

Dear Colleague

ACCREDITATION SCHEME FOR THE COLLECTION AND STORAGE OF NHS TISSUE IN SCOTLAND

Summary

1. Ministers have taken no powers to regulate the collection and storage of human tissue from the living in Scotland. This letter notifies colleagues of the non-statutory accreditation scheme for the collection and storage of human tissue in NHSScotland. This is being rolled out throughout Scotland and has been developed in consultation with NHSScotland R&D Directors, NHSScotland tissue bank managers, public partners and Healthcare Improvement Scotland.

Background

2. In the rest of the UK, the collection and storage of all human tissue, whether from the living or the dead, is covered by the Human Tissue Act 2004. The 2004 Act set up the Human Tissue Authority (HTA) to regulate and licence human tissue collection and storage outwith Scotland. When the principles of this Act were being consulted on, Scottish Ministers took the view that such an approach imposed too great a regulatory burden and instead brought in the Human Tissue (Scotland) Act 2006 to regulate the use of tissue from the dead, but not the storage, collection and use of tissue for research purposes taken from the living. However, transplants from living donors come within the 2004 Act. Also covered is DNA theft and the licensing of organisations that procure, store, test, process, distribute, import and/or export human tissues and/or cells that are intended to treat patients. That latter function is embodied in the Human Tissue (Quality and Safety for Human Applications) Regulations 2007.

3. Apart from the exceptions stated above, human tissue collection, storage and use for research in Scotland is not

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Addresses

For action
Chief Executives, NHS Boards
Chief Executive National Waiting
Times Board
Chief Executive National
Services Scotland

For information
Chief Executives, NHS Special
Boards
Chairs, NHS Boards
Directors of Public Health, NHS
Boards
Medical Directors, NHS Boards
NHSScotland R&D Directors
NHSScotland Tissue
Bank Managers

Further Enquiries

covered by the 2004 Act and as a consequence there are no licensing arrangements in place. There are a number of good reasons to introduce some form of accreditation in Scotland. Principal among these is to demonstrate the highest possible professional governance standards and also to make sure Scotland is well positioned to continue to participate in cutting edge research and not be excluded from UK studies because of a perceived lack of equivalent standards.

4. It should be noted that this scheme applies to tissue for which NHSScotland is responsible. Where there is a transfer of tissue from NHSScotland to a third party, these standards must be maintained in any contractual agreement or Material Transfer Agreement (MTA). This scheme is the Scottish equivalent of the HTA standards. For the purposes of clarity this scheme covers all tissue (tissue as defined by the HTA and includes new born infant blood spot or Guthrie cards) for research NHSScotland has responsibility for, whether stored in NHS premises or not, and all tissue stored in NHSScotland premises. Tissue stored in NHS premises contracted out to a third party is not included. Boards should ensure that any non-NHS researcher using tissue collected outwith NHSScotland in NHSScotland premises are adhering to the national governance standards.

The Accreditation Scheme

5. A Scottish accreditation scheme has been developed with Healthcare Improvement Scotland. This operational model will focus expertise in the 4 lead NHS Research Scotland (NRS) Health Boards (Grampian, Greater Glasgow & Clyde, Lothian and Tayside- see para 7 below). Healthcare Improvement Scotland has developed the scheme using and adapting the HTA standards to meet Scottish requirements. An issue raised in relation to the HTA standards is that they appear to cross into areas regulated by other bodies. CSO and Healthcare Improvement Scotland have agreed to avoid this by accepting the findings of other accreditation and regulatory bodies and focus on the following 4 main areas:

- Governance;
- Access;
- The data/audit trail; and
- Consent.

A draft version of the programme guide for accreditation can be found at Annex A, and the tissue pathway at Annex B.

6. These will ensure that: proper consent is obtained from patients to allow their surplus tissue to be used for research purposes; tissue samples can be traced from collection to destruction as well as being able to be linked to the patient's records; researchers have reasonable access to samples for their research and the human tissue collection and storage process is governed in line with the national governance principles developed by NHSScotland.

