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OPEN SCIENCE & REGULATION OF THE USE OF STEM CELLS: RESULTS OF SCRIPT INTERNATIONAL ROUNDTABLE WORKSHOP

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1. Introduction

This Report summarises the results of a Roundtable Workshop hosted by the UK Arts and Humanities Research Council (AHRC) Centre for Intellectual Property and Technology Law (SCRIPT) on the 17th September 2010 in the School of Law at the University of Edinburgh. A similar meeting followed in September 2011, which sought to identify preliminary principles that might be useful to policymakers in approaching the regulation of human stem cell lines, and possibly other emerging life sciences technologies. The Workshops, both of which involved a small group of international experts from across a number of disciplines[1] were convened in support of the PhD research of the author. The project is the last of five studentships funded by the AHRC over a period of 10 years, and augments the work of SCRIPT in medical jurisprudence, bioethics, and information technologies.

2. Objective

The aim of the doctoral research behind the Roundtable Workshops is to analyse the contribution of policies of 'openness' to the policy goal of delivery of clinical treatments and public health benefits. The author assesses the function of open access policies in regulatory strategies and mechanisms for the production of public goods.

The subject of debate at the 2010 Roundtable was 'open science and the regulation of commercialisation of stem cells'.[2] The meeting did not focus solely on the UK Stem Cell Bank (UKSCB) model for the sharing of cell lines, but covered a wider set of topics designed to elicit the core questions that need to be addressed in order to design appropriate structures or mechanisms for regulation. It considered the barriers to translation of stem cell science into clinical products, and the regulatory approaches that might facilitate both research and commercialisation of cell-based therapies in global context. This Report highlights the issues, dialogue and outcomes of the meeting and is not intended as a comprehensive record of contributions made during the Roundtable.

3. Background: the UK Stem Cell Bank

The UK is an international leader in the design of systems for the regulation of basic stem cell research. A unique aspect of this research environment is the UK Stem Cell Bank, established in 2003 in response to a public consultation on the use of human embryonic stem cell lines,[3] to strengthen public confidence by ensuring traceability of

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[1] The author acknowledges with thanks the contributions of all participants in the AHRC-SCRIPT Roundtable Workshops convened on 17 September 2010 and 8-9 September 2011: Timothy Caulfield, Aidan Courtney, Emily Culme-Seymour, Paul de Sousa, Joyce Frey-Vasconcells, Carol George, Andres Guadamuz, Natasha Hammond-Browning, Shawn Harmon, Hugh Ilyine, Yann Joly, James Lawford Davies, Calum MacKellar, Chris Mason, Aurora Plomer, Jerome Reichman, Genevra Richardson, Marilyn Robertson, Glyn Stacey, Bruce Vernon and Hugh Whittall.

[2] For an outline of the first Roundtable event, see C George , "SCRIPT International Roundtable Workshop: Open Science & Stem Cell Technology" (2010) 7:3 *SCRIPTed* 568-573.

[3] House of Lords Select Committee 2002 Report on Stem Cell Research.

the products of embryo research, and secondarily to support science by providing easy access to materials.

The UK is unique in that it makes deposition in a national stem cell bank a formal requirement. By condition of each HFEA embryo research license, a sample of every embryonic stem cell line derived in the UK, whether of clinical or laboratory grade, must be deposited in the Bank in accordance with rules established under a Code of Practice prepared by the Stem Cell Steering Committee. One of the concerns of cell developers is that this blanket approach to deposition prevents exclusive control of any lines and the selective retention of lines that have foreseeable clinical and commercial potential.

Another concern is the level of scrutiny of users and type of research conducted in relation to the deposited materials. The Stem Cell Steering Committee must approve potential users or 'Requestors' and any research proposed by them in relation to banked materials. All cells are deposited in the Bank on the terms of a standard Materials Deposit and Distribution Agreement (MDDA) and released under a Research Use Licence (RUL). Use of banked materials is restricted to 'non-commercial *in vitro* preclinical scientific research', subject to written permission by the SCSC, Depositor and NIBSC to deviate from a plan of research, use the cells for 'any commercial purpose' or transfer them to any third parties. The RUL does not grant a right or licence to the Requestor to sell or make any other commercial use of the banked materials or derivative materials or any product made on the basis thereof. If such right or licence is required, it must be negotiated between the Requestor, the Depositor and any relevant third party.

