The UK Stem Cell Bank: Developments & Challenges for International Banking

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Member UKSCB Steering Committee
Background

The UKSCB was established in 2003 following a House of Lord’s Select Committee Report into the science and ethics of hESC research:

Report recommended the setting up of a non-statutory Steering Committee to:

– monitor and approve the deposit and use of hESC lines within the UK including the import and export of stem cell lines
– establish a Code of Practice for the use of human ESC
– act as the principal oversight committee for the UK Stem Cell Bank
Role of the UK Stem Cell Bank

• To work with the scientific and clinical communities, commercial organisations and regulatory agencies to assure the quality of human stem cell lines used in research and clinical therapy

• To develop and disseminate best practice in the culture, testing, characterisation and preservation of stem cell lines: permitted only to undertake research relating to curation.

• To establish, test and release well-characterised stocks of ethically-sourced adult, foetal and embryonic stem cell lines within a stringent quality framework

• To promote basic research in the UK and abroad through the provision of “Research Grade” cell banks

• To establish “Clinical Grade” cell banks under EU GMP conditions as starting material for therapeutic uses
Current Activity

72 Cell lines approved by the SC
30 Cell lines Banked for distribution
15 Cell lines released for use
No clinical grade lines yet available
(2 awaiting approval from the HTA)
No iPS lines (unlike WiCell)

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UK stem cell bank

• Institutional: UKSCB seen as strong public institution; no research also reinforces service role/independence

• Public engagement/support: see Stem Cell Dialogue report

• Legal background: HFEA – permissive regime

• Bureaucratic regulation: complex – multiple sites of regulatory authority and influence
UK Stem Cell Tool Kit

A regulatory tool for those conducting human stem cell research in the UK.

Navigate your way through the regulations by responding to a series of key questions and building your own route map.

Start new route map
Click here to begin answering a series of questions that will help establish a regulatory route for your stem cell project.

Retrieve existing route map

Need another Tool Kit?
The MRC has developed other research Tool Kits which you may find useful:
- Clinical Trials Toolkit
- Experimental Medicine Toolkit
- Data and Tissues Toolkit
International collaboration (1): Collaboration requires standardisation across labs

- Standardising stabilises discovery-led science; need for common criteria under which data gathered across different labs can be classified and retrieved
- ISCI re hESC – UKSCB plays pivotal role
ISCI collaboratory

Private firm: culture

Legal and resource base to the project: data sharing and IPR

Participating labs

RN, DNA

UKSCB

Specialist reference labs (e.g., Gene Services for RNA/DNA fingerprinting)

antibodies
In order to identify agreed characteristics for differentiation the collaboratory must *reduce* the differentiated and heterogeneous ways in which lines are identified and cultured across discrete labs. It must try to overcome the local contingencies that are defining of lines, to avoid a situation where:

‘A *conclusion about a line might be a conclusion about a lab*’  (respondent at ISCI Forum 2007)
Standardisation: in banks

Full characterisation of cells

Standardisation of protocols

GMP/GLP: but what counts as a ‘clinical grade’ line?

Quality and safety of lines deposited in bank

Need for flexibility in characterisation?: classification of cell lines/quality measures needs to be dynamic enough to support ongoing and changing understanding of cells by biologists

SO: need to engage with researchers on iterative basis

To avoid…’A conclusion about a line might be a conclusion about a bank’
Long–term regulatory issues

• consistency in bio-processing and in therapeutic results (GMP as basis for stable product)

• securing repeatable cultures

• standardising and optimising cell cultures is repetitive work but this will add value to the regulatory (GMP) process inasmuch as would be producing feed-stocks for both public and private R&D and reduce development costs.
The *Review and Refresh of Bioscience 2015* report (industrial body)

Recommendation 17: Translational scale-up centres for Regenerative medicine

Create two cell scale-up centres at research institutions to build capacity and capabilities (skills training and technology) in this specialist area of bioprocessing. Centres should work at the interface between the researcher, the manufacturer and the physician.

Source: Bioscience Innovation and Growth Team, 2009
International collaboration (2): Standardisation across banks

Exchanging lines: lines carry the context of their production

Duplicative/alternative sources of lines: cannot claim to be distributing the same material until they can demonstrate they are using the same practices

Banks as curators: how do quality assurance systems record information about stem cell lines – does this vary?

Bilateral and/or multilateral exchange: which bank acts as source of authorisation for ethical use of material deposited/donated in one country?

Common Materials Deposition/Use/Access Agreements? – IP issues here – e.g. UKSCB does not allow restrictions on 3rd party use when deposit
Trans-national banking

• ISCB Initiative 2008 – research grade lines only
• Harmonisation or standardisation?
  - common understanding of goals but expressed differently in different countries
• Harmonisation not an end-point but process
• *Ethics interoperability* to complement bank interoperability – discrete codes of ethics possible
• Arrival and exchange of clinical grade lines will require subscription to *other* forms of ‘soft governance’ (such as ISSCR Dec 2009 guidance on CTs)
• Role of bank re iPS??
Conclusion: Regulatory challenges for banking at national and international levels

Lack of an internationally unified regulatory framework for stem cell and tissue transplantation (e.g., problem of cross-jurisdictional transfer of hESC lines). Problems with inconsistent tissue banking procedures, inconsistent donor consent, uncertain efficacy and discordant regulatory standards.

Solutions will be socio-technical