Operational Model

7. The accreditation scheme will cover how NHSScotland Boards collect, store and transfer tissue to the end user for research as an individual Board and all the tissue

collections under the guardianship of that Board. Each individual collection will not receive its own accreditation. The Boards in para 5 above will extend their governance model to their regional partner Boards in a “hub and spoke” model. Accreditation will focus on the 4 “hub” Boards but will include their partner “spokes”, which will also be expected to meet national standards. A self reporting model is proposed. It will be assessed independently by Healthcare Improvement Scotland on a 3 yearly cycle. All NHSScotland Boards who collect or supply tissue for research or who host research using tissue will require accreditation under this scheme.

Financial Implications

8. Healthcare Improvement Scotland has indicated that it will cost approximately £14k per three year accreditation cycle for each “hub” Board. The cost is favourable compared to the rest of the UK. Healthcare Improvement Scotland expects that after the initial accreditation process the cost will fall in future cycles to practically nil as the system will move to one administered online by Healthcare Improvement Scotland. For the “spoke” Boards, Healthcare Improvement Scotland anticipate initial costs of less than £1,000 over the first 3 year cycle and again, it is expected this will fall.

Pilot/Implementation Timetable

9. Healthcare Improvement Scotland will run a pilot of the scheme based on the programme guidance at Annex A during 2011. This will allow the accreditation tool to be tested; 2011-12 will be used to set the accreditation scheme baseline. There will be no cost to the Boards for the pilot or the baseline accreditation. The first 3-year accreditation cycle will commence on 1 April 2012.

Action

10. Chief Executives are asked to ensure that all appropriate staff are aware of the scheme and are prepared for commencement by ensuring their Board is ready to implement the accreditation scheme set out in Annex A by 31 March 2012. This will include ensuring each Board has a record of all the collections it has responsibility for and they are:

- consented for research use; and
- content they can be used for future research.

Each Board should have systems in place to:

- approve release of tissue for research;
- locate all the tissue it has responsibility for;
- can track it from collection to use; and
- know at all times how much storage space is available for new tissue samples in line with the national governance principles.

11. Where a Board considers a collection it is responsible for has no future research potential it should ensure that it is disposed of appropriately.

Yours sincerely

Harry Burns

HARRY BURNS

Human Tissue Banks in Scotland

Accreditation Programme Guidance

1 Introduction

Healthcare Improvement Scotland has been requested by the Chief Scientist Office (CSO) of the Scottish Government to develop and implement a scheme of accreditation for NHSScotland Human Tissue Banks. It should be noted that this scheme will accredit NHS Boards rather than individual tissue banks or tissue collections.

This document sets out the quality assurance accreditation arrangements that will be undertaken by Healthcare Improvement Scotland in relation to NHS Boards in Scotland. Arrangements for accreditation of the banks will sit with the 4 regional hub Boards in NHS Grampian, NHS Greater Glasgow & Clyde, NHS Lothian and NHS Tayside with external scrutiny of these arrangements being undertaken by Healthcare Improvement Scotland.

