The Hinxton Group
An International Consortium on Stem Cells, Ethics & Law

Statement on Policies and Practices Governing Data and Materials Sharing and Intellectual Property in Stem Cell Science

PREAMBLE

Tension is increasing between fairly new and pervasive policies and practices governing data and materials sharing and intellectual property in science ('proprietary structures'), and norms of openness and free exchange. While intellectual property rights (IPR) can bring private investment into areas underfunded by governments and help bridge gaps between scientific invention or discovery and useful technologies, some new and emerging policies and practices risk slowing innovation in research and development (R&D) and skewing attention toward large markets, to the disadvantage of small markets, such as those for rare diseases and in some emerging economies. This is of concern, as one central goal of the life sciences is to improve global health: our shared humanity and the potential for biological knowledge to benefit all people create this obligation. Further, the self-regulatory structures within scientific communities, as much as the legal institutions we consciously erect for science, should be responsive to this goal.

While the proprietary dilemmas currently faced in stem cell science confound many if not all areas of cutting edge life science, they are especially pronounced in the field of stem cell research. First, the tree-like shape of cellular differentiation makes the field especially prone to IPR holdings that can function as tollbooths to broad areas of work, creating a drag on investment and slowing down basic research. Second, the consequences of such slowing are especially severe in the stem cell field, where novel cell lines, reagents and related technologies function as platforms for broad areas of follow-on work. Third, the competition to stake out aggressive patent positions is accentuated in the current context of competitive national innovation policies featuring stem cell science.

It should be noted that our research and deliberations focused primarily on human pluripotent stem cells (embryonic stem cells—ESCs, and induced pluripotent stem cells—iPSCs), and their derivatives, rather than tissue specific stem cells, in part because the ability to derive human pluripotent stem cells is relatively new and because of the considerable excitement these cells have generated (political as well as scientific), but also because their origins and very nature create special problems relating to IPR. Indeed, the pluripotency of ESCs and iPSCs is a major issue in terms of utility and overlapping patent claims. However, it is quite likely that many of our deliberations and recommendations could equally apply to tissue specific stem cells, whether these are fetal, umbilical cord blood, or adult in origin. We encourage those working on these other stem cell types to consider adopting similar measures to those proposed here and to contribute to common resources for data and materials.

Human pluripotent stem cell science is a young field, but one that has already progressed from initial invention to enrolling the first subject in a clinical trial. This rapid progress has occurred in the public eye, against a background of significant moral disagreement within and across nations, and within a complex regulatory environment hosting a patchwork of divergent and often conflicting responses. Furthermore, with its great potential to advance both basic and translational science, stem cell research has become a focus of national economic, innovation and competitiveness strategies. And finally, though many fields of science have reached a similar point in their development, now is the time in stem cell science for the sorts of collective reflection and action proposed herein.

This statement has benefited from the input of an international group of stem cell scientists, scholars of IPR and innovation, ethicists, lawyers, physicians, and representatives from funding bodies, governmental bodies, industry, and scientific journals. In this statement, we make several recommendations to address the challenges raised by proprietary practices and policies in stem cell research in a way that promotes *both* scientific innovation and the public good. Admittedly, we do not address all issues faced by stakeholders in this arena; we have tried to target challenges faced by multiple stakeholders and for which we could develop concrete and actionable recommendations. We also acknowledge that some of the most important ways to align stem cell research with the goal of global justice pertain less to IPR, and more to the kinds of research questions that are asked, and the sorts of projects that find funding.

While we do not, by our constitution, represent the views and interests of all the varied stakeholders in the stem cell science enterprise, we do hope this statement will nonetheless help to articulate the kinds of global obligations we share in the study of biology writ large, and how those obligations may be honored in the field of stem cell science. We also hope that these recommendations will help stimulate a broader dialogue among communities, scientists, patients, ethicists, regulators, and others about how proprietary practices and policies in stem cell research can best serve the global public interest.

Recommendation 1a*. Establish a central hub for accessing global stem cell registry information*

Statement of the Problem
Data sharing is a critical factor in the progression of stem cell science; though currently, sharing is hampered by the behavior of individual scientists and laboratories, the speed with which the field is moving, and by fragmentation of data across local, regional and national registries and banks, and the related barriers to knowledge of and access to this disparate set of resources. In part due to the speed with which the field is moving, many cell lines are being derived and characterized, though not all lines are being published in the literature, even in the academic sector. Furthermore, useful cell lines created from human materials (especially those created with public funds) and their associated data should be distributed and used widely, constrained only by the wishes of the materials' donors.

