware that the law in respect of organ transplantation is currently under consideration in the Scottish Parliament’s Health & Community Care Committee.
LEGAL BACKGROUND

The Human Tissue Act 1961

20. As this is central to the work of the Review Group, its text is given here in full, as amended by the Anatomy Act 1984 and the Corneal Tissue Act 1986:

An Act to make provision with respect to the use of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research and with respect to the circumstances in which post-mortem examination may be carried out.

Section 1: Removal of parts of bodies for medical purposes

(1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.

(2) Without prejudice to the foregoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe –

(a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or

(b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.

(3) Subject to subsections (4), (4A) and (5) of this section, the removal and use of any part of a body in accordance with an authority given in pursuance of this section shall be lawful.

(4) No such removal, except of eyes or parts of eyes, shall be effected except by a registered medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct.

(4A) No such removal of an eye or part of an eye shall be effected except by –

(b) a registered medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct; or

(c) a person in the employment of a health authority or NHS Trust acting on the instructions of a registered medical practitioner who must, before giving those instructions, be satisfied that the person in question is sufficiently qualified and trained to perform the removal competently and must also either:

(i) have satisfied himself by personal examination of the body that life is extinct, or

(ii) be satisfied that life is extinct on the basis of a statement to that effect by a registered medical practitioner who has satisfied himself by personal examination of the body that life is extinct.

(5) Where a person has reason to believe that an inquest may be required to be held on any body or that a post-mortem examination of any body may be required by the coroner, he shall not, except with the consent of the coroner –

(a) give an authority under this section in respect of the body; or

(b) act on such an authority given by any other person.

(6) No authority shall be given under this section in respect of any body by a person entrusted with the body for the purpose only of its interment or cremation.

(7) In the case of a body lying in a hospital, nursing home or other institution, any authority under this section may be given on behalf of the person having the control and management thereof by any officer or person designated for that purpose by the first-mentioned person.

(8) Nothing in this section shall be construed as rendering unlawful any dealing with, or with any part of, the body of a deceased person which is lawful apart from this Act.

(9) In the application of this section to Scotland, for subsection (5) there shall be substituted the following subsection:-

(5) Nothing in this subsection shall authorise the removal of any part from a body in any case where the procurator fiscal has objected to such removal.
(10) In this section “health authority”-

(a) in relation to England and Wales, means a Health Authority established under s 8 of the National Health Service Act 1977 or a Special Health Authority established under section 11 of that Act;

(b) in relation to Scotland, means a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978 and “NHS trust” means a National Health Service trust established under the National Health Service and Community Care Act 1990 or the National Health Service (Scotland) Act 1978

2. Post-Mortem Examinations

(2) No post-mortem examination shall be carried out otherwise than by or in accordance with the instructions of a fully registered medical practitioner, and no post-mortem examination which is not directed or requested by the coroner or any other competent legal authority shall be carried out without the authority of the person lawfully in possession of the body; and subsections (2), (5), (6) and (7) of section one of this Act shall, with the necessary modifications, apply with respect to the giving of that authority.

21 The Anatomy Act 1984. The main sections relevant to the Review Group’s work are sections 1 – 6.

22 The Access to Medical Records Act 1990. This was substantially amended by the Data Protection Act 1998, which limited those who can obtain access under the 1990 Act to, in effect, the patient’s personal representatives and any person who may have a claim arising out of the patient’s death.

23 Human Rights Issues. The European Convention on Human Rights has been relevant in Scotland for a number of decades. However, it has gained greater significance with the coming into effect of the Scotland Act 1998, so far as the actings of the Scottish Executive and the Scottish Parliament are concerned, and in respect of public authorities due to the implementation of the Human Rights Act 1998. While the Convention proceeds on the basis of a legal person securing rights and freedoms under the Convention, and therefore cannot be invoked by those who are deceased, there may well be rights and freedoms a living person may wish to enforce arising out of, or after the death of, another person.
In particular, Article 2 (right to life), Article 3 (prohibition of torture), Article 8 (right to respect for private and family life) and Article 9 (freedom of thought, conscience and religion) would appear to be the Articles most relevant to consideration of the issues considered by this committee. This list, however, is not exhaustive.

In addition, the new proposed legislation on Freedom of Information in the Scottish Parliament and the European Convention on Human Rights and Biomedicine, which has not yet been adopted by the UK Government, may well also have relevance.

These issues and considerations must therefore be looked at against the background of the Convention and other rights. However, the issues which we have looked at are not capable of general guidance against a developing legislative framework, and how the Convention and other legislation will have effect, must be a matter for the particular circumstances of each case.

Devolution. The Human Tissue Act 1961 is not reserved to the Westminster Parliament because it is not listed in Schedule 5 to the Scotland Act. This means that the Scottish Parliament has the competence to amend the Act as far as Scotland is concerned, and the Review Group has taken full advantage of that situation. Given the problems both of style and of content in the Human Tissue Act 1961, the Review Group strongly recommends that it should be replaced by new legislation taking full account of our recommendations. The Review Group is aware, however, that there is similar work under way in other parts of the UK, and has attempted to keep abreast of that. Just as the family support groups have made it clear that they value consistency of approach across Scotland, the Review Group believes broad consistency across the UK is valuable too, and during the rest of its existence it will keep in touch with proposals as they develop in other parts of the UK, to ensure consistency and to share good ideas about the best means of making provision for the future. Some issues, however, such as regulation of the health professions, data protection and genetics are reserved to Westminster, and the Review Group has taken this into account in shaping its recommendations. This is another reason for wanting to maintain a broad UK approach.

The process of completing this report has been greatly assisted by the support groups we have already referred to. We have met with them on a number of occasions and have striven to ensure that they have been kept well informed of our thinking. We are grateful to them for their helpful input to the terms of the report and for sharing their own difficult personal experiences with us. We wish to acknowledge their willingness to co-operate in producing a new
legal template which should ensure that, in the future, other families will be able to have confidence that their legitimate interests in a deceased relative – particularly where that relative is a child – will be dealt with sensitively and honestly, and will be respected. We also hope that those families who have not wished to become involved do not feel that their private grief has been intruded upon any more than was absolutely necessary for completion of this task. We also wish to acknowledge the co-operation of hospitals and medical staff and their willingness to move forward.
Given the problems both of style and of content in the Human Tissue Act 1961, we recommend that it should be replaced by new legislation taking full account of our recommendations.

**FISCAL POST-MORTEM EXAMINATIONS**

We have already issued recommendations to the Lord Advocate and the Crown Office and the Procurator Fiscal Service are taking account of these recommendations in ongoing work to improve the delivery of services to bereaved relatives.

**HOSPITAL POST-MORTEM EXAMINATIONS**

We are of the view that the use of the word ‘consent’ as currently legally understood is inappropriate and misleading in the context of post-mortem examination and the removal, retention and use of organs/tissue. Accordingly, we recommend that this should be replaced by the word ‘authorisation’. The limitations of the terminology of consent are particularly acute in the case of the death of a child, in that parents are given lawful authority to consent only where that decision is ‘in the best interests’ of the child. It is difficult to apply the best interests concept in the circumstances covered by this report. We are unwilling to import into new legislation any language which is inappropriate or capable of misunderstanding. The Review Group is aware that the word ‘authorise’ is currently used in the Human Tissue Act in respect of the person in lawful possession of the body. However, it must be clearly understood that as used in this present context, the word authorisation has been carefully selected for a number of reasons. We are firmly committed to its use, which emphasises our view that there is a need for repeal or substantial revision of the terms of Human Tissue Act.

**INFANTS AND YOUNG CHILDREN**

Recognition of the intimate bond between parent and child, and the privacy of the family unit, reinforces the priority of parental decision making for their infants and young children even after death. For this reason, we recommend that amendments to the law in respect of post-mortem examinations of infants and young children recognise this bond by requiring the authorisation of the parent(s) for any such examination.

**THE MATURE CHILD**

The mature child – that is, one who is legally competent – is in a different situation in law. Thus, although it is likely to be a rare occurrence, we
recommend that where such a child has left prior authorisation for a post-mortem examination, his/her wishes should be respected by law. Where no such wishes have been left, the power to authorise a post-mortem examination rests with the parent(s) of the mature child.

THE ADULT

6 At present, it would seem likely that where an adult provides authorisation for post-mortem examination, this will have been done under the terms of the Anatomy Act 1984. The Human Tissue Act as currently phrased seems to give no authority for an adult to authorise in advance of death the conduct of a post-mortem examination. We regard this as one of the anomalies of the current legal position, and as one which should be clarified in reforming legislation (see also paragraphs 11, 29 and 31 below).

INFORMATION ABOUT THE POST-MORTEM EXAMINATION

7 We have devised an information leaflet which can be found at Appendix 3 of this report. We have also devised standard authorisation forms for adult and paediatric hospital post-mortem examinations. We recommend that this leaflet and the associated forms should be used throughout Scotland.

AUTHORISING A POST-MORTEM EXAMINATION

Infants and Young Children

8 We have already indicated that a parent or parents have the authority to authorise a post-mortem examination in respect of their children. However, the Review Group has also addressed the situation where parents with authority to agree to a post-mortem examination are in dispute with each other over whether or not the examination should go ahead. If a full and frank discussion with the refusing parent as to the reasons for, and potential benefits of, a post-mortem examination does not lead to an agreement, then it would, we believe, be difficult to proceed. In addition, we also recognise that there may be others who have a legitimate interest in the deceased child, such as partners or step-parents who may have reared the child, and that some biological parents may have played no part in the rearing of the child. We believe this to be a very complex issue, and recommend that there should be further consultation on this matter, which is in urgent need of clarification.

Mature Children

9 We have noted that parental powers in respect of younger children are different in law from those that they hold in respect of mature children. However, this should not be taken to imply that – where the deceased child has indicated no preferences before death – the involvement of parents should
be any less. The familial bonds we describe will also operate in these circumstances to provide parents with the authority to decide in the absence of the expressed views of the mature child. Thus, our recommendations in respect of the mature child who has expressed no views are the same as those in respect of the young child. In the event of a dispute between parents, we would also endorse our recommendation in paragraph 8, above.

10 In circumstances where the mature child has left express wishes, we recommend that these should be treated as being equivalent to those of an adult.

Adults

11 It is our conclusion that the Human Tissue Act 1961, while not actually denying it, does not positively provide to the adult person the authority to agree in advance to a post-mortem examination for diagnostic purposes. We recommend that the law in this area, and in particular the relationship between the Human Tissue Act 1961 and the Anatomy Act 1984, be reviewed and clarified as a matter of urgency. In our view, this lack of clarity reinforces our earlier recommendation that a new statute is urgently needed in this area.

CONFIDENTIALITY AND THE POST-MORTEM EXAMINATION

12 Issues arise concerning the confidentiality of information which is derived from a post-mortem examination, since it is generally expected that information about the health status of a person should be maintained in confidence. This rule, however, is of uncertain application after death, at least in some situations. We therefore believe it to be necessary that the position of such information is clarified.

CONFIDENTIALITY AND YOUNG CHILDREN

13 We recommend that the general rule should be that information about the findings of a post-mortem examination on a young child should be made fully available to the parent(s) who have authorised it, if they wish to receive that information.

14 We recognise, however, that there may be particular sensitivities about certain kinds of information. For example, there may be reasons why a parent or parents would not wish to receive information about a genetic condition, as this will necessarily have an impact on any existing or future children, and indeed may tell them something about their own genetic status that they may prefer not to know. This is clearly a complex issue and we recommend that it be drawn to the attention of the Human Genetics Commission, which we understand is currently considering the general question of personal genetic information.
CONFIDENTIALITY AND MATURE CHILDREN/ADULTS

15 In line with our earlier recommendations, where specific directions have been left by a mature child, we recommend that the law should be clarified so as to ensure that these directions are given full effect. (Subject to the qualifications in paragraph 17, below.)

16 Where no such directions are left, the situation as to confidentiality of information should be the same as that in respect of the infant or young child.

17 We recommend that any directions as to confidentiality of information left by a deceased adult person should be followed. Where no directions have been left by a deceased adult (or a mature child) or there is reason to believe that the health of another person may be affected by the medical condition of the deceased, we believe the present legal position to lack clarity over whose interests should prevail. Any new legislation in respect of this matter should, therefore, address this point specifically, with particular attention being paid to the implications of genetic information, and taking account of the results of any inquiry on this subject by the Human Genetics Commission.

18 We further recommend that the relevant terms of the Access to Medical Records 1990 Act (as amended), data protection and freedom of information legislation should be clarified in respect of the confidential status of medical information after the individual’s death.

GENERAL

19 The question of when does confidential information become historical fact remains. It seems that medical records of patients treated within the NHS in Scotland come within the scope of the Public Records (Scotland) Act 1937. We believe it to be important that the question of when otherwise confidential medical information may be made publicly available requires clarification.

AUTHORISATION FOR THE RETENTION AND USE OF ORGANS AND TISSUES

Infants and Young Children

20 The principles that have guided our approach to the provision of authorisation for a post-mortem examination are equally relevant to the removal and retention of organs or tissue at or following an authorised post-mortem examination. Most of the concerns expressed to the Review Group related to this issue. The evidence received by the Review Group suggests that there is more cause for concern about the quality of the information provided about the possible removal, retention and use of tissues or organs than there is about the post-mortem examination itself.
We have already made it clear that parents should have the ultimate authority to authorise or refuse a hospital post-mortem examination in respect of their child. It must be equally clear that they have exactly the same authority in respect of the removal and retention of organs and major pieces of tissue. Amendments to current law must clarify this position.

But there are also practical implications which flow from this conclusion. Where parents wish to receive information about the post-mortem examination, it must be made clear to them that in some cases a post-mortem examination, if it is to be properly and professionally carried out, will require the removal from the body of certain organs, and possibly their retention in the ‘fixed’ state for some 4 – 6 weeks. It must be made absolutely clear to parents that this is the case, and options must be presented to them in terms of the funeral arrangements for their child or the separate disposal of organs. Some parents may prefer to bury the child only after the organs have been returned to the body, necessitating delay in the funeral. Still others may prefer to have the organs returned to them after analysis for separate burial or cremation; some may prefer the hospital to dispose of the organs and yet others may wish to authorise the use of the organs for educational or research purposes. We recommend that each of these options should be clearly explained to parents before their authorisation to proceed with a post-mortem examination is sought (unless the parents do not wish to receive this information) in circumstances which provide them with adequate explanation and time to come to terms with them. Particular sensitivity will be required of those who have the responsibility of providing this information to bereaved parents.

We note that other committees of inquiry have indicated their support for the appointment of bereavement officers in hospitals, and indeed this suggestion was also made to us by some witnesses. While we commend the further development of such a role in hospitals, we believe that families should nonetheless be entitled to discuss these sensitive matters with an appropriate individual of their choice, such as the clinician involved with the care of their relative. This will require that hospitals will need to ensure the availability of individual healthcare providers, and reinforces our earlier recommendations (see our preliminary report) about education and training of hospital staff, and the availability of appropriate facilities in which any such discussions can take place.

Some families will not wish to be given information of this sort. Where this refusal of information is coupled with a refusal to provide authorisation for a post-mortem examination or the removal or retention of organs, these wishes should be respected.
25 Other families may not wish to receive any information, but not object to the retention and use of organs. Where this is the case, we recommend that organs or tissue may be retained and used for legitimate medical education or research. In all cases, families should be given the opportunity of taking home a copy of our information leaflet, and those discussing these matters with families should ensure that the wishes of the family are clearly and accurately recorded on our authorisation form, a copy of which should also be provided to the family.

The Mature Child

26 The mature child has the power to direct the uses which can be made of his or her body after death. Where no such direction has been competently given, authority should rest with the parent(s), and be subject to the same conditions outlined above.

The Adult

27 Where a competent adult has left written instructions on this matter, these wishes should be respected, irrespective of the views of surviving relatives. The current legal requirement to discover whether or not this agreement has been withdrawn should remain, but it must be clear that the relatives have no legal role in circumstances where the deceased has made known, and not retracted, his or her wishes.

28 In order that this recommendation is not unduly insensitive to the feelings of relatives, we also recommend that individuals wishing to make such instructions should discuss this matter with those relatives before death, wherever possible.

29 We note that the Human Tissue Act 1961 currently provides that directions made 'orally in the presence of two or more witnesses during his last illness' may provide the person lawfully in possession of the body with the authority to use the body or specified parts of the body after death. We are concerned that verbal agreement is currently lawful only if provided in the course of a final illness. This seems an unnecessary constraint on the individual's freedom to make decisions. Although it may be that written authorisation carries more apparent weight than verbal authorisation, we do not subscribe to the view that only written agreement is valid when the decision is made in the absence of a final illness. We recommend, therefore, that a competently expressed verbal agreement at any stage of adult life should be sufficient in law to permit the directions to be carried out and that any new legislation should make this clear.

30 In cases where no such directions have been left, the law currently requires that a reasonable enquiry is made by the person in lawful possession of the body to ascertain whether or not the deceased had objected to such use.
during his or her lifetime, and whether any surviving relative objects. Even although the existing legislation is poorly phrased, we believe it implies that the wishes of the deceased should be those which count. We reiterate our view that it is for the deceased during his or her lifetime to direct, if they so wish, what is to be done with their body after death. Where the adult has left no explicit directions, a similar regime should be in place to that which we have already recommended in respect of the post-mortem examination itself. In other words, authorisation should be sought from the appropriate third party.

31 We note that current law gives authority to the spouse or any surviving relative in these circumstances. There may be very good reasons why a spouse should be given such power, and this is a position with which we are in general agreement (although it is true to say that this would not always be the case given that spouses may be separated or otherwise in dispute). However, we note that, even where spouses have been in compatible co-habitation, according to the terms of the current legislation, their views are given no more than equal significance to those of any surviving relative, however distant. This situation appears to us to be inappropriate. Where what is being sought is the authorisation to proceed with removal and use of organs at post-mortem examination we recommend that the amended law should seek to prioritise those with the closest relationship to the deceased person. It is important that the provisions of legislation should not ignore the reality of many contemporary relationships, which may, for example, not involve marriage or may be of single sex. If the aim of the legislation is to seek authorisation from the person who is most likely to be affected by the decision, then we believe that amended legislation should take account of the reality of the arrangements in which many adults now live by making provision for those most closely linked to the person – whether or not by marriage – to be given the right to authorise the use of organs post-mortem or to refuse to provide such authorisation.

Sanctions

32 We recommend that retention of organs and tissues in the absence of appropriate authorisation, or failure to adhere to the terms of any authorisation given, should be subject to a penalty imposed by law.

Tissue Blocks and Slides

33 The preparation of tissue blocks and slides is an important part of a thorough post-mortem examination. We recommend, therefore, that in seeking to gain authorisation for a post-mortem examination, it should be made clear to those whose authorisation is being sought that, in the absence of a specific objection, the preparation of blocks and slides will be regarded as an integral part of that authorisation, unless they have indicated that they do not wish to receive information of this sort.
34 We are clear that no pressure should be put on the bereaved to agree to this, and that sensitivity must be shown to those who have, for example, religious objections.

35 We further recommend that once a properly informed decision has been made to authorise a post-mortem examination, including the preparation of tissue blocks and slides, interest in the prepared blocks and slides should pass to the hospital authority who may retain and use them as part of the hospital record, or for legitimate research and educational purposes.

MEDICAL EDUCATION AND RESEARCH

36 The value of medical education and research is, we believe, incontrovertible. Indeed, as we have noted, this value was fully endorsed by all of the families who gave evidence to the Review Group.

37 We recommend that it is made clear in the form authorising a hospital post-mortem examination that authorisation for the research use of retained organs and tissue can be either specific or general. However, for this to satisfy the interests of the surviving families, information about research uses should be freely and publicly available.

38 We further recommend that those with the legal capacity to authorise such retention and use should be informed that they can change their mind at any time. We accept that, if this occurs in the course of a research project, it may have an adverse effect on the specific research, but this should occur only very rarely if proper authorisation has been obtained in the first place and people have been given the chance to register any objections to specific kinds of research.

SCRUTINY OF MEDICAL RESEARCH

39 At present, medical research undertaken on NHS patients is scrutinised by Local Research Ethics Committees (or in some cases by Multi-Centre Research Ethics Committees). These Committees are designed to ensure that any research undertaken meets certain scientific and ethical requirements.

40 We are concerned that the current framework may, in some situations, be insufficiently robust to ensure that the ongoing conduct of research is adequately monitored. For this reason, we recommend that consideration should be given to placing such committees on a statutory basis, with specific and clear powers given to the committees to monitor the conduct of research projects.

41 We also recommend that issues concerning membership and training of ethics committees should be addressed as part of our recommendations for reform.
42 We recognise that reform of the law in this area may take some time, although we consider that it is a matter of some urgency. We recommend, therefore, that the Independent Review Group (or equivalent) should remain in place until reform of the law has been completed, with a specific remit to provide ethical review of all research projects involving human tissue removed from deceased persons.

43 In some circumstances, non-invasive research may be conducted on retained slides in order to improve diagnosis. For example, in the case of cot deaths, lawfully retained slides may be stained as a way of identifying a true cot death. Such non-structured research does not currently require ethics committee approval, and we do not recommend that it should.

44 It is clear that there may be financial issues surrounding the use of human organs or tissue for research purposes. We do not commend the use of concepts such as ‘ownership’ in respect of parts of the human body, although we do recognise that it is no longer appropriate to suggest that the human body has no value in financial terms. We recommend that the law should be clarified in this area.

45 Research may also result in the availability of genetic information which, as we have already noted, may be highly sensitive – even unwanted. We recommend that this matter be referred to the Human Genetics Commission for their consideration as a matter of urgency.

GENERAL

46 We recommend that an advertising campaign is prepared and launched to ensure that families are aware of our recommendations and of their rights. The campaign should be sufficiently sensitive to ensure that those who wish to receive information may do so, while at the same time recognising the sensitivities of those who do not wish to know.

47 In May 2001, the Review Group received a communication from representatives of the following support groups: the Association for Children with Heart Disorders, the Scottish Cot Death Trust, the Scottish Organisation Relating to Retention of Organs at Post-Mortem (SORRO) and the Stillbirth and Neonatal Death Society (SANDS), concerning the recommendation in our preliminary report that there should be a 5-year moratorium on the use of unclaimed organs and tissue. Their concern was that this might mean that valuable research would be unable to proceed during that time, with potentially harmful consequences for families and individuals. We respect their concern in this matter.
48 We accordingly recommend that the 5-year recommendation is modified in the following way. As part of the continuing campaign to inform relatives of their rights in this respect, it should be made clear that research which is non-destructive and important may be carried out on currently retained tissue after a period of one year from the start of the 5-year period. By non-destructive, we mean research which is either observational or which requires only minute samples of the tissue, and by important we mean where the research is evaluated as being likely to make a significant contribution to diagnosis or therapy.

49 As we have said, we recognise that for some families the removal of even the smallest sample of tissue is objectionable. The advertising campaign, therefore, must encourage those who object even to this limited research to make that objection known, even if they have not yet decided whether they wish to be given information about any retained samples or what they ultimately wish to be done with such material.

50 We also recommend that it is made clear that parents can, as of now, specifically authorise the use of any retained tissue for research purposes. Even if they are unsure about whether or not tissue has been retained, and even if they do not wish to know, they can contact the hospital concerned at any time to provide such authorisation. Hospitals should, therefore, continue to provide a dedicated telephone number for these purposes and produce clear and accurate records of any discussions that take place on this issue.

51 We recommend that any tissue still in existence at the end of the 5-year period can be reclaimed by those who provided authorisation for its removal and retention in the first place.

52 We additionally recommend that unclaimed tissue at the end of the 5-year period should be legally deemed to be under the authority of the relevant hospital authority, which may make use of it for legitimate research or educational projects, or must ensure its respectful disposal. This would also mean that the material could be available for return even after the expiry of the 5-year period.
In its preliminary report, published in February 2001, the Independent Review Group on the Retention of Organs at Post-Mortem summarised the goals for the future in this way:

Public confidence has clearly been severely shaken by the events which have unfolded over recent times both in Scotland and in England. It is vital that trust is re-established in order that relatives can be confident that they, and their relatives, are treated with the utmost sensitivity by hospitals and that legitimate medical research is able to continue.¹

The legitimate concerns both of many of the families who gave evidence to the Review Group, and of the wider public, pointed the Review Group clearly to some fundamental matters which have formed the basis of the second phase of its work. Although not every family who gave evidence to us felt the same way, the majority undoubtedly believed that reform of past practices was necessary. As we noted in our preliminary report, those families who have been through the trauma of discovering that organs or tissue have been taken from their relatives without their knowledge or agreement did not dispute the value of medical education and research. Rather they objected strongly to the fact that this had been done without their knowledge and agreement. It is not in dispute by families, the medical professions or this committee that such practice is unacceptable. Indeed, as we noted in our earlier report, even although it would appear that this was common and accepted practice, this does not mean that it was not open to challenge at the time.

Few people are familiar with the purposes and techniques of the post-mortem examination and there is no doubt that explaining these to newly bereaved relatives² may be difficult and disturbing for both the family and the doctor. The additional distress generated mandates the creation of a system within which the essential information can be delivered sensitively and clearly and in a way that can be easily understood. The Independent Review Group has always envisaged the main function of its Phase 2 work as being to improve that understanding and this constitutes the main purpose of the report. In so doing, the Review Group, in this second phase of its work, has addressed the legal regulation surrounding post-mortem examinations and practice, and makes a number of recommendations for law reform.

¹ Paragraph 22
² In using words such as ‘families’ and ‘relatives’ we do not mean to preclude others who have formed a close bond with the deceased. This will be considered in more detail in the section concerned with adult deaths.
Post-mortem examination of the human body is governed, in the main, by two statutes; the Human Tissue Act 1961 and the Anatomy Act 1984. The latter is specifically directed to examination of the body in the dissecting room for educational purposes. It, therefore, has a limited, but still significant, role to play in the work of the Review Group. The Human Tissue Act, by contrast, is described as:

An Act to make provision with respect to the use of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research and with respect to the circumstances in which post-mortem examination may be carried out,

which is a far wider remit.

It is, in a way, unfortunate that the 1961 Act deals with both organ transplantation and post-mortem examination, since attitudes to each may be very different. The Review Group was not asked to consider organ transplantation and, unless there is a useful comparative point to be made, we will confine ourselves to the research or educational use of body parts that are obtained during the routine post-mortem examination.

Of course, there may be certain limitations on the information which can be discussed with families where a post-mortem examination is carried out on the instructions of the Procurator Fiscal. Such limitations may arise, for example, where disclosure of information might impede an investigation. The majority of this report relates to the hospital post-mortem examination. Although many of the problems which have been exposed appear to have related to post-mortem examinations carried out on the instructions of the Procurator Fiscal, the Review Group has already issued recommendations to the Lord Advocate, and the Crown Office and Procurator Fiscal Service are taking account of these recommendations in ongoing work to improve the delivery of services to bereaved relatives. Broadly, the Review Group concluded that:

... these post mortems must be dealt with in as sensitive a manner as are hospital post mortems. Bereaved individuals must be given time to deal with the information on an occasion of great personal loss. The information provided should be expressed in clear language, and such information as relatives wish to receive should be made available to them by the Procurator Fiscal.

The Crown Office and Procurator Fiscal Service are implementing a number of initiatives to support its strategic aim of improving services to victims, witnesses and bereaved next of kin. Of particular importance is the

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1 but see our comments in paragraph 27 above

2 Paragraph 13
development of the Victim Liaison Office. This initiative will involve the establishment of a Division of the Crown Office and Procurator Fiscal Service which will be devoted, inter alia, to the provision of information to victims of serious crime, to certain categories of witness and to the bereaved next of kin when a death is under investigation. Pilot Victim Liaison Office sites are operational in Aberdeen and Hamilton and there are plans to establish further offices by Spring 2002. This initiative will complement services currently available to bereaved families. These include:

- Attendance at meetings with Procurators Fiscal to discuss the findings of deaths investigations and to express a view in relation to the holding of a Fatal Accident Inquiry.
- Involvement in ‘pathology clinics’ where relatives have an opportunity to discuss the findings of the post-mortem examination with the pathologist and the Procurator Fiscal.5

In general, the Lord Advocate has welcomed the Review Group’s preliminary report and indicated his acceptance of the spirit of our recommendations. The Crown Office and Procurator Fiscal Service is currently working towards implementation of the recommendations, subject only to such modification as is necessary to take account of operational logistics and necessary differences in local arrangements.

8 Problems of ‘consent’ or authorisation lie at the heart of the Review Group’s discussions, and we must make it clear that there is no need for consent or agreement to be sought for post-mortem examinations which are instructed by the Procurator Fiscal. That is a matter of law. However, in those which are carried out by hospital staff to clarify and/or enhance diagnosis, it might reasonably be anticipated that some form of permission should be obtained before touching the dead body just as it must be in the case of the living.6 Currently the law governing post-mortem examination is broadly speaking covered by a combination of common and statute law. The terms of the Human Tissue Act are relevant, as also is the common law.

