Healthcare Improvement Scotland is committed to equality. We have assessed the inspection function for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Officer on 0141 225 6999 or email contactpublicinvolvement.his@nhs.net
Cells were first discovered in 1665 when Robert Hooke (1635–1703) identified small holes in cross-sections of cork which he called cells in his book *Micrographia*. The term cell came from the Latin cella, meaning “small room” and Hooke compared the cork cells he saw through his microscope to the small rooms monks lived in. We now know that cells emerged on earth at least 3.5 billion years ago.

Tissue is a collection of similar cells from the same origin that together carry out a specific function. Scientists and doctors have been studying and collecting tissue for many years as part of research into disease. As technology and our understanding develops, managing and storing such collections has become more complex.

Scotland has a rich research background. It is critical that we can demonstrate to the world that our tissue collections are properly managed if our tissue is to be used in worldwide research.

I became involved in developing the first accreditation scheme for NHSScotland’s human tissue banks in 2010. In carrying out an initial review of the tissue banks at that time, it was clear that while they all took great care of their collections, they all had significant improvements to make. None of them could have achieved the standards we had set. Since then, they have locally and collectively raised the standard in Scotland which has now been subjected to national scrutiny. I am pleased to report that all four regional human tissue banks have achieved accreditation.

A great number of people have been involved in this, and their hard work and professional approach is warmly acknowledged. In particular, the tissue bank managers, and their teams, have worked hard to achieve accreditation and are rightly proud of their banks. This process would also not have been achieved without the invaluable help of the members of the Human Tissue Bank Accreditation Steering Group and the Human Tissue Bank Accreditation Review Panel. I would like to thank all members involved for their important contributions. The Chief Scientist Office has provided strong national leadership. Finally, I want to mention our public partners who have continually grounded us and provided useful challenge from their perspective.

The work is not over by any means, but we are now well informed about what we need to do. We have made a number of recommendations which the Chief Scientist Office and the human tissue banks will consider and will take forward. We have also confirmed there is a strong commitment to the continual improvement of this service in Scotland.

Professor James W Ironside
About Professor James W Ironside

Professor Ironside has over 35 years of research experience. He has an international reputation and is fully committed to the safe and ethical use of human tissue for research. He is particularly focused on appropriate consent and public involvement.

Professor Ironside is the clinical lead for the Healthcare Improvement Scotland accreditation programme for NHS human tissue banks in Scotland.

As our clinical lead on this work he has provided leadership, credibility and expertise over the last 3 years. He has a wide network of contacts and balances a pragmatic approach with a clear understanding of the governance needed to provide public assurance on such a critical matter. He understands that tissue donation is a gift that benefits us all. Like all gifts we need to value and treasure them.
Introduction

This report emphasises the importance of human tissue donation for use in scientific and medical research. It also outlines the work of the four regional human tissue banks in NHSScotland and most importantly the benefits of donating tissue for research.

The report describes the strict governance arrangements in place for the collection, storage and use of human tissue in the regional human tissue banks and also the governance links between the regional human tissue banks, The Chief Scientist Office (CSO) and Healthcare Improvement Scotland.

The report provides details of the Healthcare Improvement Scotland accreditation process, which applied to the four regional human tissue banks. It outlines the recommendations and findings from the outcome of the first phase of this process which took place between February 2013 and March 2014. Each human tissue bank was asked to provide evidence that it met all the quality standards of operation to achieve accreditation status.

The report also outlines the next steps for human tissue banks and accreditation to support ongoing research both nationally and internationally.
Background

Why is human tissue important?

Human tissue is used in scientific and medical research, to improve understanding of how diseases start, how they progress and what keeps us healthy. Types of research involving human tissue include:

- developing screening tests for different types of cancer
- testing new treatments for conditions such as heart disease and diabetes
- looking at how the immune system works to help understand how it combats diseases, and
- researching how stem cells could be used to treat conditions like Parkinson’s disease and multiple sclerosis.

There are many different types of human tissue including blood, skin, body parts, organs, stem cells and bone and they have different uses in research.

Collecting and storing human tissue

A human tissue bank is a collection of tissue that may be used in many different research projects. There are rigorous standards in place for the collection (including patient consent), storage and use of human tissue. Sometimes tissue banks are referred to as biobanks or biorepositories. In this report, we have used the term human tissue banks.

