Healthcare Improvement Scotland is committed to equality. We have assessed the accreditation 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 Advisor on 0141 225 6999 or email contactpublicinvolvement.his@nhs.net
Contents

Introduction 4
The accreditation process 6
What we did 7
Our findings 8
Next steps 11
Appendix 1: Review panel members 12
Introduction

The scientific study of human tissue (such as blood, cells, joints) is an essential part of medical research across Scotland. Donated tissue can be used to improve our understanding of how diseases start, how they progress and what keeps us healthy. This tissue is provided by donors with their explicit consent and stored and monitored in a quality-controlled environment.

The Chief Scientist Office (CSO) announced the introduction of an external accreditation programme covering the use of human tissue for research in Scotland in 2011. Since this time, Healthcare Improvement Scotland has developed and implemented a proportionate accreditation programme for the regional human tissue banks in Scotland.

The first cycle of accreditation was carried out in 2013 which concentrated on the four NHS boards that house regional human tissue banks (NHS Grampian, NHS Greater Glasgow and Clyde, NHS Lothian and NHS Tayside). All four achieved accreditation and the findings were published in our Accreditation of Human Tissue Banks in Scotland: Summary Report (April 2014).

During this second cycle of accreditation, the review panel assessed applications from the four regional human tissue banks. All four (NHS Grampian, NHS Greater Glasgow and Clyde, NHS Lothian and NHS Tayside) have been successful in achieving re-accreditation – valid until 1 August 2019.

This report provides an update on the external accreditation programme and includes areas of innovation and good practice and areas for improvement following the second cycle of accreditation.

For more information about the accreditation programme, please visit our website (www.healthcareimprovementscotland.org/our_work/governance_and_assurance/human_tissue_banks.aspx).
‘Receiving accreditation status is a great achievement. It is beneficial for companies or pharma as they can reassure their own clients that the tissue they provide has been sourced in the most ethical manner.

The hospital has celebrated the award of accreditation by communicating the news on screens throughout the hospital to spread the word to clinical teams and in particular patients in order to provide reassurance for them during the consent process.’

– Human tissue bank manager
The accreditation process

The aim of accreditation is to demonstrate the highest possible standards relating to consent, governance and storage for human tissue, and accompanying data, used for research. This provides public assurance that current and future donations are treated with respect and are not just stored, but actively used to improve healthcare.

Each application for accreditation is evaluated by a multidisciplinary review panel made up of suitably experienced senior clinicians and policy representatives, including an independent representative from outwith NHSScotland and a public partner (see Appendix 1). Applications are assessed against our quality standards of operation to assess how tissue is collected, stored and transferred for research.

Accreditation is awarded for 3 years subject to an annual self-declaration. Each accredited NHS board must sign a declaration form to inform us of any changes in operation or if there have been any significant changes that would affect its accreditation status.

‘...there are certainly a lot of people from outwith Scotland who ask if we are HTA licensed. They are reassured when we explain to them that this is not applicable for us in Scotland but that we are Healthcare Improvement Scotland accredited. I feel it does give us a mark of quality and I’m sure in many cases it does encourage them to work with us.’

– Human tissue bank manager
What we did

Satellite NHS boards

Following the successful first cycle of accreditation, the CSO asked us to consider key issues relating to the extension of the existing programme to cover the satellite NHS boards (those NHS boards that were not included in the initial accreditation programme).

We set up a task and finish group to consider the challenges and opportunities of extending this process which included representation from regional human tissue banks and satellite NHS boards, clinical governance colleagues and review panel members. Earlier this year, the review panel carried out a baseline review of all satellite NHS boards. Analysis of submissions showed that currently all satellite NHS boards only collect tissue either:

• as part of an ethically approved project, or
• to transfer to one of the four regional human tissue banks.

The CSO confirmed that:

• accreditation is required when an NHS board collects and stores tissue from NHSScotland patients and has access to the retained tissue for future research.

• accreditation is not required when an NHS board only collects and stores tissue for use in a specific Regional Ethics Committee approved project and the tissue is subsequently destroyed or transferred to an accredited regional human tissue bank following completion of the project.