AUTHORISATION AND POST-MORTEM EXAMINATIONS

9 For the sake of clarity, the Review group felt it necessary to consider this matter sequentially by age group as the law is not the same in respect of each group.

The Infant or Young Child

10 At common law, parents are given legal authority to make certain decisions – including health care decisions – for their children, within certain constraints.

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5 Because of operational logistics these clinics will not be available everywhere.
6 In some adult cases, of course, the deceased will, during life, have expressed a view on post-mortem examination. This will be discussed in more detail in the section dealing with adults.
As Lord Fraser said in the case of Gillick v West Norfolk and Wisbech Area Health Authority\(^7\) [p]arental rights to control a child do not exist for the benefit of the parent. They exist for the benefit of the child.\(^8\) The primary constraint on the exercise of parental authority is that the decision taken must be seen to be in the ‘best interests’ of the child, otherwise its legal standing can be challenged. It is also clear that parental power may be relatively wide, in that ‘best interests’ may not necessarily be limited, or equivalent, to best medical interests. In other words, courts may hold that, even although parental decisions may result in going against the best medical advice, they may nonetheless be given effect.\(^9\)

However, this apparently simple statement of the common law disguises some underlying problems which the Review Group has addressed. It is absolutely clear to us, as it was to the inquiries held in England, that parents must have overriding authority in respect of consent to hospital post-mortem examinations in respect of young children.\(^10\) However, it is not quite so clear that the most effective way of doing this is simply by use of the language of consent as currently understood in law. As we have said, the authority granted to parents by the common law of consent is confined to decisions which are in the ‘best interests’ of their child(ren). It is understandably difficult to find a use for the notion of ‘best interests’ in the context of the deceased. It might, perhaps, be argued that, since the post-mortem examination of a child may be in the best interests of surviving or future family members, and since the interests of many others may be enhanced by accurate diagnosis, sound medical research and the proper education and training of doctors, the deceased child, as a member of the family concerned, or simply of the ‘human family’, has a continuing interest (albeit not an experienced one) in these benefits of his or her brief life and untimely death accruing to others. But this interpretation of interests, while possible, is also contestable. It expands the concept too broadly to be safely used in the context of any attempt to develop the common law understanding of parental consent, which interprets ‘best interests’ in terms of benefit accruing to the child him or herself.

As will become clear later, the Review Group is concerned to ensure that the law in the future should be a significant improvement on the current law. Although consent (in a non-legal sense) is a word commonly used in everyday language, we are reluctant to propose law reform that is based on wording which is inherently inappropriate in this context. While we are still formally committed to recognising and endorsing the vital interests of

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\(^7\) [1985] 3 All ER 402  
\(^8\) at p. 410  
\(^9\) Re T (a minor) (wardship: medical treatment) [1997] 1 All ER 906  
\(^10\) the position of the mature child will be considered later
bereaved parents, we are anxious not to import the legal concept of consent as it is presently understood into our proposals for change.

13 Thus, the Review Group explored other possible avenues which might explain the legitimacy of the role of parents clearly and unequivocally. One possible option was to use a property-based model. Although it is conventionally accepted that the human body is not susceptible of ownership, we felt that this option should be explored, although in our preliminary report we deliberately did not use the word property because, as we explained, ‘... we do not propose that a right of ownership is created, as we are reluctant to use such language in respect of a person rather than a thing.’\textsuperscript{11} We remain of the view that – irrespective of whether or not a deceased person remains a ‘person’ for legal purposes – it would be inappropriate to use the language of property about what has once been a person.\textsuperscript{12}

14 One further possibility was to speak of possession rather than to focus on the kind of ownership which traditionally relates to things. Possession is a term already familiar to our law. The terms of the Human Tissue Act 1961, for example, refer to the person ‘in lawful possession of the body’. However, although we accept that, once a post-mortem examination has been authorised, the pathologist may be in temporary possession of a body, with all of the responsibilities which flow from that, and that a hospital authority may also have lawful possession of the body until it is claimed for burial or cremation by those with the responsibility for arranging this, we also believe that the concept of possession is in itself inadequate to clarify and reinforce the very real interests that parents have in their children, even after their death.

15 We turned, therefore, to an analysis of the family unit and in particular to the obligations and powers which flow from the notion of parenting itself. Page suggests that ‘parenthood is seen as having a special value in itself and not simply as a means to the care and protection of children and the continuation of the human race. This special value attaching to parenthood constitutes the ultimate foundation of parental rights.’\textsuperscript{13} If we think of the right of parental decision-making in respect of the deceased child as deriving from the value of parenting, then we can logically distance it from the problems associated with the constraints which arise from the legal concept of parental consent, most notably the requirement to act in the best interests of the child. Viewing the relationship between parent and child in this way, rather than simply as an amalgam of legal rights, obligations and interests, also places the parental role in an appropriate context. As Schoeman says:

\textsuperscript{11} paragraph 51
\textsuperscript{12} The difficulties surrounding this view are discussed below at paras 73, 108 et seq
\textsuperscript{13} Page, E., ‘Parental Rights’, Journal of Applied Philosophy 1,2, 187 (1984), at p. 196
... the relationship between parent and infant involves an awareness of a kind of union between people which is perhaps more suitably described in poetic-spiritual language than in analytical terminology. We share ourselves with those with whom we are intimate... This makes for non-abstract moral relationships in which talk about rights of others, respect for others, and even welfare of others is to a certain extent irrelevant.\(^{14}\)

16 To say that parents have a right to make decisions on behalf of their infants and young children is not to say that these are rights against these infants and young children; rather they are rights against third parties, such as the state or the medical profession, which might otherwise interfere with the intimacy of family relationships. Such rights might in any event be reinforced by the terms of the Human Rights Act 1998 which incorporated the European Convention on Human Rights\(^{15}\) (and particularly Article 8 – the right to private and family life) into UK law. What we propose, then, is that if we adopt this understanding of the bond between parents and their children we can circumvent the problems we have already identified which might arise from a straight translation of the law of consent into the post-mortem examination. Recognising the intimate bond between parent and child, and the privacy of the family unit, allows us to reinforce the priority of parental decision-making for their young children even after death. For this reason, **we recommend that amendments to the law in respect of post-mortem examinations of infants and young children recognise this bond by requiring the authorisation of the parent(s) for any such examination.** For the avoidance of doubt it must be remembered that this recommendation does not apply where a post-mortem examination is instructed by the Procurator Fiscal. However, we have recommended to the Lord Advocate that there should be effective and sensitive communication between the Procurator Fiscal and the bereaved families.

17 The use of the word ‘authorisation’ rather than ‘consent’ strengthens the role of parents in decision making about the way in which their children should be dealt with and clarifies the scope of the (legally valid) decision making powers which they have in respect of such children in these circumstances. Equally, the use of the term ‘authorisation’ rather than consent meets the concerns of those parents who do not wish to receive information about post-mortem examination and/or the subsequent removal and retention of organs or tissue, but who do not object to this. Whereas, in law, a valid consent is generally expected to follow the provision of information\(^{16}\), authorisation is not constrained by this requirement. Parents may, therefore, authorise procedures without having information forced upon them. **The Review**

\(^{14}\) Schoeman, F., ‘Righ\(\text{ts}\) of children, rights of parents and the moral basis of the family’, Ethics 91, 6 (1980) at p. 8


\(^{16}\) For further discussion, see M.\(\text{c}\)Lean, S.A.M., A Patent’s Right to Know, Aldershot, Dartmouth, 1989
Group is aware that the word ‘authorise’ is currently used in the Human Tissue Act in respect of the person in lawful possession of the body. However, it must be clearly understood that as used in the present context, the word authorisation has been carefully selected for the reasons, and with the meaning, outlined above. We are firmly committed to its use, which emphasises our view that there is a need for repeal or substantial revision of the terms of Human Tissue Act 1961 (see our recommendation in paragraph 27 of Introduction).

The Mature Child

18 While the bond between parent and child does not necessarily weaken as the child matures in age, the legal position changes. We have already referred to the Gillick case – a case that was heard in the House of Lords, but which was decided under English Law. The position in Scotland at common law, however, is widely believed to be equivalent to that presented in Gillick; namely that as children mature they acquire more rights to act for themselves, or as Lord Denning put it in the case of Hewer v Bryant ‘[p]arental rights start with the right of control and end with little more than advice.’ In addition to common law rules, however, the relationship between parents and mature children is also covered by statute.

19 It is probably the case that in Scotland mature children under the age of sixteen always had their own authority to agree to interventions such as medical treatment. However, the law was clarified by legislation. The Age of Legal Capacity (Scotland) Act 1991 s1(1)(b) gives anyone over the age of sixteen the right to enter into any legal transaction, defined in section 9 as meaning ‘the giving by a person of any consent having legal effect’. In terms of medical treatment, therefore, the young person of sixteen years or more has absolute decision-making authority for himself or herself. Those under sixteen may also have the power to make legally binding decisions about medical treatment. In terms of s2(4) of the Act:

A person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or the treatment.

20 This is reinforced by the terms of the Children (Scotland) Act 1995. Section 15(5) of this Act makes it clear that a person may act as a child’s legal representative only where the child is incapable of acting on his or her own behalf. So if the child acquires capacity (which can happen under the age of

17 [1970] 1 QB 357, at p. 369
18 Scottish Law Commission, Consultative Memorandum No 65, Legal Capacity and Responsibility of Minors and Pupils, at p. 51
sixteen) then the parent or guardian loses the right to act in respect of the particular transaction. The child can acquire capacity under the terms of s2(4) of the 1991 Act, and if this occurs then the child has the right to give consent to medical procedures even in the face of objections by its parents.

21 Although we believe that this would rarely arise, it would seem logical, therefore, to presume that the mature child should be able to authorise in advance the carrying out of a post-mortem examination. Where no such expression of intent has been made, the role of the parent(s) of a mature child below the age of sixteen should be the same as that in respect of the infant. By contrast, the child over the age of sixteen must be treated as an adult.

The Adult

22 As we have already seen, for the purposes of making legal transactions including medical and associated treatment or interventions, adulthood begins in Scotland at the age of sixteen. It is thus for people over the age of sixteen themselves to make decisions about medical procedures, including post-mortem examination and the subsequent use of the body. It is only in exceptional circumstances that an adult will request a post-mortem examination on him or herself for diagnostic purposes. Where such a request has been made, it is likely to have been made in terms of the Anatomy Act 1984, which has no relevance to the hospital post-mortem examination. As regards the latter, it is far more likely that the deceased will either have expressed indifference – which is not the same in law as agreement – or will have left no directions, in which case the law is to be found in the Human Tissue Act 1961 section 1(2).

No post-mortem examination shall be carried out otherwise than by or in accordance with the instructions of a fully registered medical practitioner, and no post-mortem examination which is not directed or requested by the [Procurator Fiscal]... shall be carried out without the authority of the person lawfully in possession of the body....

23 Thus, it is for the person who has lawful possession of the body to provide, or withhold, authorisation for post-mortem examination unless that examination is required by the Procurator Fiscal or Coroner (in England and Wales). It seems to be accepted that the person with lawful possession is the hospital authority - at least until relatives claim the body for burial or cremation. The relationship between the person in lawful possession of the body and those with familial or emotional bonds with the deceased is discussed in detail in paragraphs 40 to 46 below.

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19 The comparable authority in the Anatomy Act is s.4(3). The fact that s.1(1) of the Human Tissue Act may not apply to post-mortem examination is discussed in para 39 below.

20 Human Tissue Act s.2(4)
AUTHORISATION AND INFORMATION IN THE POST-MORTEM EXAMINATION

Information needed for the authorisation of a post-mortem examination

24 As we said in our preliminary report, the crux of the matter relates to the availability of information, if wanted. Just as an apparent consent can be challenged by evidence that it was not based on the provision of accurate or adequate information, so too an apparent authorisation by a surviving relative of a post-mortem examination will not be valid unless it follows the opportunity to receive relevant information. This matter was fully explored in our preliminary report, and requires little more here than a restatement of our earlier recommendations, namely:

People vary greatly in terms of the amount of information and detail that they wish to know about the post-mortem examination. Clinical staff need to be sensitive to relatives’ wishes in this respect.

Information must not be deliberately withheld, for any reason, unless at the express wish of the deceased. Relatives cannot reach an informed decision unless they have all the information which they themselves consider necessary to the making of their decision. Relatives need to be given the opportunity to decide how much detail they wish to know about the post-mortem examination and possible retention of organs. If they indicate that they wish to receive only limited information, it should nonetheless be made clear to them that they can come back with a future request for more information at any time.

25 We have devised an information leaflet which can be found at Appendix 3 of this report. We have also devised standard authorisation forms for adult and paediatric hospital post-mortem examinations. We recommend that this leaflet and the associated forms should be used throughout Scotland in all circumstances where persons are asked to authorise a post-mortem examination.

Information resulting from post-mortem examination

26 Issues about confidentiality and access to medical records may arise in the course of, and following, a post-mortem examination. It would seem that the right to have clinical information maintained in confidence may survive even after death. The General Medical Council, for example, tells doctors that they:

... still have an obligation to keep information confidential after a patient dies. The extent to which confidential information may be disclosed after a patient’s death will depend upon the circumstances. These include the nature of the information, whether that information is already public...

21 Chatterton v Gerson [1981] I All ER 257
22 paragraph 83
knowledge or can be anonymised, and the intended use to which that information will be put.23

Rules about medical confidentiality are generally conceded to exist in modern medicine to protect patients from the unwarranted spreading or use of information which they have every right to regard as being private or confidential in nature. Details about individuals’ states of health can be very sensitive, and this sensitivity may well be enhanced by the increasing ability of genetics to tell us about our history, our present and our future health as well as the history and the present and future health of our families.

CONFIDENTIALITY AND INFANTS OR YOUNG CHILDREN

27 In the situation currently under consideration, it seems to be wrong in principle to suggest that the results of a post-mortem examination should not be disclosed to parents. Knowledge about the cause of a child’s death may provide families with information vital to their decisions, for example, about having more children in the future. Where the child is young, it might be argued that in any event doctors have an obligation to disclose information to his/her parents, and certainly - in line with the nature of the family relationship as we have described it - it would be entirely appropriate that this should be done. In the case of the young (legally incompetent) child, therefore, it would seem that agreement to authorise a post-mortem examination implies a right of the parents to receive information about the results of that examination unless they have indicated that they do not wish to receive such information.

28 In the case of the young child, in law there is some doubt about whether or not there is a right to confidentiality, in that doctors may choose (against the wishes of a young child) to inform parents of proposed medical treatment. Any such decisions will normally be made where the doctor believes it to be in the best interests of the child’s health and this suggests that there may be circumstances when other interests may prevail over the importance of confidentiality. Thus, breaches of confidentiality may be made where the value of the information is deemed important either for the individual child (which is unlikely in the case of post-mortem examination) or - more likely - where disclosure may benefit present or future members of the family. Information obtained from post-mortem examination of their child may be of great value to parents, providing, for example, an explanation as to the cause and mode of death. It may also benefit present or future members of the family in other ways. Again, the provision of this information to a parent or parents is in line with the view we have taken of the family unit.

29 Difficulties may arise if information gained from a post-mortem examination discloses a condition which is inheritable; that is, a genetic condition. In these
circumstances, doctors may well feel that they have an obligation to tell relatives (who may also be affected) in order to allow them to make informed decisions about their own health care and even reproductive practices. We are inclined to believe that disclosure can be justified in the interests of the family unit. However, people must also be free not to know such information. It is unclear how a doctor would be able to identify situations in which families would not wish to receive such information, beyond sensitive discussion and questioning. The danger is that the discussion or questions themselves may alert people to the possibility of a problem about which they would have chosen not to know. This is clearly a complex issue and we recommend that it be drawn to the attention of the Human Genetics Commission which we understand is currently considering the general question of personal genetic information.

An alternative route might be to consider the terms of the Access to Medical Records Act 1990. Assuming that a hospital post-mortem examination forms part of the medical record, the deceased’s personal representative (in this case the parent(s)) could apply under section 3(1)(f) for sight of the report. Other interested parties may also do so but only if the information is relevant to any claim which may arise out of the patient’s death. It should, however, be noted that this Act has been substantially amended by the terms of the Data Protection Act 1998. Information that is likely to cause serious harm to the physical or mental health of any individual may be lawfully withheld by the Health Board. We recommend, therefore, that the general rule should be that information about the findings of a post-mortem examination on an infant or young child should be made fully available to the parent(s) who have authorised it, if they wish to receive that information.

CONFIDENTIALITY AND MATURE CHILDREN/ADULTS

The situation in respect of those to whom an unequivocal obligation of confidentiality is owed is arguably more complex. It is normally the case that information about one’s health is regarded as confidential, and as we have seen it is thought that this obligation of confidentiality survives death. Thus, it might be the case that there is no automatic right of access to the findings of a post-mortem report by those closest to the deceased, where an obligation of confidentiality arises. In addition, it might be thought that Article 8 of the European Convention on Human Rights could protect privacy even after death, on the basis of the rights of the living when revealing sensitive information, although this is not entirely obvious as it is not clear how the terms of the Human Rights Act could be used in respect of a person who has died.

24 Which is not entirely clear as s 11(1)(b) relates to the care of the individual
25 s5(4)
26 s5(1)(a)
Unlike the situation of the young child, there may be many and powerful reasons why an older person may not wish post-mortem findings to be released even to those closest to them. HIV status or the presence of genetic conditions are two useful examples. On the other hand, the presence of these same conditions might provide families with an apparently strong reason to wish to receive the information, in the interests of their own health and perhaps that of their present or future children. We recommend that the general rule should be that information about the findings of a post-mortem examination on a mature child should generally be made fully available to the parent(s) who have authorised it, unless the mature child has left directions that this should not be done. We accept that there may be competing interests here, and believe that the decision as to which interest should prevail is one of some urgency.

In respect of adults, it is arguable that the bonds which legitimise the disclosure of information which might otherwise have been held to be confidential are weaker. Even although individuals, such as sexual partners, may have an interest in knowing about the HIV status of a deceased adult, and even although family members may have an interest in genetic information derived from a post-mortem examination, it is more contentious whether a breach of confidentiality can be justified in these circumstances, for the reasons already discussed; most particularly we believe it is important that the wishes of the deceased adult are respected after death.27 We are certainly of the view that, if the deceased has expressed a wish that his/ her clinical status should not be disclosed then normally this should be respected. Where no such request has been made, generally speaking the decision will be left to the clinician, taking into account the various interests involved. We recommend that any directions left by a deceased adult person should be followed. Where no directions have been left by a deceased adult, or there is reason to believe that the health of another person may be affected by the medical condition of the deceased, we believe the present position to lack clarity concerning whose interests should prevail. Any new legislation in respect of this matter should, therefore, if necessary address this point specifically, with particular attention being paid to the implications of genetic information, and taking account of the results of any inquiry on this subject by the Human Genetics Commission. We further recommend that the relevant terms of the 1990 Act (as amended), data protection and freedom of information legislation should be clarified in respect of the confidential status of medical information after the individual’s death.

27 A person’s expressed wishes are not necessarily the same as a person’s legal rights. See para 46 below
GENERAL

34 The question of when does confidential information become historical fact remains. It seems that medical records of patients treated within the NHS in Scotland come within the scope of the Public Records (Scotland) Act 1937. We believe it to be important that the question of when otherwise confidential medical information may be made publicly available requires clarification.

POTENTIAL DISAGREEMENTS IN AUTHORISING A POST-MORTEM EXAMINATION

35 We have already made it clear who we believe should have the capacity to authorise a post-mortem examination. However, it has also been necessary to take account of the fact that a disagreement may arise.

Infants and Young Children

36 In the case of infants and young children, we have already recommended that it should be made absolutely clear that the parent(s) should have the power to decide whether or not a post-mortem examination should proceed (except of course in cases where these are instructed by the Procurator Fiscal). However, parents may not always agree with each other on this subject. In our view it would be invidious for us to attempt to prioritise the decision of one parent over another - irrespective of their current marital status or living arrangements. To proceed to post-mortem examination against the wishes of one parent would arguably be to do great disservice to the intimacy of the parental bond that we have described. If a full and frank discussion with the refusing parent as to the reasons for, and potential benefits of, a post-mortem examination does not lead to an agreement, then it would, we believe, be difficult to proceed. However, we also recognise that there may be others who have a legitimate interest in the deceased child, such as partners or step-parents who may have reared the child, and that some biological parents may have played no part in the rearing of the child. We believe this to be a very complex issue, and recommend that there should be further consultation on this matter, which is in urgent need of clarification.

Mature Children

37 We have already indicated that parental powers in respect of mature children are different in law from those that they hold in respect of younger children. However, this should not be taken to imply that - where the deceased mature child has indicated no preferences before death - the involvement of parents should be any less. The familial bonds we describe will also operate in these circumstances to provide parents with the authority to decide in the absence of the expressed views of the mature child. Thus, our recommendations in respect of the mature child who has expressed no views are the same as those in respect of the young child. In circumstances where

28 Guidelines on the length of time for which medical records are retained can be found in MEL (1993) 152
the mature child has left express wishes, we recommend that these should be treated as being equivalent to those of an adult. In addition, our recommendations about the need to resolve matters when parents are in dispute also hold good here.

Adults

38 As discussed in paragraph 22 above, an adult’s positive request that his or her body be used after death for any other than therapeutic use (i.e. donation of organs for transplantation) is likely to have been made under the Anatomy Act 1984, section 4 of which states:

(1) ... if a person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body be used after his death for anatomical examination

(2) ... if the person lawfully in possession of his body after death has no reason to believe that the request was withdrawn, he may authorise the use of the body in accordance with the request.

39 The Human Tissue Act 1961, section 1(1) says very much the same thing modified for the removal of individual parts of the body. Unfortunately, while not actually denying it, the Act does not positively apply section 1(1) to a post-mortem examination. The distinction, if it is to be made, has relatively serious implications which we discuss below. Common sense rejects the suggestion that such a distinction is intended and the rest of this section proceeds on the basis that section 1(1) applies to post-mortem examination – if only by implication. However, in light of this uncertainty, we recommend that the law in this area, and in particular the relationship between the Human Tissue Act 1961 and the Anatomy Act 1984, be reviewed as a matter of urgency. In our view, this lack of clarity reinforces our earlier recommendation that a new statute is urgently needed in this area.

40 Subject to these considerations, we are of the opinion that, in all cases where the now deceased adult has left instructions about the use of his or her body after death, these should be respected unless there is reason to believe that the deceased had a change of mind before death. The person lawfully in possession of the body is generally agreed to be the hospital authority, at least until the point at which relatives claim the body for burial or cremation. Under existing legislation, the responsibility on the hospital authority is to enquire whether the deceased has left legally valid instructions and has not changed his/her mind, and, in their absence, to establish whether the deceased would have objected to the use of the body or parts of it. However, very often interpretation of the law has gone beyond its strict requirements. Doctors will virtually always ask relatives actively to agree to the use of the dead body, rather than simply asking

29 One problem lies in definition. The Anatomy Act authorises dissection for ‘the study of morphology’ – that is, the structure of the body and its organs or ‘anatomy’ as it is commonly understood. The Human Tissue Act is concerned with the use of parts of the body for therapeutic purposes and for purposes of medical education and research. Thus, there is no statutory authority for a person to express a legally binding wish for a purely diagnostic post-mortem examination unless s 1(1) is held to apply by implication.
about the wishes of the deceased. While this practice is understandable given the circumstances, it fails spectacularly to respect the competently expressed wishes of the person now deceased.

41 It might, of course, be argued that the deceased person has no surviving interest in what happens to his or her body and therefore that any respect due is due to the wishes of the surviving relatives. To counter this, it could be contended that the interest which the deceased person has, is the interest during his or her life time of knowing that his or her wishes will be respected after death. A similar, but not completely analogous, respect is shown when property is disposed of in terms of a valid will. What is absolutely clear in law is that relatives of an adult have no automatic legal rights to make decisions on his or her behalf.

42 The only other area of law which might seem to be analogous in this situation would be the acceptance that, by and large, advance directives (or advance statements/living wills) should be given legal effect once the people who competently made them become incompetent and their situation is on a par with the circumstances they envisaged. This has been endorsed by the British Medical Association amongst others. However, the situation where someone has left directions about treatment is not necessarily the same as where someone has left directions about the use of their body after death. In the former case, the rule would appear to be that these may not be legally binding, in as much as there is some scope for re-considering their validity if, for example, they are insufficiently clear or appear to be based on insufficient information. In the case of statements about post-mortem use of the body, however, there will generally be little room for doubt as to the intention of the person now deceased. In these circumstances we recommend that the expressed wishes of the individual adult, competently made before death, should take priority over the wishes of surviving relatives. The current legal requirement to discover whether or not this agreement has been withdrawn should remain, but it must be clear that the relatives have no legal role in circumstances where the deceased has made known, and not retracted, his or her wishes. We recognise that this might seem harsh, but we regard an important concomitant of this recommendation to be a campaign directed at those who may wish to make such a declaration to encourage them to discuss their wishes freely and fully with those who will ultimately be asked about the deceased’s intentions, and where possible to record those wishes in a readily accessible place and form. In this way, we would trust that any potential distress to surviving relatives would be obviated, or at least minimised.

43 If the relevant section is redrafted in line with our recommendations, we are also of the view that one further aspect of current law should be considered. We are concerned that verbal agreement only has lawful authority if provided in the course of a final illness. This seems an unnecessary constraint on the
individual’s freedom to make decisions. Although it may be that written authorisation carries more apparent weight than verbal authorisation, we do not subscribe to the view that only written agreement is valid when the decision is made in the absence of a final illness. We recommend, therefore, that a competently expressed verbal agreement at any stage of adult life should be sufficient in law to permit the directions to be carried out and that any new legislation should make this clear.

Additionally, it must be clear that, whereas ideally a decision should follow the provision of adequate information, we do not believe that this is essential. Just as families may not wish to be given details about organ removal, retention and use, so too adults and mature young people may prefer to receive no, or limited, information. This strengthens our view that the appropriate terminology should be that of ‘authorisation’ rather than consent, which does seem to imply some information disclosure, and reinforces our commitment to people having their decisions about their own bodies respected.

Equally problematic, however, are the terms of section 4(3) of the Anatomy Act 1984 and section 1(2) of the Human Tissue Act 1961 which apply when the deceased has left no prior directions. They state:

...the person lawfully in possession of the body {of a deceased person} may authorise it to be used for anatomical examination {the removal of any part from the body for therapeutic purposes, medical education or research} if, having made such reasonable enquiry as may be practicable, he has no reason to believe -

(a) that the deceased either in writing at any time or orally in the presence of two or more witnesses during his last illness had expressed an objection to his body being so used [dealt with] after his death, and had not withdrawn it; or

(b) that the surviving spouse or any surviving relative of the deceased objects to the body being so used [dealt with].

There are a number of problems with the terms of these subsections, the first of which, again, relates to their application to the post-mortem examination. Section 4(3) of the Anatomy Act is subject to the dominant section 4(1) which empowers the expressed wishes of the deceased. It appears, however, that there is no such overriding personal control over a post-mortem examination authorised under the Human Tissue Act 1961. Thus, it seems that, in strict law, the relatives have an absolute power of veto in the latter case, irrespective of what the deceased said in life. This is important because many people, in expressing a wish to be of value to the community after death, will not have stated the statute under which they are acting. In such circumstances, it seems that the 1961 Act would take precedence even if the ‘educational’ element consisted of anatomical examination. The case for review of the law is, thereby, strengthened.
DEFINITIONS

47 It will be useful at the outset to define the terms we are using in this section of the report. Indeed, we believe it to be vital that appropriate language is used in order that relatives are clear as to what is being discussed and aware of what it is they are being invited to authorise. As we said in our preliminary report:

The failure to obtain full and open consent in respect of the retention of organs has been compounded by the use of vague and misleading terminology. ‘Tissue’ has been widely used as a euphemism for ‘organ’, or doctors themselves may have been confused by the terminology.34

Accordingly, we offer the following definitions:

**Organs**: An organ comprises a collection of different tissues which form a distinct structure in the body and perform a particular function or functions, for example heart, brain, liver, kidney.

**Major Portions of Tissue**: Pieces of tissue sufficiently large to be readily recognisable as coming from a particular organ.

**Tissues**: These are parts of organs that are removed for further study. They will normally be preserved in a fixative (formalin) and stored in jars in the laboratory.

**Blocks**: Particular pieces of tissue measuring about 2.5 x 2 x .75 cm, which are later embedded in paraffin wax or a similar medium. They are normally stored in boxes.

**Slides**: These are essentially shavings of tissue blocks about 1/100th mm thick, which are mounted on glass slides and stained in various ways in order to facilitate diagnosis. They are normally stored in marked boxes. The total volume of tissue on a slide approximates to that of a nail clipping.

ORGANS

48 Basically there are three reasons for removal and retention of organs which can be described as diagnostic, medico-legal and archival retention.

