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REPORT

Similarities and Differences Among Stem Cell Research Policies: Opportunities for Policymakers, Patients, and Researchers

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IASCR Mission:

The Interstate Alliance on Stem Cell Research (IASCR) (http://www.iascr.org/) is a voluntary body whose mission is to advance stem cell research (human embryonic and adult) by fostering effective interstate collaboration, assisting states in developing research programs, and promoting efficient and responsible use of public funds. The goals of IASCR are to: (a) identify and increase opportunities for interstate collaboration; (b) identify and decrease obstacles to collaborative research across state lines; and (c) assist states that wish to develop or improve upon public funding programs in this area.

The Role of Public Policy:

Stem cell science is a relatively new field of biomedical research through which patients, doctors, and scientists aspire to better understand disease and identify opportunities for effective treatments. Toward these goals, IASCR states and affiliates directly fund stem cell research or have developed supportive laws and policies. The success of the field depends, in part, on the ability to create collaborations including the sharing of cell and other research materials across state and international borders.

State and national policies have the potential to facilitate or hinder collaborative research. One concern is that lack of harmony could hinder scientific collaboration that ultimately aims to improve patient care. IASCR performs ongoing analysis of research policies from participant states (http://www.iascr.org/states.shtml) and affiliates (http://www.iascr.org/participants.shtml). This analysis is intended to evaluate how policy differences may affect the sharing of research materials and other collaborative work.

Policy Comparison and Potential Impact:

State and national policies include requirements to ensure research is conducted ethically. Important ethical and regulatory frameworks governing stem cell science in supportive jurisdictions may be found at http://www.iascr.org/framework.shtml. IASCR seeks to examine how differences in these policies may affect opportunities for collaboration and exchange. Three specific areas of policy variance are the focus of this article:

1. Research activities authorized in particular jurisdictions,
2. Requirements for voluntary informed consent from the donors of research materials, and
3. Criteria governing allowable payments to donors.

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IASCR continues to compare participating jurisdictions' policies to gain a more complete understanding of potential barriers to and opportunities for the field.[1]

▸ AUTHORIZED RESEARCH ACTIVITIES

IASCR tracks the types of research activities that are authorized in participant jurisdictions. Variation exists in the types of cells and embryos that are allowed for use in research. Some non-IASCR jurisdictions prohibit research that destroys a human embryo, thus only somatic cells may be used in experiments designed to create cell lines (category 1). Other jurisdictions limit derivation of human embryonic stem cell lines to use of excess in vitro fertilization (IVF) embryos—embryos that were created for reproductive use but are in excess of need or unsuitable for clinical use (category 2). Most IASCR jurisdictions authorize somatic cell nuclear transfer (SCNT)—a technique where an embryo-like product is created exclusively for research use. Certain jurisdictions authorize SCNT, but do not allow an embryo to be created through IVF procedures solely for research (category 3). Several IASCR jurisdictions permit a wide range of research activities, including but not limited to SCNT (category 4). Table 1 summarizes authorized activities for the jurisdictions listed.

[1] The information presented in this report represents our current understanding of jurisdiction policies at the time of writing. Policies are subject to change or revisions. For current status of any particular policy, we recommend contacting the designated IASCR jurisdictional representative (http://www.iascr.org/participants.shtml).

Table 1: Research Authorized by IASCR Participants for Stem Cell Derivation

	More restrictive →	→	→	→	→	→	Less Restrictive
	Category 1: Somatic cell only (iPS); no embryo use	Category 2: Surplus IVF embryo only		Category 3: SCNT authorized but no embryo creation by fertilization for research			Category 4: All research authorized with 14-day limit in culture
CA							✓
Canada		✓					
CT							✓
ISSCR							✓
MA				✓			
MD		✓*					✓
MO				✓			
NAS							✓
NJ							✓
UK							✓

* For state-funded research; however, a broader range of research including SCNT is permissible without the use of state funds.

This variance is important if scientists want to perform collaborative research. Consider the example of SCNT. The work can be done only if scientists' respective jurisdictions permit such derivation work. Further, if a jurisdiction does not permit a type of derivation work (such as SCNT), scientists may be uncertain whether that restriction extends to their *use* of lines derived permissibly by this technique elsewhere.

▸ INFORMED CONSENT

Human embryonic stem cells typically have been derived from human embryos that were created for in vitro fertilization (IVF) therapy and are in excess of the couple's need or unsuitable for clinical use. To use such embryos for stem cell research, IASCR participants' policies generally require that researchers obtain voluntary, informed consent from the individuals whose sperm and oocyte (gametes) were used to create the embryos. In some cases, the couple may have used a third-party oocyte or sperm donor to create their IVF embryos, and some states require consent to research from *all* these parties, including the IVF patient and partner plus the gamete donor. Table 2 shows the jurisdictions that call for consent from all of these parties. It also shows certain jurisdictions that either do not require consent from a gamete donor (leaving the decision to the IVF couple) or are silent on the gamete-donor consent issue.

The reason these consent differences matter to scientists and patients who support this research is that IVF embryos in some states cannot be used for stem cell research even if an IVF couple wishes to donate them. This would be the case if the couple used a third-party gamete donor to create the embryos, and that person could not be re-contacted for consent to the research (for privacy or other reasons). Some other states do not explicitly require consent from the third-party gamete donor, so it appears the IVF couple alone could consent; presumably in such a case, the gamete donor has ceded dispositional rights and there is ethical review and oversight through an institutional review board (IRB).