The main objective of a human tissue bank is to support approved medical research by streamlining access to tissue and associated clinical data within a robust ethical and legal structure. This involves not only the collection and management of tissue samples, but also supporting activity to make sure people know they have an opportunity to donate tissue for research. A diagram which shows the journey a tissue sample takes can be found in Appendix 1.
Safeguarding human tissue for research: the story in Scotland

Across the world there are many human tissue banks. Some are commercial and others are managed by academic institutions or by healthcare organisations such as the NHS. They are funded from a wide range of sources including charities. Research is often carried out using tissue from sources worldwide which means that transportation of samples is an important element of the daily work of a tissue bank.

There are three levels of safeguarding in place in every NHSScotland human tissue bank.

- **Local (or internal) safeguarding** – This is managed by the NHS Research Ethics Committee which maintains the rights, safety and dignity of those who donate their tissue to the NHS. They review applications for research and research cannot go ahead without their approval and advice.

  All NHS boards have local safeguarding in place for the regional human tissue banks and have well-documented ethical approval for their processes. They are all required to provide an annual report to their ethics committee and there was evidence that the committees challenge these when required. Regular reporting to ethics committees is important and should be maintained.

- **National safeguarding** – The CSO for Scotland is part of the Scottish Government Health and Social Care Directorates. It supports and promotes high quality research in Scotland.

  The CSO and NHS Research Scotland (NRS) are collaborating to link all Scottish NHS boards in one national system to supply human tissue for research (National Tissue Bank Network). The CSO contributes to the funding of one human tissue bank in each of the four NRS regions who, in turn, are responsible for the tissue governance of their partner NHS boards. NHSScotland has four regional human tissue banks based in Aberdeen, Dundee, Edinburgh and Glasgow.

- **External quality assurance** – In 2011, the CSO announced the introduction of an external accreditation process covering the use of human tissue for research in Scotland. Human tissue banks in the rest of the UK are licensed by the Human Tissue Authority under the Human Tissue Act 2004\(^1\), while Scotland has separate legislation under the Human Tissue (Scotland) Act 2006\(^2\). Scotland must demonstrate its tissue banks meet the same standards as banks elsewhere and that the appropriate governance arrangements are in place. Healthcare Improvement Scotland is the organisation responsible for developing the required standards and assessing performance against these. These standards make sure that NHS boards adequately address three key aspects when using human tissue for research:
  - consent and authorisation
  - governance, and
  - premises.

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Accreditation

Healthcare Improvement Scotland are also responsible for the development, management and co-ordination of the external human tissue bank accreditation process. The aim of accreditation is to demonstrate the highest possible governance standards for human tissue used in research. This provides public assurance that their current and future donations are treated with respect and are not just stored, but actively used to improve healthcare. It also promotes Scotland’s role in continuing to participate in pioneering research.

In 2011, we developed quality standards of operation based on those standards used by the Human Tissue Authority (see Appendix 2). These were consulted on widely and tested before launching the first round of accreditation in Scotland during 2013–2014. All the four regional human tissue banks must be accredited in order to participate in the National Tissue Bank Network.

Each application for accreditation is evaluated by a multidisciplinary review panel and the human tissue bank must demonstrate that it meets every standard. Where a standard is not met, conditions are set. In this round of accreditation one tissue bank had conditions to meet before accreditation could be awarded. A further review panel meeting was held in order to assess these conditions had been achieved.

This review panel was led by Professor Ironside and included subject experts from the Medical Research Council, tissue banks outwith Scotland and public partners. The review panel members are listed in Appendix 3.

Accreditation is awarded for 3 years subject to an annual self-declaration. However, the review panel has the authority to set conditions for accreditation or provide recommendations for improvement and can request additional reviews at any time during the 3-year period.

Additionally, the regional human tissue banks have a responsibility to notify us should any changes occur during the accreditation period which may affect its accreditation status.
The regional NHS human tissue banks in Scotland

This section provides a short overview of each of the four NHS regional human tissue banks and provides the context for our findings on the first phase of accreditation.

NHS Grampian

NHS Grampian’s regional human tissue bank was established in September 2011. The main research programmes which are supported by the regional tissue bank are in translational cancer research including both academic and commercial studies to support researchers in local, national and international projects.

The tissue bank holds 1,350 fresh frozen Colorectal samples, 350 fresh frozen lung samples and 62 samples used in the Markers and Paracetamol Poisoning study.