DIAGNOSTIC RETENTION

49 It should be noted that, overall, the post-mortem examination takes some time and the thorough examination of slides takes even longer. Moreover, in certain circumstances, the relatively long-term retention of organs is essential.
to the purposes of the examination. For present purposes, it can be said that the ‘relatively long time’ will certainly exceed the normal interval between death and return of the body to the family or executors and is likely to run into weeks. It is unfortunate that the two organs that will be needed most often for diagnostic retention are those that carry the greatest emotional significance - the brain and the heart - and we must include the congenitally defective infant heart as a special case. Decisions, particularly in the latter case, can be very finely balanced - both the need for, and the antipathy to, retention are maximal.35

**MEDICO-LEGAL RETENTION**

50 It may be highly desirable or, indeed, essential to retain organs as ‘best evidence’ in any later litigation, which, of course, may or may not arise. Many cases where it is known before the post-mortem examination that there is the possibility of litigation will be under the control of the Procurator Fiscal whose instructions would be binding. However, this would not necessarily apply to all civil litigation including, say, contested insurance claims.36 As things stand, authority to retain organs obtained from a hospital post-mortem examination would need to be obtained from the people who are able to authorise the examination itself. Authority to retain organs for medico-legal purposes or post-mortem examinations conducted under the instructions of the Procurator Fiscal is subject to separate arrangements, as we have already seen.

**ARCHIVAL RETENTION**

51 It may be desirable to retain an organ - particularly a heart - for demonstration and/or comparative assessment. In such circumstances, any advantage to the memory of the deceased or to the person giving authorisation is, at best, indirect, arising from the potential benefits which may accrue to medical education and training. Pitted against a sincerely held aversion to retention on the part of the person with authority to agree to it, the case for archival retention can seldom be strong. However, where no such objection is present, there may be good reasons to retain organs for archival purposes.

**AUTHORISATION FOR THE RETENTION OF ORGANS AND TISSUES**

52 The principles that have guided our approach to the provision of authorisation for a post-mortem examination are equally relevant to the removal and retention of organs or tissue at or following an authorised post-mortem examination. Most of the concerns expressed to the Review Group related to this issue. The evidence received by the Review Group suggests


36 The Procurator Fiscal is likely the instruct a post-mortem examination in many cases where civil litigation is very likely; for example, a death in the course of employment
that there is more cause for concern about the quality of the information provided about the possible removal, retention and use of tissues or organs than there is about the post-mortem examination itself. In this part of our report, we will deal only with organs and tissue. In some cases, it may be that only a part of the organ is removed or retained, and in this situation, for our purposes, these major portions of tissue will be considered to be the same as the complete organ. We will consider tissue blocks and slides as a separate issue later.

**Infants and Young Children**

53 We have already made it clear that parents should have the ultimate authority to agree to, or refuse, a hospital post-mortem examination in respect of their child. It must be equally clear that they have exactly the same authority in respect of the removal and retention of organs and major pieces of tissue. Any revision of the current law must clarify this position. But there are also practical implications which flow from this conclusion. Where parents wish to receive information about the post-mortem examination, it must be made clear to them that in some cases a post-mortem examination, if it is to be properly and professionally carried out, will require the removal from the body of certain organs, and possibly their retention in the ‘fixed’ state for some 4–6 weeks. It must be made absolutely clear to parents that this is the case, and options must be presented to them in terms of the funeral arrangements for their child or the separate disposal of organs. Revelation of this information may assist parents in deciding whether or not to authorise the post-mortem examination in the first place. Equally, where authorisation is provided, some parents may prefer to bury the child only after the organs have been returned to the body, necessitating delay in the funeral. Still others may prefer to have the organs returned to them after analysis for separate burial or cremation; some may prefer the hospital to dispose of the organs and yet others may wish to authorise the use of the organs for educational or research purposes. We recommend that each of these options should be clearly explained to parents before their authorisation to proceed with a post-mortem examination is sought (unless the parents do not wish to receive this information) in circumstances which provide them with adequate explanation and time to come to terms with them. Particular sensitivity will be required of those who have the responsibility of providing this information to bereaved parents. We note that other committees of inquiry have indicated their support for the appointment of bereavement officers in hospitals,37 and indeed this suggestion was also made to us.38 We commend the further development of such a role in hospitals, but believe that families should nonetheless be
entitled to discuss these sensitive matters with an appropriate
individual of their choice, such as the clinician involved with the care
of their relative. This will require that hospitals will need to ensure the
availability of individual health care providers, and reinforces our
earlier recommendations about education and training of hospital
staff, and the availability of appropriate facilities in which any such
discussions can take place.\(^39\)

54. As we have noted, some families will not wish to be given information of this
sort. Where this refusal of information is coupled with a refusal to provide
authorisation for a post-mortem examination or the removal or retention of
organs, their wishes should be respected. Other families may not wish to receive
any information, but not object to the retention and use of organs. Where this is
the case, we recommend that organs or tissue may be retained and used
for legitimate medical education or research. In all cases, families
should be given the opportunity of taking home a copy of our
information leaflet, and those discussing these matters with families
should ensure that the wishes of the family are clearly and accurately
recorded on our authorisation form, a copy of which should also be
provided to the families.

55. Giving parents the clear legal right to provide or refuse authorisation respects
their bond with their dead child, provides them with the opportunity of
obtaining fuller information about the circumstances of their child’s death, and
offers the possibility that some benefit may flow either to themselves or to other
families if medical research is also authorised, always assuming that they wish to
receive this information. The parents who gave evidence to the Review Group
were, it must be emphasised, very positive about the benefits of medical research.
It was not research itself to which they objected – indeed the opportunity for
altruism, which was denied to them by failing to involve them in decisions
about their deceased child, was felt very strongly as an additional insult to them.
**Authorisation for retention of organs for medical education and
research is an absolute prerequisite of the lawfulness of any retention
of organs. Failure to adhere to this requirement is unacceptable.**

56. We have already recommended that a copy of the form of authorisation should
be held in the patient records as well as being available to the pathologist who is
to conduct the post-mortem examination. A copy should also be retained by the
parents.

**The Mature Child**

57. As with authorisation of a post-mortem procedure, and in line with both
common and statute law, the mature child has the power to direct the uses
which can be made of his or her body after death. Where no such direction has been competently given, authority should rest with the parent(s).

The Adult

58 At present, the provision and retention of organs for research, therapeutic or educational purposes is covered by the terms of the Human Tissue Act 1961 and, following anatomical dissection, by the Anatomy Act 1984. As we have already indicated, where an adult has competently left instructions on this matter, these wishes should be respected. In cases where no such direction has been left, the law currently requires that a reasonable enquiry is made by the person in lawful possession of the body to ascertain whether or not the deceased had objected to such use during his or her lifetime, and whether any surviving relative objects. Even although the existing legislation is poorly phrased, we believe it implies that the wishes of the deceased should be those which count. We have already noted that doctors will nearly always seek the ‘consent’ of relatives, thus potentially prioritising their wishes over those of the deceased. We reiterate our view that it is for the deceased during his or her lifetime to direct, if they so wish, what is to be done with their body after death. Depending on the outcome of the further consultation processes which we have recommended above, the law should be clarified to ensure that there is no doubt about its intentions in this respect.

59 Following on from this, we note that the relatives referred to in the 1961 Act are specifically designated as a surviving spouse or ‘any surviving relative’. There are doubtless good reasons why a surviving spouse should be given such power, and this is a position with which we are in general agreement (although it is true to say that this would not always be the case given that spouses may be separated or otherwise in dispute). However, even where spouses have been in compatible co-habitation, according to the terms of the current legislation their views are given no more than equal significance to those of any surviving relative, however distant.

60 This situation appears to us to be inappropriate. Where what is being sought is the authorisation to proceed with removal and use of organs at post-mortem examination we recommend that the amended law should seek to prioritise those with the closest relationship to the deceased person. This is entirely compatible with the terms of the Mental Health (Scotland) Act 1984 and the Adults with Incapacity (Scotland) Act 2000. In addition, it is important that the provisions of legislation should not ignore the reality of many contemporary relationships, which may, for example, not involve marriage or may be of single sex. If the aim of the legislation is to
seek authorisation from the person who is most likely to be affected by the decision, then we believe that amended legislation should take account of the reality of the living arrangements entered into by many adults by making provision for those most closely linked to the person - whether or not by marriage - to be given the right to authorise the use of organs post-mortem or to refuse to provide such authorisation.

Where the adult has left no explicit directions, a similar regime should be in place to that which we have already recommended in respect of the post-mortem examination itself. In other words, authorisation should be sought from the appropriate other party (which may include those closest to the deceased rather than those related to the deceased).

GENERAL

Any retention or use of organs obtained at post-mortem examination not authorised by parents, the deceased or an appropriate other person is a serious betrayal of trust, and we therefore recommend that retention of organs and tissues in the absence of appropriate authorisation, or failure to adhere to the terms of any authorisation given, should be subject to a penalty imposed by law.

TISSUE BLOCKS AND SLIDES

We have chosen to deal with tissue blocks and slides separately because we believe that they raise personal and professional issues which may be quite distinct from those associated with organs and major tissues.

TISSUE BLOCKS

We accept that for some individuals, perhaps because of religious convictions, these small pieces of tissue have the same significance as the organs referred to above. We also agreed in our preliminary report that, for the time being, families should be able to retrieve tissue blocks and slides on the basis that:

In the light of the distress caused to some relatives by past events, it seems only right that relatives should be given this option, especially if doing so would allow them to achieve a sense of closure.42

This recommendation arose from the considerable distress caused to some families by the failure to seek their authorisation for retention of tissue blocks and slides. However, given our revised information leaflet and forms for authorisation, it will no longer be possible to prepare and keep such blocks without lawful authorisation and for that reason we believe that different rules should apply in the future. These are discussed below.

42 paragraph 70
Tissues

66 Tissues to be retained within the present context are here defined as fragments of organs that are not readily recognisable as being part of that organ. They will be used for two purposes – the preparation of paraffin blocks or of ‘frozen sections’. The latter are slides for microscopy that have been prepared from tissues solidified by freezing rather than by embedding in paraffin.

67 Tissues taken at post-mortem examination for these purposes must as a technical imperative be small. Multiple tissue blocks may properly be taken, 20 being a reasonable number although this depends on the nature of the death – a large number will, for example, be taken in the event of a cot death, which is defined as an infant death for which no cause can be found after thorough investigation. Tissues are usually stored in formalin in bottles under normal laboratory conditions. Insofar as they are the precursors to the preparation of slides for microscopy, the retention of small tissue blocks must be regarded as an essential component of a full and comprehensive post-mortem examination.

Paraffin Blocks

68 If adequate paraffin blocks have been prepared, there is very little need for long-term storage of organs or major pieces of tissue in many cases. Paraffin blocks consist of blocks of hard paraffin in which tissue is embedded and from which slides can be made. The tissue has been treated and dehydrated and remains unrecognisable as such. The average block is small, and consists of some 50% tissue. Its preliminary purpose is served once an adequate number of slides have been prepared for the immediate investigation. Nonetheless, it is customary to preserve the blocks more or less indefinitely, largely because one never knows that one’s study of a death will not be shown to have, perhaps, been incomplete. This may arise because new information is received about the individual case or about such deaths in general. A classic example of the latter arose when, in 1999, it was reported that the presence of iron-laden scavenger cells in the lungs could be used to distinguish cot deaths from those due to mechanical asphyxiation. Every pathologist would have wanted the opportunity to re-examine his or her cases using special staining methods to see if there were any in which the diagnosis ought to be altered, and the testing of such hypotheses is of vital concern to families past, present and future.

69 Paraffin blocks will usually be stored in individual boxes within the laboratory. They represent the intermediate, and essential, stage between...
tissues and slides for microscopy; again, therefore, their preparation is an
integral part of the post-mortem examination process.

SLIDES FOR MICROSCOPY

70 Aside from the preparation of frozen sections, which is unusual in the
ordinary run of hospital autopsies (although as we have said earlier, it may be
done), slides for microscopy are prepared by cutting shavings of tissue – or
sections – from paraffin blocks. The maximum useable thickness is 10 µm – or
1/100th mm. It is, perhaps, worth noting that an extra number of sections will
be cut as, due to the nature of the process, the quality of many will be
substandard. The tissue section is then transferred to a glass slide, stained –
often several sections are stained with different dyes for different purposes –
protected by a cover-slip and secured permanently by means of a self-
hardening resin (it is to be noted that the bond is very difficult to break once
it is set). A mass of work is involved and the tissue is transformed so that it is
well-nigh impossible to regard the material on the slide as meaningful human
tissue; it is more rational to compare the status of the slide with that of a
retained X-ray film. Slides for microscopy are commonly stored in designated
boxes and are generally stored indefinitely – effectively, as part of the patient’s
clinical record. We believe that they should, in fact, and in law, be seen as part
of the medical record.

71 The concept of the clinical record sums up the general purpose of retaining
slides. The particular reasons for their preparation are almost too many to
count up. Those that spring to mind include:

- They show incontrovertibly the spread of disease and the efficiency, say, of
  surgery. For example, they may show that the excision was inadequate or
  that a specific piece of tissue was in fact removed.
- They show the presence of unsuspected disease.
- They demonstrate the effect of a disease on other than the target organ.
- They are the ultimate arbiter between malignant and benign tumours.
- They go some way to satisfying the public interest in research.
- Above all, they provide concrete and permanent material for reference and
debate as to the cause and mode of death in both the medico-legal and
academic spheres.

72 Slides for microscopy represent the logical end of the post-mortem
examination and, to many, a post-mortem examination without a permanent
record is a wasted opportunity. The balance of benefit in the retention of
slides differs significantly from that involved in the retention of organs or
major portions of tissue for purposes other than diagnosis.
73 It is obvious from the example given at paragraph 68 above that the distinction from research may, at times, be blurred; the question of ownership of blocks and slides is, therefore, of real significance. We have already indicated that we believe the concept of property to be inappropriate in respect of organs and tissue as constituents of the human body. However, it is part of our law that when one thing is transformed by the efforts of a third party into something different, as arguably is the case with paraffin blocks and slides, then it may become the property of the person who undertook the work on it. For example, in light of the decision in *R v Kelly*, paraffin blocks and slides may in fact be susceptible of ownership by the person undertaking the work which transforms them into diagnostic tools. As the law stands in this situation at least it is plausible to argue that the concept of property has relevance.

74 However, we prefer to concentrate on the general value ascribed to, and derived from, the retention of blocks and slides. As we have indicated, they form an important – sometimes vital – part of the medical record of the deceased person and may provide valuable information for other members of their family, now or in the future. In addition, the capacity to refer to them in the future if, for example, new hypotheses about certain illnesses or conditions become available and require to be tested, means that they can have a major public health importance. We believe that this should be explained clearly at the time authorisation of a post-mortem examination is sought, and have therefore included this point in our information leaflet. The provision of authorisation to conduct a post-mortem examination would, unless expressly refused by those with the authority to provide it, necessarily include agreement to the preparation and retention of these blocks and slides. This is in the interests of the family and of public health. Without the capacity to prepare blocks and slides, the post-mortem examination is incomplete and may fail to fulfil the purpose for which it was intended. We recommend, therefore, that in seeking to gain authorisation for a post-mortem examination, it should be made clear to those providing any authorisation that, in the absence of a specific refusal, the preparation of blocks and slides will be regarded as an integral part of that authorisation, unless they have indicated that they do not wish to receive information of this sort. We are clear that no pressure should be put on the bereaved to agree to this, and that sensitivity must be shown to those who have, for example, religious objections. We further recommend, in common with the Alder Hey report that once a properly informed decision has been made to authorise a post-mortem examination, interests in the prepared blocks and slides should pass to the hospital authority who may retain and use them.

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45 *R v Kelly* [1998] 3 All ER 741, CA
for proper study and research purposes. This recommendation is also in line with those of the Nuffield Council on Bioethics⁴⁷, which considered the question of whether or not tissue banking and archiving may fall beyond the scope of the exiting legislative framework. Their conclusion in this respect was as follows:

We recommend that removal of tissue from the dead for purposes which are acceptable in that they contribute directly or indirectly to medical treatment, but may not be expressly provided for by statute, should, if appropriate consent has been obtained, be regarded as lawful.⁴⁸
The value of medical education and research is, we believe, incontrovertible. Indeed, as we have noted, this value was fully endorsed by all of the families who gave evidence to the Review Group. They told us that if they had been asked to authorise the use of organs and tissue for medical research they would almost certainly have agreed to this request. We have already made it quite clear that the failure to seek the authorisation of any person with the power to provide it (for example, the parents of young children) was and is unacceptable, and we are confident that this lesson has now been learned. Our recommendations as described above should ensure that in the future the legitimate authority of these people will not be ignored.

As part of medical training, it is imperative that students are able to appreciate the complexities of the human body. By observing post-mortem examinations or by themselves undertaking dissections they will gain an improved understanding of anatomy. The gift of human organs and tissue for these purposes is an act of public spirit by individuals who have made known their wishes before death or by others in the face of great distress. These individual acts of altruism in the family may lead to great public good. We are all beneficiaries, or potential beneficiaries, of the information and experience gained from post-mortem examinations and research carried out in the past. However, it is quite clear that not all post-mortem examinations or retention of organs and tissue in the past arose following the informed desire of individuals or their families to provide this benefit, although, as we have already seen, with hindsight many families would have willingly agreed. Nevertheless, this hindsight and generosity do not mean that assumptions about altruism can or should be made, nor does the fact that public benefit may be reduced if individuals or their families refuse to agree to the retention of organs or tissue mean that there is any justification for failing to obtain appropriate authorisation in the future. Rather, it requires public confidence in the system to be restored, proper and full information to be given in a sensitive manner and recognition of the value of the contribution made by those agreeing to the use of organs and tissue after death to be clear.

Medicine also depends on research in order to progress. However, medical research conducted in the absence of authorisation is research which is inherently flawed. Medical research has, over the last 30 or more years,
become the subject of close professional scrutiny and has been the focus of international interest ranging from the Nuremberg Code \(^{49}\) to the Declaration of Helsinki. \(^{50}\)

78 The most recent guidelines from the Medical Research Council (MRC) say:

The human body and its parts should be treated with respect. Researchers should ensure that they are aware of cultural or religious differences in the meaning and significance attached to the body or specific bits of it before approaching potential donors. \(^{51}\)

The MRC further recommends that:

Informed consent \(^{52}\) is required from the donor (or the next of kin, if the donor has died) whenever a new sample is taken wholly or partly for use in research. Donors should understand what the sample is to be used for and how the results may impact on their interests. Consent must also be obtained for storage and potential use of samples. \(^{53}\)

Draft recommendations from the General Medical Council indicate the following to doctors:

Seeking consent to retain organs and tissues

You must get informed consent from patients or, if appropriate, their representatives before taking or retaining organs and tissues for research purposes. This applies whether tissues or organs are to be obtained during a research project, a surgical intervention or a post-mortem examination.

You must be satisfied that patients or their representatives have made an informed decision and understand the amount and nature of tissues or organs which will be taken, and how it will be used and/or stored for future use. You must be prepared to respond honestly and sensitively to questions about any of these issues. In particular, you must be compassionate and considerate when obtaining consent from and giving information to the family or other representatives of a deceased patient. \(^{54}\)

\(^{49}\) United States v Brand (case no 1) 1 Trial of War Criminals 3 (1949). Article 1 states unequivocally that "The voluntary consent of the human subject is absolutely essential. See also Trial of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No 10, Vol 2, Nuremberg, October 1945 - April 1949, Washington, D.C., U.S. Government Printing Office, 1949, pp 181-182. The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocured by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts."

\(^{50}\) The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Adopted by the World Medical Association General Assembly, Helsinki, Finland, June 1964, most recently revised by the 52nd WMA General Assembly, Edinburgh, Scotland, 2000. Available at http://www.wma.net

\(^{51}\) Medical Research Council, Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines, April 2001. Available at http://www.mrc.ac.uk

\(^{52}\) While understanding what is meant by this term, we have explained elsewhere why we regard it as inappropriate in the context of a deceased person, at least where that person has not expressed their wishes in advance of death

\(^{53}\) Medical Research Council, note 48 above, at p. 3

\(^{54}\) General Medical Council, Medical Research: The Role and Responsibilities of Doctors, draft guidance, March 2001. Available at http://www.gmc.org.uk/standards/standards.htm
Also, as we have already noted, there are essentially two statutes which cover removal of tissue from the dead, namely the Human Tissue Act 1961 and the Anatomy Act 1984. Their terms have already been discussed.

79 In addition to statutory provision, for over 30 years hospitals have been required to establish Local Research Ethics Committees (LRECs) whose function is to review the ethics of all proposed research involving NHS patients and to give or refuse permission for that research to proceed. As has been said:

Ethics committee approval is effectively mandatory before funding or publication is possible and it is unlikely that a researcher’s colleagues would quietly stand by if an unscrutinised project were to be undertaken. To that extent, patients, volunteers and researchers themselves are benefiting from the protection offered by the scrutiny which ethics committees offer.55

80 As we noted in our preliminary report, when authorisation for the research use of retained organs or tissues is being sought it should be made clear to those from whom that authorisation is being sought that legitimate research will only be conducted under the authorisation of such a committee (or, where the research involves a number of centres, under the auspices of the relevant Multi-Centre Research Ethics Committee (MREC)). However, the Review Group has come to the conclusion that there may be reasons to reconsider the existing Research Ethics Committee structure in light of the concerns which have emerged from past practice. The disclosures which led to the establishment of the Review Group have highlighted once again the sensitivities of the use of human material in research projects. Indeed, in the aftermath of the Bristol and Alder Hey disclosures, the Royal College of Pathologists has issued fresh guidelines about the research use of tissues taken at biopsy from live patients.56 With some exceptions, these recommendations broadly embody the same approach as we are taking, and in particular they reinforce the need for LREC or MREC review of proposals. We do, however, feel that any legislation should be so drafted as to distinguish between structured research and ad hoc further study directed to the better understanding of individual cases. For example, a simple staining technique might help to identify true cot deaths. Of course, such research can only take place where samples have been retained lawfully. It is arguable, however, that it would be unproductive to require Research Ethics Committee approval before a pathologist could lawfully stain retained slides from his or her previous cases. Although he or she would, strictly speaking, be engaged in research, general agreement from the relatives to allow retention and further study of tissue blocks and slides should suffice in such cases. At present, this

56 Royal College of Pathologists, Transitional guidelines to facilitate changes in procedures for handling ‘surplus’ and archival material from human biological samples, June 2001
kind of research does not require approval from a Research Ethics Committee, and we do not propose that it should.

81 The Review Group is concerned that its final recommendations should both be acceptable to parents and concerned others and have the capacity to restore or enhance public confidence in practice and research within the discipline of anatomic pathology. To this end, the Review Group cannot, and does not, condone the routine removal or retention of organs or tissue for no intended purpose. This would not inhibit the development of tissue banks for research, for example, into CJD, HIV or Alzheimer’s disease; such research is of vital public importance. It is true that situations may arise where the researchers may have no specific project in mind when seeking authorisation for the removal and retention of organs or tissue, but they will nonetheless have established protocols for their storage and management which should be of the highest possible standard and open to public scrutiny. Moreover, any actual piece of research conducted will still require Ethics Committee approval. In such circumstances it may be said that the removal and retention of human material is done with the intention of its use for approved research in the future. Thus, the retention is for that general purpose.

82 An important issue arises from this. The request for authorisation to remove or retain tissues may be couched in general or specific terms. That is, tissue may be requested for inclusion in a research project which is already under way or which is shortly to be submitted to the relevant Ethics Committee, or it may be requested for future—as yet unknown—projects. We firmly believe, and have had this confirmed to us by families giving evidence to us, that neither of these would be objectionable as long as appropriate authorisation is obtained, based on proper disclosure of relevant information. We recommend, therefore, that it is made clear in the form authorising a hospital post-mortem examination that authorisation for the research use of retained organs and tissue can be either specific or general. However, for this to satisfy the interests of the surviving families, information about research uses should be freely and publicly available. We also recommend that those with the legal capacity to authorise such retention should be informed that they can change their mind at any time. We accept that, if this occurs in the course of a research project, it may have an adverse effect on the specific research, but this should occur only very rarely if proper authorisation has been obtained in the first place and people have been given the chance to register any objections to specific kinds of research.
However, restoration of public confidence may, we feel, require a more radical revision of current structures. Confidence must relate not just to the process of obtaining authorisation but also, we believe, to the organisations charged with evaluating the ethical nature of research.

The Medical Research Council recommends that:

All research using samples of human biological material must be approved by an appropriately constituted research ethics committee. This is an important way of ensuring that the interests of donors are safeguarded.\textsuperscript{57}

They note that Ethics Committees are advisory bodies only, but they indicate that Ethics Committee approval is necessary before MRC funded research can take place.

At present, proposals for research on human biological materials are required to go before an NHS Research Ethics Committee if they involve:

- NHS patients, i.e. those subjects recruited by virtue of their past or present treatment by the NHS including those treated under contract with the private sector
- Foetal material and in vitro fertilisation involving NHS patients
- The recently dead in NHS premises
- Access to records of past and present NHS patients
- The use of, or potential access to, NHS premises or facilities (including NHS staff).\textsuperscript{58}

Ordinarily, samples taken from a dead body would be covered by one or more of the above NHS provisions. The requirement for medical research to come before NHS Research Ethics Committee is not generally enshrined in law\textsuperscript{59} but arises from a Department of Health report\textsuperscript{60} and, indirectly, from the general rule that most refereed journals will not accept research otherwise, thus effectively ruling out publication. In effect, the conduct of research can be described as falling within the framework of self-regulation by the professionals themselves, even although there is a requirement that some ‘lay’ representatives must sit on each committee.

It is our view that there are currently a number of issues relating to the role of Research Ethics Committees which are worthy of consideration and possibly reform. These might broadly be summarised under the following headings:  

\textsuperscript{57} Medical Research Council, note 48 above, at p. 4 
\textsuperscript{58} Central Office for Research Ethics Committees (COREC) website: http://www.corec.org.uk This advice comes from Department of Health, Local Research Ethics Committees HSG 91(5) s.22, London DoH 1991
\textsuperscript{59} with the exception of research conducted in terms of the Adults With Incapacity (Scotland) Act 2000, s.51(3)(c) 
\textsuperscript{60} Department of Health, Local Research Ethics Committees HSG 91(5), London: DoH 1991
i) membership
ii) training
iii) policing/monitoring of ongoing research and researchers

Arguably, the first two are outside the remit of the Review Group, although some concerns have been expressed over the years about the constitution and training of committee members, and we believe that these matters should also be addressed as part of our recommendations for reform. We note that there has recently been a 3-year Consultation on Developing Ethics Committees in Europe, which concluded that:

- the mission of hospital ethics committees should be to promote ethical reflection, raise relevant ethical issues in the context of patient care, promote the protection of patient rights, and provide an education framework for ethics within the hospital setting;
- it is necessary for structures that support and/or reinforce ethics reflection and decision-making to be developed in European Hospitals;
- it is up to each national context to determine the most appropriate type of structure;
- the general approach should be through ‘partnership ethics’: ethics that aims at shared decision-making through the discussion and the avoidance of asymmetrical relationships.61

While these comments are to be welcomed, they still in our view do not satisfy all of the concerns that we have identified. In particular, they do not make firm recommendations about the monitoring and policing of research, about which we have a particular concern. At present the job of the LREC or MREC is finished once it has given authority to proceed with a research project. Although researchers will be expected to stick to the agreement they reached with the Research Ethics Committee, there is no way at present of ensuring that they have done so.

Equally, it must be borne in mind that not all research will be done by those who have a therapeutic relationship with the research subjects or their proxies; thus the principles of medical ethics will not necessarily form part of the professional etiquette of all researchers. Even when they do, it is arguable whether or not they are sufficient to ensure best practice throughout a research project. Although the vast majority of researchers are committed to ensuring the ethical quality of their work, ‘unethical’ research has sometimes been published and some submissions to academic journals are not accepted because the editor has doubts about their ethics. For the moment, therefore, it can be concluded that the system does not always work as well as it might.

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90 Given the sensitivities aroused by the disclosure that organs were being removed and retained without proper authorisation, ostensibly for research purposes, it seems an appropriate time to consider whether or not the entire process of ethical review requires to be strengthened. There will be less reason for concern about the functioning of Ethics Committees themselves if our recommendations concerning the obtaining of authorisation are carried out. However, this does not entirely obviate the problems identified. It is clear that at Alder Hey the removal and retention of organs and tissue did not result in many cases in their use in research projects. Although we would anticipate that such practices would cease, we believe that this should be carefully monitored. Our earlier recommendations about seeking authorisation for a specific or general proposal should at least ensure that families are aware of the use to which organs or tissue are to be put, or will ensure that they have agreed to provide authorisation for legitimate research in general.