Another reason the consent differences matter is because some jurisdictions apply their requirements to both *derivation* of new cell lines from human embryos and the *use* of cell lines created elsewhere. For example, in California, consent from the IVF couple and gamete donor is needed to make a new human embryonic stem cell line, AND researchers can use a line created elsewhere only if the scientists there obtained consent from all relevant parties. This means that scientists in states or countries that do not require gamete-donor consent can make lines in compliance with their local

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rules, but scientists in other states may not be able to work with or collaborate on studies of those lines. There are ethical and policy considerations underlying all the jurisdictions' positions; IASCR simply seeks to identify where the differences are and what their effect may be.

▶ PAYMENT RESTRICTIONS

IASCR compiles information on allowable payments. Many jurisdictions limit allowable payments to donors of embryos or gametes for stem cell research, but these jurisdictions often define allowable ''payments'' differently. At one end of the spectrum, no payment (even a reimbursement) is allowed, while at the other end, unrestricted payment can be made. Most jurisdictions fall in between: for example, a majority of IASCR participants have policies consistent with the National Academy of Sciences (NAS) Guidelines, which permit reimbursement of direct expenses and lost wages. The United Kingdom permits an entity to offer a discount on IVF services if some oocytes are donated to research. Again, the reason these differences in allowable payment rules matter is because they can pose challenges to cross-border collaborations (i.e., Whose non-payment rule applies?), and because cell lines derived under one jurisdiction's rules may not be acceptable for use in a state that has a more restrictive non-payment rule.

Table 2: Informed Consent Requirements for IASCR Participants

	Level of Consent Requirement for **Embryo Derivation**	Level of Consent Requirement for **Use of hESCs**	Comments
CA (CIRM)	All donors of gametes and embryos	All donors of gametes and embryos	Lines may be derived from non-identifiable somatic cells without specific consent if done by reprogramming (consent is needed for SCNT)
Canada	All donors of gametes and embryos	All donors of gametes and embryos	
CT	All donors of gametes and embryos	All donors of gametes and embryos	
ISSCR	All donors of gametes and embryos	All donors of gametes and embryos	
MA	All donors of gametes and embryos, using federal consent rules.	Law is silent.	Some interpretive questions under consideration re: third-party gamete donor consent
MD	Embryo donors (state-funded research)	Law is silent.	In *state-funded* research, consent is needed from a donor of any ''unused materials'' from infertility care (this permits donation of embryos, but oocytes from such care cannot be donated in state-funded research).
MO	Embryo donors	Law is silent.	
NAS	All donors of gametes and embryos	All donors of gametes and embryos	
NJ	Embryo donors	Law is silent.	State-funded research generally follows NAS.
UK	All donors of gametes and embryos	Legal authority does not specify, for cell lines used for research purposes (non-clinical applications).	
Note that within the United States, federal consent rules may apply in addition to state requirements.			

IASCR also tracks policies governing the research use of embryos created for reproductive purposes from gametes for which a donor was paid (''paid gametes''). Payments in excess of reimbursement typically are made to donors of oocytes or sperm provided for reproductive purposes. Such payments are allowed in most states if the gametes are being provided for fertility care. The relevant issue is, generally, whether stem cell research—including derivation and use of stem cell lines—is allowable if the embryo used for research was created partly from a ''paid gamete''; in other words, does payment beyond reimbursement to a sperm or egg donor for fertility purposes ''taint'' the resulting embryo such that it cannot later be donated to research. Potential policy positions range from permission to use embryos created with paid gametes if donated to research (where the payment for reproductive purposes included reimbursement of direct costs, compensation for indirect costs, and/or incentive payments), to the direct opposite, i.e., prohibition on the research use of embryos originally created with paid gametes. Table 3 shows the distribution of IASCR participant policies on whether embryos containing ''paid gametes'' can be donated to research and whether resulting human embryonic stem cell (hESC) lines can be used in different jurisdictions.

The reason this matters to policymakers, scientists, and patients who support stem cell research is the ''paid gamete'' rules narrow the availability of embryos that may be used for research in some jurisdictions. The inability to use paid gamete embryos for research may

impact the quality and nature of research (since embryos with donor gametes may often be of higher quality than embryos of some infertility patients/partners). If the jurisdiction extends its restrictions on using embryos with ''paid gametes'' to using lines created elsewhere with ''paid gametes'' (even where payment is permissible), then some researchers will not be able to exchange lines freely due to these policy differences.

▸ SUMMARY

The goals of IASCR are to: (a) identify and increase opportunities for interstate collaboration; (b) identify and decrease obstacles to collaborative research across state lines; and (c) assist states who wish to develop or improve upon public funding programs in this area. This comparative analysis demonstrates that stem cell research policies are, at a high level, generally consistent across most participant jurisdictions. There are areas of variance, which pose potential barriers and risks to interstate collaboration and exchange. Given the general compatibility of jurisdictional policies, however, this variance can be reduced or eliminated through policy initiatives intended to harmonize stem cell research and policy.

Table 3: Summary of State and Jurisdictional Policies

State or Jurisdiction		Derivation: Can IVF embryos containing ''paid gametes'' be used to derive new hESC?	Utilization: Can hESC lines derived from IVF embryos containing ''paid gametes'' be used?
CA-CIRM		Yes*	Yes*
Canada CIHR		No	No
CT		Yes	Yes
ISSCR		Yes	Yes
MA		Yes**	Yes**
MD		Yes**	Yes**
MO		Yes	Yes
NAS		Yes**	Yes**
NJ		Yes**	Yes**

* Provided the IVF embryo was created before August 2008.

** No explicit restriction.

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