Recommendation
A publicly available central hub or information portal for accessing global stem cell registry information should be established and maintained as a resource for and service to the community, easing access to information and reducing barriers to sharing. The Global Hub for Stem Cell Registry Information should enhance and create linkages between and build upon existing efforts (e.g., the NIH Human Embryonic Stem Cell Registry, the International Stem Cell Registry at the University of Massachusetts, the European Human Embryonic Stem Cell Registry).

A good model for such a linked resource is the network of three publicly funded databases used for DNA sequence data, protein data, and other biological information: GenBank at the National Center for Biotechnology Information (NCBI; Bethesda, Maryland, USA); EMBL-Bank at the European Bioinformatics Institute (EBI; Hinxton, UK); and the Center for Information Biology and DNA Data Bank of Japan (Mishima, Japan). Each of the three groups collects a portion of the total data, and all new and updated database entries are exchanged between the groups on a daily basis. Thus the funding, physical security, transparent operation and collective ownership of the database as a whole is assured more securely than if it were located in a single place. Data in the public databases are free to anyone to read, to download and analyze without restriction, including for commercial use, and in the context of clear rules for appropriate access and attribution.

Databases, such as these and others [e.g., the Kyoto Encyclopedia of Genes and Genomes (KEGG)] have proved successful for a number of reasons. First, there was collaboration among stakeholders (journals, funding agencies, governments) and the development of incentives for participation (e.g., priority rules and the need for a common database against which to compare newly discovered sequences). Database operators negotiated with major scientific journals to establish database accessions as a requirement for publication. This

became standard practice in the field as other journals followed suit, and assured open access to research results. In the same way, provision of stem cell information to the Global Hub or one of its constituent registries could be made a condition for grants and publications; alternatively, it could be left voluntary with incentives to contribute. The goal is a successful data resource, as measured by how comprehensive, complete, and accessible it is.

The 'linking' function of the Global Hub will require coordination and cooperation across many organizations, along with a robust programming effort to allow the hub to usefully draw from diverse databases and resources. Agreements to store data in a standard format across databases will be crucial to success. At minimum, the Global Hub should include information on cell lines (including those with specific mutations, those created for screening/discovery purposes, those with potential medical utility, etc.), and any associated attributes (such as characterization data and provenance information) that can be gleaned from available sources; research tools (reagents, technologies and methods); and, publication information (via links to PubMed and the relevant journals). For the sorts of data that should be available for cell lines, proposed and evolving standards should be consulted (e.g., the International Stem Cell Banking Initiative's *Consensus Guidance for Banking and Supply of Human Embryonic Stem Cell Lines for Research Purposes*), but should include accession numbers for related materials, as well as such information as donor ethnicity, HLA phenotype, sex, available clinical history and informed consent details, including any restrictions put on the use of the cells. Agreement on a minimum data set (for both characterization and provenance) for cell lines included in the associated databases will maximize the utility of the resource.

Recommendation 1b*. Establish a central hub for accessing information about stem cell patents*

Statement of the Problem

Many research institutions, private entities, and individuals have obtained patents relevant to stem cell research and its application. These patents have been studied by individual groups of scholars. Some of the main conclusions from that body of scholarship are that (1) the public databases of patents are often difficult to search, and can be out of date, and incomplete; (2) despite generally similar legal criteria, the outcomes of patent examination in different patent jurisdictions are quite different; (3) IPR are copious and atomized into a profusion of patents with overlapping claims; and (4) no one is curating the global body of patent data. This has created a situation in which even a diligent stem cell researcher or entity that wishes to respect IPR will face considerable uncertainty and enormous costs if they try to survey the IPR landscape. Everyone suffers when there is no map for a new research area, and individual explorers are in no position to do the mapping and have no incentive to satisfy the needs of other stakeholders.