91 However, the current structure of ethical review does not include a number of safeguards which we believe would enhance confidence in the system and provide a clear framework to ensure best practice for the future. First, ethical review is essentially confined to the preliminary stages; that is, ethical scrutiny of the research protocol. Once embarked upon, the ethics committee has no further direct role to play in the manner in which the research is carried out. If our recommendations that families should be able to object to certain kinds of research, for example, are to be meaningful it is, we believe, imperative that projects are closely monitored to ensure compliance. Equally, ethics committees have no authority to take legal action against researchers who breach the terms of approval, although approval could be withdrawn with consequences for the publication of results. In addition the Department of Health has stated that:

If it comes to the attention of a committee that research is being carried out which it has not been asked to consider or which it has considered but its recommendations have been ignored, then the local research ethics committee should bring the matter to the attention of its appointing authority, the relevant National Health Service body and to the appropriate professional body.62

92 The question, however, remains just how Research Ethics Committees would normally become aware of any such problem. The absence of a clear monitoring role once research permission has been given makes the possibility of identifying problems remote. We are not suggesting that researchers enter into research projects with the intention of ignoring ethical review – indeed,
there is good evidence that they take the process of ethical review seriously. However, scientific fraud is a reality. We believe that, particularly in respect of this most sensitive area, it is imperative that all steps are in place which can both minimise the risk of unethical behaviour and maximise confidence in the system.

93 The creation and operation of Research Ethics Committees has also recently been addressed by an EU directive.63 The directive is prescriptive on a number of matters about the conduct of clinical trials and the responsibilities of ethics committees. Member states are expected to have around three years to implement this directive. While this directive is specific to clinical trials and therefore does not cover the retrieval of, or research on, tissues/organisms taken after death, it will have a significant impact upon the work of ethics committees. Many of the requirements regarding the operating procedures of ethics committees might be considered equally applicable to consideration of research on human tissue. In addition, there are a number of developments already under way in the legal and regulatory framework for research, including a Research Governance Framework issued by the Department of Health, concerning accountability for aspects of research.64 It sets standards, details the responsibilities of the key people involved in research, outlines the delivery systems and describes local and national monitoring systems. Clarification of the role and remit of Research Ethics Committees in Scotland has also been undertaken by the Scottish Executive Health Department.65

94 Similarly there has been a recent review of Institutional Research Boards (broadly equivalent to the UK research ethics committees) in the United States. Institutional Review Boards (IRBs) are committees of scientists and lay people, independent of the research being conducted, who review and approve the research. As part of their review, boards approve the research before it can begin, provide ongoing review of amendments and adverse event reports, and conduct continuing reviews at least annually. IRBs seek to ensure adequate protections are in place and that subjects are given the opportunity to provide informed consent.66

95 It can be seen, therefore, that the role of the IRB is very similar to that of the LREC or MREC in the UK, although arguably more emphasis is placed on their performing a continuing role in monitoring the progress of research. However, a recent report from the Department of Health and Human Services, Office of the Inspector General, Protecting Human Research Subjects: Status of Recommendations, April 2000, OE1-01-97-00197, at p. 8

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Services criticised IRBs on the basis that:

Continuing IRB review of research after it has been initially reviewed is a low priority at many IRBs. IRBs know little of what actually occurs during the consent and research processes.  

96 In the United States, research activity is expected to conform to what is known as the Common Rule. This developed over a number of years in this way:

HHS/NIH regulations were established in 1974 and in 1991 became the basis for the Common Rule for 17 Federal Departments and agencies. The FDA established another set of regulations in 1981 which were later harmonized, to the largest extent possible, to conform to the Common Rule in 1991.  

97 Thus, there is a federally approved set of rules to which it is expected IRBs will conform. However, in a report published in 1998, it was found that:

- IRBs face major changes in the research environment;
- they review too much, too quickly, with too little expertise;
- they conduct minimal continuing review of approved research;
- they face conflicts that threaten their independence;
- they provide little training for investigators and board members;
- neither IRBs nor HHS devote much attention to evaluating IRB effectiveness.  

98 Each of these criticisms could be levelled at the UK situation, and we suggest that there is a need to clarify and reform the practice of scrutinising research. We believe that a structural change to the ethical review of research is required if confidence in the aims, values and conduct of research is to be enhanced.

99 We therefore consider that there is a need to consider placing research ethics committees on a statutory basis, with a remit covering training and membership issues, but also - and very importantly - with clear statutory powers over all forms of research using human tissue removed at post-mortem examination and the power to police and monitor research in progress and take specific action against any researcher(s) who fall below certain statutory requirements.

100 There are, however, alternative solutions which we also believe it might be valuable to explore, before reaching a final conclusion on the exact form of
any statutory body created and its method of working. In the United Kingdom, models already exist in other areas of research which might usefully be considered. Under the Animals (Scientific Procedures) Act 1986 (ASPA), it is an offence, except under licence, to carry out any scientific procedure on non-human vertebrates (later extended to include the invertebrate Octopus vulgaris). A personal licence is required by everyone carrying out regulated procedures: licensees must first undertake a training course, including law and ethics. A project licence is required for every scheme of work: applications for this must show that non-animal alternative methods have been considered, that the objectives and expected benefits are practicable, and that the use (and severity of use), numbers and types of animals are justified. Regulated procedures may be conducted only in designated premises, each of which is required to have an Ethical Review Process (ERP): this (including researchers, animal care and welfare officers and normally an independent external member) oversees the preparation of project licence submissions (and any subsequent applications for amendments to the licence) and all aspects of animal welfare in the establishment. Licences are issued (or refused) by the Home Office, ultimately on the basis of the ‘cost-benefit principle’: ‘in determining whether and on what terms to grant a project licence the Secretary of State shall weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the programme specified in the licence’. The Act is administered (over the UK as a whole) by 20-30 Home Office Inspectors, who assess licence applications and inspect premises to ensure compliance with the regulations. If necessary an Inspector can stop a project or revoke a personal or project licence. A report with statistics of animal use, infringements of the Act etc. is published annually. In addition to the Inspectorate, the Home Secretary is advised by the Animal Procedures Committee (APC), an independent body whose members include members of animal welfare and anti-vivisection bodies, and which also issues its own annual report. Inquiries by the APC and the Inspectorate have led to refinements of the working of the Act, such as bans on the use of great apes, LD 50 tests, and of animal use in the testing of alcohol and tobacco products and cosmetics.

The ASPA regulations are stricter than those governing LRECs in two respects: they are statutory and they include provision for monitoring of research (unless amendments are approved, deviations from the original plan may be infringements, which incur penalties, and premises and projects are inspected). Among the reasons for greater strictness is the absence of a consent requirement, so that there is a consequent need for the interests of animals to be protected in other ways. While the use of human organs and tissues in research differs from the use of animals, we believe that elements of
the ASPA system might be relevant to strengthening control of the former. The Home Office Inspectorate’s monitoring of projects is highly effective, but also very economic. The system also charges ERPs with being the ‘conscience’ of the establishments where animal research is conducted, and in this and other respects, the ASPA system has effects which go beyond the merely bureaucratic, to changing the culture of research in ways that are responsive (through ERPs and the APC) to public opinion. In our view, LRECs may have a useful extended role to play (like ERPs) in changing the culture of research (which to some extent they already do through their feedback to researchers on, e.g. patient information). The introduction of a limited number of Inspectors (in Scotland, maybe only two or three) could be a more effective way of reassuring public opinion and re-establishing public confidence.

A further option would be to consider establishing a Human Tissue Research Commission with overall responsibility for monitoring all research which uses human tissue, including tissue banks. The major advantage of this model would be that it would have a statutory basis and wide-ranging authority over relevant research projects. It would be in a position to make specific recommendations to research ethics committees and would be able to inspect and monitor research projects on a basis similar to that provided by the terms of the Animals (Scientific Procedures) Act 1986. The Review Group notes that a similar proposal has been made by the Royal College of Pathologists in respect of the handling of ‘surplus’ and archival material from human biological samples. Their recommendation is as follows:

Oversight of these safeguards [outlined in the report] will fall to local ethics committees. However, a central body should be created (or an existing body given powers):

• to oversee all uses of human tissues
• to guide research ethics committees in the oversight of such use.

We, therefore, recommend that the current consultation exercise should include consideration of the value of creating a statutory underpinning of research on human tissue, and believe that the models outlined above should be given serious consideration. We are, of course, aware that any such radical review of the law will take some time. We also, therefore, further recommend that the current Review Group (or equivalent) should remain in place, until reform of the law is completed, with a specific remit to provide ethical review of all research projects involving human tissue removed from deceased persons.

70 see the document in note 56, above, recommendation 7
One further issue in terms of research also merits consideration and, we believe, legal clarification. Although we have said that there is generally believed to be no property in the human body, it would be a nonsense to suggest that human tissue has no actual value.

FINANCIAL ASPECTS OF RESEARCH

There is evidence to suggest that people make a moral distinction between commercial and non-commercial medical research. There is widespread support for medical research in general, but the most favoured model of this research is the medical scientist who pursues research for the benefit of humanity and who makes the results of his or her research available to all who are in need of it. The extensive departure from this ideal in contemporary biomedical research is well established, with the result that a very substantial proportion of such biomedical research is today conducted either by commercial companies or by those who are paid to conduct research on their behalf. It is possible that this is not altogether known to the public at large, and it may be that public opinion on the morality of commercial research in medicine and pharmacology is based on a misunderstanding of the financial realities of modern science. These realities have been accentuated recently by the progressive switch from state-funded to industry-driven scientific research.

In spite of this, antipathy towards commercial involvement in biomedical research exists and this, crucially, is reflected in differences in the attitude that people have to the use of human material in research. This distinction was confirmed, for example, in research undertaken by the Human Genetics Commission into public attitudes towards the research use of genetic materials: respondents were markedly more willing to allow research on their DNA if the research was non-commercial than if it was commercial.

What is the basis of this objection? Various factors may be at play here, but a powerful consideration is likely to be some notion of exploitation. The commercial use of tissue is seen as using the individual from whom it has been extracted. The commercial researcher makes a profit from the use of a substance obtained from another’s body. The donor obtains no benefit from the use of his tissue, although it is has come from him or her. This is a classic exploitation argument.

Of course it is more complicated than that. The fact that the human body is involved raises particular objections. Many people are uncomfortable about any use of the human body because it offends the notion that the human body is special: our sense of our humanity is intimately associated with the
human body, and the body should therefore be extra commercium. We object strongly to the sale of human beings, and the moral repulsion that we feel to that spills over into a moral disquiet over the purchase and sale of bodily materials. This has led to the passage of legislation in the United Kingdom specifically outlawing the sale of organs for transplantation purposes. This legislation, however, does not prevent the sale of other forms of human tissue, suggesting that the evil sought to be addressed in the legislation was not so much a trade in human materials but in non-renewable tissue, the loss of which placed the donor at some risk. These moral scruples about the commercial use of tissue are not universally shared: there are, for example, some who would argue that to forbid a person to use his or her body as he or she wishes is an infringement of personal autonomy.

109 In Western Europe the commercial use of bodily products, other than those coming within the definition of organs, is a fait accompli. Medical products are on sale which are derived from human bodily materials, and these products are the subject of commerce. However, even if we accept such commercial exploitation of human tissue, we may wish to ensure that it will only involve those who agree to it. An appropriate legal regime for this must therefore include the safeguard that human tissue can only be put to commercial use if the person from whom it was removed had been informed of that possibility or intention and had specifically agreed to it. In the case of a third party agreement (for example, where parents provide authorisation in respect of a deceased child) the person being asked to provide authorisation should be given the same information.

THE CURRENT LAW

110 Scots law on the ownership of human tissue is undeveloped because this issue has not arisen in the past. This is not surprising. The common law has not had to contend with the question, and legislation has been concerned with limited aspects of the issue (anatomical dissection and organ transplantation). It is therefore difficult to make a comprehensive statement on the law. Some guidance can be obtained from English common law, as it is likely that a Scottish court would pay particular attention to the few English and Commonwealth decisions on the matter, although the Scottish courts would not be bound by them.

OWNERSHIP OF THE HUMAN BODY AND MATERIALS EXTRACTED FROM IT

111 The common law systems have generally declined to recognise ownership in the human body in its integral state. There is now an extensive literature on this subject, the general conclusion of which is that neither the human body

71 Human Organ Transplants Act 1989
nor its individual parts are owned by the person whose body it is and it,
therefore, cannot be the property of another. At the same time, the law has
recognised certain rights of control over a dead body which might be
exercised by executors or family members. The language of ownership,
however, never sits very comfortably with these rights.

The common law systems have recognised in cases such as Doodeward v
Spence\(^2\) and R. v. Kelly\(^3\) that parts of the body may become the object of
legal protection (whether this is based on the notion of property protection
or on some other basis) provided that they had been subjected to processes or
treatment (usually to enhance their value for a particular purpose). No
Scottish court has considered this issue, but a Scottish court may well find the
English law solution in this respect attractive, in that it recognises the de facto
property interest which people acquire in bodily parts.

Can human tissue be sold or otherwise transferred to the ownership of
another in Scots law? In principle, there is no reason why it may not – always
provided that it is not an organ. No Scottish court has ruled on the question
of whether human tissue can or cannot be owned, although Roman law
(which has considerably influenced Scots law) suggests that it cannot be.
There is no authority to the contrary in any institutional writings of Scots
law. If human tissue is a res (a thing), then it can only be excluded from the
normal civil law rules if it is deemed to be extra commercium. A court might
declare human tissue to be extra commercium on grounds of principle, but that
would have the result of effectively excluding the legal protection of the sale
of any medicinal product which was manufactured from human bodily
materials, unless the critical factor was not the origin of the materials, but
rather the way in which they had been processed or treated.

THE IMPLICATIONS OF AN OWNERSHIP REGIME

If ownership can be asserted in human bodily materials it means that the
person who acquires the property is entitled to put it to such use as desired
(subject, of course, to any regulatory restrictions which might be imposed by
law). A company acquiring human tissue might therefore exploit its
commercial potential without thought to the wishes of the original donor or
vendor as the latter has no continuing interest in the property.

Such a system has the attractions of simplicity and finality. However, it would
only be defensible if the ownership issue were very clearly defined. In other
words, there must be an unambiguous transfer of all rights in the tissue. In
practice, this issue tends to be unclear. Tissue removed from persons in
hospital may not have been the subject of any discussion. The person from
whom it is taken may be unaware of the fact that it has been taken; s/he may

\(^2\) 6 CLR 406 (1908)
\(^3\) [1998] 3 All ER 741
have no idea that s/he is abandoning it or transferring it; and s/he may have no idea of the identity of the person to whom it is being made over. This lack of clarity and common understanding as to what is actually happening seriously weakens the validity of the simple ownership model. Indeed, the transaction lacks many of the basic features which characterise valid transactions in other areas of the civil law (e.g. certainty as to price, agreement as to identity of the object of a sale, corresponding offer and acceptance in contract). In addition, it is fundamentally inappropriate since the person from whom the material is taken has never owned it in legal terms.

116 Another powerful objection to the ownership approach is the fact that it fails to acknowledge that people may not wish to surrender all rights in relation to bodily materials extracted from them. Human tissue is generally regarded as special, and it is therefore probably necessary to recognise a continuing interest on the part of the person from whom it is taken. This interest may be defined (at its simplest) as an interest in being able to control the uses to which tissue will be put and, if desired, in preventing any use of it. This interest is not incompatible with the surrender of rights in the tissue. It is incompatible, however, with a simple commodity-based approach. It should be remembered that the ‘rights’ of which we speak are not rights such as those which would derive from ownership, but are rather rights to bodily integrity and privacy as guaranteed by the Human Rights Act 1998.

117 In practical terms, the recognition of an interest in controlling tissue means that authorisation becomes extremely important. In particular, authorisation must be obtained for those aspects of tissue use which are sensitive, commercial use having already been identified as one such aspect. A further continuing interest is an interest in possibly preventing DNA analysis of tissue which can be linked to a particular individual. If a person agrees to the use of a bodily sample in research into, say, arthritis, then it cannot be assumed that he or she consents to the analysis of the DNA in the sample. Such an analysis may reveal information which s/he wishes to keep private, or it may reveal information that s/he does not wish to be revealed in the first place. Again, this challenges the adequacy of the simple ownership model. However, in view of our earlier concerns about the extent to which such interests can be said to survive death, and our concerns about the potentially competing interests of family members, we again recommend that this issue is referred to the Human Genetics Commission for their consideration as a matter of urgency.

118 For the moment, therefore, it appears that there are some uncertainties in the
law which we believe require clarification. It may be that this matter is beyond the remit of the Review Group, but we believe that it is an important issue in light of our proposed clarification and strengthening of the law in this area. We therefore suggest that consideration be given to the development of a legal regime which balances the various interests concerned. The development of such a regime might usefully consider the following:

(1) The commercial use of human tissue is an accepted practice in contemporary medical science.

(2) The law relating to this use is unclear, but is probably based on untested notions of property, or lack of it, in tissue.

(3) There is a degree of public sensitivity to some uses of tissue removed from living donors. This sensitivity is arguably even stronger in relation to tissue removed from the dead who cannot give their views on this.

(4) In the recent ethical debate on the use of human tissue, there is overwhelming support for a central role to be given to authorisation (what would previously have been referred to as ‘consent’).

(5) The fact that tissue will be used commercially should be made explicit in the obtaining of authorisation/consent, given sensitivities to commercial activity in this area.

(6) There has been no legal recognition of any right on the part of the donor to participate in the profits of commercial use of tissue. Such a ‘right’ has not attracted substantial support in the debate, although there are plausible arguments as to why it should do so.

Until this matter is finally resolved, we recommend that, provided that authorisation has been properly given for the storage or use of human tissue removed at post-mortem examination for research, and provided that the tissue is only used or stored in accordance with the authorisation, any rights in the tissue are deemed to have been relinquished by the person(s) providing authorisation. In line with the recommendations of the Royal College of Physicians, therefore, the tissue should become subject to the overall authority of the hospital authority, save that their authority only extends to storage and use of the tissue in the terms of the authorisation given.74

74 It is to be noted that it is lawful ‘to have possession of’ tissues which have been obtained by virtue of the authority given under the Anatomy Act 1984, s.6
INTERIM REGULATIONS

120 In our preliminary report we made a number of recommendations in respect of organs/tissue which are currently stored. Most importantly, we recommended that such retained tissue should not be disposed of until the end of a period of five years from the date of our report. A publicity campaign to ensure the effective dissemination of this recommendation is currently being organised. We further recommended that where organs have not been reclaimed within that period, Trusts may wish to dispose of them, and that this should be done respectfully.

121 In May 2001, the Review Group received a communication from representatives of the following support groups: the Association for Children with Heart Disorders, the Scottish Cot Death Trust, the Scottish Organisation Relating to Retention of Organs at Post-Mortem (SORRO) and the Stillbirth and Neonatal Death Society (SANDS). This letter followed a meeting of these groups after their attendance at a meeting of the Review Group. In it, it was suggested that if the 5-year period meant a total prohibition on the use of retained tissue this would significantly hamper efforts to find better diagnostic and therapeutic tools and thus could contribute to potential suffering for families in the future. The Review Group recognises the importance of this concern. As a result, it is proposed that the 5-year recommendation is modified in the following way. As part of the continuing campaign to inform relatives of their rights in this respect, it should also be made clear that research which is non-destructive and important may be carried out on currently retained tissue after a period of one year from the start of the 5-year period. By non-destructive, we mean research which is either observational or which requires only minute samples of the tissue and by important we mean where the research is evaluated as being likely to make a significant contribution to diagnosis or therapy. We are grateful to the families concerned for this proposal and wish formally to record their compassion and altruism in making this suggestion. However, we also recognise that for some families the removal of even the smallest samples of tissue is objectionable. The advertising campaign, therefore, must encourage those who object even to this limited research to make that objection known, even if they have not yet decided whether

\[ ^{75} \text{paragraph 25(c)} \]
\[ ^{76} \text{paragraph 25(d)} \]
they wish to be given information about any retained samples or what they ultimately wish to be done with such material. However, it must also take account of the fact that some families will not wish to have old wounds re-opened by an aggressive advertising campaign. We thus intend to ensure that the agency creating the campaign will have access to a variety of views on this subject in order that the campaign can be both sufficiently sensitive and effective. Implementation of our main recommendations will ensure that this problem will be resolved at the end of the 5-year period; therefore these recommendations will only be in force until the expiry of that 5-year period.

We also recommend that it is made clear that parents can, as of now, specifically authorise the use of any retained tissue for research purposes. Even if they are unsure about whether or not tissue has been retained, and even if they do not wish to know, they can contact the hospital concerned at any time to provide such authorisation. Hospitals should, therefore, continue to provide a dedicated telephone number for these purposes and produce clear and accurate records of any discussions that take place on this issue.

122 We recommend that any tissue still in existence at the end of the 5-year period can be reclaimed by those who provided authorisation for its removal and retention in the first place.

123 However, we are also concerned that valuable research may be impeded if tissue which has not been reclaimed requires to be disposed of at the end of this period. In particular, the tissue banks which have been so important in the identification of conditions such as CJD would need to be disposed of. It is not part of the Review Group’s intention to impede such research, nor – as we have already said – is this the intention of the families to whom we have spoken or from whom we have received evidence. Indeed, it is very much in the public interest that medical research should be facilitated. Thus, we additionally recommend that unclaimed tissue at the end of the 5-year period should be legally deemed to be under the authority of the relevant hospital authority, which may make use of it for legitimate research or educational projects, or must ensure its respectful disposal. This would also mean that the material could be available for return even after the expiry of the 5-year period.
The report on the first phase of the Review Group’s work discussed, in paragraphs 74-77, the concerns of relatives relating to the disposal of organs, tissue blocks and slides retained at post-mortem examination under past practice. The Review Group was keenly aware that the ability to achieve disposal in the manner which the family thinks most fitting is a key element in the process of allowing these families to draw a line under the past.

In paragraph 74 of our preliminary report we drew attention to the fact that the term ‘disposal’ was felt by some relatives to be less than respectful, but noted that discussions with families had failed to produce a suitable alternative. It has since been suggested to the Review Group that ‘final funeral arrangements’ might be a more fitting expression. We commend this for further consideration in circumstances where it is appropriate.

The Review Group noted with concern in its first report the lack of consistency of practice across the country, and has heard those concerns reiterated while it has been at work on the second phase of its remit. It fully supports the efforts of those families who wish to see consistency of approach across the country as a whole. The Review Group is aware that the Scottish Executive Health Department is bringing together all the agencies involved in disposal in order to promote that consistency. It also understands that the Department intends to issue guidance which will be available to each family so that they can be aware of all the factors they need to bear in mind when considering their preferred method of disposal.

There is a particular urgency about this work, as the guidance needs to be in place before the first wave of publicity announcing the start of the 5-year period during which families will be notified of their entitlement to reclaim organs retained under past post-mortem practice without their knowledge or agreement. The need for sensitive disposal will, however, also apply in relation to organs, and to tissue blocks and slides which do not form part of the medical record, retained with proper authorisation under the new procedures the Review Group has recommended, since the standard authorisation form developed by the Review Group will allow families to express their wishes on this point.

The range of disposal options which families have made it clear they wish to be able to pursue has put existing legislation under strain. Most of it, particularly that relating to burials, is of considerable age. When the legislation was passed, it had never been contemplated that families themselves might wish to reclaim organs, blocks and slides for disposal. The same considerations
also apply to the administrative procedures associated with burial and cremation. The Review Group has been encouraged by the extent to which many of the agencies involved have sought to respond to the wishes of families once they were clear how important the act of sensitive disposal was to those families. They have, clearly, to operate within the existing law, but interpretations of the law have varied from one part of the country to another.

The Review Group is in no doubt, however, that the law, and administrative practice, must adapt themselves to the wishes of the families. For those aspects of disposal which depend on administrative procedures, we recommend that the guidance being produced by the Scottish Executive Health Department should aim as far as possible to promote consistency of approach across the country as a whole. For those aspects of disposal where removal of the barriers can only be achieved through changes to regulations or primary legislation, the Review Group recommends that the necessary amendments be identified and implemented as soon as possible.

PROCURATOR FISCAL POST-MORTEMs

The Review Group appreciates that a number of cases, both involving past practice and in the future, will relate to the disposal of organs, tissue blocks and slides retained as a result of a post-mortem examination carried out on the instructions of the Procurator Fiscal. In line with its general principle that these cases should be conducted with the same sensitivity as applies to hospital post-mortem examinations, the Review Group recommends that the Minister for Health and Community Care should make a formal reference to the Lord Advocate, enjoining him to make sure that Procurator Fiscal offices should co-operate as fully as possible, consistent with their responsibility for the administration of justice, in the implementation of the family’s preferred option. This should be reflected in the documents on Fiscal post-mortems being prepared by the Crown Office for use by relatives, and the Crown Office should also ensure that there is maximum consistency of approach across Scotland.

Implementing this recommendation means above all, as we pointed out in paragraph 90 of our preliminary report, that a system needs to be put in place to ensure that Procurators Fiscal are notified explicitly and promptly when organs, tissue blocks and slides are retained as a result of a Fiscal post-mortem examination, and that the Procurator Fiscal in turn ensures that the pathologist in possession of the organs, tissue blocks and slides is made aware when retention for the Fiscal’s purposes is no longer necessary. At that stage, there must be appropriate arrangements which will ensure that disposal of those organs, tissue blocks and slides then takes place in accordance with the wishes of the next of kin. The inclusion in this system of the possibility of seeking an authorisation from the next of kin for the use of those organs, tissue blocks and slides for research purposes should also be considered.
### APPENDIX 1

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<tr>
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- Edinburgh University
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- Lecturer in Medical Law
- Glasgow University
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- Professor of Medicine & Therapeutics
- University of Aberdeen and Hon. Consultant Physician/Nephrologist
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- Emeritus Professor of Pathology
- University of Glasgow
- Phase 1
- Emeritus Professor of Forensic Medicine
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- Phase 2
- Professor of Medical Law
- University of Edinburgh
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APPENDIX 2

PRELIMINARY REPORT

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1 **EXECUTIVE SUMMARY**

1 Considerable distress was caused to a number of relatives throughout Scotland when it emerged that organs taken from their relatives at post-mortem had been retained without their consent having been given. Additional distress has been generated for them by the difficulties associated with trying to acquire information about whether any organs continued to be retained and the fate of those organs. Mistakes in recording of information in hospitals, or a lack of effective communication, have only added to that distress.

2 The Review Group was brought into existence as a result of the particular concerns of parents relating to organ retention without consent. It became clear during the Review Group’s work that the sensitivities surrounding paediatric post-mortems were far greater than those related to adult post-mortems. The death of a child is a reversal of the natural order, and parents clearly feel the need to continue to protect the child after death, as they have in life. The present problem for many is that past practice has resulted in a sense of betrayal of that protective role. Everyone who comes into contact with bereaved parents needs to be aware of the unique bond which gives rise to these feelings.

3 The Group is extremely grateful to all those who have felt able to share their experiences with it. For many, this will not have been easy and will have re-awakened some of their most painful memories. The Group feels that relatives are owed a personal apology by the hospitals concerned for the distress they have undergone.

4 While the Group found no evidence in Scotland of the shocking practices discovered at Alder Hey, it is in no doubt that past practice in Scotland has also led to a significant breakdown in trust between relatives and the medical profession. While the medical profession has acknowledged the shortcomings of such past practice, the Group has identified a clear need for a major cultural shift if this trust is to be restored. Education of everyone affected by the post-mortem process will have a fundamental part to play in bringing about this change. The Group feels that harnessing the experience and goodwill of the voluntary sector, including support groups in this context should be given very serious consideration by all concerned. The overall aim should be to re-build a climate of trust, based on openness and mutual respect.

5 It became clear to the Review Group at a very early stage that the fundamental issue of concern relates to consent to post-mortem examination, which is relevant only to hospital post-mortems. This highlights the need to
make it absolutely clear to relatives whether a post-mortem is being instructed by the Procurator Fiscal or is being requested by the hospital itself.

**Hospital Post-Mortems**

6 Hospital post-mortem permission has in the past been sought by medical staff, and the post-mortem examination is carried out in the hospital mortuary by a pathologist employed by the Trust. Rarely, a General Practitioner may request a post-mortem examination. The results of the post-mortem examination are sent to the requesting doctor.

7 Where consent for post-mortem examination is required (that is, in hospital post-mortems) the Review Group addressed the question of who is the most appropriate person to seek it. We feel that it would be unwise to be too prescriptive on this matter, as the evidence from relatives demonstrated that individuals may prefer to have this extremely distressing conversation with different people – for example, midwives, senior clinicians or pathologists. At the public meeting, which was held in Glasgow on 25 January 2001, there was also some support for the establishment of a bereavement officer within hospitals. Such an individual might be responsible for liaison with relatives and clinical staff, record-keeping, referring relatives to support groups and so on.