Other academic studies include:

- colorectal cancer studies including:
  - the molecular taxonomy of stage 2/3 colorectal cancer
  - understanding the signalling network of colorectal cancer metastasis
  - biomarkers in colorectal cancer translation research projects looking at biomarkers in lung cancer

- TRANSCOG is a translational study involving molecular analysis of oesophago-gastric tumour samples.

The bank also provides tissue samples to Cytosystems which is developing new biomarkers of bladder cancer and has provided 200 tissue samples to AstraZeneca for a collaborative research project on translational research.

Between March and July 2013, 62 samples were donated by patients.

The tissue bank received 12 requests for tissue (442 samples) during March 2012 and March 2013 and 7 requests (259 samples) between March 2013 and July 2013.

You can find more information at www.nhsgrampian.org/r&d
NHS Greater Glasgow and Clyde’s regional human tissue bank was set up in 2002. This research infrastructure houses collections of samples to support researchers in almost all areas of biomedical research. In addition to banking samples for future research projects, the tissue bank facilitates the collection and transfer of fresh tissue samples for a wide range of active studies. These studies require samples to be unprocessed, i.e., to develop cell cultures or to be used in functional and pharmacodynamic studies. It also stores national collections including the Scottish ‘Guthrie test’ collection which includes blood spot tests from every baby born in Scotland since 1966.

The tissue bank has developed a web-based electronic application process for researchers to request access to tissue for a particular study. This system supports the review and approval process and makes the procedure more effective. The tissue bank receives approximately 140 new requests for tissue each year and the demand is increasing.

NHS Greater Glasgow and Clyde is the first and only human tissue bank in the UK to have an electronic surplus tissue authorisation form (e-STA). This e-form holds a record of the patient’s wishes as part of their electronic medical record regarding the use of any leftover (surplus) tissue which has been removed for therapeutic and or diagnostic reason. Currently more than 10,000 patients each year are asked and their wishes are recorded using this electronic system.

This human tissue bank supports research within all four of the CSO Health Research Priority areas, cancer (including lymphoma), cardiovascular disease, mental health, and public health.

Although the majority of studies are in the field of cancer they also support research in rheumatology and inflammation, virology, cystic fibrosis, stem cell research and biomedical engineering.

Current national collaborations include:

- Cancer Research UK’s Stratified Medicine Programme
- sample collection for translational studies in colorectal cancer
- The UK Ovarian Cancer Translational Collaborative
- participation in the Scottish Early Rheumatoid Arthritis inception cohort and biobank.

The human tissue bank also participates in the following international studies:

- Persistent Virus Infection in Diabetes Network
- The Genomic Landscape of Pancreatic Ductal Adenocarcinoma
- Characterisation of cellular hierarchies of human breast, and
- REMOVAL – a study to discover whether metformin, a commonly-used medicine in type 2 diabetes, can slow or prevent the early changes which lead to these problems in type 1 diabetes.

Another key role for NHS Greater Glasgow and Clyde’s tissue bank is to provide support for medical research in industry. This includes a number of Scottish small to medium enterprises and close collaborative projects such as the new Scottish Stratified Innovation Centre based in Glasgow and joint funding applications, for example Technology Strategy Board funding awards and Horizon 20/20.

You can find more information at www.nhsgbr.org.uk
NHS Lothian

NHS Lothian’s regional human tissue bank was established in 2011. It is referred to as a ‘virtual bank’ as there is not one location to house all the human tissue samples collected. The virtual bank collects tissue for specific research projects based throughout NHS Lothian. NHS Lothian has worked hard to make sure that the collections are managed within the one governance structure.

NHS Lothian had the challenge of bringing together over 130,000 samples held throughout numerous collections and banks. The NHS Lothian human tissue bank also hosts various national and international resources. For example the brain bank resources which are used in essential studies into dementia, as well as in research of the effect on the brain of trauma and alcohol. This collection holds over 100,000 samples at present and receives approximately 70 requests for tissue each year.

Numerous projects are ongoing under the ethical approval and governance of the NHS Lothian tissue bank, supported by the provision of tissue on a local, national and international basis. In its first 9 months of operation from March 2011, it facilitated 24 projects. In 2012 it facilitated 132 projects, and in 2013 it facilitated 137, making a total of 293 projects since the start date.

Approximately 50 commercial studies have also been facilitated by the human tissue bank. These projects vary from a need for a small number of tissue samples, through to the provision of almost 600 prostate biopsies from 300 individuals for an international trial (where more than three quarters of patients came from NHS Lothian). This work has been published and the technology developed given FDA approval.