The Code and MTAs also attempt to manage property rights in relation to the banked materials. The Depositor, rather than the Bank, retains ownership of the deposited cell lines and all intellectual property rights in them; the Requestor owns intellectual property arising from its use of the banked material, but agrees to grant back to the Depositor and to the Bank a non-exclusive, royalty-free licence (without the right to sublicense) to use any intellectual property or results or discoveries or inventions or derivative materials, whether or not they are patentable, that may have been generated by its non-commercial research.[4]

Finally, a significant contribution of the UKSCB to the research community is its role in the technical qualification of cell lines in accordance with NIBSC international standards. This is an important quality and safety function in relation to research on laboratory-grade cell lines, which for UK regulatory purposes are treated as 'ordinary' human tissue. Anyone handling cells for human application is in any event subject to detailed quality and safety regulations under EU legislation.

4. Key Questions

For a list of questions identified by convenors during the first (2010) Roundtable, please see the preliminary report: C George, "SCRIPT International Roundtable Workshop: Open Science & Stem Cell Technology" (2010) 7:3 *SCRIPTed* 568-573.

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[4] UKSCB, Research Use Licence, s. 3.3.

5. Discussion

5.1. Barriers to innovation

The following were itemised as potential barriers and incentives to research and innovation:

- Funding agencies driving basic science toward commercialisation;
- Institutional and government strategies for economic development and the protection of national interests;
- Migration of IP protection into the upstream basic science arena;
- Fragmented and overlapping IP rights in upstream research;
- Failure of IP in the downstream phase to do the job of transferring technology;
- Uncertain investment environment: economic risks and free-rider problem;
- Uncertainty related to the patent system:
    - The *patent information infrastructure: difficulties in obtaining accessing to patent* databases and identifying existing patents; and
    - *Patent subject matter criteria:* difficulty in determining the scope of potential patent subject matter, to draw boundaries. Huge problem with respect to biosciences in stem cells. Potential bar to innovation due to uncertain ability to protect interests in downstream applications.
- Cost of clinical trials is the main hurdle to be overcome (in the absence of blocking patents). The private sector cannot be asked to supply a public good; the result will be an under-supply. The government should therefore reimburse a large percentage of this cost once the product is at the third trial stage.
- Pressure of commercialisation; all other issues are part of this global challenge.
- *'Translation'* or technology transfer: 'the valley of death'. Other issues are part of the larger problem: IP, the patent system, the complexity of the regulatory system, clinical evaluation procedures, expense and associated financing issues. Cannot address innovation in isolation from commercialisation / translation. Innovation no longer the problem.

5.2. Translation

Four theoretical models were proposed for the facilitation of translation or technology transfer: commercial secret, proprietary/IP, 'mixed' or controlled access, and open science.

5.2.1 Commercial secret

This has very limited value for stem cell technology. Secrecy is 'open' in that it does not create an exclusive right of control. It creates a natural semi-commons: anyone is free to reverse engineer the technology in order to obtain access to it, after which secrecy no longer exists. In practice (and particularly in relation to stem cell technology) reverse engineering can be difficult.

5.2.2 Proprietary science

'Proprietary science' is aligned with intellectual property protection, and values competition, individualism, and entrepreneurship. It is a reward system, signalling that something is worth protecting, and a tool for valuation of intangible assets and for financing academia (especially under the US Bayh Dole Act). Patents are however very expensive to obtain, maintain, and defend and may impede academic research rather than transfer technology. Various derivated strategies involving IP include the use of patent pools, and a more integrated approach in which the inventor does not license his IP but takes the product through to the marketplace.

5.2.3 Open science

Open science embodies the traditional norms of the Republic of Science. It values collaboration, sharing and the public good. It is inexpensive, and facilitates collaboration and segmentation of the work, but also has the potential for free-riding, and industry may lack interest in technology transfer. Free-riding can promote inequalities: while the ideal is equal access by all within the public domain, those with most funding and scientific capacity are likely to respond most quickly and do something with it. Derived strategies include defensive publishing to prevent others from patenting.