8 The Review Group is firmly of the view that – irrespective of who has the responsibility of asking relatives for consent – it is a matter which must be dealt with in the most sensitive manner possible. Bereaved individuals must be given time to deal with the information on an occasion of great personal loss. **For grieving relatives, there is no good time for seeking consent.** The request should be expressed in clear language and such information as relatives wish to receive should be made available to them from whomever they feel would be the person best placed or most appropriate to do so. Hospitals should make available a dedicated area in which these conversations can take place and should at all times respect the wishes of relatives. There are some differences in the legal position between children and adults which will be considered later.

9 A second matter of great concern relates to the retention and use of organs removed at post-mortem. Where an adult deceased has made prior notification of their wishes, these take precedence in terms of the law over the wishes of the relatives. Hospital staff will wish to establish sensitively that the relatives are aware that they intend to act on the wishes of the deceased. In cases where consent has been given to post-mortem, no organ should be retained without the specific consent of the deceased or, in the absence of this, the family, nor should it be used for any purpose to which the deceased or the family has not agreed.
Naturally, there will be some relatives who wish neither to receive information about the post-mortem nor to be told what may become of the organs after post-mortem, and their right not to receive this information must also be respected. This accentuates the need for sensitivity on the part of the persons seeking agreement. Where relatives express a wish not to be involved in these decisions, they should nonetheless be reassured that they can at any stage in the future come back to the hospital for any or all of the information which they had previously declined and they should be made aware of who is the appropriate person to contact for it. In cases where medical staff feel unable to issue a death certificate and a Fiscal post-mortem is therefore required, no organs should be retained for educational or research purposes unless consent for this is subsequently obtained.

Where relatives give consent to the retention and use of organs, it must be made clear to them that they can change their minds about this at any stage, and again they should be provided with information as to whom they should contact. Bereavement and grieving are not one-off events—coming to terms with loss is an ongoing process, and hospitals must be sensitive to this and ensure that appropriate staff are available to assist relatives through the process as required. We are also concerned that relatives have confidence that their agreement to the use of organs for research or educational purposes need not apply to all research or education, and that they are made aware that they can also request information in the future about the use to which organs are put. Indeed, it should be clear to them that they can retract their agreement at any stage. Relatives should be given the opportunity to provide a general consent for research and/or educational purposes, or to agree only to specific uses of organs.

**Procurator Fiscal Post-Mortems**

In the case of Procurator Fiscal post-mortems, it must be made absolutely clear that consent to the post-mortem itself is not required from relatives, but that the Fiscal can only retain organs for as long as is necessary to establish the cause of death and other relevant matters relating to the deceased’s death.

The Review Group is firmly of the view that these post-mortems must be dealt with in as sensitive a manner as are hospital post-mortems. Bereaved individuals must be given time to deal with the information on an occasion of great personal loss. The information provided should be expressed in clear language, and such information as relatives wish to receive should be made available to them by the Procurator Fiscal.

The majority of Fiscal post-mortem examinations are performed on people dying in the community where death is unexplained, sudden or violent. This includes all cases of sudden death in infancy. In a minority of cases death...

occurring in hospital may require to be reported to the Fiscal, for example where death occurs during anaesthesia. In these cases, the post-mortem examination is usually performed by a pathologist employed by the Crown Office in a police mortuary, although in paediatric cases it is often conducted in the hospital where the child died. In some cases, specialist pathologists, for example, neuropathologists or paediatric pathologists from the National Health Service may be involved.

15 Once the Fiscal’s purposes have been satisfied, we believe that relatives should, if they so wish, be given the opportunity to decide on the appropriate and respectful disposal of the organs, including their possible use in research or education. It is vital, therefore, that liaison between Fiscals, hospitals and relatives is effective and that good channels of communication exist. We would also commend the ‘clinic’ system which has been set up in Glasgow, as a result of which relatives have an opportunity to discuss issues of concern with pathologists after the completion of the post-mortem examination. We appreciate that this has resource implications but believe that it is an admirable and worthwhile initiative which could ideally become a Scotland-wide practice.

Training and Educational Issues

16 It is clear that many of our recommendations can be effected by increased sensitivity of staff and the development of more effective lines of communication. This will require appropriate training of clinical staff both in their undergraduate and postgraduate studies and in hospital practice. Many medical schools already offer such training, but they, and in particular Postgraduate Deans, should consider whether their curricula include appropriate training in this respect. Similarly, nursing schools should also consider the need for such training. The Group also identified a need for training of those in the Fiscal service who come into contact with relatives. However, training alone will not solve the problems – it is also imperative that a culture is created which recognises the needs and the rights of relatives.

Place of Post-Mortem in Patient Care

17 The Group shares the view that the hospital post-mortem examination should properly be regarded as an integral part of patient care, which continues even after death. Seen in this light, it is therefore a clinical governance issue, with ultimate responsibility for the conduct of the post-mortem process resting with the Chief Executive of the relevant Trust.

18 It is widely accepted that there can be value in carrying out a post-mortem examination and retaining organs for diagnostic, research or educational purposes. For example, advances in knowledge of heart and brain diseases rely
to a considerable extent on the availability of these organs from post-mortem examinations - the discovery and characterisation of vCJD would not have been possible without the availability of brains from affected cases.

19 In fact, none of the relatives from whom we received evidence at any stage sought to dispute this. However, the good that can come out of organ retention at the moment has arguably been overshadowed by the practice in some hospitals of not seeking specific consent from relatives for hospital post-mortems. The failure to respect the role of relatives is likely to have been counter-productive, as well as unacceptable, as relatives (with the exception of those from certain faiths) might have been willing to agree to retention and use had they been consulted. At present many people may be reluctant to agree to such a request. Re-establishing trust will clearly be crucial to addressing this problem.

Medical Research

20 None of the relatives to whom we have spoken has denied the value of medical research and advance. Indeed, for some of the relatives concerned, it is this research which may prevent them from ever having to go through the loss of a child again. However, in our view, these relatives are entitled to be partners in the process, not passive bystanders. It is not our intention that doctors should be discouraged from seeking consent to post-mortem examination, nor that they should be discouraged from seeking agreement to the subsequent use of organs removed at post-mortem. Rather, it is vital that appropriate consent should be obtained.

The Legal Position

21 There are also wider issues about the need for law reform, which will be considered in the next stage of the Review Group’s work, but it seems clear already that it will be necessary to review the out-dated and vague laws which currently govern the conduct of post-mortems, and in particular the question of organ retention, use and disposal. Nonetheless, we are confident that the acceptance of our recommendations will ensure that past practice cannot recur. This, of course, requires that an effective audit of practice is put in place. As previously stated, this is a matter of clinical governance, and responsibility for auditing hospital practice rests with Chief Executives of Trusts. They will therefore need to satisfy the Health Department that their audit arrangements are robust and regularly monitored.

22 Public confidence has clearly been severely shaken by the events which have unfolded over recent times both in Scotland and in England. It is vital that trust is re-established in order that relatives can be confident that they, and their relatives, are treated with the utmost sensitivity by hospitals and that legitimate medical research is able to continue.
2 RECOMMENDATIONS

23 Although the Review Group has considered both hospital and Fiscal post-mortem practice, the recommendations below largely concern practice in hospitals, since they come within the responsibility of the Minister for Health and Community Care, to whom the Group is reporting. Recommendations to the Lord Advocate regarding Fiscal post-mortems are detailed in section 9.2.

24 These recommendations are intended to ensure that the role of relatives, particularly parents, in the post-mortem process is recognised and respected. These recommendations are also intended to ensure that the hospital post-mortem examination is seen as part of the continuum of patient care. If properly implemented, they should help to make the post-mortem examination part of the healing process for relatives. They are also intended to promote a climate of mutual trust and confidence between relatives and hospital staff.

25 Two recommendations (f and g) have already been made by the Review Group and were issued to the service on 17 January 2001. The Group is concerned that not all Trusts have yet implemented these and they are urged to do so imperatively.

a No hospital post-mortem examination should be undertaken without agreement and no organs should be retained without specific consent. Full information should be provided by a senior member of the medical staff or another appropriate person at every stage for those who want it, but those who do not want information should not have it forced on them. The right of relatives to withdraw their consent at any stage of the process should be made clear at all times.

b Data provided to the Group by Trusts on organs currently retained should be independently validated as a matter of urgency.

c Both in oral evidence and at the public meeting, it became clear that a time limit should be placed on retention of organs currently retained. In order that families have sufficient time to consider their choices, we recommend that a period of five years should be imposed. This provides opportunities for families to reach decisions. It would also accord organs a similar level of respect to that shown to embryos, although there is no real scientific parallel. During that period, relatives should have every opportunity to reclaim organs, if they so wish, and their entitlement to do so should be made clear by a wide variety of methods including sensitive advertising, public information notices on television, use of GP surgeries, libraries and other means.
d Where organs have not been reclaimed within the 5-year time period, and Trusts might wish to dispose of them, this should be done respectfully and taking account of experience gained from discussions with relatives about disposal.

e The British Cremation Authority should remove any administrative obstacles to cremation of individual organs in order to ensure consistency of approach across the country.

f NHS Trusts in Scotland are to follow the example of Yorkhill Hospital in meeting the burial costs where organs have been retained without proper consent.

g All NHS Trusts in Scotland are required to nominate a specific member of staff with a dedicated helpline to act as a liaison officer for enquiries from bereaved parents.

h Where relatives do decide to inquire, hospitals should, where appropriate, offer them a meeting to discuss any concerns they might have.

i Under no circumstances should relatives be approached by the hospital regarding the current retention or disposal of organs about which they will have no knowledge. Relatives should be given every opportunity to inquire, but the wishes of those who do not wish to know must be respected.

j A standard consent form for use across Scotland, and preferably the UK, should be drawn up with the help of a professional designer on the basis of the key points identified by the Group and with input from relatives.

k The communication problems identified between the Neuropathology Department at the Southern General and Yorkhill must be addressed as the misinformation resulting from this problem has been a particular cause of additional distress to relatives. Given the fact that the referral base covers half the population of Scotland, the Neuropathology Department at the Southern General Hospital must be adequately resourced to overcome these and related problems.

l Record-keeping within pathology departments must be improved preferably with the aid of electronic databases. This will greatly facilitate the audit process, ensure proper governance of this important clinical area and will help relatives receive speedy and accurate information.

m Relatives must be made aware that in certain circumstances it will be necessary to retain organs for a longer period, possibly several months, in order to complete the post-mortem examination. They should then be made aware of the option that these organs could be returned to them for disposal in due course if they so wish or that, in some circumstances the funeral may be delayed until the organs can be reunited with the body.
n All staff involved in post-mortem procedures, including medical, nursing, Fiscal and police, require to be educated and trained to deal sensitively with relatives and their concerns at a time of great distress. This is of particular importance in the case of the death of a child. There is also a need for greater public education in this area.

o In cases where doctors think it appropriate, doctors should consult the Procurator Fiscal on the need for a post-mortem before approaching relatives.

p Where hospitals are aware of objections to post-mortem examination on religious or other grounds, this information must be brought to the attention of the Procurator Fiscal so that the Fiscal can consider these objections.

q The Clinical Standards Board for Scotland should be encouraged to incorporate a standard relating to the post-mortem process in their generic standards, as the most effective way of monitoring implementation of our Code of Practice for hospital post-mortems.

r While this whole area has been a source of great concern, there are nevertheless examples of good practice, and these should be disseminated fully and speedily. The Group therefore recommends that staff nominated by Trusts to handle approaches from relatives should actively develop mechanisms for sharing their experiences and achieving a uniformly high standard across the country. These mechanisms should be audited independently for their effectiveness.

3 BACKGROUND TO THE REVIEW GROUP

3.1 UK Inquiries

26 The establishment of the Review Group on the Retention of Organs at Post-Mortem stemmed from the Inquiries in the rest of the UK into past post-mortem practices. The Alder Hey Internal Inquiry (reported 20 December 1998), the Alder Hey Independent External Inquiry (reported 30 January 2001) and the Bristol Inquiry (Interim Report May 2000), heightened public concern and led to confirmation by a number of Trusts in Scotland that organs had been retained following post-mortem examination, in some cases without specific consent. Public concern has focused on six hospitals in particular: The Royal Hospital for Sick Children, Yorkhill; the Royal Hospital for Sick Children, Edinburgh; the Southern General Hospital, Glasgow; Aberdeen Royal Infirmary; Stirling Royal Infirmary, and Crosshouse Hospital, Kilmarnock.
3.2 Existing Policy

27 NHS Circular GEN (1992)33 advised that ‘permission from relatives should be sought for a post-mortem examination unless there is a legal requirement for one. In these cases, the necessity should be explained and relatives kept informed of the arrangements for the examination. Where a post-mortem is carried out, especially at the request of the Procurator Fiscal, it is important that the next of kin are told as soon as possible the cause of death finally determined. Consultants and general practitioners can find this helpful when counselling relatives, especially when a child has died. Provider units should therefore ensure that the clinicians involved know the post-mortem’s findings quickly and where appropriate can obtain a copy of the report’.

28 The Report Autopsy Services in Scotland issued by the National Advisory Committee for Scientific Standards in May 1994 highlighted the need to ‘adopt a sensitive and informative approach’. It advised that the benefits of a post-mortem examination should be explained and backed up by an information leaflet but that no undue pressure should be brought to bear on the bereaved in their vulnerable state. It also recognised diversity of ethnic and religious beliefs and advised that these should be honoured wherever possible.

29 The Scottish Executive Health Department issued MEL (2000)21 in April 2000 advising Trusts to adopt the approach set out in the Royal College of Pathologists’ Guidelines for the Retention of Tissues and Organs (March 2000). This instructed Trusts to ensure that relatives were fully and sensitively informed of the organisation’s policy on post-mortems, specifically why the post-mortem was necessary; how it would be carried out; whether organs would need to be retained; and the options for their subsequent respectful disposal. The Medical Research Council (MRC) has also developed interim guidance for researchers on ethical, legal and management issues relating to Human Tissue and Biological Samples for Use in Research (November 1999) which has been issued to Research Ethics Committees throughout the UK. The Chief Scientist Office has drawn that guidance to the attention of Health Boards and Trusts in Scotland.
4 ESTABLISHMENT OF THE COMMITTEE, MEMBERSHIP AND REMIT

4.1 Establishment of the Review Group

In September 2000 the Minister for Health and Community Care announced that she would be setting up an Independent Review Group to review past post-mortem practices in Scotland. The Review Group understands from the Minister that her decision to set it up rather than to hold a formal public inquiry reflected a number of considerations. In particular, although it was clear that some relatives wished for a full-scale public inquiry, others had contacted the Minister to say how strongly they felt that such an inquiry would be too invasive, re-opening highly emotive issues and prolonging their period of grief. The Group understands that its establishment was designed to allow key questions concerning past practice to be addressed quickly but thoroughly and by an independent panel, thereby allowing relatives to draw a line under their experiences as quickly as possible. These considerations have dictated the manner in which the Group approached its task within the very challenging timetable set for its first phase. The speedy completion of phase one in the form of this Report has been made possible because of the matter being dealt with by this Group rather than through a protracted and formal public inquiry.

4.2 Membership

The Independent Review Group is chaired by Sheila McLean, Professor of Law and Ethics in Medicine at Glasgow University. The membership of the Review Group is designed to reflect a range of interests and incorporates medical expertise, including pathology, and expertise in legal and ethical issues. Its independence has been ensured by its predominantly ‘lay’ membership. A list of the members of the Group can be found at Appendix 1.

4.3 Remit

The formal remit of the Review Group is:

‘to review previous post-mortem practice in Scotland, in particular in relation to organ retention, and current documentation on consent and guidance, taking account of developments across the UK; to develop a Code of Practice for Scotland with particular emphasis on issues of informed consent and the most effective mechanism for keeping that Code of Practice under review; and to clarify current legal issues with a view to making recommendations’.

Although the publicity has focused mainly on paediatric post-mortems, the issue of the retention of organs at post-mortem also relates to adult post-mortems, and is thus covered by the remit of the Review Group.
The Group's work falls into two phases. The first phase, of which this Report marks the completion, has undertaken a review of past practice in order to answer the key questions that parents and relatives have asked about post-mortem consent, organ retention and the disposal of organs at hospitals across Scotland. This phase of the work included disclosure of organs retained at these hospitals, as well as in university collections. It also has resulted in the preparation of a Code of Practice designed to ensure that organs will, in future, only be retained from hospital post-mortems with the specific agreement of relatives.

In the second phase of its work, the Review Group will undertake a review of the law relating to consent, removal, retention, use and storage of organs, as well as issues relating to the ownership of human tissue and post-mortem procedure. This phase is due for completion in autumn 2001.

5 METHOD OF WORKING

From the outset, the Review Group was determined that all its proceedings would be characterised by complete openness and transparency. It has gathered information concerning past post-mortem procedures using four main mechanisms: by writing to key individuals and organisations; by advertising for members of the public to share their views and experiences with the Group; by hearing Oral Evidence from individuals and organisations; and by visiting a number of hospitals where it is known that organs have been retained.

5.1 Written Evidence

The Review Group began its work by contacting in the region of 150 organisations and individuals. These included parental support groups; religious organisations; organisations representing ethnic minority groups; medical Royal Colleges, associations, and councils; and experts in medical law and ethics. A list of organisations and individuals contacted is included at Appendix 2.

All primary care and acute NHS trusts in Scotland were contacted and asked to provide detailed information relating to numbers of organs retained, and past and present consent procedures. A list of the responses received from acute trusts is included at Appendix 3. The responses received can be viewed on the Group's website (http://www.show.scot.nhs.uk/scotorgrev). A copy of the responses will also be available for public viewing at the Scottish Executive Library located at Saughton House, Broomhouse Drive, Edinburgh. Those wishing to consult these documents should telephone 0131 244 4552 to arrange an appointment.
39 Listening to the experiences and views of the public, in particular bereaved relatives, played a key part in addressing the problems of the past and developing a Code of Practice to ensure that organs are never again retained without proper consent. The Group placed advertisements in a number of newspapers in December 2000 with the aim of encouraging people to share their views and experiences. We have been advised that this would ensure coverage of approximately 75% of the population. In order to facilitate responses a Relatives Questionnaire was also drawn up for those who wished to use it. Where the express permission of the individuals concerned was granted, letters, emails and completed questionnaires received from members of the public are available on the website or from the Secretariat.

5.2 Oral Evidence

40 In addition to this written evidence, the Group has held 23 Oral Sessions, gathering evidence from a total of 59 individuals. Those represented included bereaved individuals and parent support groups, hospital trusts, representatives of the Crown Office and Procurator Fiscal Service, the British Medical Association, the Royal College of Nursing, Strathclyde Police, pathologists, paediatricians, neuropathologists, autopsy technicians, funeral service providers, and those involved in considering or carrying out research which involves use of retained organs. A list of the Oral Sessions is included at Appendix 4. These Sessions have all been transcribed and the transcriptions are available on the website or at the Scottish Executive Library under the same arrangements outlined above.

5.3 Hospital Visits

41 Visits by individual members of the Group have supplemented and followed up on the written and oral information received. The hospitals visited were the Royal Hospital for Sick Children, Yorkhill, the Royal Hospital for Sick Children, Edinburgh, the Southern General Hospital, Glasgow (Neuropathology Department), Aberdeen Royal Infirmary, and Stirling Royal Infirmary. (Due to time constraints Crosshouse Hospital was not visited, but oral evidence was taken from the Trust.)

42 These visits have proved highly productive, serving to validate information given and to highlight areas where improvements in practice might be made. In particular it was felt that communication problems between one tertiary centre and referring hospitals needed to be addressed. We return to this issue later.
6 TERMS OF THE RELEVANT LEGISLATION

6.1 Hospital Post-Mortems

There are two statutes which are relevant to post-mortem practice: the Human Tissue Act 1961 and the Anatomy Act 1984. The relevant sections of the 1961 Act read as follows:

(1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body or any part or, as the case may be, the specified part, for use in accordance with the request.

(2) ... the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe-

(a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or

(b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.”

Some interpretation of these provisions may be in order, given their wording. The Act attempts to deal with two main situations. First, it provides that a competent adult may in advance of death make a written or verbal statement concerning the use to which their organs may be put after death. This may include an agreement that ‘tissues may be retained for diagnostic, teaching and research purposes’. In these circumstances, the person ‘lawfully in possession of the body’ may act in accordance with the wishes of the deceased, and strictly speaking does not require to obtain the additional consent of relatives, although it is common practice to do so. Secondly, the Act indicates what, in the absence of such a request, the person ‘lawfully in possession of the body’ (which seems to mean the hospital in which the death took place) may proceed to authorise in respect of the use of tissue, once they have made reasonable enquiries to ensure that the deceased had no objection to this and nor do surviving relatives.

Thus, the Act focuses on an absence of objection rather than on the provision of agreement. Although review of this legislation will form part of the second phase of the Group’s work, it is clear from the introduction to the Report that we believe this emphasis to be wrong. In focusing on an absence of objection rather than on a clear consent, the law has, we believe, placed the
emphasis in the wrong place. Our draft Code of Practice and information sheet seek to redress that balance. In addition, the Act fails to clarify adequately the rights of control of the body of the deceased (including issues relating to the bodies of children) and the rights of possession and control over organs, body parts and tissues retained at post-mortem as well as materials derived from them. It should be noted that issues of ownership of organs, body parts and tissue raise particularly substantial and complex issues. The possible need for law reform will form part of the second phase of the Review Group’s work and is therefore not addressed in this Report.

6.2 Procurator Fiscal Post-Mortems

46 Procurator Fiscal post-mortems are carried out to establish the precise cause of death and to gather evidence which may be used in any further proceedings. The Procurator Fiscal has common law power to instruct a post-mortem examination of the body. The consent of relatives is not required for these post-mortems. Where the removal and retention of an organ is necessary to further the Procurator Fiscal’s inquiry into the cause of death and other relevant matters (on the instructions of the Procurator Fiscal) the consent of the next of kin is also not required. We believe, however, that relatives should be informed sensitively by the Fiscal about the nature of the procedure and particularly about the possible retention of organs for the Fiscal’s purposes, where the relatives wish to be given such information. Consent is only required where the retention is for some other reason such as for training or research purposes.

47 The Procurator Fiscal’s post-mortem must not be used as a pretext to obtain organs for research unrelated to the Procurator Fiscal’s purposes. Using organs for research or other purposes which have not been authorised by the Human Tissue Act currently carries no specific penalty under the Act, but should not form part of practice. Where the pathologist believes there would be value in retaining the organs for any other purpose which does not arise directly from the Procurator Fiscal’s instructions or requirements, he or she must obtain the consent of the next of kin. The pathologist in such a case should ask the Fiscal what information, if any, has previously been provided to the family in this context. Once such consent has been obtained the pathologist must also make the Procurator Fiscal aware of that consent and ensure that the Procurator Fiscal has no objection to the proposed course of action.

48 There is no statutory framework regulating post-mortem examinations instructed by Procurators Fiscal, although the Sudden Death and Fatal Accident Inquiries Act 1976 provides authority for the investigation of sudden, suspicious or unexplained deaths. There are over 20 circumstances in which doctors
must report a death to the Fiscal, who will then decide whether a post-mortem is required. The Group believes that the current list of circumstances would benefit from review. In any event, it strongly recommends that doctors contact the Fiscal prior to approaching relatives regarding the possibility of a post-mortem, to ensure absolute clarity about the basis on which the post-mortem examination would be conducted.

7 COMMON LAW CONSENT REQUIREMENTS

49 In recent years, it has become increasingly evident that many people both wish, and have a right, to be actively involved in their medical treatment. Their interest in so doing does not inevitably lapse upon their death and it is, in our view, correct that those who wish to make provision for disposal of their body parts after death should have these wishes respected.

50 In situations where the individual cannot make such a decision, for example in the case of babies and young children, it is generally accepted that parents have the authority to make treatment decisions on behalf of their children. Parents are obliged to take treatment decisions which are ‘in the best interests’ of their children. They do not have absolute rights in the issue of treatment, and their decisions can be, and have been, challenged in a court of law. However, as previously stated, in cases where post-mortem organ retention and use, rather than treatment, is under consideration, the law seems unclear and unhelpful.

51 It has become clear to the Group that there are unique sensitivities surrounding the death of children and issues relating to post-mortem consent for hospital post-mortems. It is in our view uncontentious that parents should play a continuing and informed role in what happens to their children after death, should they so wish. In saying this, we do not propose that a right of ownership is created, as we are reluctant to use such language in respect of a person rather than a thing. However, it is consistent with the rights that parents have in treatment decisions that they should also be actively involved in decisions taken subsequent to their child’s death, and this is reflected in our draft Code of Practice and associated documents. This is a matter of respect rather than ownership.

8 PAST PRACTICE

8.1 Hospital Post-Mortems

Consent

52 In the past the medical profession has taken a paternalistic attitude towards post-mortem examinations, believing that it was in the interests of bereaved
relatives not to describe the details of how post-mortem examinations were carried out, as this would only add to their grief and distress. Consent for the retention of organs for whatever purpose was previously viewed by pathologists as implicit in the granting of permission for post-mortem examination by relatives of the deceased. Whether or not such assumed consent was legally effective, it is difficult to justify it on ethical grounds. In the course of hearing evidence, a number of people have pointed to the fact that what appeared to be acceptable in the past should be judged against the culture of that time, rather than against current perspectives. It is certainly true that recent decades have seen a revolution in attitudes towards consent and the relationship between the medical profession and the public. However, while past post-mortem practice may have arisen in a different context, this clearly does not provide a justification for it. Even accepted medical practice can be challenged. Nonetheless, it should be stated that we have found no evidence that past practice was motivated by anything other than the tradition of medicine in seeking to improve care of future patients.

53 The failure to obtain full and open consent in respect of the retention of organs has been compounded by the use of vague and misleading terminology. ‘Tissue’ has been widely used as a euphemism for ‘organ’, or doctors themselves may have been confused by the terminology. Perhaps at this juncture it is worth making clear that an organ comprises a collection of different tissues which form a distinct structure in the body and perform a particular function or functions, e.g., heart, brain, liver, kidney. Tissue blocks on the other hand comprise very small amounts of tissue (2x2x0.5cm in size) which are processed and then retained in paraffin wax. Thin sections or shavings one-hundredth of a millimetre thick are cut from these blocks, stained and mounted on glass slides for examination under the microscope.

54 While in the past relatives may not have been given full information, in an attempt, the Group understands, to minimise their grief and distress, it has become abundantly clear that relatives vary in the amount of information they wish to receive. For whatever reason, and however well intentioned, the lack of full and frank discussion has, for some relatives, resulted in a loss of the trust which they need to have in those who looked after their relatives. For all of these reasons, past practice must be viewed as unacceptable.

Information

55 The distress experienced by many parents has been compounded by the lack or inadequacy of information concerning standard post-mortem procedures. As previously noted, in the past it was apparently common for little or no information to be offered to relatives in the belief that such information
would be distressing. There has been a general failure of communication and in many cases a lack of sensitivity in understanding the needs of relatives at such a traumatic and emotional time. Relatives have not always been given adequate information on the post-mortem prior to consent being obtained, nor have they been given specific information on the possible retention of organs and their subsequent use. In addition, information on options for disposal of such organs has not been provided in the past. Finally, relatives have not always been offered adequate information or the opportunity to discuss the findings following the post-mortem. Given the technical nature of the post-mortem report, the Group feels that such opportunities are crucial to ensuring the full understanding to which relatives are entitled.

8.2 Procurator Fiscal Post-Mortems

56 Although consent of relatives is not required for Procurator Fiscal post-mortems or for the retention of organs for the Fiscal’s purposes, past practice in relation to these post-mortems has been seriously deficient in a number of respects. Indeed, it should be noted that the majority of the representations received by the Group from relatives on past practice relate to Procurator Fiscal post-mortems. In the majority of cases the problem seems to have arisen as a result of a failure on the part of Fiscal service to provide relevant information and the opportunity for relatives to discuss their concerns.

57 Where a hospital wishes to retain organs obtained from a post-mortem examination for further use after the Fiscal’s enquiries are complete, the pathologist must seek the agreement both of the Fiscal and the relatives. The Review Group noted that the Crown Office and Procurator Fiscal Service in October 1999 wrote to the University Pathology Departments to make this explicit.

Designation as a Procurator Fiscal Post-Mortem

58 The evidence received by the Group suggests that there are problems with the designation of post-mortem as a Procurator Fiscal case in some instances. In a number of situations, the Fiscal has an obligation to instruct a post-mortem examination. In others, for example where doctors are unable to issue a death certificate because they do not know the cause of death, such a post-mortem may be instructed. Concerns have, however, been expressed both by bereaved relatives and representatives of the Procurator Fiscal’s service that in some instances the decision by doctors not to issue a death certificate has been unnecessary and may have been motivated by the feeling that relatives were likely to deny permission for a hospital post-mortem. Some relatives may also have felt pressurised into agreeing to a hospital post-mortem so that doctors would issue a death certificate. The Group has also received evidence that on
some occasions there may have been a serious failure of communication between hospitals and the Procurator Fiscal, with hospital staff failing to pass on to the Procurator Fiscal information concerning strongly held religious beliefs or other grounds for objection to a post-mortem examination.