Regional human tissue banks

The review panel met in February this year to consider the applications submitted by the four regional human tissue banks for the 2016–2019 cycle of accreditation. Each human tissue bank was asked to provide evidence that it met all the quality standards of operation. All four have now been awarded accreditation as they have met every standard.
Our findings

All four regional human tissue banks (NHS Grampian, NHS Greater Glasgow and Clyde, NHS Lothian and NHS Tayside) have been successful in their second cycle of this accreditation programme (2016–2019).

During this round of accreditation we found that all regional human tissue banks had made efforts to improve the process of collecting, storing and transfer of tissue samples collected for the purposes of research.

Innovation and good practice

The review panel identified the following areas of innovation and good practice.

- **NHS Grampian**'s use of a single consent form which is presented to patients, as opposed to many forms for various research studies, so not to confuse or overwhelm potential donors.

- **NHS Grampian** is considering the development of procedures to involve children and young adults to become possible donors.

- **NHS Greater Glasgow and Clyde** reported the NHS board is creating two additional patient information sheets: one for children (8–11 years old) and one for young people (12–16). Both forms have had input and support by Patient Voices and the review panel recommended that this information is shared nationally.

- **NHS Greater Glasgow and Clyde**'s detailed annual report template could be shared with the other regional human tissue banks in NHSScotland.

- **NHS Lothian**'s robust process to manage the withdrawal of consent.

- **NHS Lothian**'s systematic approach to make sure consent procedures and processes are followed.

- **NHS Tayside**'s effective management of the transition of tissue bank management, maintaining stability and managing risk.

- **NHS Tayside** evidenced its progress in bringing its aligned satellite NHS boards under the governance of the regional human tissue bank.
Areas for improvement

The review panel noted some general areas for development across all regional human tissue banks which do not directly apply to this accreditation process but would add value going forward.

- Compare Competency Based Frameworks in order to create a national framework for similar roles such as research nurses, laboratory assistants, biomedical scientists, administrators and managers.

- Continue to strengthen relationships with each other and aligned satellite NHS boards.

- Schedule regular external audits by human tissue bank staff from another regional area. While the review panel acknowledged the audit activity conducted in each NHS board area, each human tissue bank could benefit from being audited from an external opinion. This could also further strengthen the links and sharing of information.

- Consider developing and producing a general patient information sheet in Braille. Although it is acknowledged that face to face support is offered to people who are visually impaired, all regional human tissue banks could benefit from having an information sheet that the patient could take away to consider consent fully. We understand that NHS Greater Glasgow and Clyde is in the early stages of developing such an information sheet.
‘When the biorepository is supplying tissues for a large EU research contract, we are asked to provide information on our standards and quality of material, the Accreditation Certificate allows the contractor to include the tissue banks on their accredited supplier list.’

– Human tissue bank manager
Next steps

During this second accreditation cycle, we have continued to work closely with the CSO, regional human tissue banks and satellite NHS boards. We will work with satellite NHS boards to make sure they are aware that any changes to their operational status must be highlighted to the CSO and their aligned regional human tissue bank.

We have established links with the Regional Ethics Committees to provide a better understanding of the accreditation programme and make sure the panel understand the process that goes into seeking ethics approval.

We have met with the managers of the four regional human tissue banks in Scotland, and the CSO, to discuss the feasibility of our recommendations.

Over the next 3 years, we will:
• review the quality standards of operation to maintain their relevance and make sure they include any changes in regulations
• make sure satellite NHS boards are aware they must advise the CSO, and their aligned regional human tissue bank, of any intentions to apply for tissue bank status, and
• assess the applications for the next cycle of accreditation for the four regional human tissue banks.

The next cycle of accreditation is due to be completed by 1 August 2019.

‘When our researchers are applying for grant funding the accreditation standard, I believe, gives additional comfort to the funders. Of course I think the standards do raise the quality of our samples and service.’

– Human tissue bank manager
Appendix 1: Review panel members

James Ironside (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

Chris Morris
Senior Lecturer
Newcastle University

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