Active research tissue banks (with additional ongoing projects) which come under NHS Lothian’s governance include:

- Edinburgh Reproductive Tissue Bio Bank (ERTBB)
- Medical Research Council Brain Bank
- Scottish Collaboration on Translational Research into Renal Cell Carcinoma (SCOTRCC)
- HPV Archive
- Female Reproductive Tract Tissue Resource
- Adipose Tissue Bank, and
- MND (motor neurone disease) DNA Bank.

To date, NHS Lothian regional human tissue bank has collected samples from 2,547 consented participants and this has generated 9,785 samples.

You can find more information at www.ACCORD.ed.ac.uk
NHS Tayside

NHS Tayside’s regional human tissue bank collection is the longest standing in Scotland having commenced in 1997 and now contains around 50,000 samples, mostly tumour material from around 10,000 different patients. The bank has attracted funding over the years from Medical Research Council, Cancer Research UK and Breast Cancer Campaign, including for the Dundee node of the Breast Cancer Campaign Tissue Bank. Approximately 750 patients are approached each year to seek consent to retain any surplus tissue that may arise from their operation. Tissue (with or without a matching blood sample) is subsequently available from about 550 patients.

In Dundee, the most common sites from which tissue is collected is breast, colorectal, skin, kidney and gynaecological samples, largely reflecting local research interests and specialties. The bank also provides investigators with a range of technical services to assist with tissue analysis. Provision of these services is advantageous to many investigators as they may have limited access to, or experience of, such procedures or irregular need for them. In addition, the human tissue bank facilitates and provides logistical support for many clinical trials (e.g. IMPORT, ASPECT) that are being conducted locally, nationally or internationally, often as part of multi-centre studies.

In 2013, NHS Tayside regional human tissue bank collected tissue from 214 cases of breast cancer, 124 colorectal cases, 40 skin cases, 41 renal, 16 gynaecological, and 45 other cases. Approximately 40–50 applications for tissue samples are received each year for a broad variety of studies that vary in size and complexity.

Each approved study is listed on the NHS Tayside tissue bank website. Other areas of work at present include the following.

- The bank is one of two centres selected to store samples for the Medical Research Council international Add-Aspirin trial.
- DNA, RNA and fixed tissue sections from patients with breast cancer have been sent to the Sanger Institute in Cambridge for intensive sequencing and analysis of their genetic make-up.
- The bank recently contributed stomach, liver and oesophageal cancer specimens to The Cancer Genome Atlas (TCGA). This is a comprehensive and co-ordinated international effort led by the US National Cancer Institute (NCI) to accelerate our understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing.
- Governance of other sample collections including the large diabetes bioresources held in Tayside.

As a result of the tissue samples that patients donate and the research that this enables, the bank contributes to, and is acknowledged in, around 20 peer-review publications each year. The list of publications is posted on the website.

You can find more information at www.tissuebank.dundee.ac.uk
Our findings from the first phase of accreditation

The first phase of accreditation, which applied to the four regional human tissue banks, took place between February 2013 and March 2014. Each human tissue bank was asked to provide evidence that it met all of the quality standards of operation to achieve accreditation status.

All four regional human tissue banks have been awarded accreditation as they have met every quality standard listed in Appendix 2. Accreditation is valid for 3 years. Each NHS board is required to provide an annual update and notify us of any changes that may affect its accreditation status. We can also review accreditation status at any time.

The review panel made some specific recommendations to each tissue bank which could improve the service provided. These recommendations were based on the expert knowledge of the panel and had no impact on the accreditation status of each host NHS board. Some general recommendations were also identified that the review panel regarded as continual improvement beyond this first phase of accreditation. These are outlined below.
Recommendations
These recommendations apply to the four regional human tissue banks in Scotland.

Patient information materials – the human tissue banks have put a lot of work into developing their patient information materials and all of them have ethical approval. At present, patient information and consent materials differ widely across the country. We recommend the introduction of a consistent approach to the development of core patient information materials.

Reporting and accountability – the four host NHS boards all have clinical governance and risk management support teams that provide expertise across their organisation. We recommend that the regional human tissue banks engage with these teams and use their expertise, particularly in relation to general risk assessment. We found the tissue banks tended to focus mainly on the risk to the tissue without always considering the broader context such as the risk to the organisation. This is important as the bank needs to be visible to, and supported by their host NHS board. We recommend that the tissue banks report annually to their host clinical governance committee through the NHS board’s Director of Research and Development.