Information Concerning Procurator Fiscal Post-Mortems

59 The written and oral evidence received by the Group suggests that in some cases the communication failure previously referred to stems from a lack of clarity over whose role it is to impart the information. In the cases of deaths referred to the Procurator Fiscal from hospitals there has been a lack of clarity over whether it is the duty of hospital staff or Procurator Fiscal staff to provide this information to relatives. It should be remembered that in cases where the Fiscal instructs the post-mortem the overall responsibility for the process surrounding it, including provision of information and communication with the relatives, lies with the Fiscal and not with doctors. While it may on some occasions be important for the family to obtain information from the pathologist carrying out the post-mortem this would have to be initiated through the Fiscal’s office.

60 Such discussions must be dealt with by the Procurator Fiscal in a sensitive manner and, where possible and required by next of kin, full explanations should be provided. However, it is accepted that there may be circumstances where the Procurator Fiscal cannot provide full explanations because of the nature of his inquiry and the risk of prejudice to a criminal investigation.

61 The Review Group observes that the Crown Office and Procurator Fiscal Service have acknowledged the need for improved liaison with bereaved next of kin and that a number of initiatives are underway to pursue this objective.

62 In sudden or suspicious deaths at home, or in the case of someone being brought into hospital after death, the doctor’s function is only to pronounce life extinct. In this situation, imparting information to relatives may be undertaken by the police. However, responsibility again lies with the Fiscal to make sure that relatives are kept fully informed.

8.3 Retained Organs

Numbers of Organs Currently Retained

63 One of the most important aspects of this phase of the Group’s work has been to investigate the number of organs currently being retained by Scottish NHS Trusts. Openness and transparency in respect of past post-mortem practice are essential to regaining the trust of the public in relation to future post-mortem practice. Further, it is hoped that the disclosure of the numbers
of organs that have been retained in Scotland will play a significant role in allowing distressed relatives to draw a line under their experience, and have confidence in future practice.

The table below details the number of organs currently retained by Scottish NHS Trusts and the period over which these organs have been retained. As post-mortem rates vary greatly from hospital to hospital, some Trusts will inevitably have a much higher number of organs retained than others. For this reason, the retention figures have been set in the context of the total number of post-mortems carried out over the period from which organs were retained. In addition, some hospitals may have a higher number of organs in their possession because they are tertiary referral centres. No hospital post-mortems would have been carried out in the absence of any form of consent, however inadequate. In many instances, specific consent will also have been sought for retention of these organs. The figures include organs which are being stored pending further investigation under the auspices of the Procurator Fiscal.

In the short time-scale available, Trusts have responded to the best of their ability to the Group's request for this information. However, the Group is conscious that more detailed and validated information is required. Data provided to the Group by Trusts on organs currently retained should be independently validated as a matter of urgency.

It should be made clear that, in contrast to the findings of the Alder Hey inquiry, the majority of these organs are hearts and brains. There is absolutely no evidence of any cases of retention of a body’s entire set of organs. In some cases, organs may not yet have been used for education or research purposes, but this does not mean they will not be used for those purposes in the future. Their potential value is considerable, as indicated in paragraphs 17-20.

We recommend that hospitals which retain organs should, in future, maintain information on their databases of any use to which specific organs are put. Having this information readily available could help the healing process as far as relatives are concerned, and could also be relevant to any future decision they might make about continued retention of those organs.
Table 1
Number of Organs Currently Retained in Scottish NHS Trusts

<table>
<thead>
<tr>
<th>Trust</th>
<th>Number of Organs</th>
<th>Period Stored Over</th>
<th>Number of PMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argyll &amp; Clyde</td>
<td>75</td>
<td>1987-2000</td>
<td>4,278&lt;sup&gt;77&lt;/sup&gt;</td>
</tr>
<tr>
<td>Ayrshire &amp; Arran</td>
<td>30</td>
<td>1988-2000</td>
<td>7,813</td>
</tr>
<tr>
<td>Borders</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Dumfries &amp; Galloway</td>
<td>7</td>
<td>1968-1978</td>
<td>3,752</td>
</tr>
<tr>
<td>Fife</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Forth Valley</td>
<td>4</td>
<td>1999-2000</td>
<td>439</td>
</tr>
<tr>
<td>Grampian</td>
<td>154</td>
<td>1995-2000</td>
<td>1,913</td>
</tr>
<tr>
<td>N Glasgow</td>
<td>2,527&lt;sup&gt;78&lt;/sup&gt;</td>
<td>1946-2000</td>
<td>49,034</td>
</tr>
<tr>
<td>S Glasgow</td>
<td>174</td>
<td>1950-2000</td>
<td>25,785</td>
</tr>
<tr>
<td>S Glasgow Neuropathology&lt;sup&gt;79&lt;/sup&gt;</td>
<td>1,479</td>
<td>1973-2000</td>
<td>22,315&lt;sup&gt;80&lt;/sup&gt;</td>
</tr>
<tr>
<td>Yorkhill</td>
<td>432</td>
<td>1953-2000</td>
<td>16,000</td>
</tr>
<tr>
<td>Highland</td>
<td>1</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Lanarkshire</td>
<td>19</td>
<td>1993-2000</td>
<td>1,254</td>
</tr>
<tr>
<td>Lothian</td>
<td>558</td>
<td>1984-2000</td>
<td>43,324</td>
</tr>
<tr>
<td>W Lothian</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Tayside</td>
<td>500</td>
<td>1903-1975</td>
<td>30,000&lt;sup&gt;81&lt;/sup&gt;</td>
</tr>
<tr>
<td>Shetland</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Orkney</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>W Isles</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5,960</strong></td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

68 Hospitals will, in the past, have retained organs briefly i.e. perhaps for a few days for educational purposes. In such cases, there will almost certainly be no record of retention or disposal of these organs.

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<sup>77</sup> Organs have been retained since 1987 from Vale of Leven Hospital. Post-mortem figures for this hospital have been estimated at an average of 206 per year since 1992. The total number of post-mortems for this hospital since 1987 has been estimated on the basis of this figure of 206.

<sup>78</sup> There are in addition 1,926 organs stored as part of the Historical collections. The period over which these organs have been retained is currently unclear, but the vast majority pre-date 1970.

<sup>79</sup> These figures relate to the number of brains or significant parts of brains currently retained by the neuropathology department in the Institute of Neurological Sciences and includes museum specimens. The department itself only performs 20-30 post-mortems per year, but receives between 700-900 specimens per year from departments all over Scotland.

<sup>80</sup> This figure relates to the total number of specimens sent to the department over the period in 1973-2000 rather than total number of post-mortems performed by the department (see note 3 above).

<sup>81</sup> This figure relates to the number of post-mortems carried out after 1930 only. No figures exist for the number of post-mortems carried out prior to this date.
The Group is aware from discussions with relatives and hospitals that serious concerns exist over communications between Yorkhill and the Neuropathology department within the Southern General Hospital (where brains from a large region of Scotland are sent to be fixed). The Group investigated these concerns and believe that the problems stem in part from inadequate resourcing of the Southern General Neuropathology Department.

Retention of Tissue Blocks or Slides

Table 1 does not include blocks of tissue which have been retained as part of the patient’s record. Tissue blocks and slides are an important part of the patient record and in some cases can provide relatives with additional information which helps with future reproductive or health care choices. The legal status of these blocks and slides will be considered in the second part of the Group’s work. In the short term, the Group recommends that any relatives wishing to reclaim blocks and slides should be able to do so. In the light of the distress caused to some relatives by past events, it seems only right that relatives should be given this option, especially if doing so would allow them to achieve a sense of closure. A clear explanation should, however, be provided as to the potential value of their retention in the patient’s records. The exception to this recommendation would be in the case of a Fiscal post-mortem where tissue blocks and slides had to be retained for legal reasons. There is an argument in favour of retaining materials for possible further examination in Sudden Infant Death Syndrome cases where the ‘cause of death’ remains inconclusive pending medical advances.

Audit Procedures

The Review Group has been dismayed to discover that for a number of relatives obtaining information about which organs, if any, have been retained, and the purpose for that retention, has been unnecessarily complex. We have required all hospitals with retained organs to undertake an audit of this to ensure that relatives can be given accurate information. The Minister has already accepted our preliminary recommendation that each hospital set up a dedicated help line which should be widely publicised, in order that relatives can obtain the information they need without being forced to make numerous requests. Regrettably, the response from hospitals to this request has not so far been good, and we recommend that this should be pursued by the Health Department as a matter of urgency.

The Group recommends that audit of post-mortem practice, including the circumstances in which post-mortem consent is sought, should be part of the clinical governance arrangements in each Trust. The Chief Executive should ensure that an appropriate audit process is developed and implemented, and included in the Trust’s annual clinical governance report. Where the audit
process shows cause for concern, disciplinary procedures should be invoked if appropriate.

73 The Group also recommends that relatives be involved in the audit process. To achieve this, the post-mortem consent form should include a section about willingness to be contacted in the future for this purpose. The Clinical Standards Board for Scotland has developed a number of generic standards applicable to most hospital clinical services. The Standards Board should be encouraged to incorporate a standard relating to the hospital post-mortem process in their generic standards as this would provide a very effective way of monitoring implementation of the Review Group's Code of Practice for hospital post-mortems. The data available through the audit process referred to above will enable the Standards Board to assess a hospital's performance against this generic standard. Improved record-keeping and the use of electronic databases will greatly facilitate the audit process and the Standards Board's work and ensure proper governance of this important clinical area.

Disposal of Organs

74 The Group recognises that the use of the term 'disposal' is felt by some relatives to be less than respectful in the context of organs. However, consultation with relatives has failed to establish a suitable alternative.

75 Bereaved relatives naturally expect that the organs of their relatives will be dealt with respectfully in every case. Where agreement to retention is given, relatives remain concerned about ultimate disposal. Indeed, even where consent for retention is not required (in Procurator Fiscal post-mortems), relatives may wish to be consulted about the disposal process. Hospitals have expressed concern to the Group that their ability to respond to relatives' wishes is seriously constrained by Health and Safety Regulations. This means that organs have to be disposed of as clinical waste. This is not only distressing but also belies the value which some relatives place on the organs.

76 Relatives need to be made aware of the available options, which are: postponing the funeral until organs can be reunited with the body; asking the hospital to respectfully dispose of the organs; or asking for return of the organs at a later date so that the relatives themselves can dispose of them according to their own wishes.

77 Both the written and oral evidence provided to the Group make clear that there are inconsistencies across the country where relatives have approached crematoria with a request that individual organs be cremated, after the body itself had already been cremated. It has been suggested that some crematoria have been unwilling to cremate organs as they believe that this is not
permitted under current regulations. The Group understands that there is nothing in the Cremation (Scotland) Regulations 1935 to support this view. The problem appears to be an administrative one. The Group understands that the British Cremation Authority is in the process of changing its rules, and urges them to tackle this problem in view of the emotional importance to some relatives of being able to cremate the organs of their loved ones.

9 THE WAY FORWARD

9.1 Code of Practice for Hospital Post-Mortems

Due to the wide variety of circumstances in which death occurs, and variations between relatives in terms of preferences and needs, it would not be appropriate to be overly prescriptive on the level of information given to relatives. The Code represents the response that should be given to those relatives who wish for the fullest information. Where relatives do not wish to know details concerning post-mortem practice, it is imperative that this wish is respected. A wide spectrum of views was presented to the Review Group ranging from those who would choose not to know the detail to those who felt strongly that they should be fully informed of the procedures and practices involved. The key point is that staff should be sensitive to the needs of each individual.

The way in which the process of seeking permission for a post-mortem examination is conducted has an inevitable effect on the quality or validity of any consent obtained. As it currently stands, the law seems to be concerned, with the exception of adults who have expressed their views in advance, with determining the presence or absence of objection to post-mortem, rather than specifically requiring a consent. In cases where the deceased has made their wishes clear in advance of death, hospital staff will want to be sure that the relatives are aware of this. In all other cases in future, relatives must be given the opportunity of being fully involved in the decision to give consent to a post-mortem examination. Where the deceased has left no explicit instructions, relatives should be given the opportunity of being fully involved in any decision to retain organs. Relatives must also, where the deceased has left no explicit instructions, be given the opportunity of being fully involved in any decision as to future use of retained organs for training, educational or research purposes. Where relatives have given consent to the retention of organs for educational purposes, they should be given a clear explanation of what this will entail, for example, dissection or observation. Relatives should be given the opportunity of stipulating what may be done to organs as part of the agreement to retention for educational purposes. Where organs are retained for research purposes, relatives should be informed that any research
undertaken either has been or will be approved by the relevant Research Ethics Committee and should further be informed that they may choose to be notified should new research, to which no specific agreement has been given, be contemplated. Relatives should be given every opportunity to obtain as much information as they need about the conduct of post-mortem examinations, and possible retention of organs. However, relatives should also be able to decline such information if they do not wish it.

**Deciding to Hold a Post-Mortem**

80 The whole process of seeking relatives' permission must be governed by respect for the body of the deceased and for the relatives' feelings.

81 It is vital that the hospital staff can explain to relatives why they think a post-mortem would be of value. Where the decision to hold a post-mortem is taken by a less experienced member of staff, it should be confirmed by a more experienced member of the medical staff, before any approach is made to relatives to discuss whether they would be willing to give their permission. Hospital staff should also explicitly consider whether or not alternatives, for example imaging or more limited procedures, could be used in place of a full post-mortem, and the conclusions of these considerations should be made clear to the relatives. Where a Fiscal post-mortem is a possibility, medical staff should consult the Fiscal prior to approaching the relatives. In the case of all post-mortems, relatives should be told what disposal options are available, including delaying funeral arrangements in order to permit the retained organs to be reunited with the body. In every case, discussions should be held in appropriate surroundings.

**Who Requests Consent?**

82 A key factor to be considered is which member(s) of staff should be involved in obtaining consent. Relatives' preferences in this matter vary. For some, the midwife is the most appropriate person, for others it is the pathologist or another senior member of staff. Still others have suggested that there should be a dedicated individual within the hospital who should approach relatives in these distressing circumstances. This wide variety of opinion makes it inappropriate that the Review Group should be overly prescriptive, although it is absolutely clear that, whoever the individual may be, they must be appropriately skilled and trained to take on such an important role. The following guidance may, however, be helpful in this area, in the light of the lessons learned from past practice.

- Wherever possible, relatives should be approached for post-mortem consent by someone who has already established a relationship with the family.
someone whom they know and trust, and ideally a senior member of the
medical team.

• A team-based approach may well be appropriate in many circumstances. Nursing staff can play a key role in offering emotional support through the process. In particular, in cases of stillbirths and neonatal deaths the midwife will almost always be the most appropriate individual to raise the issue of post-mortem with the parents, and in conjunction with medical staff, will play an important role before, during and after post-mortem consent is sought. Consideration should be given to the use of Bereavement Counsellors, following the model which some Trusts have already adopted.

• As most hospital deaths occur out of normal working hours it is likely that in many cases the doctor on call will not know or be known to the patient's family. In addition, he or she is unlikely to be in a position to answer all of the questions that relatives might have concerning post-mortem examination. In such circumstances, it may be more appropriate to ask the relatives to return the following morning to discuss these issues with a senior member of the clinical team, possibly in conjunction with a pathologist, if the relatives wish. Where this is not possible, or where the relatives wish to proceed immediately, the seeking of permission should be undertaken by a member or members of staff who are familiar both with post-mortem practice and with the family or the deceased.

• All members of staff involved in obtaining post-mortem consent should have had appropriate training, and possess the skills necessary for conducting such sensitive discussions. Medical and Nursing schools should consider including appropriate training in, for example, post-mortem procedures and dealing with the bereaved, in their curriculum. This should be supplemented by training and relevant experience in hospitals. The role of relatives' support groups in providing such training should always be kept in mind.

• It is important that staff are aware of the legal and medical aspects of post-mortem procedures, and the retention of organs. In case of uncertainty, it should be clear to staff where they can go to seek advice.

• Obtaining consent should be viewed as a process rather than a single event. Relatives should be given the name and contact details of an individual to whom they can put additional questions if necessary and if they so desire.

• Individual circumstances, and the views and wishes of relatives, will reflect in the decision as to which member of staff should act as the contact point. Some relatives may prefer to have ongoing contact with a member of the
nursing staff, while others may prefer to deal with a senior clinician or in some cases the pathologist who is going to conduct the post-mortem examination.

- In any event, relatives should be given the opportunity for a follow-up meeting to discuss the post-mortem findings, with a senior clinician, together with the pathologist, if they so wish, subject only to the rules of medical confidentiality which also apply to medical information about a deceased person.

**Timing/Location of the Request for Consent**

- The circumstances in which post-mortem consent is sought are important. Consideration should be given to the use of a dedicated room for bereavement interviews, a facility which some Trusts already have available.

- It is impossible to be prescriptive about the timing of the approach, as, inevitably, relatives’ wishes and needs will vary greatly. Medical and nursing staff need to be responsive to this fact. Some relatives may wish to discuss the issue of post-mortem in full immediately. Others may prefer to return the following day when a more senior member of the medical team will be available. Some relatives may want a series of discussions, others may prefer not to have to revisit the issue. Relatives’ wishes should be respected and accommodated at all times.

- Hospital staff need to bear in mind that many, if not all, people find it hard to take in information immediately after the death of a loved one. Relatives should therefore be given adequate time to reflect on their decision in respect of post-mortem examination, and indeed time to change their minds if wished. If the deceased has previously expressed an agreement to post-mortem or the removal and use or retention of organs, these wishes should be treated as evidence that an agreement has been given. Where the prior wishes of the deceased or any other close relative are known, these should be taken into consideration during the discussion process, particularly in relation to retention and use of organs.

**The Amount of Information to be Disclosed**

People vary greatly in terms of the amount of information and detail that they wish to know about the post-mortem examination. Clinical staff need to be sensitive to relatives’ wishes in this respect.

- Information must not be deliberately withheld, for any reason, unless at the express wish of the deceased. Relatives cannot reach an informed decision unless they have all the information which they themselves consider necessary to the making of their decision. Relatives need to be given the
opportunity to decide how much detail they wish to know about the post-mortem examination, and possible retention of organs. If they indicate that they wish to receive only limited information, it should nonetheless be made clear to them that they can come back with a future request for more information at any time.

- Verbal information should always be supported by a clearly written information leaflet which relatives can take away with them and read as part of their decision-making process.

- If relatives give their consent to organs being retained, it is important that the likely length of retention and the possible uses to be made of retained material and future disposal options are discussed and covered in the consent form, unless relatives do not wish this information.

- In any discussion about retention of organs, relatives should be given information about potential benefits in terms of education, research and training that can derive from the post-mortem examination. The feeling that something positive can result from an otherwise tragic event often gives comfort to relatives.

Format of Forms and Written Information

84 Template consent forms and information leaflets are included at Appendices 5 and 6. It is important that these forms should be standardised throughout Scotland, and preferably throughout the UK, to ensure that post-mortem consent is uniform. In order to achieve this, the Group recommends that someone with professional skills in the design of forms should be commissioned to produce a draft, based on the templates. The Group would then consult widely on the resulting draft form. Trusts in the process of reviewing their forms should continue to do so, as the experience gained will be of value in commenting on the draft standard form.

85 The following points should be taken into consideration in that review process:

- The best evidence of consent or refusal is the competent previously expressed wishes of the deceased, but hospitals should be sensitive to any distress this might cause relatives.

- Where consent is sought from relatives, consideration should be given to establishing a hierarchy of those whose permission is most legally valid (this will be considered by the Review Group in the second phase of its deliberations).

- Plain English should be used at all times, and technical medical terms avoided wherever possible. If such terms are necessary, they should be explained clearly in the text.
• Consideration should be given to the use of more personalised language, particularly in the case of forms for perinatal and paediatric use. For example, words such as ‘baby’ rather than ‘relative’ might be used.

• The structure of the form should be considered carefully. It may be helpful to have three separate sections for each type of consent required: (a) to the post-mortem itself; (b) to the retention of organs, with details of the specific organs covered by that consent; and (c) to the use which may be made of retained organs. Each section should be signed by the relative and the member of the medical or nursing staff who has discussed the implications of consent with the relatives. The relatives’ signature should indicate that they have had the opportunity to see and consider the information forms. If they don’t want to see them this should be recorded.

• Ideally the form should be in triplicate, so that a copy can be kept in the deceased’s medical record, a copy in the pathology department, and a third copy that relatives can retain.

• It should be made clear to relatives on the form that they are free to change their mind about any procedures consented to or not consented to, up until the point that the post-mortem is undertaken, or the organs have been used for educational or research purposes. In the case of agreement for the retention of organs, it should be made clear that relatives may change their mind at any time during the period of retention. Relatives should also be given the option of specifying the length of time for which organs may be retained, and the purposes for which they may be used.

9.2 Recommendations for the Lord Advocate regarding Fiscal Post-Mortems

86 The Review Group is aware that the Crown Office is revising the information which should be made available to bereaved relatives about post-mortems instructed by the Procurator Fiscal. It welcomes this, as there is a real need for clarity about the distinction between hospital and Fiscal post-mortems.

87 When a post-mortem is instructed by the Procurator Fiscal, the question of seeking the relatives’ consent does not arise. However, this does not diminish the need to make sure that relatives are informed, as fully as is consistent with the Fiscal’s role in the administration of justice, of the nature and purpose of the post-mortem examination. Verbal information should always be supplemented by written information which relatives can take away with them. All members of staff involved in informing relatives of post-mortem procedure should possess the skills necessary to conduct sensitive discussions. They should have had appropriate training in Fiscal post-mortem procedures.
and in dealing with the bereaved, and should have sufficient relevant experience to support this. The role of relatives' support groups in providing such training should be borne in mind, and the physical surroundings in which such discussions take place should be appropriate to the sensitivity of the situation.

88 In the case of Fiscal post-mortems, we recommend that the Fiscal should explain to the family the reasons for requiring a post-mortem, including which organs will or may be removed and/or retained, as soon as this is known. Where relatives object, the Fiscal should explain clearly why the post-mortem must proceed. When objections are made, the Fiscal needs to be clear whether those are based on religious belief, and, if so, to decide the extent to which those beliefs can be accommodated according to the circumstances of the particular case. If the relatives wish, the Fiscal should be prepared to hold a meeting with them to explain the need for a post-mortem. In particular, it is the Fiscal's responsibility to make clear that organs can only be retained after a Fiscal post-mortem for the purposes of determining the cause of death and other related matters. Fiscals should make clear to relatives what will be done with these organs once this process is completed and should inform relatives clearly about disposal options, including the possibility of returning the organs to the relatives and delaying funeral arrangements in order to permit the retained organs to be reunited with the body. Where appropriate, it should be made clear to relatives that retention of organs, blocks and slides may be necessary for legal purposes.

89 Regional Fiscals already have a role in auditing the practices of individual Fiscals, and we would consider it to be an inherent part of that responsibility that the provision of information to relatives should be standardised and included in this audit. The involvement of the pathologists, as in Glasgow, in meeting with relatives and assisting in the explanation of procedures and process is a commendable initiative.

90 One of the main lessons of past practice is that there is clearly a communication gap which needs to be closed at the point when the Fiscal decides that organs retained at post-mortem are no longer required for his purposes. A system needs to be put in place to ensure that Procurator Fiscals are notified explicitly and promptly where organs are retained and to ensure that the Procurator Fiscal in turn ensures that the pathologist in possession of the organs is made aware when retention for the Fiscal's purposes is no longer necessary. Appropriate arrangements need to be made to ensure that disposal of the organs then takes place in accordance with the wishes of the next of kin. The Procurator Fiscal should ensure that systems are in place to obtain such information from the next of kin.
91 Two key steps need to be taken to avoid any blurring of the distinction between hospital and Fiscal post-mortems. Where the post-mortem has been instructed by the Fiscal in respect of a child, and that post-mortem is conducted in a hospital paediatric pathology department, the Fiscal must take particular pains to make relatives aware of the fact that s/he has instructed the post-mortem and it is being conducted by a pathologist retained by the Crown Office.

92 Where medical staff find themselves in the position of having to explain to relatives that a Fiscal post-mortem has been instructed, the Fiscal needs to provide a form of words which medical staff can use to give the relatives an initial explanation which does not interfere with the proper discharge of the Fiscal’s responsibilities.

10 CONCLUSION

93 It is clear that past practice must be abandoned – indeed, it is to be hoped that it has been. However, the value of sensitive and effective communication should inform both current and future practice. Uniform information sheets and a standard consent form must be developed throughout Scotland to ensure that practice is consistent and takes account of our recommendations. But it must also be borne in mind that the reason that past practice has been deemed unacceptable is not simply that people are demanding more information. It must also be conceded that, whatever the motivation, attempting to insensitively disengage relatives from their loved ones after death is unacceptable.

94 It is in the interests of everyone that relatives if they so wish are fully involved in decisions which are taken about post-mortems and the retention and use of organs. The second phase of the Review Group’s work will address the underlying legal regulation in this area, but the completion of this first stage should provide a sound basis for the establishment of good practice in this area.

11 NEXT STEPS

95 The second phase of the Group’s work will be to undertake a review of the relevant statute and common law. Pending that review, the Group expects the recommendations detailed above to be implemented in full, as if they had the force of law.

96 Organs currently retained should not be disposed of unless this is specifically requested by the relatives, who should also be given the option of reclaiming organs for disposal as they see fit until the expiry of the 5-year period.
The data supplied by Trusts on organs currently retained must be validated independently as a matter of urgency, in order to provide relatives with the most accurate possible information in each case. Further information will be sought from Trusts regarding the relative proportions of adult and paediatric hospital post-mortems which have been undertaken. Information is also required on the number of Fiscal post-mortems undertaken over the same period being looked at for hospital post-mortems. The Group will, in addition, obtain information regarding tissue blocks.

Once the standard consent form has been designed, the Group will consult widely on this, in particular seeking the views of all of those who have contributed to the first phase of its work.

The Secretary of State for Health has announced as part of his response to the report of the Alder Hey inquiry that he is establishing a Retained Organs Commission, which will take the form of a temporary Special Health Authority, to oversee the return of organs from across England. While this is probably a response to the scale of organ retention in England, the Minister for Health and Community Care has asked the Review Group to consider whether there is any justification for a similar mechanism in Scotland.