5.2.4 Mixed models

Unlike an open commons, a mixed model does not permit unrestricted access. It may be used to control access and avoid exclusive licensing where it is desirable to protect the development of a technology for the common good. Research participants may be protected from potential re-identification. Conditions are imposed on access, but to a lesser extent than in the proprietary/IP system. Open source software is a good example of a hybrid model. In a *public private partnership* or hybrid business model, the technology may be initially developed in a controlled commons and later licensed to industry. A *network model* would involve several groups working in parallel on different aspects of an innovation within a controlled commons.

Hybrid models have the strengths of both proprietary and open science models. They are goal-oriented and have some of the benefits of IP (copyright) protection, and facilitate collaboration. The weakness is that this approach is expensive. Controls have to be imposed, ideally through IP (often patents), which are expensive, or contracts, which are usually not as strong. This model is not clearly defined; there is no perfect licensing model. There is also an uncertain level of private sector interest.

5.3. Ethical considerations

5.3.1 Principles

It was agreed that the creation of a rational regulatory environment requires a set of principles for the guidance of policymakers. Principles should provide policymakers with a reference tool for the creation of a regulatory environment. Ideally they would be explicit enough that each part of the system could be tested against them, to determine whether the system is serving 'the things that we are actually interested in on a principled basis'. It is unclear in the stem cell field who is leading the policy

front, because there are various interests and perspectives that might be represented: legal, health, economic development etc.

- What principles drive or should drive policy? Openness and public good.
- What do we want to test the system against, either at a fundamental level or in regard to parts of the regulatory system?
- How should regulators use principles? Instrumentally, to influence the development process and shape the system, or more impartially?

The discussion focused on the concept of the public good. Among the many different ways in which the public good could be pursued, one is found in the (UK) HFEA prescription of research purposes for embryo research: the development of treatments for serious disease.

A regulatory system is there to support the things that we *do* want, as well as to prevent those we do not. The purpose of a tissue bank is to enable the use of material for its intended purpose in an efficient manner, rather than having it hoarded in private collections. A stem cell system should not just mandate the consent of donors, but facilitate the work that we invite them to participate in. The system should not impede research in the UK where the attitude is permissive, subject to legislative criteria that provide clarity for researchers and build public confidence. To impose barriers to the delivery of products to market is to fail to respect the altruistic contribution of donors of materials for that purpose.

5.3.2 Informational responsibilities to donors and recipients

The debate over informed consent - the nature and extent of the information that is necessary in order to legitimate consent to donation of human tissue - is relevant but not particular to stem cells. How much information must be provided to donors of embryos or other sources of primary tissue? Is broad/general consent a sufficient basis for all types of research? The group provided various responses.

- There is a responsibility to give as much information as possible, and as much as the donor may want (this differs from person to person).
- Potentially sensitive research (eg creation of gametes/embryo from stem cells) requires reconfirmation of donor consent, even if prior consent was general.
- Ideally 'informed' consent requires that donors should be apprised of potentially sensitive uses of the material they are donating.
- The UKSCB Steering Committee will police consent from individual donors, because despite broad consent to *ongoing research*, use must still be aimed at the provision of *health benefits*. Research proposed by users of materials withdrawn from the Bank will be examined for appropriateness (is it non-trivial?) and will be linked back to the original donor consent.
- Where there is potential commercial value very specific information should be provided. Transparency generates trust. The donor has a different position to the institution granting ethical approval.
- From the UKSCB perspective, there are difficulties in obtaining further consent from donors on the basis of new information about potential specific or sensitive uses once the donation has been made. There are practical issues in maintaining

contact with donors: they move or die without notification to the Bank and there is no good mechanism for keeping track of them.

- In support of broad consent, a set of core, key principles and questions can be included in a consent form (see the UNESCO group) to underscore the altruistic nature of the donation and advise patients regarding potential commercial results of the product of their tissues, which they will not have access to.
- What is the precise ethical justification for a claim that the donor's right to determine the use of tissue should prevail over that of the public good? The tissue has been voluntarily donated. The donor does not have to donate.
- Any right of withdrawal of consent in stem cell research ends once the cell line is established. Stem cell derivation provides only a limited time to withdraw, as the primary tissue that is donated is disaggregated and the cells cultivated. The donated tissue is not the cell line that is ultimately banked.