Premises – the tissue banks are housed in very different premises within their host NHS board. NHS Greater Glasgow and Clyde has recently moved into a new, purpose built department which provides state of the art facilities. NHS Tayside also has modern facilities. NHS Lothian collections are housed in various departments and NHS Grampian has older premises. All are fit for purpose. We recommend that the banks include an update on premises in their annual report so their host NHS boards are aware of the challenges and opportunities.

Collaboration between human tissue banks – All four regional human tissue banks are members of the Human Tissue Bank Managers Network which is hosted by CSO. They meet regularly and this is a useful forum to develop national materials and to share experience and good practice. We recommend that this forum of sharing of information is strengthened between human tissue banks and that information is shared more widely across healthcare organisations.

Tissue for local use – some regional human tissue banks reported that they retained 20-25% of the tissue collected for local use. We appreciate local study is an important part of practice and development. We recommend work is carried out to determine how much of this locally retained tissue is used and how results of local studies is shared with others to drive improvement.

Safely shipping samples – there was not much evidence of follow-up activity when samples are shipped to successful research applicants in any of the four regional human tissue banks. This would be beneficial to make sure that samples arrived at their destination intact and that they are suitable to carry out the required study. We recommend this process is developed further. We propose a short national survey form could be developed for this purpose.
Recommendations to be considered by the CSO

The following recommendations will be discussed between CSO, Healthcare Improvement Scotland and all four human tissue banks.

**Standard Operating Procedures –**
Traditionally, human tissue banks use Standard Operating Procedures (SOPs) to set out processes in detail. This is in line with recognised good practice and all tissue banks provided evidence that these are in use and are regularly updated. The review panel identified an opportunity to build on this and introduce a more improvement-focused approach bringing together all SOPs into one quality manual. This would help to demonstrate how all SOPs fit together and to assess risk for different activities. It also provides the chance to align operations more closely with corporate or organisational objectives. We recommend this is considered by CSO as a possible national development.

**Patient information materials –**
While consent is voluntary, and may be withdrawn at any time, this is difficult to achieve in the case of tiered consent. Tiered consent is necessary when donors are given the choice to opt out of a specific research area, such as research involving DNA analysis. This is the recommended approach. Currently, most human tissue banks work on the basis that if consent is held back on one specific area of research, the tissue sample cannot be used for any research. This is due to the limitations of a system to track specific consent. Generic consent, consent for all types of research, is a clearer process for donors and can be managed accurately. We recommend that this requires national discussion which could be led by CSO. It is important that a consistent approach is taken across Scotland.
Next steps for human tissue banks and accreditation

It is important the accreditation process drives improvement and we have identified the following as prime areas for development and improvement.

National research portal – all human tissue banks in Scotland now have IT systems in place that allow them to reliably track samples and manage consent, including the withdrawal of consent. While there is not a single system in use across the country, they all meet the core requirements. The next stage is to link these systems together to create a national research portal and work is already under way on this.

Local human tissue collections – we are mindful of the various local collections operating throughout Scotland and the need to bring them under the governance of their regional human tissue banks. Some have started to progress this while others are still at early stages. The CSO has asked us to consider a proportionate form of accreditation for these smaller local collections. We recognise this will be a challenge, and it is likely to take some time, but it is important that a plan is in place to provide public assurance and make sure all the tissue collected is managed safely and the research community is aware.

Public involvement – all the regional human tissue banks have made good progress in developing their governance arrangements but there have been challenges. While there are some research projects and collections, the public may be aware of as a significant part of healthcare, such as Cancer Research UK, much of this work is not widely publicised. We suggest the banks work with their local public involvement teams and their local Scottish Health Council office to explore ways of increasing public involvement in this important area.
Conclusion

Over the last 3 years, we have developed and implemented a robust accreditation process for the regional human tissue banks in Scotland. The four banks have all been reviewed by an expert review panel and have all achieved accreditation. This has been a challenging process for all four tissue banks and they have all required support. One regional tissue bank has introduced major changes to achieve accreditation including the complete transfer of retrospective data from manual records to an electronic data entry system.

Accreditation of Scotland’s regional tissue banks is an important milestone in the improvement of patient care as the material collected, stored and managed by these banks is a vital healthcare research resource. Without this, it would not be possible to learn as much as we currently can about diseases, treatments and the human body.