This Document

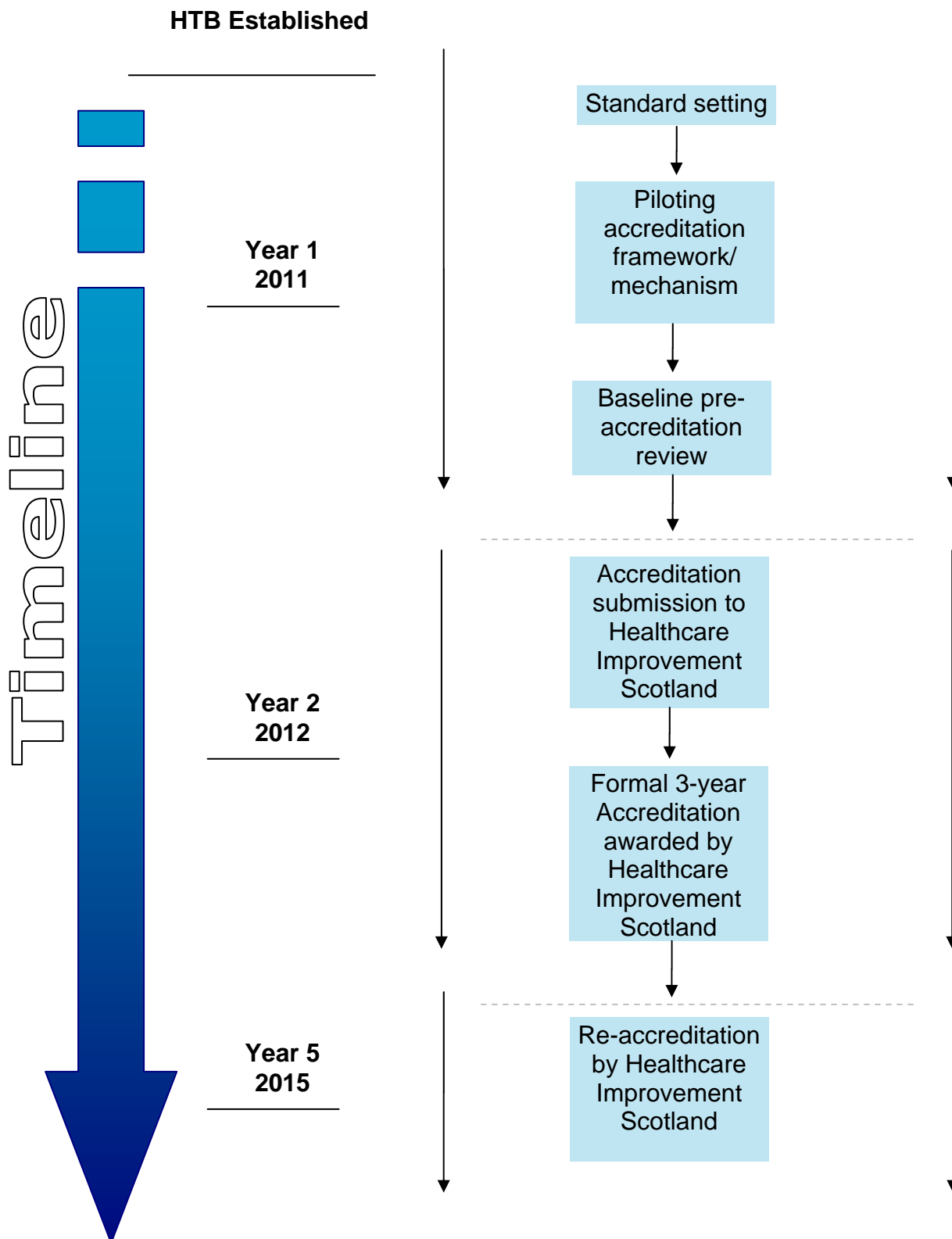
This document guides the reader through the steps required to establish accreditation of Boards in NHSScotland

These steps include:

- setting standards for the quality of operation for human tissue banks (HTB)
- designing the assessment mechanism
- accreditation of the Boards
- establishing a 3-year rolling programme of accreditation

2 Human Tissue Banks in NHSScotland Quality Standards of Operation Accreditation Programme Timeline

Figure 1



3 Quality Standards of Operation

A key component of the Accreditation Scheme is a set of quality standards of operation against which the performance of the Boards can be assessed. These standards will be drawn from existing guidance, such as:

- Healthcare Improvement Scotland clinical governance and risk management standards
- Human Tissue Authority (HTA) standards, and
- International standards.