Appendix 1 List of Review Group Members

Appendix 2 Organisations and Individuals Contacted

Appendix 3 List of Responses from Acute Trusts*

Appendix 4 List of Oral Sessions with Witnesses*

Appendix 5 Template for Hospital Post-Mortem Consent Form

Appendix 6 Template for Relative's Information Leaflet for Hospital Post-Mortems

*Due to volume it has not been possible to include the Responses from Acute Trusts or the Transcripts of the Oral Sessions as appendices to this Report. However, both can be viewed on the Group's website at http://www.show.scot.nhs.uk/scotorgrev

A copy of the responses will also be available for public viewing at the Scottish Executive Library located at Saughton House, Broomhouse Drive, Edinburgh. Those wishing to consult these documents should telephone 0131 244 4552 to arrange an appointment.
Preliminary Report: Appendix 1

Membership of the Review Group on Retention of Organs at Post-Mortem

Chairman
Professor Sheila McLean  Professor of Law and Ethics in Medicine
Glasgow University

Members
Reverend Dr Kenneth Boyd  Senior Lecturer in Medical Ethics
Edinburgh University
Miss Sarah Elliston  Lecturer in Medical Law
Glasgow University
Mrs Doris Littlejohn  Chairman, Forth Valley Primary Care NHS Trust
Mrs Margaret McKay  Chief Executive of Children 1st
Professor Alison MacLeod  Professor of Medicine & Therapeutics
University of Aberdeen
Hon. Consultant Physician/Nephrologist
Grampian University Hospital NHS Trust
Professor Sir Roddy MacSween  Emeritus Professor of Pathology
University of Glasgow
Professor R A A M Call Smith  Professor of Medical Law
University of Edinburgh
Mrs Caroline Thomson  Chairman Highland Health Board
Mrs Geri Watt  Head of Policy Group
Crown Office

Observers
Dr Aileen Keel  Deputy Chief Medical Officer
Scottish Executive
Mrs Lynda Towers  Head of Group, Solicitor’s Office
Scottish Executive

Secretariat
Mr William S Scott  Scottish Executive Health Department
Dr Charlotte Carpenter  Scottish Executive Health Department
Preliminary Report: Appendix 2

Organisations Contacted

Action for Sick Children
Action of Churches Together in Scotland
Africa Centre Scotland
Agency for Inter-faith Relations Churches Together in Britain
Asian Concern
Asian Welfare Association
Associated Presbyterian Churches of Scotland
Association for Children with Heart Disorders
Association Church of Scotland Churches
Association of Clinical Pathologists Baptist Union of Scotland
Bangladesh Welfare Council
British Medical Association
British Paediatric Pathology, Scottish Branch
Church of Scotland
Church of Scotland National Association for Welfare of Children in Hospital
Citizens Advice Scotland
Clinical Standards Board for Scotland
Commission for Racial Equality
Conference of Scotland Council of Christians and Jews
Crown Office (Edinburgh)
CRUSE Bereavement Care
Dr Alison Sinclair, Department of General Practice, Edinburgh University
Ethics & Advisory Committee, Royal College of Paediatrics and Child Health
Evangelical Alliance Scotland Faculty of Advocates (Edinburgh)
The Free Church of Scotland
The Free Presbyterian Church of Scotland
General Medical Council
Hospital Chaplains Association
Law Society of Scotland
Local Health Councils
Local Medical Research Ethics Committees
Local Research Ethics Committees
Edinburgh & District Chinese Association
Medical & Dental Defence Union of Scotland
Medical Research Council
Methodist Church of Scotland
National Association of Funeral Directors
NHS Trusts' Patients Councils
NHS Trusts
Office of the Chief Rabbi
The Patients Association
Procurator Fiscal's Society
Professor D Pounder, Ninewells Hospital and Medical School
Professor J K Mason, Edinburgh University
Professor K Norrie, Strathclyde University
Reformed Presbyterian Church of Scotland
Reform of Synagogues of Great Britain
Religious Society of Friends (Quakers)
Rev Stuart McGregor, Chaplain, Royal Infirmary of Edinburgh
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Nursing, Scottish Branch
Royal College of Paediatrics & Child Health
Royal College of Pathologists (Scotland)
Royal College of Physicians & Surgeons of Glasgow
Royal College of Physicians of Edinburgh
Royal College of Surgeons of Edinburgh
Scottish Association of Health Councils
Scottish Cot Death Trust
Scottish Council for Voluntary Organisations: Voluntary Sector Health Network
Scottish Deans Medical Curriculum Group
Scottish Episcopal Church
Scottish Ethnic Social & Cultural Organisation Council
Scottish Inter-Faith Council
Scottish Law Commission
Scottish Medico-legal Society
Scottish Neonatal Consultants' Group
Scottish Organisation Relating to the Retention of Organs (SORRO)
Scottish Partnership Forum
Scottish Regional Council, Institute of Biomedical Sciences
Stillbirth and Neonatal Death Society (SANDS)
UK Central Council for Nursing, Midwifery and Health Visiting
United Free Church of Scotland
Preliminary Report: Appendix 3

List of Responses from Acute NHS Hospital Trusts

- Argyll and Clyde Acute Hospitals NHS Trust
- Ayrshire and Arran Acute Hospitals NHS Trust
- Borders General Hospital NHS Trust
- Dumfries and Galloway Acute and Maternity Hospitals NHS Trust
- Fife Acute Hospitals Trust
- Forth Valley Acute Hospitals NHS Trust
- Grampian University Hospitals NHS Trust
- N Glasgow University Hospitals NHS Trust
- S Glasgow University Hospitals NHS Trust
- Yorkhill NHS Trust
- Highland Acute Hospitals NHS Trust
- Lanarkshire Acute Hospitals NHS Trust
- Lothian University Hospitals NHS Trust
- West Lothian Healthcare NHS Trust
- Tayside University Hospitals NHS Trust
- Shetland Health Board
- Orkney Health Board
- Western Isles Health Board
Preliminary Report: Appendix 4

List of Oral Sessions with Witnesses

Organisations/Groups Represented

- Association for Children with Heart Disorders
- Ayrshire and Arran Acute Hospitals NHS Trust
- Bereaved Parents (two meetings)
- British Medical Association
- Department of Forensic Medicine & Science, University of Glasgow
- Department of Pathology, Western Infirmary, Glasgow
- Ethics Sub-Committee on Reproductive Medicine and Paediatrics, Lothian University NHS Trust
- Forth Valley Acute Hospitals NHS Trust
- Grampian University Hospitals NHS Trust (two meetings)
- Lothian University Hospitals NHS Trust
- National Association of Funeral Directors & Society of Allied Funeral Directors
- Neuropathology Department, University of Edinburgh
- Regional Procurator Fiscal, Glasgow & Crown Agent Edinburgh
- Royal College of Nursing, Scottish Branch
- Scottish Cot Death Trust
- Scottish Organisation Relating to the Retention of Organs (SORRO)
- Senior Anatomical Pathology Technician, North Glasgow NHS Trust
- South Glasgow University Hospitals NHS Trust
- Stillbirth and Neonatal Death Society (SANDS)
- Strathclyde Police
- Yorkhill NHS Trust
Preliminary Report: Appendix 5

Template for Hospital Post-Mortem Consent Form

Form should be accompanied by an information booklet to be retained by the relative(s).
A copy of the completed form should be provided to the relative.

Identifying Information
Name of deceased.
Relative's/partner's/carer's name.
Relationship.

Information as to Purpose of Post-Mortem Examination
Have been given the information leaflet.
Have been given the opportunity to discuss further with a member of the medical staff.
Understand that the purpose of the post-mortem examination is to provide further information as to the cause of death and to the possible effects of treatment.

Consent Options For the Post-Mortem Examination (*can be deleted as appropriate)
*Agree to a full post-mortem examination being carried out to provide further information as to the cause of death and to the possible effects of further treatment and do not wish to be given any additional information or consulted further.
*Agree to a post-mortem examination involving the retention of samples of fluids or small pieces of tissue to be examined by microscope.
*Agree to a post-mortem examination involving the removal and retention of the *brain/*heart/*other organ for investigation.
*Agree to a limited post-mortem examination confined to specific areas of the body.
*Agree to a limited post-mortem examination confined to *external examination/*external photography/*x-ray.

Where an agreement is given which involves the retention of tissue or organs, an opportunity must be given to specify the time during which tissue or organs may be retained and the purposes for which they may be used.
Consent Options for the Disposal of Retained Material
(*can be deleted as appropriate)
*Would like the hospital respectfully to dispose of any retained *tissues/*organs.
*Would like any retained *tissues which are not required as part of the medical record/*organs to be returned for cremation/burial. I understand that it may be necessary for these tissues/organs to be retained for tests for a period of several months.
*Would like any retained *tissues which are not required as part of the medical record/*organs to be re-united to the body for burial/cremation. I understand that this might cause a delay in the funeral arrangements.

Consent for Medical Research and Education
(*can be deleted as appropriate)
*Agree to *tissue/*any organs/*certain organs being retained *indefinitely/*for a specified period of time for *medical research/*educational/*training purposes. I understand that where organs are to be used for research purposes the project will have been approved by an Ethics Committee.
*Although agree in principle to organs being retained for medical research would like to be consulted on the types of research for which the organs/tissues can be used.
Understand that at any stage I may revoke my agreement for the continued retention of material or for its use for medical research, educational or training purposes.

Signed
Indication that it is possible to change any of the above decisions.
Indication that neither the deceased nor any close relatives are known to (have) object(ed) to any of the above decisions.
Signed and dated (by both parents if possible in case of child).
Signed and dated by person obtaining consent accompanied by their contact details.
Preliminary Report: Appendix 6

Template for Relative's Information Leaflet for Hospital Post-Mortems

Introduction
Hard to make decisions when grieving.
But need to decide as soon as possible whether to allow the hospital to carry out post-mortem examination.
Leaflet aimed to provide information to help make this decision. Should also be given the opportunity to talk to consultant/pathologist/member of the nursing staff about the post-mortem examination and be given the opportunity to have any questions answered. Space for name and contact details of relevant member of staff to be included on the form.

Purpose/Benefits of a Post-Mortem Examination
Brief explanation of what a post-mortem is.
To establish cause of death and the effect of treatment.
Can sometimes provide important information about genetic diseases/conditions.
Can also provide information which will help treat other patients.
Can provide information about disease/therapy as a result of research.
May be of benefit for medical education.

Types of Post-Mortem Examination
Hospital Post-Mortem
Consent must be given either in advance by the now-deceased person where competent to do so, or by relatives, before a post-mortem examination can be carried out.
The views of the deceased on this matter and of any other close relatives should be reflected in the final decision. The wishes of the deceased, when an adult, as to disposal of organs, etc. should be respected and where no information is available about this, the views of the relatives should be followed by the hospital.
Consent should only be sought from relatives after they have been given the opportunity of having an explanation of the purpose of the Examination and there has been an opportunity for relatives to ask any questions.
Relatives will be able to change their mind about any decisions made.

Procurator Fiscal's Post-Mortem
Circumstances under which such a post-mortem is necessary.
Consent of relatives not necessary for the post-mortem but the procedures should
be explained and relatives should be given the opportunity to ask questions.
Although a Procurator Fiscal post-mortem is requested by the Fiscal, hospitals
often have a role to play in the dissemination of information. Hospitals also
remain responsible for any retained organs or tissues that they may have as a result
of a Procurator Fiscal post-mortem.
Guidelines and information concerning Procurator Fiscal post-mortems should be
obtained from the Crown Office and Procurator Fiscal Service.

Explanation of a Post-Mortem Examination

Background
Carried out by pathologist and assisted by a technician.
Carried out in the hospital mortuary/local public or police mortuary.
Carried out with the same care and attention as any other operation, in a
respectful manner and with regard to the feelings of bereaved relatives.

Detail
Definition of tissue and organ
External examination possibly with photographs and x-rays.
Cuts made on the front of the body and at the back of the head (sometimes
possible through pre-existing surgical incision).
These will not be visible once the body has been sewn up and dressed for
burial/cremation.
Removal of internal organs for examination. These will be returned to the body
immediately after the examination unless consent has been given for them to be
retained for further examination as part of the post-mortem or for other specified
and agreed purposes.
Retention of tissue blocks and fluid samples. These are usually kept indefinitely as
they form an important part of the patient’s record. Possible to request for them
to be destroyed or returned once the initial diagnosis has been made.

Keeping Some Organs
Sometimes necessary to keep organs once the post-mortem has been completed
so that they can be studied in more detail to allow a fuller diagnosis to be made.
Only to be done with consent of relatives, or the deceased where an adult.
Should be given the opportunity to discuss this with the consultant/pathologist.
Should also be given the opportunity to discuss what should happen to the
organs once tests have been completed.

- respectful cremation by the hospital.
- return for cremation/burial.
- may be possible for the organs to be re-united with the body prior to the
  funeral but this might mean that the funeral would be delayed.
Keeping Organs and/or Tissues for Research/Education

Sometimes might be useful for organs or tissue samples to be kept for:
  - education/training
  - research.

Benefit of this.
Consent necessary and may be refused.
Clinician/pathologist should explain how long the organs/tissues blocks will be kept for.
Should discuss what should happen to the organs once they are no longer needed:
  - respectful cremation by the hospital
  - return for cremation/burial.

In the case of research should be given the opportunity to express their views on what they view to be the acceptable parameters of potential research, or to give a general consent for research use without the need to be re-contacted.
In the case of research, there should either be evidence that the project has been approved by the appropriate Research Ethics Committee, or that any research protocol will be submitted to the Research Ethics Committee for approval before it is commenced.
Consent for continued retention by relatives can be withdrawn at any time.

Other Post-Mortem Options

May be possible for a limited post-mortem to be carried out.
  - Can be confined to an external examination.
  - Can be confined to certain organs/parts of the body.

Implications of partial post-mortem for establishing cause of death.
Should be given the opportunity to discuss a limited post-mortem with the consultant/pathologist, or other appropriate member of the health care team (for example, nurses/midwives here).
In some cases, imaging may be sufficient – this option should be discussed by the consultant/pathologist/other member of the health care team.
Timing of the Post-Mortem and Results

Timing
Carried out as soon as possible after death (generally within two/three working days).
Efforts should be made to carry it out sooner if required for religious reasons.
Examination may take up to three hours.
Full post-mortem may take longer if detailed examination of certain organs is necessary- possibly several weeks. This will delay the funeral if the organs are to be united with the body before burial/cremation.

Post-Mortem Results
Will be sent to the consultant and GP by the pathologist, normally six to eight weeks after the post-mortem.
Can request an appointment with the consultant/GP to discuss the results.
Can also request a report in non-medical language from the pathologist.
Procedure for Procurator Fiscal post-mortems.

Bullet Point Summary of Main Points
Support and Information Contact List
(Glossary of terms to be avoided by the use of clear language and explanation of any necessary technical terms within the text.)
SUMMARY

1 Introduction

1.1 Thank you for considering the possibility of giving your authorisation for a hospital post-mortem examination on your relative. The aim of this leaflet is to ensure that you have been given enough practical information about the questions people most often ask, and we hope it will help you make a decision on whether to authorise a post-mortem examination.

1.2 Hospital staff are well aware that it is difficult for people to take in information at such a time. They know from experience that people need to be given time to think this issue through, and that everyone needs to take their own time. Hospital staff would not be asking you about a post-mortem examination unless they felt it was important, but they will not put you under any pressure to reach a decision. If there is anything you are unclear about, or would like to have explained to you in more detail, please ask the member of hospital staff who gave you this leaflet. Their details are shown in the box below. You may also want to speak to the doctor who would carry out the examination (the pathologist), and the hospital will arrange that for you. There is also a glossary of words at the end of this leaflet.

1.3 Of course, you may well want to talk over such an important decision with those close to you, or your own doctor, or your religious adviser. It is important that you have all the information and support you need to reach the decision which is right for you and your relative. At the back of the leaflet there are also details of how you can contact some organisations which may be able to help.

1.4 Paragraphs 3.1–3.4 give a brief explanation of the present law. It is generally regarded as unsatisfactory, and the Review Group on the Retention of Organs at Post-Mortem is making recommendations for changing it.
1.5 If you are entitled to authorise a post-mortem examination, and decide that you might be willing to do so, a member of the hospital staff will take you through the authorisation form which needs to be completed in each case. It has been designed to go with this information leaflet. We understand that you may find this process distressing, but please remember that you can ask whenever you want for more time to think things over. You can also ask for as much or as little information about the post-mortem process as you wish. The Clinical Standards Board for Scotland has drawn up standards for hospital post-mortems and these are available in the room where the discussion about authorisation takes place.

1.6 You need to be aware that if you do give your authorisation, the examination will take place quite quickly, so you probably will not be able to change your mind about the examination itself. There are other issues, to do with the keeping and use of organs and tissues from the examination, that you can change your mind about at any time.

1.7 What has been said so far applies only to hospital post-mortems. In some cases, the Procurator Fiscal may order a post-mortem examination. In these cases, your authorisation is not required. However, if there are religious or cultural considerations you want taken into account, you should contact the Fiscal. S/he will consider your views and will advise if alternative action is available. Some more information is given about Fiscal post-mortems in this leaflet, but it is very important that you understand which type of post-mortem you are dealing with.

2 The purpose and benefits of a hospital post-mortem examination

2.1 A hospital post-mortem examination is the final step in the investigation of your relative's illness. It is part of the complete process of caring for patients, a process that continues even after death. It is a careful internal examination of the person who has died, and it can give valuable information about an illness and its effects on the body. The examination can help to confirm the accuracy of the diagnosis which the clinicians had made. It may also help to rule out any problems which you may have suspected or feared. It is often the only way hospitals have of checking how new ways of diagnosing and treating illnesses are working, and helping find ways of improving them.

2.2 While the hospital will be concerned to help you to come to terms with your loss, the findings of a hospital post-mortem examination are also very important for the staff who cared for your relative, as it means they may be able to do more to help others in the future. They can also provide vital information for research, again for the benefit of others in the future.
may well find it difficult to think about such things at a time like this, but these are benefits which later on can give people some comfort.

2.3 Even after a hospital post-mortem examination some questions may be left unanswered. This can be distressing, but it may at least help to know that an illness which could have been treated was not missed.

3 The differences between hospital post-mortem examinations and procurator fiscal post-mortem examinations

The hospital post-mortem examination

3.1 If your relative has left written permission, or said in front of at least two people during their last illness what they wanted done about the possible use of their organs for medical treatment, education or research, then the hospital is entitled in law to do what your relative wanted. They can follow those wishes without having to ask anyone else’s views.

3.2 If your relative did not record his or her wishes, the hospital staff will ask you whether you know what your relative’s wishes were. If your relative expressed no views on the subject, the hospital will try to find out the views of the surviving husband or wife, or of any surviving relatives. That is because under the present law you cannot object to a hospital post-mortem examination unless you are the husband or wife or a relative of the deceased. (This is, of course, out of touch with modern circumstances, and the Review Group on the Retention of Organs at Post-Mortem recommends that those who were closest to the deceased should be consulted.) If you are entitled to be consulted, and object to a hospital post-mortem examination being carried out, the hospital will not proceed.

3.3 Authorisation is needed for a hospital post-mortem examination. A standard authorisation form has been drawn up which is aimed at making sure you have been given all the information you need to make a proper decision about whether you wish to agree to the hospital post-mortem examination or not. You should not sign the authorisation form unless you have been given the opportunity to find out as much information as you want, and feel that all your questions have been answered satisfactorily.

3.4 You do not need to give reasons for not wishing to authorise a hospital post-mortem examination. Refusal will be sufficient.

The procurator fiscal post-mortem examination

3.5 The Procurator Fiscal is a public official with legal responsibility for the investigation of certain types of death. S/He can authorise a post-mortem examination in certain circumstances without needing the authorisation of
relatives. There are over 20 circumstances in which doctors must report a death to the Fiscal, for example where death occurs during an operation. The Fiscal will then decide whether or not to investigate that particular death. The Procurator Fiscal also has responsibility for the investigation and prosecution of crime, but most deaths referred to the Fiscal do not involve suspicious circumstances. The majority of cases which the Fiscal requires to investigate are reported to him because the death is unexplained, sudden or violent. This includes all cases of sudden death in infancy. In these circumstances the issuing of a death certificate may not be possible until the conclusion of the post-mortem examination.

3.6 The purpose of the Procurator Fiscal post-mortem examination is to establish the precise cause of death, and to provide information about the circumstances of the death. In most cases the post-mortem examination confirms ‘natural causes’ as responsible for the death and rules out criminality. Where further legal proceedings (a prosecution or a Fatal Accident Inquiry) may arise, the post-mortem examination can provide valuable evidence regarding the circumstances leading to the death.

3.7 Many relatives are alarmed to learn that a death has been referred to the Procurator Fiscal and become distressed to learn that there will be a post-mortem examination. However, the Fiscal is aware of the need to make sure that relatives are informed of the nature and purpose of the post-mortem examination. Where an inquiry can be concluded without delay, the Fiscal may decide not to contact the relatives. However, s/he will attempt to contact a member of the family where it is intended to hold a post-mortem examination (although often in the aftermath of a sudden death it can be difficult to establish such contact). If you are uncertain about the action to be taken by the Fiscal, or if you want to express a view about the Fiscal’s inquiry, you should feel free to contact the Fiscal. Generally, it will be the office for the area in which the death took place or for the place where a fatal accident (or crime) occurred. Where the death occurred in hospital, the hospital staff may be able to advise you which Fiscal office is dealing with the case.

3.8 Relatives should let the Fiscal know if they have objections to post-mortem examinations on religious or cultural grounds.

3.9 If the Procurator Fiscal decides that a post-mortem examination is required, you should be aware that the pathologist who carries out the examination is acting on the instructions of the Fiscal and independently of the NHS, even though the post-mortem examination may take place in a hospital. The pathologist reports the findings of the examination to the Fiscal, not the hospital.
3.10 Further information on the role of the Fiscal in relation to sudden deaths is available from the Crown Office website: www.crownoffice.gov.uk or from local Procurator Fiscal offices which are listed in telephone directories.

4 What happens during a post-mortem examination

4.1 A post-mortem examination, also sometimes known as an autopsy, is an examination carried out when someone has died. The reasons for wanting to carry out a hospital post-mortem examination are given in section 2.

4.2 The doctor who carries out these examinations is a pathologist, someone who has had specialist training in carrying out such examinations and interpreting the findings. In the case of the death of a child, the post-mortem examination would normally be carried out by a paediatric pathologist or a perinatal pathologist, someone who has additionally specialised in diseases of babies and children. You may also hear references to a neuropathologist, someone who has made a special study of diseases affecting the brain. The pathologist is assisted in carrying out the examination by a Mortuary Technical Officer (MTO), who is a person specially trained to assist pathologists. Medical or nursing staff or others with a legitimate interest may also be present to observe the examination as part of their training.

4.3 Pathologists perform post-mortem examinations to standards set by the Royal College of Pathologists. The most important of these standards is that the examination must be carried out in a respectful manner, and with full regard for the feelings of the bereaved relatives.

4.4 Hospital post-mortem examinations are carried out in special facilities provided in the hospital mortuary. The body will be moved in a respectful manner from the place of death to the place where the examination is to be carried out.

4.5 The first thing the pathologist does is to carry out a careful examination of the outside of the body, much as would be done in a clinic during life. Photographs and X-rays may be taken for more detailed study.

4.6 The internal part of the post-mortem examination then begins. Sometimes the examination can be performed through an existing surgical incision. If not, an incision is made down the front of the body. These openings, are however, made in places which are as concealed and unobtrusive as possible. When the brain is to be examined, an incision is made in the hair at the base of the head. The pathologist will make every effort to avoid visible signs of the examination, but some may be inevitable. As part of the assessment, the internal organs are taken out for detailed examination. They will be returned
to the body immediately, but some organs, for example the brain, may have to be ‘fixed’ (see paragraph 6.2 for an explanation of this) before work can be done on them. In some cases, authorisation is given for other organs to be retained for further examination, either as part of the post-mortem process or where there is specific agreement to retain them for other purposes. More information on this point is given in section 6.

4.7 In some cases, this examination provides the pathologist with sufficient information. In most other cases, though, a more detailed examination of various organs may be needed. This involves examining tissue with a microscope. A small portion of tissue, usually about the area of a thumb nail, is removed and preserved in a chemical known as a fixative. The tissue will be specially processed in the laboratory at a later stage. This is similar to what happens to the pieces of tissue that a surgeon removes during an operation and which he then sends to be examined by a pathologist. The tissue is embedded in paraffin wax, sliced very thinly and then stained with special dyes so that it can be examined under a microscope. This process can take several days.

4.8 The making of these slides is a most important part of the post-mortem examination. They are really a part of the medical record, in much the same way as X-ray films, and as such form part of the record of care for the patient.

4.9 [Adult cases]. If you wish, it is possible for you to see and spend time with your relative, both before and after a post-mortem examination. You can obtain guidance from the hospital staff still caring for your relative as to the degree of contact it is advisable for you to have with the body.

4.9 [Paediatric cases]. In relation to a post-mortem examination involving your child, his or her body will be as carefully restored as possible, and there is no reason why you should not be able to see your child after the examination, either at the mortuary chapel or at the funeral director’s chapel of rest. Babies can be dressed in their own clothes afterwards, usually in a high-necked gown, dress or sleeping suit, and a cap or bonnet. You should be aware that the appearance and colour of your baby’s skin will change naturally after death. This will happen whether or not a post-mortem examination is carried out.

5 Timing of hospital post-mortem examinations and results

5.1 The post-mortem examination is normally carried out within two working days after authorisation is given, but may take place sooner than that. The
examination itself may take up to three hours, but, as explained in paragraph 4.7, getting the results will take longer if tissue has to be examined under the microscope, which is usually the case. Some examinations, particularly those related to the brain, can take up to several weeks.

5.2 Facilities for post-mortem examinations are not available at all hospitals. Where this is the case, the body will need to be moved to another hospital with such facilities.

5.3 Where religious observance requires a funeral within 24 hours of death, the same religious beliefs will probably not favour a post-mortem examination. In exceptional circumstances where such an examination is undertaken, probably after discussion with a religious adviser, every effort will be made to carry out the post-mortem examination within the time required by the religious beliefs of your relative and yourself. Refusal will be respected.

5.4 Once the initial examination is complete, a short initial report setting out the major findings will be sent to your relative's consultant on the day of the examination. This will be followed by a final report of the examination, which in most cases will be available within 21 working days. This is because it will have been necessary to examine small sections of tissue under the microscope, and to investigate other things such as genetics or infection. The final report goes to your relative's consultant and general practitioner (GP). If you have given permission for a neuropathologist to examine your relative's brain, there will also be a neuropathology report. That will take longer. You can arrange an appointment with your relative's consultant before the final report is available, if you would find that helpful.

5.5 The doctor in charge of your relative will be able to explain the results to you. You can ask for an appointment with the consultant who cared for your relative, or a member of the medical staff, or with your relative's GP, or with the pathologist who carried out the post-mortem examination. [Paediatric leaflet: Information about the results of a post-mortem examination should be made fully available to the parents who authorised it.] [Adult leaflet: The hospital will respect any wishes expressed by your relative about disclosure of the results of the post-mortem examination. Where no such wishes have been expressed, the results may be made available to you through your relative's GP or consultant.]

5.6 A death certificate is usually given to the relatives at the time of death, before a post-mortem examination is carried out. The issuing of the death certificate is therefore independent of the post-mortem examination.
Effect of post-mortem examination on funeral arrangements

5.7 Your relative's body will usually be released to the undertaker on the day of the post-mortem examination. When the post-mortem examination has been carried out late in the afternoon, this will usually happen the following morning. There should therefore normally be no delay to the funeral arrangements.

5.8 As pointed out in paragraphs 4.8 and 4.9, some investigations are more complex, needing detailed examination of the organs, most often the brain. This may take several days or even weeks. This would delay the funeral only if you wanted to have all the organs reunited with the body before the funeral. The choices are: to postpone the funeral until the organs can be reunited with the body; to go ahead with the funeral and ask the hospital to dispose of the organs respectfully; or to ask to have the organs returned to you at a later date, so that you can dispose of them according to your own wishes and in a lawful and appropriate way.

5.9 You may wish to specify a time by which the examination must be completed, to allow you to make funeral arrangements. If it cannot be arranged before then, your wishes about the timing of the funeral will be respected, and there will be no post-mortem examination.

6 Retention of organs and tissues

6.1 The meaning of 'organs' and 'tissues' is given in the glossary of words at the end of this leaflet.

6.2 During the post-mortem examination, small samples of tissue are removed from the major organs and retained, as described in paragraph 4.7. In addition, there are a number of reasons why pathologists may wish to keep a whole organ, particularly the brain. Different areas of the brain have different functions, and a fatal disease may affect only a tiny part. It can be very difficult to find such areas if the brain, which is very soft, is examined during the post-mortem. To obtain the most accurate diagnosis, the whole brain is hardened in formalin for two to three weeks before the key areas are selected for preparation as wax blocks and glass microscope slides. This examination is usually undertaken by a neuropathologist who specialises in diseases of the brain. Between 10 and 20 wax blocks may be prepared in complex diseases of the brain. Further selection of blocks may be necessary to achieve full diagnosis, and this can take several weeks.

6.3 Similarly there may be a need to retain the heart in patients with complex heart diseases or malformations, to allow careful examination by a specialist doctor.
6.4 You will be asked if you agree to the retention of whole organs for these diagnostic purposes. Whole organs may occasionally be retained, primarily for teaching or for research, but the purpose of retaining an organ will be made clear to you and you will have the opportunity to make your wishes known. If an organ has been retained, you will be asked whether you wish the remaining tissue which has not been selected for wax blocks to be returned to you or disposed of respectfully by the hospital or retained for further research studies. Advances in knowledge of heart and brain diseases rely to a great extent on availability of these organs from post-mortem examination. Disorders such as CJD or Alzheimer’s disease could not have been identified without the availability of brains from affected cases. Complicated and unusual abnormalities of the heart can be studied to help the paediatric cardiac surgeon deal with complex cases in future.

6.5 As explained in paragraphs 4.7 and 4.8, the blocks and slides made from tissue retained at post-mortem examination form part of the diagnostic process and become a key part of the medical record, in much the same way as an X-ray. They will not be used for any other purpose unless you have given your permission.

6.6 You may be asked to authorise organs or tissues being retained because they would help with research which is being carried out, or to be kept for use in future research projects which have not yet been set up. The various issues raised by research are dealt with in paragraphs 6.11-6.13 below.

6.7 Organs and tissue may also be retained for the education and training of medical students and doctors, but your authorisation is needed before they can be used in this way.

6.8 The pathologist who undertakes the hospital post-mortem examination will not keep any organ or tissue (other than those which form part of the patient’s medical record) for any reason unless you have given written agreement that this can be done. Where organs and tissues are retained, they are kept in safe and secure conditions.

6.9 The authorisation form makes clear your right to decide whether you wish to authorise any organs or tissues being retained. If you do, you can decide how long they can be kept for, or you can make it indefinite.

6.10 The form also makes clear that if you do agree to organs and tissues being retained indefinitely following a hospital post-mortem, you have the right to withdraw that agreement at any time. If you do make that decision, you can then discuss with the hospital what should happen to the organs or tissues.
The hospital can either dispose of them for you in a respectful way, or return them to you. There is more information on disposal in section 8.

6.11 There is a specific section of the authorisation form dealing with medical research. No organs or tissues retained with your authorisation at post-mortem examination will be used for medical research unless you have signed this part of the form saying that you authorise this.

