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THE SCOTTISH OFFICE

National Health Service in Scotland
Management Executive

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Dear Colleague

SUPPORTING RESEARCH AND DEVELOPMENT IN THE NHS

Summary

1. This letter outlines the main objectives of the review of funding arrangements for research and development in the NHS (Annex A) and interim arrangements for supporting research being carried out in the NHS by others (Annex B).

2. It also includes an Implementation Plan (attached) designed to develop and put in place new funding arrangements.

Action

3. Recipients are asked to note the contents of the Implementation Plan and begin to identify their local R&D and related activity; guidance to help with this will be issued later in 1995.

4. Principles to guide the provision of service support in this interim period are attached at Annex B. They have been agreed with the Medical Research Council (MRC) but apply equally to other research being conducted in the NHS in Scotland. Please ensure that the principles are implemented as soon as possible and note, in particular, the requirements for local action at paragraphs 7 and 8 of the Annex.

Yours sincerely

DR K WOODS
Director of Purchasing

PROFESSOR I A D BOUCHIER
Chief Scientist

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Health Boards

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ANNEX A

REVIEW OF FUNDING ARRANGEMENTS FOR R&D IN THE NHS

1. In 1994 the Department of Health published a report on support for research in England "Supporting Research and Development in the NHS" - the Culyer Report - which recommended the introduction of a single funding stream and new arrangements for the allocation and management of support funding. DH recently published an implementation plan for securing new arrangements.

2. The funding arrangements for supporting research in Scotland are different to England but similar issues have arisen in the new purchaser/provider climate and many of the Culyer Report's recommendations are accepted as broadly appropriate in our situation. In Scotland the main support for R&D is through the Additional Cost of Teaching ACT(R) which includes an element for research. Other elements of support come more directly from Boards, Trusts and the Chief Scientist Office. The Implementation Plan for a review of these funding arrangements in Scotland, is closely parallel to that for England and we will be working towards a similar timescale because of the need for new funding arrangements to be introduced across the UK at the same time. The main objectives of the Plan are to:

- introduce a single funding source for R&D and its support in the NHS;

- provide better management and accountability for the funds devoted to NHS R&D; and

- provide for a smooth transition to the new arrangements.

3. The key milestones in the Implementation Plan timetable are:

- establishing an initial levy for R&D by 1 April 1996;

- providers to send declarations of R&D expenditure by May 1996;

- a full levy to be established on 1 April 1997;

- introduction of cost based contracts with quality standards and arrangements for assessing quality, from 1 April 1997; and

- operation of new assessment arrangements from 1 April 1998.

4. The work involved in meeting this timetable falls into 2 parts: the development of policies for the operation of a single levy and its funding categories; and the work needed to translate these policies into practice. The Department has established a Project Management Group and an Advisory Group to take these matters forward.

ANNEX B

INTERIM ARRANGEMENTS FOR SUPPORTING R&D IN THE NHS

1. Until new funding arrangements can be put in place it is important that research is adequately supported, whether MRC funded research, including multi-centre trials, or research funded by other organisations such as the Chief Scientist Office. Researchers are being asked to ensure that they have identified the service support requirements and have discussed and agreed how these will be met with the NHS organisations involved. The attached principles have been agreed with the Department of Health and the MRC to guide the provision of service support until new funding arrangements are put in place. They apply to all service support requirements irrespective of the funding source.

2. The Additional Cost of Teaching (ACT(R)) includes a component for the service support of research and is disbursed through the 4 Teaching Boards. It is not possible to be precise about the size of this component in advance of the work of the Advisory Group, but it is sufficiently substantial for those Boards and Trusts to be able to manage research support on an interim basis by discussion and agreement. For non Teaching Boards and Trusts where there is no existing funding stream, and for all Boards and Trusts in relation to research and service support issues relating to the primary care and community care sectors, we have an obligation to meet such costs and Boards and Trusts are requested to arrange to meet those which arise on an interim basis.

PRINCIPLES FOR THE INTERIM PROVISION OF NHS SUPPORT FOR CLINICAL RESEARCH PENDING IMPLEMENTATION OF NEW FUNDING ARRANGEMENTS

Definition of cost categories

1. Costs associated with research in the NHS fall into 3 categories:

   (i) research in the NHS may be associated with an existing or new service being delivered for patients. **Service costs** are those costs that would be incurred by the NHS if a service were being provided outside the context of research. In the case of a new or modified service under evaluation, the service costs are those costs which the NHS would expect to continue to bear after the research had finished and, assuming the trial or evaluation was successful, the service had been put into place;

   (ii) **research costs** are the costs of data collection and analysis and other activities needed to answer the questions that a piece of research is addressing. They include pay and indirect costs of staff carrying out the research;

   (iii) **excess service costs** are costs of a service provided in the context of research which cannot reasonably be attributed either to service costs as (i) above or research costs as at (ii) above. Examples would include patient tests, inpatient stays or outpatient visits over and above those associated with a 'routine' service.