Recommendation
We propose the creation of an Information Resource for Stem Cell Intellectual Property Rights (IPR Resource) that would function as a field-specific hub to link and build on existing resources, such as the patent landscaping efforts of the Japan Patent Office and the UK Intellectual Property Office, and academic efforts, including work of the Stanford Program on Stem Cells in Society. The IPR Resource would link all relevant facets of stem cell IPR and represent a searchable database of *primary patent data*, i.e., patents and patent applications (e.g., drawing on the newly online US Patent Application Information Retrieval system, private patent compiling services, etc.), and be linked to *secondary resources*, such as related academic publications (via PubMed, and including both scientific manuscripts and those on stem cell IPR), cell line information, etc. [The Public-Sector Intellectual Property Resource for Agriculture (PIPRA) and the Database of Genotypes and Phenotypes (dbGaP) represent partial models for this.]

As with the Global Hub, the 'linking' function of the IPR Resource will require coordination and cooperation across many organizations, along with a robust programming effort to allow the hub to usefully draw from diverse databases and resources. The 'building' function of the IPR Resource will require staff, and the development and maintenance of the set of documents that are not being captured by existing resources that could feed into a hub (e.g., information from patent offices not covered by searchable patent databases). Staff will also be needed to search for and capture available licensing and assignment information (i.e., scanning the trade press, Securities and Exchange Commission filings, company annual reports, etc.), and scholarly literature that presents first level analysis of the evolving landscape of stem cell patents (e.g., landscaping). There is, of course, a language problem that will need to be addressed, as patents, government documents, and academic literature are not written in a single, common language globally. There may also be a role in the IPR Resource for a wiki-type component, wherein scholars and other experts in the field develop patent digests for selected technologies, or otherwise help curate the resource.

A resource such as the one proposed here will require both champions and funding. We envision an international consortium of public and private funding partners, with interests in science, innovation and equitable access to information.

Recommendation 2*. Encourage, support and coordinate international human stem cell banks and human tissue and cell repositories*

Statement of the Problem
Many individual labs in academia do not have the capacity to share cell lines broadly; however, norms of open science presume broad circulation of data and materials, in part to reproduce results as a basic tenet of science. In addition, consent documents signed by tissue donors frequently refer to benefits for particular communities, and usually for

general public or societal benefit. Currently, many human pluripotent stem cell lines are being derived in laboratories around the world, though norms around storing and sharing these lines are unsettled. Among all the individual parties using existing banks, there are duplicated legal negotiations, especially around material transfer agreements (MTAs), and duplicated investigations of provenance that delay the sharing of materials. Differing operating procedures and end uses across research and clinical domains also create challenges. Furthermore, the scientific enterprise is developing in the direction of desiring to acquire increasing levels of medical information associated with the tissues used to derive cell lines, and we may need new, internationally coordinated mechanisms to deal with emerging issues related to informed consent and privacy.

Recommendation

a. Current human pluripotent stem cell banking efforts (e.g., UK Stem Cell Bank) already address some of the challenges of materials sharing and should be encouraged, funded, and coordinated internationally.

b. Existing cell banks and repositories should coordinate with regard to standards, and network across national boundaries and disease communities; this could have synergies in enhancing access for the general research and development community. While not necessarily global in scope, a well-networked international set of cell banks and repositories could quickly and efficiently distribute existing and newly generated human stem cell lines of common interest. In addition to stem cell banks, banks of human tissue or differentiated cells (e.g., skin fibroblast cells) could also provide cells to the stem cell community that could be reprogrammed and circulated in a similar fashion to provide a comparable level of access. Cell and tissue banks, over time, develop expertise that can be used to develop standards, such as in cell culture and storage methods, and coordinate practices of data, cell and tissue distribution (see the International Stem Cell Banking Initiative's *Consensus Guidance for Banking and Supply of Human Embryonic Stem Cell Lines for Research Purposes*).

c. Importantly, and in addition to circulating materials within the research community, many banking efforts also manage provenance information related to the human materials they bank. This practice should be adopted and coordinated across cell banks and repositories, as provenance investigations and findings facilitate the critical function of ensuring that consent for research uses at the procurement stage is honored as R&D are pursued with the resulting stem cell lines.

d. Given the costs of maintaining such banks, these efforts could encompass, initially, a small set of well-characterized human iPSC lines. The selection of particular cell lines should be justified and transparent. For example, a criterion for inclusion of cell lines could seek a balance between how popular these lines are in the academic community versus how applicable they are for particular therapeutic efforts, and deliberation on this balance

should be publically available. Another relevant criterion may be the level of constraint on the use of a cell line based on the consent obtained at the time of materials procurement.