Further, what are the informational responsibilities towards *recipients* of therapies? How much do they need to know about origin and provenance of the cells? How much information must 'travel' with cell lines? If we open access and increase interactions through a cell bank, the informational implications expand accordingly. The question is whether the system can cope with the necessary transfer of information.

5.3.3 Differential treatment of stem cell lines on basis of origin

Does appropriate use of human embryonic stem cell lines require that their regulatory treatment should differ from that of cells of non-embryonic derivation? Should they be specially monitored on the basis of public sensitivity related to products of embryonic derogation? Does origin affect the expectations of providers of material regarding information? Do they need to be informed about potential usage or research outcomes?

- No practical differentiation in the UKSCB. The focus of the Bank is not monitoring, but the support of research. All depositors are required to submit an annual summary of research data.
- No EU legislative distinction. By virtue of divergence among EU Member states over the acceptability of embryo research and use of embryonic stem cells in therapy, the EU Tissues and Cells Directive and the ATMP regulations are drafted in such a way that there *is no* distinction between embryonic and non-embryonic stem cell lines.
- EU funding. The European Commission has agreed *not to fund* the destruction of embryos through the derivation of embryonic stem cells, but given that the legal framework permits member states to establish their own national policies on the matter, it will fund all the other research on the resulting cells. The group discussed the lack of coherence between the European legal framework and funding policy and whether the consensus reflects any deeply held set of beliefs.
- Public perception. Once a stem cell line is established, is uniform treatment appropriate? The public might consider uniform treatment as a circumnavigation of our legislation restricting *embryo* research to specific 'non-trivial' purposes including research into treatments for serious diseases. That needs to be applied

to embryonic cell lines as well as embryos in order to maintain public confidence, although it is not clear whether that will continue in the future. We need to educate the public if scientists want to be able to do other research with embryonic cell lines. Arguably the legislation on embryo research already addresses all ethical concerns arising from derivation and there are mechanisms (HTA and MHRA) for developing stem cell lines into a product, so the crucial question is *for how long do we have to treat the resulting material as a person?* This will probably be answered politically and socially rather than scientifically or legally. The perception that there is a concern will fade, in the absence of a scandal.

5.3.4 Public confidence

Questions: *what do you actually have to do in order to reassure the public,* and does it work. How reassuring is the presence of soft regulation on the research use that is made of stem cell lines? Can we assume that patients will be advised of the cellular origin of the stem cell treatment that they are receiving? Does the length of time from the act of derivation dilute the ethical sensitivity related to the origin of an embryonic stem cell therapy?

There is a key concern that the public is going to hold the Bank accountable for the (predictable) problems with the *first* products. Once we move into clinical use, EU regulations on advanced therapies require both *traceability* and *product labelling* as to cellular origin.

5.4. International Collaboration

There is variation between jurisdictions at all levels in international issues, regulations, policies, the international environment and international collaboration. We looked specifically at research ethics policy and commercialisation.

5.4.1 Research ethics and regulatory policy

Open systems will have to deal with wide jurisdictional variation in this area. There is a global 'patchwork' of research ethics and regulatory policy; variation exists even between culturally similar jurisdictions. Variation impacts on the kind of research that goes on in each jurisdiction and is relevant to any kind of international collaboration. The regulatory environment has an impact on output: more permissive regimes produce more research.

Policy uncertainty, such as questions of legality and constitutionality makes international collaboration and perhaps international investment difficult. Avoidance of uncertainty may provide motivation to leave a field in order to move ahead, and makes other jurisdictions more attractive and competitive.

Harmonisation seems an obvious or logical way to create more collaboration internationally. But there are questions as to whether harmonisation is always good or necessary. Industry wants harmonisation for purposes of efficiency. The research community wants it for purposes of creating an open research environment. What is easiest to harmonise? It is impossible to harmonise the moral status of the embryo. Perhaps small changes in cell culture standards and cell line banking.

5.4.2 Commercialisation and funding

Variations in rules and ethos re commercialisation and IP also threaten to hinder collaboration. In Canada there is an increasing pressure to commercialise. The objectives of the CIHR (Canadian Institutes of Health Research) are to encourage innovation, facilitate *commercialisation* of health research in Canada and promote *economic* development. The language is the same worldwide: in Singapore, the UK, Japan and even Qatar. Justification for doing or investing in stem cell research is founded on economics. There is a global race to find cures. Open systems will be difficult to devise if they are to be a research platform for national objectives.

