



**Healthcare
Improvement
Scotland**

Accreditation of NHS boards human tissue collection for research

Sharon Baillie, Programme Manager

HUMAN TISSUE AUTHORITY

- Tissue banks in the rest of the UK are licensed by the Human Tissue Authority (HTA) under the Human Tissue Act 2004.
- Scotland has separate legislation under the Human Tissue (Scotland) Act 2006.
- HTA standards are not aligned to the Scottish Act for use throughout NHSScotland.

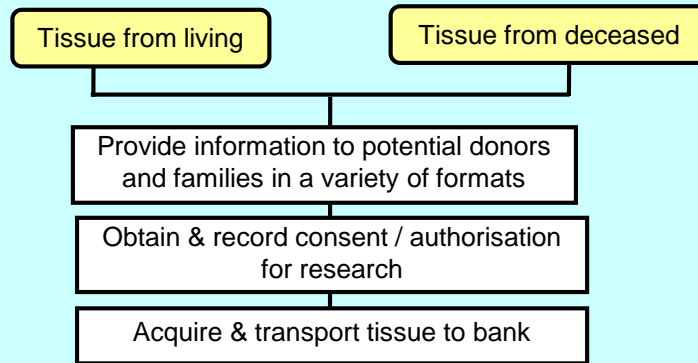
BACKGROUND

We have developed and implemented an accreditation process for the regional human tissue banks in Scotland.

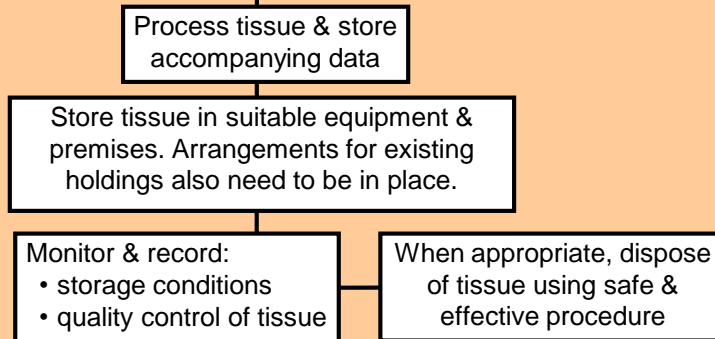
The standards set out three key areas of operation for NHS boards when using human tissue for research:

- consent/authorisation
- governance, and
- premises.

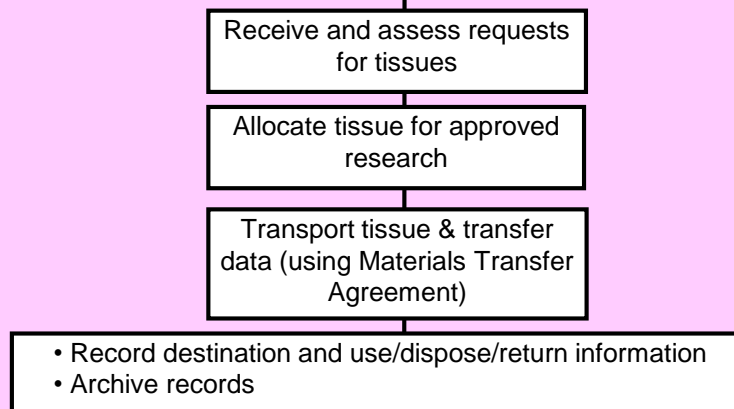
Acquiring



Storing



Using



Accreditation criteria

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



APPLICATION PROCESS

- Assessment form is completed, signed by NHS board CEO and Director of R&D
- Pre panel checks undertaken
- Panel meets to consider application
- Accreditation letter awarded to NHS board CEO
 - annual declaration process
 - list of notifications

BENEFITS FOR SCOTTISH RESEARCH

- Provide assurance to donors, funders and collaborators that tissue is **consented**, **stored** and **used** in line with national quality standards of operation.
- Promote Scotland's reputation for research on a UK, European and international level.

PHASE ONE

- **2007** – Healthcare Improvement Scotland asked by CSO to lead in developing and implementing accreditation for the four NHS Scotland regional human tissue banks.
- **2007–2008** – development of quality standards of operation and implementation of 3-yearly quality assurance and accreditation process
- **2013–2014** – the four regional tissue banks (NHS Grampian, NHS Greater Glasgow and Clyde, NHS Lothian and NHS Tayside) all achieved accreditation.

PHASE TWO

- **2015** – Healthcare Improvement Scotland asked by CSO to consider an extended proportionate accreditation programme to the satellite NHS boards (all other NHS boards who are not considered a tissue bank).
- **2015–2016** – Analysis of submissions showed that currently all satellite NHS boards only collect tissue for either:
 - transfer to one of the four regional tissue banks, or
 - as part as a REC approved project.
- **August 2016** – CSO confirmed that accreditation will only be applicable to NHS boards who carry out the functions of a tissue bank.
- **August 2016** – Four regional tissue banks achieved re-accreditation.