Recommendation 3*. Develop and institute incentives for data and materials sharing through publication, participation in information hubs, and other mechanisms*

Statement of the Problem
In a rapidly expanding field with numerous publications reporting on research involving stem cells, it can be difficult to access certain types of data (e.g., cell characterization data), and such data are often not easily comparable across publications. Moreover, there is concern about the efficient sharing of materials, especially in an international and often competitive environment. Currently, there are *disincentives* to early publication and distribution, especially in industry: competition is restricting data and materials sharing both within and across academia and industry; there is a lack of vehicles for publishing certain types of data (especially negative data); and, there is a reluctance to distribute materials after publication. Recommendations 1 and 2 are concerned with the establishment and operation of central information hubs and cell banks to help ameliorate these problems. However, the utility of these hubs and banks is dependent on the participation of scientists, research institutions, funders and governments.

Recommendation
a. Funders, research institutions and journals should encourage and support the establishment of relevant databases and/or "hubs" where these do not already exist, and where and when they do, insist on the deposition of data, with release on (or in a specified time after) publication. There is a comparable model successfully used by the top 20 clinical journals (e.g., *NEJM*, *Lancet*, *Blood*), begun by the US National Institutes of Health in 2000: ClinicalTrials.gov. This site features 90,000 clinical trial records. Trial aims and design must be registered before any results will be published. Other relevant examples include the Minimum Information About a Microarray Experiment (MIAME) standards, which describe the data deemed necessary to evaluate and reproduce a published experiment, and to which over 50 journals hold microarray-based papers as a condition of publication; the Bermuda Principles, which reinforced the existing genome databases; and databases and biomaterial repositories for model organisms—e.g., the mouse resources at the Jackson Laboratory, the KOMP Repository of the Knockout Mouse Project, FlyBase (for *Drosophila*), WormBase (for *Caenorhabditis elegans*). Many scientists are already used to dealing with these and similar repositories, and recognize the benefits of submitting data and materials, the advantages they give in efficiency and cost of distribution, and the added value these repositories provide to the relevant communities.

b. Funding bodies and journals should insist that sufficient information is provided on

methods in (or associated with) a publication, to allow other researchers to evaluate and replicate published experiments. In the event that it is discovered post-publication that insufficient methodology accompanied a manuscript, there should be mechanisms to add this information in a way that it is linked to the paper, via a mechanism similar to corrigenda and errata, perhaps as Amendments.

c. Regulatory bodies, research institutions, funding bodies, companies, and journals should develop a consistent policy for sharing data and materials post publication. Support for these activities should be itemized in research grants, and mechanisms should be implemented to monitor compliance with the policy.

d. At the time of submission for publication, funders and journals should inquire and researchers should share whether any useful negative data were generated in the course of a project. If so, this information should also be made available in publications, as supplementary data or as an accession number to a research information database or hub. Mechanisms may be required to ensure that negative data have been obtained in a rigorous manner, which may impose an unfair burden on journals and reviewers. It is therefore recognised that additional incentive and support mechanisms may need to be developed.

e. Scientists and clinicians should advise journals and funders on appropriate standards for data completeness and norms of behaviour that should be incorporated into guidelines or rules.

Recommendation 4*. Explore options for formal collaborative networks, patent brokering, and formation of patent pools when those mechanisms for collective management of intellectual property can move the field forward*

Statement of the problem

Copious IP, including patents, has accumulated. Collective action could be taken to reduce transaction costs and bureaucratic friction that can intrude on market mechanisms to advance stem cell R&D and its early clinical applications. The profusion of patents signals that individual research institutions are hedging their bets, seeking patent rights as a matter of course, in the unlikely event that one of these patents will result in a huge financial payoff, but thereby creating a culture of pervasive patent infringement married to a potential option for prosecuting selected infringement later. The result is a broad shadow of uncertainty about freedom to do research and pursue applications. Another result is likely to be under-investment in new firms, high barriers to entry for new innovators, and slower progress for the field than if individual research institutions were more constrained and targeted in their seeking of patent rights. No one can move ahead without fear of later encountering lawsuits by patent-owners, and yet many of the key patents are held by research institutions with public missions.

Collective resources, such as cell banks and registries; central hubs, such as those proposed elsewhere in this document; and consistent policies among research institutions and funders can reduce some friction. It seems likely, however, that some form of collective management of accumulated IPR may also be needed. Of note, the recent US National Research Council report on "Managing University Intellectual Property in the Public Interest" makes clear that the missions of creating knowledge and disseminating knowledge need to guide the patenting and licensing policies of universities and nonprofit research institutions.