For empirical research demonstrating that more commercialisation equals less collaboration, see T Bubela et al, "Commercialization and Collaboration: Competing Policies in Publicly Funded Stem Cell Research?" (2010) 7 *Cell Stem Cell* 25-30.

5.4.3 International Stem Cell Banking Initiative

- The ISCBI is a UKSCB collaboration with other stem cell banks (160 participants from 21 countries), attempting to harmonise different standards of operation and different quality of reagents, as well as IP. The goal is to have the major players establish some minimum standard.
- Inaugural 2007 meeting resulted in "Consensus guidance for banking and supply of human embryonic stem cell lines for research purposes" (2009) 5(4) *Stem Cell Review* 301-314. See also L Healy, T Ludwig and A Choo, "International Banking: Checks, Deposits and Withdrawals" (2008) 2 *Cell Stem Cell* 305-306.
- ISCBI develops best practice guidance for the procurement, banking, testing and distribution of human ES cell lines for research purposes. It addresses what characterises a bank, what is a public service facility for distribution of cells, criteria for delivery of 'reference cell banks', necessary procurement arrangements, systems for traceability, testing etc.
- Guidance taken up by WHO: referenced in a revision of its guidance on cell substructure used for manufacturing purposes. See the WHO document for industrial occupations. Regulators have been very interested.

5.5. Organisational Models

5.5.1 UK model: UKSCB

- Mandatory deposit. It is a policy *requirement* in the UK, *not an option,* that (human embryonic stem) cell lines (derived in the UK) are deposited with the Bank.
- Objectives: To ensure ethical provenance and ethical use of the cells. To make cell lines available for clinical purposes *and* exploitation. To coordinate with industry to facilitate development of cell lines. To permit research to enable development of regenerative medicines.
- Ownership: Lies not with the Bank but with owner or purchaser of the cell lines.
- Property rights are formalised through agreement or licence. Basic research will be governed by a Research Use Licence between the owner, Bank and user.

- Use related to potential clinical application, or commercial exploitation, will require commercial licence between owners and recipients of the cells.
- The UKSCB model does not permit exclusive control of stem cell lines. The 'one-size-fits-all' approach (deposit and licensing of all cells in similar manner) was appropriate at the beginning when the issue was public perception and not commercialisation, but is now subject to review by the Bank. The cell industry favours a situation in which the vast majority of research grade lines, which have no value, would be freely available while a more exclusive licensing strategy could be applied to a limited number of lines.

5.5.2 Microbial research commons model

See:

- Lewis, Reichman and So, *"Treating Clinical Trials as a Public Good: The Most Logical Reform" Law and Economics Workshop*, UC Berkeley, 2006, available at: http://escholarship.org/uc/item/3cn7258n.
- J Reichman, P Uhlir and T Dedeurwaerdere, "Designing the Microbial Research Commons: Global Intellectual Property Strategies for Accessing and Using Essential Public Knowledge Assets" (2010), draft under review.
- A Rai et al, "Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery" (2008) 8 *Yale Journal of Health Policy, Law and Ethics* 53-89.
- J Reichman, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation" (2000) 53 *Vanderbilt Law Review* 1743-1798.

Problem

- Overly-restrictive material transfer agreements of US culture collections, limiting research.
- The bulk of all the microbial materials in collections have no known commercial application and are only valuable as inputs of basic scientific research.
- Informal exchanges of bio-resources based on trust are diminishing as labs restrict 'commercial uses', though distinction between commercial and non-commercial research is not tenable.

Proposition

That optimal sharing of upstream research inputs in the life sciences depends on the formation of digitally integrated research networks that afford willing participants greater reciprocity benefits than those likely to accrue from hoarding materials, data and information.

Design

- Contractually constructed research semi-commons; standardised MTA to regulate all willing participants.

- Key premise: depositor of material in the research semi-commons does not forfeit all rights to benefit from downstream commercial applications that emerge.
- Participants contribute materials having no known or likely high pay off commercial potential.
- Individual collections must maintain the highest quality standards.
- No restrictions on upstream public research functions with respect to all the deposited material.
- Worldwide research exception. 'Do what you want with it' rather than 'do what you want if its non-commercial'.
- Must track all uses with *bio-markers,* and fullest attribution / reputational benefits should be given to depositors.