The next challenge is to extend these practices to the many smaller tissue collections that thrive in Scotland using an approach that is proportionate and risk based.

We are also aware that similar activities are being undertaken by groups in other areas of the UK and overseas. We are keen to engage with these groups to share best practice and help improve further accreditation activities in NHSScotland human tissue banks.
Appendix 1: Human Tissue Pathway

**Acquiring**
- Tissue from living
  - Provide information to potential donors and families in a variety of formats
  - Obtain & record consent/authorization for research
  - Acquire & transport tissue to bank
- Tissue from deceased

**Storing**
- Process tissue & store accompanying data
- Store tissue in suitable equipment & premises. Arrangements for existing holdings also need to be in place.
- Monitor & record:
  - storage conditions
  - quality control of tissue
- When appropriate, dispose of tissue using safe & effective procedure

**Using**
- Receive and assess requests for tissues
- Allocate tissue for approved research
- Transport tissue & transfer data (using Materials Transfer Agreement)
- Record destination and use/dispose/return information
- Archive records

**Accreditation criteria**
1. There is a formal procedure for obtaining consent/authorization to donate tissues that has received ethics approval. In addition, systems to deal with any subsequent withdrawal of consent/authorization are in place.
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
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).
Appendix 2: Quality standards of operation

Accreditation criteria 1: consent/authorisation

Quality standard statement 1:
There is a formal, ethically approved, procedure for obtaining consent/authorisation to donate tissues.

C1 a) There is a formal procedure for obtaining consent/authorisation to donate tissues which meets the principles of the Human Tissue Authority Codes of Practice on Consent from living donors (15 September 2009), and the provisions of the Human Tissue (Scotland) Act 2006 for donations from the deceased.

C1 b) Consent/authorisation procedures have received NHS research ethics approval.

C1 c) Consent is taken in line with common law requirements (including statutory considerations with respect to adults not able to consent for themselves and incapable children) with respect to the collection, storage and use of tissue and associated data.

C1 d) Patient information on tissue donation is available in a variety of formats, and with provision for those with hearing or visual impairments.

C1 e) There is a clear policy for the management of withdrawal of consent/authorisation.

Accreditation criteria 2: governance

Quality standard statement 1:
All aspects of the tissue bank’s work are supported by documented policies and procedures, as part of the overall governance process.

GQ1 a) There are documented procedures on how tissue samples should be collected, processed, logged, stored and released.

GQ1 b) There is an established governance structure which:

supports regular governance meetings, and

defines the governance structure/relationships and lines of accountability between the establishment and NHS boards/academic institutions.

GQ1 c) There are documented plans to identify and bring outlying tissue resource under the governance of the NHS board's tissue bank.

GQ1 d) Staff are appropriately qualified and trained, and are continually updating their skills, as described in the Competency Framework for biobank staff.

GQ1 e) A system is in place to identify and assess risks in the biobank, including risks to staff, samples, data, equipment, premises and organisational reputation.
Quality standard statement 2: 
There is a documented system of quality management and audit which promotes 
continuous and systematic improvement.

GQ2 a) There is a document control system covering all documented policies and standard 
operating procedures.

GQ2 b) There is a risk-based system of quality audit in respect of the acquisition, storage, 
release and disposal of tissues, which verifies compliance with all protocols.

Quality standard statement 3: 
There is a systematic and planned approach to the management of records within the 
human tissue bank.

GQ3 a) Computerised records are stored on a secure system, with documented procedures 
for the back up/recovery of data and for patient confidentiality.

Quality standard statement 4: 
There are documented procedures for the distribution of tissues.

GQ4 a) A process is in place to review and authorise the release of tissues.

GQ4 b) An agreement is in place between the establishment and the organisation to which 
tissues is supplied, concerning the tracking and use of material and eventual disposal or 
return.

Quality standard statement 5: 
A coding and records system facilitates traceability of tissues, ensuring a robust 
audit trail.

GQ5 a) There is a donor identification system which assigns a unique code to each donation 
and to each of the products associated with it.

GQ5 b) There is a clear audit trail, which includes details of when tissues were acquired and 
from where, the uses to which the tissues were put, when the tissues were transferred 
elsewhere and to whom.

Accreditation Criteria 3: The premises are fit for purpose

Quality standard statement 1: 
The premises are secure and maintained.