Recommendation

Intellectual property relevant to stem cell research has several features in common with other technologies, but some features that are distinctive. Many patents have been granted in different countries and multinational patent jurisdictions (such as the European Patent Office). The accumulation of IPR is common for an emerging technology, and since 1998, this has been occurring in human pluripotent stem cell research and its applications.

The main challenge in forming collective resources is usually the recognition by a critical mass of the stakeholders that a particular problem worth solving or a particular opportunity worth exploiting exists. The frequency of laboratories and companies encountering delays and blockages may be rising fast enough, in at least some domains of stem cell research, to mobilize a consensus that the emerging IPR problems need to be addressed. The IPR surrounding iPSCs in particular are accumulating rapidly, the patent holders are diverse and numerous, and new patents are emerging on a complex patent landscape. The time may be ripe for collective action to ensure that R&D proceeds apace, and with less congestion or friction than is likely to be possible without such coordinated action.

There are several options for disposing of the accumulated IPR in a way that benefits all parties. The Information Resource for Stem Cell Intellectual Property should explore options for collective management of IPR, and identify areas in which patent pools, formally constructed semi-commons, etc., may be warranted.

Options

Patent Pools. Formal patent pools are one possible solution to reducing transaction costs around particular applications or standards (this may include iPSCs). Patent pools require a collection of issued patents that patent holders agree to "pool," meaning that they have a formal contractual agreement to not enforce the patents against one another or against others licensed by the pool. A pool requires valid patents, a gatekeeping function to determine what belongs or does not belong in the pool, a way to value and return revenues for patents in the pool, and sufficient common interests among the patent-holders to be sustained.

Three factors may make it difficult for a formal patent pool to emerge in stem cell research: (1) the claims in patents need to be valid, yet it appears that overlapping claims exist and that many broad and sweeping claims have been granted, as such, invalid claims would need to be weeded out by re-examination or legal analysis, and only patents with valid claims that can withstand legal challenge should enter the pool; (2) the interests of universities, nonprofit research institutions, small firms, and large firms using the patented inventions may not be in sufficient alignment to support a pool, and yet all those entities hold patents; (3) the valuation of the patents in the pool can be vexing, as patents may have very different value but there may be no consensus about perceived relative value, and disagreement over the formula to allocate rewards for use. Patent pools could nonetheless emerge but will likely include only a small fraction of the patent rights that have been granted to date and in the foreseeable future.

Use-now pay-later semicommons. Another model for collective management of IPR involves a set of rules designed and enforced by stakeholders, through a network of agreements. Some agreements may be informal, but a subset of rules and practices needs to be written and formal. The formation of norms and practices around IPR is easier when there is a small number of research funders, but in stem cell research, the emergence of the field from small companies, individual universities and funding by state governments within the US, and many regional and national governments internationally, but without a dominant funding organization, has led to an unusually intense problem of research coordination, coupled to a profusion of IPR held by disparate actors with divergent interests. The development of a semicommons may be a way to address this.

Patent brokers. Short of a formal patent pool, if patent-holders have generally similar licensing strategies, collections of patents managed by a neutral arbiter could emerge. A "patent supermarket" does not require a strong gatekeeper to vet the patents entering a formal pool, but only a broker to collect patents available to potential licensees to be made available on standard terms. A royalty "clearinghouse" can consolidate and simplify the transactions of incremental royalty payments for such standard term licenses.

Collaborative networks. One promising strategy is to reduce transaction costs by eliminating patents that are never enforced, licensing existing patents on nonexclusive terms except when exclusivity is needed to induce investment in product development, and generally clearing out the accumulated underbrush of IPR detritus. These actions require changes in policy among individual stakeholders in the field, and are likely to emerge only if there are explicit norms articulated by those engaged in stem cell research.