Compensatory regime

- A 'liability rule or 'take and pay' rule' is an entitlement to take: 'please use my property, do something, make it valuable, just give me equitable compensation for the uses that you have put it to.'
- Purpose is to generate equitable compensation for depositors and the collection through payment of a reasonable royalty (3 to 5%).
- Materials in the semi-commons are *pre-competitive: have* elicited little scientific interest at the present time; we are trying to generate interest in them.
- To treat these materials as valuable (golden ticket phenomenon) makes collaborative research difficult: need large and diverse microbial populations; can't negotiate enough MTAs to do this.
- Pay-off: any scientist authorised by connection to a participating institution has access to limitless resource, with view to maximising future opportunity.
- Has already been codified by an international treaty on plant genetic resources for food and agriculture.

Result

- You end up with a kind of public-private partnership.
- Enough economic incentives to contribute to the pooled resources with which you would derive more benefits than you would from holding out.
- Liability rules fully preserve and promote benefits of collaborative research model.
- Four to six projects in progress using similar models (eg Craig Venter, see below).

Application to stem cell lines

- Data. UKSCB holds genetic data from hESC lines. Issues with making it available to researchers, as it could have significant impact on donors and their families.
- Ethical questions around consent create an added dimension in stem cell situation.

- Need to distinguish pre-competitive from competitive lines from lines. Pre-competitive lines that generate basic research can go into the pool, while lines that are no longer pre-competitive, for which commercial uses can be identified, should not be handled by the bank. These so-called specialised collections can generate an array of patents. They need to go further downstream.
- Valuation. The line between valuable special collections and low value material is difficult to determine. Most microbes are not worth anything, but this may not be as true for the stem cell line. Value is an issue for UKSCB when negotiating deposit agreements with universities who are concerned about value, but have no idea what the potential products might be.
- The high cost of clinical trials is problematic for translation in stem cells. The clinical trial process is a public good; one option is that the government should reimburse private companies if they get to third stage trials.
- Most cell lines are research grade and would fit the microbial model. Clinical grade ones would not.

6. Conclusions

I. Openness and Innovation

Although the open source software experience and collaborative scientific methods suggest that openness has a capacity to foster innovation, barriers to modern life sciences research raises the question as to whether open models can be applied to biotechnology. We asked whether it is necessary to use proprietary rights (IP) as protection and incentive for downstream commercial production, and what incentives can be employed (for investing in expensive and risky stem cell development) at the upstream stage that will not create barriers to innovation or create other problems.

II. Openness and Ownership

Both openness and IP have a role to play in the technology transfer process. In the design of mixed or hybrid models it is difficult to determine the boundaries: exactly where openness should end and a proprietary system should begin. Increasingly, models of commercialisation are emerging. We should observe and compare their experiences over the next few years.

III. Stem Cells and Ethics

- The fact that there are multiple interests in the field of stem cell R&D ensures the likelihood of multiple perspectives and conflicts for resolution by regulators.
- The creation of a rational regulatory environment requires a set of principles as a reference tool against which to test the system.
- The first responsibility to donors and recipients is to facilitate the public good by doing the work that we have invited them to participate in.
- Tissue banks raise significant questions about the information of donors, the nature of consent necessary to support ongoing research, and the amount of information that must be delivered with cell therapies.

- The need to address the public perception of hESC lines as embryonic products is a basis for restrictions on their use.

IV. International Collaboration

There is huge jurisdictional variation in research ethics and commercialisation issues. This variation causes immense policy uncertainty that imposes barriers to international collaboration. There is evidence in the stem cell research field that where there is most commercialisation there is least collaboration. There is room for more international initiative toward collaboration and harmonisation of standards, quality, banking.

V. Organisational Structures

- Many of the features of the proposed microbial research commons may serve useful functions in the banking of research grade stem cell lines.
- These features include a compensatory regime under which the depositor of material does not forfeit all rights to benefit from downstream commercial applications, and virtually no restrictions on upstream research functions with respect to all deposited material.
- Regulation of human stem cell lines has an added (ethical) dimension not relevant to microbes.