PFE1 a) Policies are in place to ensure that the premises and contents of the human tissue 
bank are secure and maintained.

Quality standard statement 2: 
Systems are in place to protect the quality and integrity of tissues during transport 
and delivery to and from the human tissue bank.

PFE2 a) There is a system in place to ensure that the procedures couriers use to transport 
tissues includes risk assessment and traceability.
Appendix 3: Accreditation review panel members

James Ironside (review panel chair)
Professor of Clinical Neuropathology
National CJD Research & Surveillance Unit University of Edinburgh

Norman Gibb
Public Partner

Andy Hall
Associate Dean of Translational Research
Newcastle Biomedicine Biobank

Margaret McDonald
Public Partner

Rachel Smith
Programme Manager (Training and Partnerships)
MRC Regulatory Support Centre

Support from Healthcare Improvement Scotland was provided by:

Sharon Baillie
Programme Manager

Pamela Campbell
Project Officer

Kenny Gifford
Administrative Officer

Meg Orr
Administrative Officer

Jan Warner
Head of safe clinical practice

Steven Wilson
Senior Programme Manager
## Appendix 4: Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>accreditation</td>
<td>The process whereby NHS boards are formally assessed.</td>
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<tr>
<td>biomarkers</td>
<td>A biochemical feature that can be used to suggest the presence of a particular disease, measure its progress or the effects of treatment.</td>
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<tr>
<td>biomedical engineering</td>
<td>The application of engineering principles to medicine and biology for healthcare.</td>
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<tr>
<td>cardiovascular disease</td>
<td>A disease of the heart or blood vessels.</td>
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<tr>
<td>cell culture</td>
<td>The complex process by which cells are grown under controlled conditions, generally outside of their natural environment.</td>
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<tr>
<td>colorectal</td>
<td>Relating to or affecting the colon and the rectum.</td>
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<tr>
<td>cystic fibrosis</td>
<td>A hereditary disorder affecting the exocrine glands. It causes the production of abnormally thick mucus, leading to the blockage of the pancreatic ducts, intestines, and bronchi and often resulting in respiratory infection.</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid – the hereditary material in humans and almost all other organisms. Nearly every cell in a person’s body has the same DNA.</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration – FDA approval is needed prior to marketing a medical device.</td>
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<tr>
<td>Guthrie test</td>
<td>A Guthrie, or blood spot, is a test carried out on a newborn baby in the days after birth. The Guthrie is offered to all infants in the UK with the aim of screening for up to 5 disorders.</td>
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<tr>
<td>gynaecological</td>
<td>Relating to or affecting a woman’s reproductive system.</td>
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<tr>
<td>human tissue bank</td>
<td>A collection of tissue that may be used in many different research projects.</td>
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<tr>
<td>lymphoma</td>
<td>Cancer of the lymph nodes.</td>
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<tr>
<td>metastasis</td>
<td>The development of secondary malignant growths at a distance from a primary site of cancer.</td>
</tr>
<tr>
<td>molecular taxonomy</td>
<td>Classification of organisms on the basis of the distribution and composition of chemical substances within them.</td>
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<tr>
<td>multiple sclerosis</td>
<td>A disease affecting the nerves in the brain and spinal cord, causing problems with muscle movement, balance and vision.</td>
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<tr>
<td>oesophago-gastric</td>
<td>Relating to or affecting the oesophagus and stomach.</td>
</tr>
<tr>
<td>Parkinson’s disease</td>
<td>A progressive disease caused by the slow deterioration of the nerve cells in the brain.</td>
</tr>
<tr>
<td>pharmacodynamics</td>
<td>The study of the effects of drugs on the body and the relationship between drug concentration and effect.</td>
</tr>
<tr>
<td>rheumatology</td>
<td>The study of rheumatism, arthritis, and other disorders of the joints, muscles, and ligaments.</td>
</tr>
<tr>
<td>stem cells</td>
<td>Stem cells exist throughout the body and are found inside of different types of tissue. These stem cells have been found in tissues such as the brain, bone marrow, blood, blood vessels, skeletal muscles, skin, and the liver.</td>
</tr>
<tr>
<td>virology</td>
<td>The branch of science that deals with the study of viruses.</td>
</tr>
</tbody>
</table>
www.healthcareimprovementscotland.org

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The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group and the Scottish Intercollegiate Guidelines Network (SIGN) are part of our organisation.