Recommendation 5*. Adopt licensing practices and patent policies that promote fair, reasonable, and nondiscriminatory (equitable) access to knowledge and health care applications*

Statement of the Problem
We believe that licensing practices in the biological and biomedical sciences should reflect the goal of global justice, borne out of a human dignity common to all and a universal commitment to reduce suffering. Intellectual property is not simply a private matter: in addition to its obvious benefits and consequences for owners and users (licensed or not), it provides frameworks variably incentivizing invention and writings in accordance with societal aims, backed by the power of the state. Like real property, its state-backed power to exclude must necessarily be accompanied by awareness of its social context and utility, and reasonable limits on its use in the form of obligations towards others. With research using human materials, the case for requiring broad social benefit arguably becomes even stronger. Finally, the altruism of donors and the commitments made to ethics review bodies, funders and others, require that institutional licenses match any intention for social good promised by researchers.

Recommendation
The ethical importance of promoting access to knowledge and medicines through good licensing practices is self-evident. Accordingly, statements in this vein made by a number of professional societies must be not merely affirmed but also implemented. These statements include, but are not limited to, "In the Public Interest: Nine Points to Consider," endorsed by the Association of University Technology Managers; the Intellectual Property provisions of the International Society for Stem Cell Research (ISSCR) Guidelines for the Conduct of Human Embryonic Stem Cell Research; and the Social Justice provisions of the ISSCR Guidelines for the Clinical Translation of Stem Cells.

a. In particular, any licensing on government-funded stem cell inventions must:

- Reserve research rights for non-profit institutions;
- Promote R&D on and access to technologies that can help meet critical health needs in both developing and developed nations. This can be facilitated through the use of, wherever possible, negotiated global access terms and jurisdictional and field-of-use limitations;
- Use non-exclusive licensing of platform technologies and technologies of broad ancillary utility that are instrumental to the development of the field; and,
- Ensure that data and materials are available to government and academic researchers with a minimum of delay.

Licensing of privately funded stem cell inventions should also consider the above recommendations.

b. Technology transfer offices in government-funded research institutions should make

public their stem cell IPR, including their geographic scope and licensing history (including where rights have been reserved or non-assert clauses have been used), in order to promote transparency and greater use of stem cell technologies. This could be done easily and inexpensively with the IPR Resource proposed elsewhere in these recommendations.

c. Patent offices and key policymakers should reassess whether the current standards for granting stem cell patents are appropriate, given both the power of broad platform patents to block R&D, and the proliferation of patents that can create uncertainty and fragmentation in the patent landscape.

The Hinxton Group

An International Consortium on Stem Cells, Ethics & Law

Steering Committee:

Sarah Chan, BSc(Hons), LLB, MA (Health Care Ethics and Law)
Deputy Director & Research Fellow in Bioethics and Law
Institute for Science, Ethics and Innovation
School of Law, University of Manchester
Email: sarah.chan@manchester.ac.uk

Peter J Donovan, PhD
Professor, Departments of Biological Chemistry and Developmental & Cell Biology
Co-Director, Sue & Bill Gross Stem Cell Center
University of California – Irvine
Email: pdonovan@uci.edu

Ruth Faden, PhD, MPH
Philip Franklin Wagley Professor of Biomedical Ethics
Executive Director, Johns Hopkins Berman Institute of Bioethics
Professor, Department of Health Policy & Management , School of Public Health
Professor, Department of Medicine
The Johns Hopkins University
Email: rfaden@jhsph.edu

John Harris, FMedSci, BA, DPhil
Lord Alliance Professor of Bioethics
Director, Institute for Science, Ethics and Innovation
School of Law
University of Manchester
Email: john.harris@manchester.ac.uk

Robin Lovell-Badge, PhD, FMedSci, FRS
Head, Division of Developmental Genetics, MRC National Institute for Medical Research
Division of Developmental Genetics
MRC National Institute for Medical Research
Email: rlovell@nimr.mrc.ac.uk

Debra JH Mathews, PhD, MA
Assistant Director for Science Programs, Johns Hopkins Berman Institute of Bioethics
Assistant Professor, Department of Pediatrics
The Johns Hopkins University
Email: dmathews@jhmi.edu

Alan Regenberg, MBe
Bioethics Research Manager, Johns Hopkins Berman Institute of Bioethics
The Johns Hopkins University
Email: aregenbe@jhsph.edu

Julian Savulescu, BMedSci, MB, BS, MA, PhD
Uehiro Chair in Practical Ethics
Director, Oxford Uehiro Centre for Practical Ethics
University of Oxford
Email: julian.savulescu@philosophy.ox.ac.uk