6.12 The form also offers two choices in this area. It allows you to give a general authorisation to organs and tissues being used for medical research. Research can, however, take many forms, and it is not possible to foresee what might be undertaken in the future, or what results it might produce. You might, therefore, want to put limits on the use that could be made of organs and tissues, and the form allows you to do that. For example, you might want to say that there are religious and cultural reasons why you would not want organs and tissues to be used in particular types of research. Some people find any research involving testing on animals unacceptable, or you might object to genetic testing. The authorisation form allows for full account to be taken of your views.

6.13 Before any structured research is undertaken, approval must be obtained from a Research Ethics Committee (REC). Research Ethics Committees are set up to provide independent advice on the extent to which proposals for research comply with recognised ethical standards. The purpose of the REC in reviewing the proposed study is to protect the dignity, rights, safety and wellbeing of all actual or potential research subjects. There is an REC in each NHS Board. To find out more about the work of the REC in your area you should contact the administrator of the REC (usually based in the NHS Board headquarters). The hospital should be able to provide you with a copy of the local REC’s most recent annual report, if you are interested in what sort of research the Committee is asked to review.

7 Limited post-mortem examinations

7.1 You may be unhappy with the idea of a full post-mortem examination. If that is the case, you might want to consider agreeing to a limited post-mortem examination. This could, for example, be limited to the site of an operation, and use the same operation opening. Or you could ask that the examination should be limited to the chest, or the abdomen. Hospital staff will be able to explain what would be appropriate in your particular case.

7.2 In a small number of cases it may be possible to make a diagnosis using other investigations such as X-rays, special scans, blood or urine tests or needle samples taken from organs. You can discuss these options with the hospital staff.
7.3 A limited post-mortem examination will mean there is no information available about other organs or tissue which were not examined but which might have contributed to your relative’s death. A full post-mortem examination always gives more information.

7.4 All of these points are taken into account on the authorisation form.

8 Disposal arrangements

8.1 Once the investigations are complete, the hospital will either dispose of any retained organs or tissues in a respectful way, or, if you wish, will arrange for them to be returned to you.

8.2 If you decide to bury or cremate the organs or tissues returned to you, you should use a recognised funeral director. If you wish to dispose of the organs or tissues in any other way, you will need to follow the legal requirements which apply. You may wish to discuss your specific circumstances either with the hospital, or with one of the groups referred to at the end of this leaflet.

8.3 There are a number of issues relating to disposal which are currently being addressed, and the Scottish Executive Health Department is currently preparing general guidance on disposal of organs and tissues.

8.4 When you ask for organs or tissues to be returned to you, and you wish to arrange for a funeral for them, there may be additional expenses involved. You may wish to discuss this with the hospital.
### Glossary of Technical Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Archiving</td>
<td>Archiving is the long-term preservation of tissues or organs. Archives are important because:</td>
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<td></td>
<td>• The preserved tissues or organ can be re-examined if new diagnostic techniques or fresh knowledge about diseases might give a clearer explanation of the deceased’s illness;</td>
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<tr>
<td></td>
<td>• The education and training of medical students and doctors is helped if they can see for themselves what happens inside the body in disease;</td>
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<tr>
<td></td>
<td>• Research using archived tissues and organs can help in the diagnosis and treatment of future patients.</td>
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<tr>
<td>Banks (Tissue and Organ)</td>
<td>Rare diseases can be investigated properly only when a sufficient number of cases have been studied. This often means that, subject to agreement in individual cases, tissue or organs from post-mortem examinations may be stored safely and securely in a tissue or organ bank until enough cases have been collected and then the research can begin.</td>
</tr>
<tr>
<td>Blocks</td>
<td>These are blocks of paraffin wax within which are embedded small samples of tissue, about a quarter of an inch thick, which are taken from organs to allow for microscopic examination. See also ‘slides’.</td>
</tr>
<tr>
<td>Fixing</td>
<td>Before organs or tissues can be examined in detail, particularly under a microscope, they have to be hardened by immersion in a chemical, usually formaldehyde. This is known as ‘fixing’. The complete process may take several weeks.</td>
</tr>
<tr>
<td>Full post-mortem examination</td>
<td>The full post-mortem examination involves examination of the contents of the skull, chest and abdomen. It includes the retention of tissue blocks and slides as part of the medical record.</td>
</tr>
<tr>
<td>Incision</td>
<td>An incision is a cut in the skin, enabling the body to be opened. The incision is made in the same way as...</td>
</tr>
</tbody>
</table>
Medical Certificate of Cause of Death (Death Certificate)

A certificate showing the cause of death is required before the Registrar of Deaths can authorise final funeral arrangements for the body. Research has shown that up to 30% of the information on a death certificate may be wrong unless it is based on the findings of a post-mortem examination. The Registrar can refer the matter to the Procurator Fiscal if he is dissatisfied with the cause of death as given. Additional certificates relating to the death are required if the body is to be cremated.

Mortuary

The mortuary is a group of rooms, usually in a hospital (those outside hospitals are called public mortuaries), where bodies are kept in refrigerators before collection by undertakers. The mortuary also includes the post-mortem room where the post-mortem examination is performed.

Mortuary Technical Officers

These technicians have undergone specialist training and acquired certification in post-mortem examination techniques, including the identification of bodies, the external examination of bodies, the procedures involved in removal of organs for post-mortem examination and the return of organs to, and restoring of the body after, post-mortem examination. In this work, they co-operate with the ward staff, pathologists and funeral directors.

Organ(s)

The body contains many organs such as the brain, heart, kidneys, lungs and liver. Each carries out different functions. The organs are connected to the body by nerves, blood vessels and fibres.

Regional Centre for specialist post-mortem

Sometimes it is necessary for a body to be moved to another place for the post-mortem examination where there are special facilities and pathologists skilled in dealing with examination particular cases (for example, deaths in infancy and childhood).

Pathologist

The pathologist undertakes the post-mortem examination. He or she is a clinically-trained doctor.
who has developed specialist expertise in carrying out such examinations and reporting on the findings. They are also referred to as ‘histopathologists’, in that they have special expertise in histopathology, the microscopic examination of tissue for diagnostic purposes. Pathologists work to standards laid down by the Royal College of Pathologists.

Procurator Fiscal
The Procurator Fiscal is required by law to investigate deaths due to unnatural, suspicious or unknown causes.

Procurator Fiscal’s post-mortem
An examination instructed by the Procurator Fiscal. The authorisation of relatives is not required.

Slides
Thin sections or shavings are cut from tissue blocks, stained with dye and then mounted on glass slides for examination under the microscope.

Tissue
Organs contain tissue, collections of cells which give organs their special functions. For example, the heart contains muscle tissue composed of cells which contract to pump the blood. Samples of tissue (typically small slices about a quarter of an inch thick) are usually taken during a post-mortem examination for examination with a microscope.

Useful Contacts
- List of nominated staff in each Trust
- Details of voluntary organisations
- Clinical Standards Board for Scotland
- Crown Office website
Authorisation of a Hospital Post-Mortem Examination (Adult)

This form must be accompanied by an information leaflet to be retained by the relatives.

A copy of the completed form must be provided to the relative, a copy must be kept with the notes of any post-mortem examination undertaken and with the patient’s medical records.

Section 1. Identifying Information

| Name of patient                                      |__________________________________________|
| Date of Birth                                       |__________________________________________|
| CHI Number (where available)                         |__________________________________________|
| Name of person giving authorisation                  |__________________________________________|
| Relationship                                         |__________________________________________|
Section 2. Respecting the deceased's wishes

Section 1(1) of the Human Tissue Act 1961 provides that if the deceased expressed a request, in recognised form (see below), that his body, or any specified part of it, should be used after his death for therapeutic purposes, or for medical education or research, the person lawfully in possession of the body (generally understood as the hospital administrator) can authorise the removal from the body of any part, or such part as was specified by the deceased.

The hospital needs to have evidence of the deceased's wishes, and these have to be either in writing, which can be done at any time, or orally in the presence of at least two witnesses during the deceased’s last illness.

The power given to the person lawfully in possession of the body is discretionary and the decision whether to exercise the power, and the factors to be taken into account in reaching that decision, rest with the person lawfully in possession of the body.

I have made the deceased's husband/wife/relative(s) aware that [name of deceased] left the required evidence of his/her wishes, and have included that evidence in his/her medical records.

I have/have not authorised the removal of the relevant part/parts.

Reasons for refusal to authorise

Signature ______________________________________ Date______________________________
(On behalf of Hospital Administrator)

Name (block caps) _____________________________ Position __________________________

Where this section has been completed, the person lawfully in charge of the body will need to decide whether Section 4 or 5 also needs to be completed.
Section 3. Where the deceased did not record his or her wishes

This section deals with the situation covered by section 1(2) of the Human Tissue Act 1961, which provides that the person lawfully in possession of the body may authorise the removal of any part for therapeutic purposes, or for the purposes of medical education or research, if, after making such reasonable enquiries as may be practicable, he has no reason to believe (a) that the deceased expressed an objection to his body being so dealt with after death, or (b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.

To the best of my knowledge, [name of deceased] had no objection to a post-mortem examination.

To the best of my knowledge, [name of deceased] had no objection to his/her organs being kept for diagnostic, teaching or research purposes.

Give details of any reasonable enquiries made to establish absence of objection on the part of the surviving spouse or relatives

Signature ____________________________ Date ____________________________
(On behalf of Hospital Administrator)

Name (block caps) _____________________ Position _______________________

Now go to Section 4 or 5, as appropriate.
Section 4. Authorisation of hospital post-mortem examination where no further information required

Where the hospital is satisfied that the views of the surviving spouse or relative(s) should be taken into account, it is necessary to establish the attitude of the surviving spouse or relative(s) to whether or not they wish to be given further information about the process of carrying out a post-mortem examination. This section of the form is designed for use in those cases where the surviving spouse or relative(s) indicate they do not wish any further information.

I authorise a post-mortem examination to be performed, and authorise the hospital to undertake any action it considers appropriate following that examination, but I do not wish any further information about the post-mortem examination process or to be consulted further.

I understand that I can decide at any time in the future to request information about the purposes of the post-mortem examination.

Signature ______________________________________ Date______________________________

Name(s) (block caps)
_______________________________________________________________________

Relationship to deceased_________________________________________________________________

Signature of witness ______________________________________________________________________

Note: where this section has been completed, no other section of the form should be discussed. The person who signs this Section as witness should be the same member of hospital staff who signs Section 8.
Section 5. Authorisation of hospital post-mortem examination where further information is required

This section of the form should be used for those who have indicated that they wish more information about the post-mortem examination process.

I authorise a full post-mortem examination in order to find the cause of death and study the effects of treatment. I understand that this will involve the examination of the internal organs. I also understand that a full post-mortem examination involves the removal of samples of fluid or small pieces of tissue to be examined by microscope.

It has been explained to me that retention of organs is sometimes necessary to achieve full diagnosis of the cause of death, and I authorise retention of any organs/certain organs* for this purpose.

I understand that blocks and slides will be prepared from these retained organs and kept as part of [name of deceased]’s medical records.

*specify organs

or

I authorise a limited post-mortem examination confined to the following specific area or areas of the body:

the head ☐ the chest ☐ the abdomen ☐

I authorise the retention of any organ necessary for diagnosis from the area(s) specified.

or

I authorise a limited post-mortem examination confined to external examination/external photography/X-ray/other form of imaging [specify] ____________________________

Signature ____________________________ Date ____________________________

Signature of witness ____________________________ Date ____________________________

Now go to Section 6.
Section 6. Authorisation of retention of organs and tissues for medical research and education

I authorise the retention of tissue/any organs/certain organs* for medical research/educational/teaching purposes.

*Details

I authorise such retention indefinitely/for a specified period of time.

(If retention is for specified period of time, give details. ________________________________ )

I hereby waive all further interest in these organs/tissues.

I understand that any research will be approved by a Research Ethics Committee.

(Complete if appropriate)

I do not want the tissues or organs to be used for any research involving the following (see information leaflet for examples).

Insert details of types of research ruled out: __________________________________________

I understand that I may at any time decide that any organs or tissues should no longer be used for medical research, educational or teaching purposes, and can notify the hospital accordingly. I understand that the hospital will respect that request.

Signature ___________________________ Date ___________________________

Now go to Section 7.
**Section 7. Authorisation options for the disposal of retained organs and/or tissues which are not to be kept as part of the medical record**

I would like the hospital to dispose of in a respectful manner any retained tissues/organs when the purpose for which they were retained has been completed.

*or*

I would like any retained organs/tissues which are not required as part of the medical record to be re-united with the body for burial/cremation. I understand that this might cause a delay to the funeral arrangements.

*or*

I would like to have any retained organs/tissues which are not required as part of the medical record returned. I understand that it may be necessary for these organs/tissues to be retained for a period of several weeks.

Signature __________________________ Date________________________
## Section 8 (to be completed by the appropriate member of hospital staff)

I confirm that this form has been discussed with [name] and completed in accordance with what I understand to be his/her wishes.

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>________________________________________________</td>
</tr>
<tr>
<td>Name (block caps)</td>
<td>________________________________________________</td>
</tr>
<tr>
<td>Designation</td>
<td>________________________________________________</td>
</tr>
<tr>
<td>Date</td>
<td>________________________________________________</td>
</tr>
<tr>
<td>Any further information</td>
<td>________________________________________________</td>
</tr>
</tbody>
</table>
Authorisation of a Hospital Post-Mortem Examination (child under 16)

This form must be accompanied by an information leaflet to be retained by the parent(s).

A copy of the completed form must be provided to the parent(s). A copy must be kept with the notes of any post-mortem examination undertaken and with their child’s medical records.

### Section 1. Personal Details about your Child

| Name (block caps) |  
|--------------------|---
| Date of Birth | 
| CHI Number (where available) | 
| Name(s) of parent(s) with whom authorisation has been discussed | 

Any other information the parent(s) would like to record about their child, which the parent(s) would like to have kept with this form

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Section 2. Authorisation of hospital post-mortem examination
where parent(s) indicate no further information is required

The hospital needs to find out whether the parent or parents wish to be given further information about the process of carrying out a post-mortem examination before they decide whether or not to authorise it. This section of the form is designed for use when the parent or parents indicate that they do not wish any further information.

Note: where both parents are involved, and they cannot agree whether to authorise a post-mortem examination, it is probably better not to proceed. This should be recorded in Section 6.

I/We authorise a post-mortem examination for [name of child], and authorise the hospital to undertake any action it considers appropriate following that examination, but I/we do not wish any further information at this time about the post-mortem examination process, or to be consulted further.

Despite not wishing to discuss further the post-mortem examination process, I/we do/do not wish to be informed about the findings of the post-mortem examination.

I/We understand that I/we can decide at any time in the future to request information about the purposes of the post-mortem examination.

Signature(s) _____________________________________________________________________
Date ________________________________
Names (block caps) _______________________________________________________________

Signature of witness _________________________________________________________________
Name (block caps) ___________________________, Position ________________________________

Note: where this section has been completed, no other section of the form should be discussed. The person who signs this Section as witness should be the same member of hospital staff who signs Section 6.
Section 3. Authorisation of hospital post-mortem examination where further information is required

The hospital needs to find out whether the parent or parents wish to be given further information about the process of carrying out a post-mortem examination before they decide whether or not to authorise it. This section of the form is designed for use when the parent or parents indicate that they wish further information.

Note: where both parents are involved, and they cannot agree whether to authorise a post-mortem examination, it is probably better not to proceed. This should be recorded in Section 6.

It has been explained to me/us that a full post-mortem examination carried out in order to find the cause of death and study the effects of treatment will involve the removal of organs from the body for examination during the post-mortem examination. These will normally be returned at the conclusion of the post-mortem examination. I/We understand that a full post-mortem examination involves the removal of samples of fluid or small pieces of tissue to be examined by microscope. I/We authorise a full post-mortem examination on the basis of this understanding.

It has been explained to me that retention of organs is sometimes necessary to achieve full diagnosis of the cause of death, and I authorise retention of any organs/certain organs* for this purpose.

*Specify organs: ______________________________________________

I/We understand that blocks and slides will be prepared from these retained organs and kept as part of my child’s medical records.

or

I/We authorise a limited post-mortem examination confined to the following specific area or areas of the body:

the head     ☐  the chest ☐  the abdomen ☐

I/We authorise the retention of any organ necessary for diagnosis from the area(s) specified.

or

I/We authorise a limited post-mortem examination confined to external examination/external photography/X-ray/other form of imaging [specify] ______________________________________

Signature(s) ____________________________________ ______________________________________

Date ______ _______________________________________

Name(s) (block caps) ___________________________ __________________________

Signature of witness _____________________________________________________________________

Name (block caps) ___________________________ Position __________________________

Date _________________________________

Now go to Section 4.
Section 4. Authorisation of retention of organs and tissues for medical research and education

I/We authorise the retention of tissue, any organ/certain organs* for medical research, provided that this research has been approved by a Research Ethics Committee.

*Specify organs: ________________________________________________

(Complete if appropriate)

I/We do not want the tissues or organs to be used for any research involving the following (see information leaflet for examples):

Insert details of types of research ruled out: ________________________________________________

It has been explained to me/us that teaching and training may take place during or after the post-mortem examination, and that this may include the taking of pictures, and that this will be done respectfully.

I/We authorise the retention of tissue/any organs/certain organs* for educational/teaching purposes, provided this is undertaken respectfully.

*Details __________________________________________________________________________________________

I/We authorise such retention indefinitely/for a specified period of time.

(If retention is for specified period of time, give details _________________________________)

I/We understand that I/we may at any time decide that any organs or tissues should no longer be used for medical research, educational or teaching purposes, and can notify the hospital accordingly. I/We understand that the hospital will respect that request.

Signature(s) ____________________________________ ______________________________________

Date ______ ______________________________

Signature of witness _____________________________________________________________________

Name (block caps)_________________________________ Position ____________________________

Date ______ ______________________________

Now go to Section 5.
Section 5. Authorisation options for the disposal of retained organs and/or tissues which are not to be kept as part of the medical record

I/we would like the hospital to dispose in a respectful manner of any retained tissues/organs no longer required for diagnosis.

or

I/We would like any retained organs/tissues which are not required as part of the medical record to be re-united with the body for burial/cremation. I understand that this might cause a delay to the funeral arrangements.

or

I/We would like to have returned any retained organs/tissues which are not required as part of the medical record. I understand that it may be necessary for these organs/tissues to be retained for a period of several weeks.

Signature(s) ____________________________________ ______________________________________
Date _______________________________
## Section 6 (to be completed by the appropriate member of hospital staff)

I confirm that this form has been discussed with [name of parent(s)] and completed in accordance with what I understand to be his/her/their wishes. I also confirm that the opportunity has been provided to read, and ask questions arising from, the information leaflet.

<table>
<thead>
<tr>
<th>Signature</th>
<th>___________________________________________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (block caps)</td>
<td>___________________________________________________________________</td>
</tr>
<tr>
<td>Designation</td>
<td>___________________________________________________________________</td>
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<tr>
<td>Date</td>
<td>___________________________________________________________________</td>
</tr>
<tr>
<td>Any further information</td>
<td>___________________________________________________________________</td>
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<td></td>
<td>___________________________________________________________________</td>
</tr>
</tbody>
</table>
In the course of the second phase of the Review Group’s work, a number of matters, which we have called ‘cognate issues’, were raised. Although it was not possible for us to reach a conclusion on them, not least because they did not directly form part of our remit, we nonetheless are concerned that they may represent grey areas which a full reform of the law might wish to take into account. What follows is a brief outline of these issues.

Stillbirths and Unviable Foetuses

While not falling strictly within the terms of the remit of the Review Group, in the course of our review we did consider the issue of post-mortem examination of, and use of tissue from, miscarried foetuses. The Alder Hey Report, although detailing in the course of the Inquiry several cases of unauthorised retention of stillbirths and research upon them, made no specific recommendations about how these should be dealt with in future.

Post-mortem examination of and research upon miscarried foetuses

It appears that there is at present no specific statutory legal regulation of examination of the body of a foetus, removal or retention of foetal organs and tissue or research upon them. The foetus does not seem to be governed by legislation such as the Human Tissue Act 1961, since a nonviable foetus has never achieved legal personhood so presumably cannot come within the terms of the legislation which refers to “a deceased person”. This view was taken by the Polkinghorne Committee and appears to be supported by most commentators. Equally, the present legal authority for post-mortem examination of a foetus seems unclear. Indeed, one Department of Health document suggests that permission to perform a post-mortem or other investigation is not required where the baby is born dead before the age of viability.

The current regulation of examination and use of the foetus seems to rest primarily on a Code of Practice issued by the Polkinghorne Committee in

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While the Polkinghorne Code of Practice is not legally binding, it is the guidance followed by the Department of Health in its communications.

Broadly, the Polkinghorne Code of Practice requires that written consent be obtained from the woman for examination and use of the foetus, whether the foetus aborted spontaneously or as a result of a medical procedure. The Polkinghorne Committee was, however, concerned that decisions to terminate a pregnancy should not be influenced by any proposed use of foetal material and therefore made a number of recommendations to try to ensure separation of these issues. These included recommendations that procedures be adopted to prevent the woman from being given any information about the nature of the research intended or performed or even whether research had been carried out upon the foetus or foetal material, once permission to use the material had been given. The Code of Practice also states that:

> It may be desirable to consult the father since, for example, tests on foetal tissue may reveal a finding of potential significance to him, and because he may have knowledge of a transmissible or hereditary disease, but his consent shall not be a requirement nor should he have the power to forbid research or therapy making use of foetal tissue.\[sic\]

The Code of Practice further requires that research involving the foetus or foetal tissue should be examined by an ethics committee and that there should be no monetary exchange for foetuses or foetal tissue.

5 A number of difficult and sensitive issues arise in respect of the continued suitability of the recommendations of the Polkinghorne Code of Practice as a result of the general approach that we are recommending in this Report, such as the justification for restricting the information available about proposed research upon foetal tissue and authorisation for research being sought from only one parent. It may be felt that the context of making decisions about a miscarried foetus does justify different approaches being taken from that which we are recommending for children who die in infancy or later. However, clarification of the legal authority for examination and research upon the foetus is, we feel, a matter of importance and one which merits further careful consideration. **Given the priority we have suggested should be paid to the wishes of parents in respect of organs and tissue of children, we would suggest that consideration should also be given to the examination of the foetus and any material removed from it and to clarifying the legal position in this regard.**

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87 Paragraph 4.3
Registration and burial or cremation of miscarried foetuses

Stillbirths

6 A stillbirth is legally defined as being a child born dead after the 24th week of pregnancy (before 1992, a child born dead after the 28th week of pregnancy). All stillbirths must be registered.

7 Once the stillbirth is registered, the registrar will give the parents a certificate of registration of stillbirth and a certificate for burial or cremation. The registrar will write the baby’s name on these certificates if the name is recorded in the register. Burial or a cremation can then take place, in the same way as for any other dead child.

8 An NHS circular in 1992 states that the hospital (or midwife if stillbirth is not in hospital) should offer to arrange a funeral for a stillborn baby and, unless the parents wish to pay for it or make their own arrangements, the hospital arranging the funeral should meet the costs. Further guidance issued by the Scottish Office Department of Health National Medical Advisory Committee in 1996 states that parents must be given a choice about how and where their baby will be laid to rest although pointing out that not all parents will want to be involved in making these decisions and that this should be respected.

9 The 1996 guidance notes that in some municipal cemeteries, all babies are buried in separate graves, while in others they are buried in a shared grave in separate coffins and some hospitals have plots where babies of all gestations can be buried. It recommends that local practices should be explained to parents.

10 There is guidance from a number of sources that explains the importance of support being given to parents of a stillborn child. SANDS in particular produces a range of material for professionals and families. The 1996 Management of Early Pregnancy Loss guidance also places importance on providing parents with opportunities for showing respect for their babies with naming ceremonies, memorials and memorial services and books of remembrance.

88 Still-Birth Definition Act 1992:
89 Registration of Births, Deaths and Marriages (Scotland) Act 1965; Births and Deaths Registration Act 1926 and Births and Deaths Registration Act 1953
90 NHS Circular GEN (1992) 33: Guidance Notes Issued by the Management Executive, NHS in Scotland on Arrangements and Procedures for Dealing with Deaths of Patients in Hospital, para 2
Miscarriages of foetuses before twenty-four weeks gestation

11 Where there is a spontaneous abortion before the foetus has reached the twenty-fourth week of gestation, there is no requirement for registration. It is a legal requirement that all abortions performed under the Abortion Act 1967 (as amended by the HFEA 1990) be notified to the Chief Medical Officer of the Scottish and Home and Health Department by the doctor terminating the pregnancy within seven days of the termination.93

12 The 1992 Scottish guidance seems to make no general distinction between the principles that should apply to a foetus which is spontaneously or electively aborted. Subject to the parents not making other arrangements, guidelines in 1992 stated that all foetuses and foetal material must be incinerated according to clinical waste disposal guidelines, although as a basic requirement, separate containers must be used for foetal remains, there must be separate delivery to the incinerator and separate loading.94 However, the 1996 guidance states that where possible, incineration of foetal remains and identifiable bodies should be avoided. Where this is not the case it was said that the procedure must be carried out as respectfully as possible and again foetal remains must be kept separate from clinical waste. This guidance states that parents must be told when this method of disposal is used and should know about any alternatives open to them. They should also be advised when it is to take place in case they wish to mark the occasion with a small ceremony.95

13 A series of difficult and perhaps controversial points do, however, arise in relation to informing the parents about the methods of disposal. There are, of course, concerns about how sensitively choices about disposal of the foetus are communicated; whether this may add to any stress being suffered by a woman undergoing either a spontaneous miscarriage or an elective termination and also whether it is problematic to seek to equate a foetus of any length of gestation with a born child.

14 Another issue arises in relation to whether both the man and the woman should be given information and options about the disposal of foetal remains or whether it is sufficient to seek the views only of the woman. While, of course, it is not always the case that both parents will be available to discuss and agree on the procedures they believe are appropriate in the case of children dying in infancy or later, it is predictable that where elective terminations take place, it is more likely that the man may not be aware of the pregnancy and/or that the woman may not wish him involved. Conditions of confidentiality dictate that a man cannot be contacted to ascertain his views on foetal disposal at present without the express agreement

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94 SOHHD/DGM (1992) 4
of the woman. Presumably, it would not be suggested that this be changed, at least where the foetus is being buried, cremated or incinerated. However, as noted above, questions may arise with respect to post-mortem examination or research upon a foetus.

15 However, even where both parents are available and in agreement, a potential difficulty was noted by Mason where parents wish there to be a burial of a foetus of less than 24 weeks. While there would seem to be no legislative impediment to a burial of such a foetus, and it will be unregistrable as a stillbirth, there may be reluctance from superintendents of burial grounds to bury it in case it is in fact an unregistered stillbirth, since disposal would then be an offence. A similar problem may also presumably arise with cremations. To facilitate burials Mason reported that some doctors issue a certificate of foetal birth which, while having no official authority, superintendents of burial grounds may be prepared to accept as evidence that the foetus was not a stillbirth which required registration.

16 The appropriate method of disposal and the necessary authorisation for research upon, and examination of, miscarried foetuses remains at present largely subject to professional and local practice and thus there may be a lack of clarity and consistency of approach that is at odds with our general recommendations for future practice. We therefore recommend that the issue of the appropriate approach to the post-mortem examination of miscarried foetuses and research upon, and use of, foetal tissue, be specifically considered in the reforming legislation.

96 Mason, J.K., Medical-legal Aspects of Reproduction and Parenthood, (2nd Ed), Ashgate, 1998 at p. 177
The Defence Post-Mortem Examination

17 The autopsy for the defence poses some difficulties which are not covered by either the hospital or the Fiscal’s post-mortem examination. In particular, the relatives have already suffered from one non-consensual autopsy, and they may see no reason why the body of their kin should be used for the benefit of his or her killer and the control of the body passes to an unknown authority whose objective is to defend a client, not necessarily to observe ethical niceties. In fact, the defence pathologist owes no duty of care to the relatives while the Fiscal will find it difficult to impose conditions on the defence for fear of being seen as interfering in the course of justice.

18 Relatives should be made aware of these problems and that, unfair as it might seem to them, they are powerless to interfere with what are the undoubted rights of the accused. Thus, the defence is entitled to prepare, and retain, its own blocks and slides and can also retain organs for as long as they think necessary. There appears to be no current rules as to who should inform the relatives that this has been done – though it seems to be self-evident that it should be the accused’s representatives.

19 Similarly, there apparently no current regulations governing the return of such organs and tissues which, in addition, carries financial implications. It is therefore suggested that the rules which govern the Fiscal in this respect should also apply to the defence and that the Legal Aid Board should accept any additional financial responsibility.

20 Relatives should also be aware of the current policies for retention of the victim’s body in the event of there being no accused. At least, cremation should not be a viable option in such circumstances particularly now that the availability of DNA testing greatly extends the time for which a body may provide useful evidence.