The quality standards of operation developed by the HTBs Project Steering Group will:

- directly relate to the objectives of Boards in Scotland
- be clear and measurable
- follow the human tissue pathway, and
- be consistent across Scotland.

How quality standards are constructed

There is a quality standard statement which addresses a particular area of service, and outlines what is required to be achieved. For each quality standard statement a number of criteria are laid out. The criteria give the detail of how the quality standard statement can be achieved and should be stretching but achievable.

Figure 2, below, shows an example of a quality standard.

Figure 2

Accreditation Criteria 1: Consent/Authorisation	
Quality Standard	
There is a formal, ethically approved, procedure for obtaining consent/authorisation to donate tissues	
Quality Statement	
C1 a)	There is a formal procedure for obtaining consent/authorisation to donate tissues which meets the HTA Codes of Practice
C1 b)	Consent/authorisation procedures have received NHS research ethics approval
C1 c)	Patient information sheets are available in a variety of formats
C1 d)	There is a clear policy for the withdrawal of consent/authorisation

4 Performance assessment and ongoing monitoring

Following the development of quality standards of operation, accreditation arrangements will be put in place to measure performance against the standards. These will include methodology and assessment measures, reporting procedures and arrangements for addressing identified performance issues.

5 Accreditation and ongoing quality assurance

Accreditation is the process whereby the Board is formally assessed and approved. Ongoing quality assurance is the regular progress reporting on implementation and achievement.

The new accreditation model has 3 components:

- Developing the accreditation framework
- Establishing agreed quality standards of operation based on existing national standards (e.g. Healthcare Improvement Scotland, HTA)
- Performance assessment and monitoring arrangements, including reporting mechanisms and systems to address any identified issues.

This approach will help to ensure that there are formalised accountability and reporting mechanisms and will help to eliminate variations in practice through the adoption of agreed standards and performance reporting. By undertaking a programme of accreditation for Boards, and examining Boards' local arrangements as part of the Healthcare Improvement Scotland clinical governance and risk management reviews, services will be subject to external quality assurance reviews, the outcome of which will be publicly reported.

Accrediting Organisation

NHS Boards in Scotland will be accredited by Healthcare Improvement Scotland.

Baseline Pre-Accreditation Review

Healthcare Improvement Scotland will conduct a programme of pre-accreditation reviews of Boards during 2011. The results of these reviews will not be published and will allow an opportunity to identify areas that require further development prior to full accreditation.

Formal Submission

For formal accreditation, submissions should be made to Healthcare Improvement Scotland, together with a formal sign-off.

Healthcare Improvement Scotland will arrange to convene an accreditation panel made up of a lead clinician, an HTB manager, public partner and any other appropriate healthcare professionals. All members of the panel must be independent from the HTB seeking accreditation.

The panel will accredit the Boards or accredit with conditions or request a re-submission giving clear advice on what further action is required.

Ongoing Quality Assurance

Accreditation of the Board is valid for 3 years. The Board is responsible for contacting the accreditation body if there are any major concerns during the 3-year period.

Re-accreditation

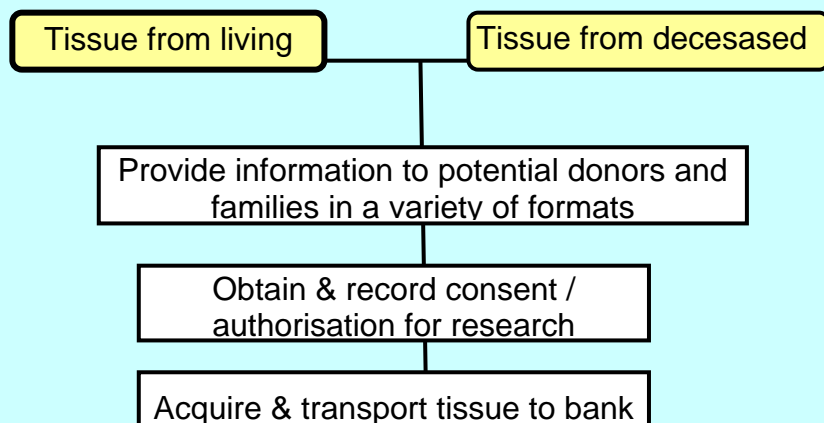
Prior to accreditation expiry, the Board will be asked to submit a revised self-evaluation demonstrating that:

- the Board has a process for systematic audit, monitoring and review
- action has been taken to implement agreed findings of audit and monitoring and review, and to measure ongoing improvement

The process for re-accreditation is the same as that for the initial accreditation.