David Winickoff, JD
Co-Director, Science, Technology, and Society Center, University of California Berkeley
Associate Professor of Bioethics and Society
University of California – Berkeley
Email: winickoff@berkeley.edu

Executive Committee:

Hinxton Group Members:

Elona Baum, JD *(Observer*)*
General Counsel
California Institute of Regenerative Medicine

Laura Biron, PhD
Greenwall Fellow in Bioethics and Health Policy, Johns Hopkins Berman Institute of Bioethics
The Johns Hopkins University

Tania Bubela, PhD
Assistant Professor, School of Public Health
University of Alberta, Canada

Francesca Cesari, PhD *(Observer*)*
Senior Editor
Nature

Haidan Chen, PhD
Post Doctoral Research Fellow, Center for STS
Zhejiang University, China

Jorge Contreras, JD
Director, Intellectual Property Program, School of Law
Washington University in St. Louis

Ishan Dasgupta
Research Program Coordinator, Johns Hopkins Berman Institute of Bioethics
The Johns Hopkins University

Matthew DeCamp, MD, PhD
Greenwall Fellow in Bioethics and Health Policy, Johns Hopkins Berman Institute of Bioethics
Fellow in General Internal Medicine
The Johns Hopkins University

Richard Gold, SJD
Professor, McGill University Faculty of Law
President, Innovation Partnership

Søren Holm, BA, MA, MD, PhD, DrMedSci
Chair, Center for Social Ethics and Policy, University of Manchester
Professor of Medical Ethics, University of Oslo

Jim Houlihan, PhD *(Observer*)*
Head of Innovation Policy
UK Intellectual Property Office

Ryuichi Ida, LLB, LLM
Professor of International Law, Kyoto University Graduate School of Law
Member, Expert Panel on Bioethics, Council for Science and Technology Policy, Japan
Member, Bioethics & Biosafety Committee, Ministry of Education, Culture, Sport, Science & Technology, Japan

Kazuto Kato, PhD
Associate Professor of Science Communication and Bioethics, Institute of Research in Humanities, Graduate School of Biostudies
Kyoto University

Annabelle Lever, PhD
Wellcome Interdisciplinary Research Fellow, Institute of Science, Ethics, and Innovation
University of Manchester

Jacob Leveridge *(Observer*)*
Biomedical Ethics & Medical Humanities Adviser
Wellcome Trust

Reinhard Merkel, Prof, Dr
Institut für Kriminalwissenschaften
Universität Hamburg

Dianne Nicol, LLM, PhD
Professor
University of Tasmania, Australia

Amanda Odell-West, PhD
Lecturer in Law, School of Law
University of Manchester

Beverly A Purnell, PhD
Senior Editor
Science Magazine

Mahendra Rao, MD, PhD
Vice President, Stem Cells at Invitrogen
Adjunct Professor, Buck Institute of Age Research
Vice President, Medicine at Life Technologies

Brock Reeve, MPhil, MBA
Executive Director, Harvard Stem Cell Institute
Harvard University

Mark Rohrbaugh, PhD, JD *(Observer*)*
Director, Office of Technology Transfer

National Institutes of Health

Mark Sheehan, PhD, MA
BRC Ethics Fellow, The Ethox Centre
James Martin Research Fellow in the Program on the Ethics of the New Biosciences
Oxford University

Glyn Stacey, PhD
Head of Division of Cell Biology and Imaging, National Institute for Biological Standards and Control
Director, The UK Stem Cell Bank

Jeremy Sugarman, MD, MPH, MA
Harvey M Meyerhoff Professor of Bioethics and Medicine
Deputy Director for Medicine, Johns Hopkins Berman Institute of Bioethics
The Johns Hopkins University

Dieter Treichel, PhD
Patent and Start-up Manager
Max Planck Innovation

Fanyi Zeng, MD, PhD
Professor, Associate Director, Shanghai Institute of Medical Genetics, Shanghai Stem Cell Institute
Shanghai Jiao Tong University, China

**Observers participated in the Hinxton Group meeting as interested parties, but are unable to formally endorse the consensus statement due to their professional positions*

Funders

We would like to gratefully acknowledge the generous support of the institutions funding this work:

The Greenwall Foundation
wellcome trust
The University of Manchester Institute for Science Ethics and Innovation
MRC Medical Research Council Leading science for better health
BBSRC bioscience for the future
JDRF Juvenile Diabetes Research Foundation International dedicated to finding a cure