WHEN IS ACCREDITATION IS APPLICABLE?

CSO has confirmed that this accreditation programme is applicable when:

‘an NHS board collects and stores tissue from NHSScotland patients with 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 REC approved project and when the tissue is subsequently destroyed or transferred to an accredited regional tissue bank following completion of the project.’

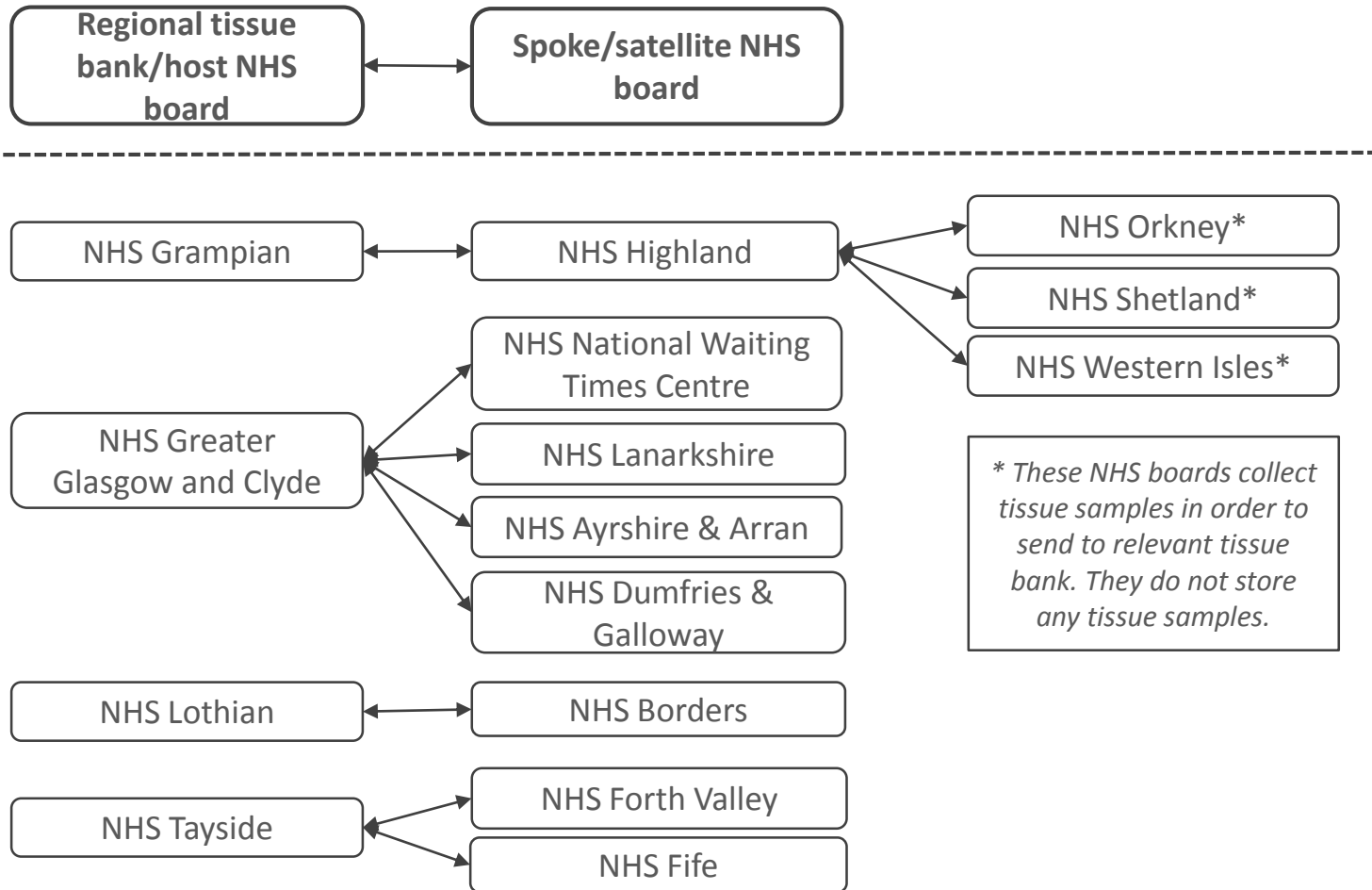
A tissue bank is defined as:

‘collection(s) of tissue from NHSScotland patients where there is managed access and oversight of the future uses of the retained tissue for research.’

GOING FORWARD

- Regional tissue banks must apply for accreditation every 3 years.
- Satellite NHS boards must advise CSO, and its aligned regional tissue bank, of any intention to change to tissue bank status.
- Review quality standards of operation to maintain their relevance and ensure they are up-to-date and include any changes in regulations.

NRS HUB AND SPOKE MODEL



THANK YOU FROM THE TEAM

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