

STEM CELL BANKING

IASCR

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The International Stem Cell Initiative (ISCI)

- A worldwide collaborative effort to establish basic criteria and techniques that will underpin the eventual development of applications for human embryonic stem (hES) cells in human medicine.

- **ISCI Registry**

International Stem Cell Banking Initiative (ISCBI)

- ISCBI has been launched with the goal of establishing an agreed set of international minimum standards for banking, characterisation and testing. The aim is to create a solid ethical framework for international stem cell banking and research.
- A key output of ISCBI has been the adoption of a “*Consensus Guidance*” for the banking and supply of hESC lines for research purposes. (clinical grade hESC under preparation)

Stem Cell Banking: Governance in an International Perspective

- Some of the initiatives under study:
 - The Spanish Cell Bank (NCB)
 - The United Kingdom's Stem Cell Bank (UKSCB)
 - The United States' National Stem Cell Bank (NSCB)
 - The European Human Embryonic Stem Cell Registry (hESCRReg)
 - ISSCR (proposed) Registry of Human Embryonic Stem Cell Provenance (ISSCR)

SIMILARITIES AND DIFFERENCES IN THE DEALING WITH GOVERNANCE ISSUES

| | CONVERGENCE | DIVERGENCE AND GAPS |
|--------------------------|---|---|
| Policy Approaches | Internally consistent with general policy frameworks relating to the permissibility of conducting stem cell research. | Mixture of public and private ordering (i.e. statutorily created or self-regulated). |
| Funding Sources | Public funding | Funding sources and their governance differ. They seldom influence the institution's independence, transparency and accountability. |

| | CONVERGENCE | DIVERGENCE AND GAPS |
|---|--|---|
| Mandate and Objectives | Often well-defined and coordinated objectives: Main goal is the centralization of quality controlled and ethically sourced hSCL. | Lack of pro-active international strategy. |
| Provenance of human stem cell lines (hSCL) | The majority of the institutions accept hSCL of different origins (embryonic, adult) and grades (research and clinical grade). | Some institutions have adopted strict criteria to further limit the kind of hSCL they can receive |

| | CONVERGENCE | DIVERGENCE AND GAPS |
|--|--|---|
| Policies for access and deposit of stem cell lines (hSCL) | <p>Mostly trans-national scope.</p> <p>Case-by-case approval by the institution's oversight body.</p> <p>Need proof of prior local ethical and scientific review and approval.</p> <p>In many cases licensing and funding requirements legally bind researchers to deposit hSCL.</p> | <p>Lack of comprehensive and transparent provisions for the trans-national transfer of hSCL.</p> <p>Criteria for deposit and access vary greatly across the institutions.</p> |
| Trans-national resource sharing and access | <p>Tend to promote the availability of hSCL and data to the widest audience.</p> | <p>Lack of clear and harmonized guidelines for the scientific and ethical assessment of hSCL derived outside the jurisdiction.</p> |

| | CONVERGENCE | DIVERGENCE AND GAPS |
|------------------------------|---|---|
| Governance Structures | <p>Most institutions adopt a centralized and multilayered structure.</p> <p>Recognition of the need for adequate scientific and ethical oversight</p> <p>All initiatives are of long term existence</p> | <p>Some governance structures are complex, inflexible and present deficiencies in terms of accountability, transparency and independence.</p> |
| Governance Bodies | <p>Range in their nature: advisory-consultative to executive-statutory.</p> <p>Mostly multilayered and collegiate bodies with limited multidisciplinary membership.</p> | <p>Degree of independence and accountability of governance bodies vary across the institutions.</p> <p>Multidisciplinary membership not always adopted; favouritism towards “professional expertise”.</p> |

Permissive approach with respect to hESC research derivation

Intermediate approach (restrictions in place for hESC research and derivation)

Restrictive approach (prohibitions on embryo research or on derivation and use of hESC embryos, or research limited to imported hESC lines)

No specific legislation in place regarding hESC research

- Federated country where hESC and derivation are both a matter of federal and state law