Formal responsibilities for funding

2. (i) **Service costs** of publicly funded research should be met by the provider(s) and/purchaser(s) involved through the normal contracting process.

   (ii) **Research costs** of research in the NHS should be met by the research funder.

   (iii) **Excess service costs** of publicly funded research should be met by the NHS. Since its inception the NHS has supported teaching and research alongside patient care. Some providers receive extra support through the research component of ACT(R). Responsibility for financing excess service costs rests primarily with NHS service providers.

Joint planning of NHS support

3. The joint planning arrangements set out below aim to ensure that agreement on arrangements for NHS support does not delay clinical research. They are written in terms which relate to the MRC because they are the largest research funder and are likely to make the greatest calls for service support. The arrangements should be applied equally, however, to all research funders.

4. It is intended that NHS support for clinical research projects should be agreed by the time the MRC take a decision on funding. The MRC will not action awards for clinical research in the NHS before arrangements have been agreed on the provision and cost of NHS support for that research.

5. To this end. the NHS must be informed about proposed clinical research at the earliest opportunity. MRC researchers requiring NHS support should therefore initiate early discussion with lead providers about the scale, cost and timing of their requirements, in parallel with discussions with the potential research funders. Where research is proposed around a new or modified service which may have significant cost implications for the NHS if the service is ultimately adopted, researchers should also involve lead purchasers in these discussions. The Chief Scientist Office (CSO) should be informed about all clinical research proposals requiring service support and brought into discussions as necessary. A single standard form has been designed by the MRC and the NHS to assist researchers in notifying all those concerned (a copy is attached and can be reproduced locally if required. Forms for CSO should be sent to the Director, Chief Scientist Office, Room 240, St Andrew's House, Edinburgh, EH1 3DG).

6. For multicentre trials, initial discussions about service support requirements should take place in the area of the principal investigator. This should establish a model for the trial, which the lead investigator should communicate with colleagues in other regions with participating centres to ensure that this model is promoted elsewhere. Principal investigators must ensure that research funders and the NHS are kept informed as early as practicable about recruitment of participating centres and of the likely number of patients to be involved in each centre.

7. Researchers, lead providers, purchasers and research funders should work together to minimise delays in agreement about NHS support for research. Providers are expected to reach agreement with researchers on the scale and provision of excess service costs without delay unless there are justifiable reasons for not doing so. If the principal researcher feels that the position being adopted by a provider and/or purchaser may hinder significant advances in research and/or patient care, the researcher should seek the views of the relevant research funder and the Chief Scientist Office, and invite them to mediate

8. The requirement to notify the NHS about proposed clinical research at the earliest opportunity inevitably means that the NHS will learn about many more proposals than the MRC eventually funds. The NHS and the MRC recognise that this implies additional administrative work in the interim period in the interests of facilitating clinical research. The operation of these principles will be monitored to ensure that the arrangements are workable. However, it is important that this additional burden is minimised. The NHS needs to know as soon as possible which proposals are likely to succeed and which are not, so that unnecessary effort is not put into planning for research which is unlikely to be funded. Both organisations will take account of the progress of research proposals in the other through the exchange of information as service support arrangements are firmed up and peer review progresses.

April 1995

INFORMATION REQUIRED FROM APPLICANTS SUBMITTING CLINICAL RESEARCH PROPOSALS WHICH HAVE NHS SUPPORT REQUIREMENTS

Please complete this form if, according to the **Principles for the Interim Provision of NHS Support for MRC-Funded Clinical Research Pending Implementation of the Culyer Report** the clinical research[1] project or clinical trial for which you are applying requires the provision of NHS support.

Copies of the completed form should be sent to the Chief Executive of the lead provider who would be involved with the project, the Chief Scientist Office in Scotland, and to the MRC or other funder, with your application.

NAME OF APPLICANT/S .....
.....
INSTITUTION/S .....
.....
PROJECT TITLE .....
.....
Brief Description of purpose of project

If your research involves the provision of a NEW or MODIFIED service, please describe the service and the changes proposed

HEALTH BOARD (If a multi-centre study is proposed please list of all other regions that are likely to be involved, and indicate which is the principal Board .....
.....

Notice to NHS of service support requirement
Please indicate below action you have taken to inform the relevant bodies and progress/result of negotiations.

	Approached (yes/no)	Person contacted	Service support agreed (yes/no/not yet known)
Local purchaser/Commissioning Agency			
Lead provider Chief Executive (Please also name provider unit)			

Please indicate overleaf if problems are being encountered in negotiations and copies of relevant correspondence should be attached.

Please ensure that the MRC or other funder, is kept informed of the progress of negotiations concerned for the provision of NHS support and any problems which may develop.

[1]Clinical research in this context is taken as that based primarily on patients or ex-patients and designed to answer a question about disease (aetiology, concomitants, diagnosis, prevention outcome or treatment) including clinical trials. In addition to direct clinical examination, it can include study of blood, biopsy material or post mortem tissue deriving from individuals, including normal subjects, where such a study relates to a disease process being investigated.