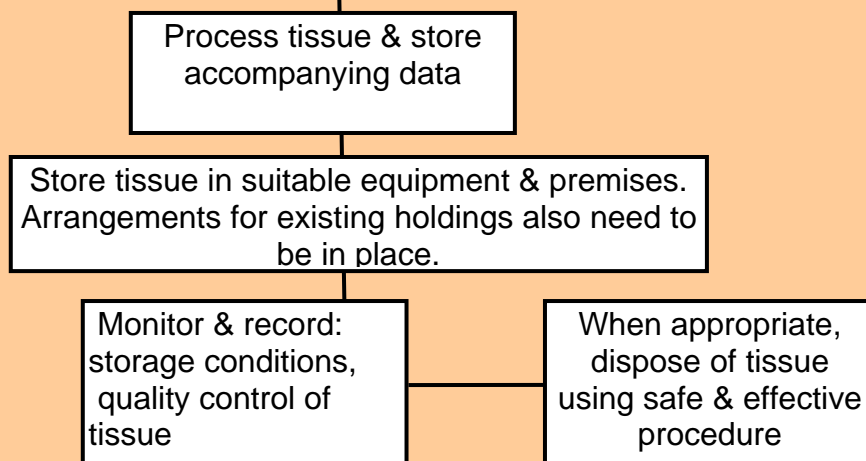
Tissue Bank Pathway

Acquiring



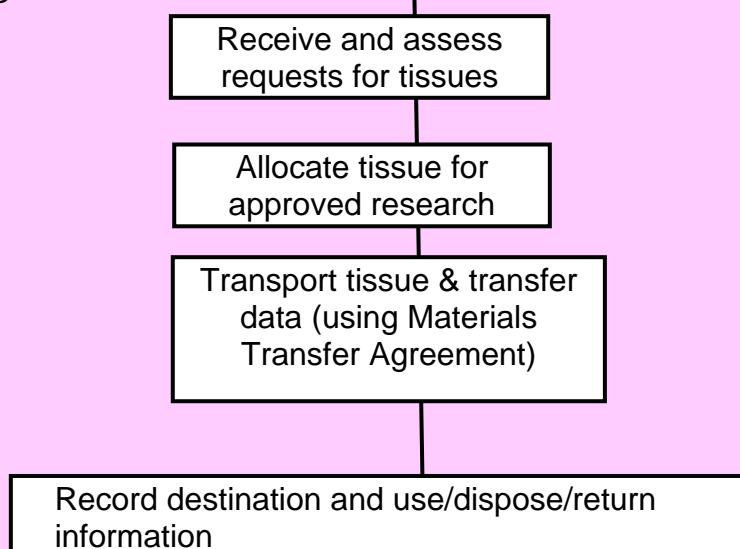
1. There is a formal procedure for obtaining consent/ authorisation to donate tissues that has received ethics and any other necessary approval. In addition, systems to deal with any subsequent withdrawal of consent /authorisation are in place.

Storing



2. There are governance processes and record keeping systems in place concerning:
a) acquiring
b) processing
c) storing
d) allocating
e) transporting
f) disposing of tissue
g) training
h) quality assurance/quality control activities

Using



3. Premises, facilities and equipment are suitable for safe storage of tissues, data, consumables and records. (The inspection of this criterion will not overlap with existing regulation relating to premises or equipment).