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Chief Executives, NHS Boards

Copy to: All Directors of Research and Development
NHS Scotland Health Board Liaison Co-ordinators

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Dear Colleague

HEALTHCARE IMPROVEMENT SCOTLAND ACCREDITATION OF HUMAN TISSUE BANKS IN SCOTLAND

In 2011, the Chief Medical Officer 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), while Scotland has separate legislation under the Human Tissue (Scotland) Act (2006). Significantly, tissue collected from the living and used for research in Scotland is generally not covered by the 2006 Act but Ministers expect human tissue banks in Scotland to meet the same standards as banks elsewhere and for appropriate governance arrangements to be in place.

Healthcare Improvement Scotland developed Quality Standards of Operation based on the standards used by the Human Tissue Authority for licensing of tissue banks. The first phase of accreditation took place during 2013–2014. Each regional human tissue bank in Scotland was asked to provide evidence that it met all of the quality standards of operation required to achieve accreditation status. The standards relate to the governance arrangements in place and not to the operational and/or clinical processes in the tissue banks. All 4 regional tissue banks, which are based in NHS Tayside, NHS Greater Glasgow and Clyde, NHS Grampian and NHS Lothian, were awarded accreditation in 2013–2014.

The remaining NHS Boards (satellite NHS Boards as set out in the attachment) that were not covered in the initial accreditation process, are each aligned to a regional tissue bank/host NHS Board. The Chief Scientist Office (CSO) has now asked Healthcare Improvement Scotland to consider key issues relating to extending the accreditation process to include accreditation of these satellite NHS Boards.

In line with the strategic plan set out by the Chief Medical Officer¹, Healthcare Improvement Scotland is now starting phase 2 of the accreditation process, which involves the development and implementation of a process to accredit the satellite NHS Boards' human tissue collections. To avoid duplication of effort and make best use of operating procedures already reviewed by Healthcare Improvement Scotland and considered compliant with the expected standards, it is proposed that the appropriate regional tissue bank will support the satellite NHS Boards in preparing their submission for accreditation. Achieving accreditation

¹ [http://www.sehd.scot.nhs.uk/cmo/CMO\(2011\)07.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2011)07.pdf)

however will ultimately be the responsibility of the satellite NHS Board(s), not the supporting regional/hub NHS Board.

This approach was developed by a Task and Finish Group, chaired by Professor James W Ironside that included representation from the Medical Research Council, R&D Directors, clinical governance leads, public partners, regional human tissue bank managers, as well as independent representation from outwith Scotland.

The Task and Finish Group was clear that the accreditation process should not adversely impact the existing productive overlap currently in place between the NHS and universities, nor should it affect the established management structure or responsibilities of the satellite NHS Boards.

As accreditation was awarded to the regional human tissue banks by Healthcare Improvement Scotland in 2013–2014, the next round of accreditation is due in 2016–2017. The satellite NHS Boards must be able to demonstrate they meet the agreed Quality Standards of Operation in relation to consent, storage and access in order to achieve accreditation status. These standards are currently being revised to reflect any updates since the first round of accreditation. Healthcare Improvement Scotland will shortly be writing to all Directors of Research & Development with a more detailed timeline for this process and they hope to be able to provide information sessions if required in order to contextualise the process between May and November 2015.

Support and guidance from CSO and Healthcare Improvement Scotland will be given to the regional tissue banks to develop collaborative working. The accreditation scheme provides assurance to donors, funders and collaborators that tissue is stored and used in line with national quality standards of operation. Successful accreditation will also help promote Scotland's reputation for research on a UK, European and international level.

Healthcare Improvement Scotland commenced work on establishing a framework for this process in January 2015. This involves working with stakeholders to develop the existing regional accreditation process to include accreditation of satellite NHS Board collections.

Yours sincerely

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