



**Interstate Alliance on Stem Cell Research
April 9-10, 2008
National Academy of Sciences
Washington, D.C.**

Meeting Summary

Participants:

States

California	Connecticut	Illinois	Massachusetts
Maryland	New Jersey	New York	Rhode Island

Countries

Canada	United Kingdom
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Organizations

International Society for Stem Cell Research
National Academies

Guest Organizations

University of Minnesota Stem Cell Institute
New York Stem Cell Foundation (NYSCF)
Harvard Stem Cell Research Institute
Coalition for Advancement of Medical Research (CAMR)
Juvenile Diabetes Research Foundation (JDRF)

Meeting Goals:

1. Receive jurisdictional updates on the following topics:
 - Scientific programs and research funding
 - Legal, regulatory or policy developments
 - Research and information needs for program implementation

Oral updates were provided by CA, CT, IL, MA, MD, NJ, NY, RI, the NAS, the ISSCR, the UK, and Canada. Electronic summaries of updates were provided for web posting by CA, CT, MA, MD, NY, NAS, and the UK.

2. Understand the needs and priorities of research and advocacy organizations and consider the role of IASCR in support. Participants were asked to give special consideration to the impact of state regulations and policies governing stem cell research programs.

See below.

3. Present the results of the IASCR survey of jurisdictional regulations and policies governing the conduct of stem cell research. Survey focuses on how jurisdictions differ on rules governing the derivation and use of human embryonic stem (hES) cells.

See below.

4. Identify priority issues for participants to inform future meetings.

See below.

Panel Discussion: Research and Advocacy Groups

Dan Kaufman: Minnesota / University of Minnesota and Mayo Clinic

- No publicly-funded research program in Minnesota, but state also does not restrict research.
- Bill in state legislature to establish a \$10 million stem cell research program has not been passed. May be some “trickle down” from support for biomedical research, in general.
- Minnesota also has great infrastructure for bone marrow and cord blood transplant work at the University of Minnesota.
- Private cord blood banks are not accessible to everyone; need to be more opportunities for couples to donate to public banks.
- University of Minnesota is thinking about forming a stem cell consortium with the Mayo Clinic to gain visibility.
- Pleas for funding for reviewers: demands for peer review are high, but state programs do not have resources to reward reviewers because can't access funds.

Amy Rick: Coalition for the Advancement of Medical Research (CAMR)

- CAMR founded in 2001 in response to President's policy restricting use of cell lines; goal of CAMR to overturn that policy, but have not succeeded, although they successfully lobbied for passage of two bills that were vetoed. In 2008-09, CAMR wants to keep the issue alive.
- How much did the announcements about induced pluripotent stem (iPS) cell breakthroughs impact thinking of legislators – CAMR doing a survey of Congress (Kim's survey). Most members say they get that it is just a new door that has opened, but a few are confused. CAMR is helping to educate them.
- No reason to think there are strong differences among three main Presidential candidates on stem cell research. If the ban is lifted after 2009, it looks like there will be a need for Federal guidelines. CAMR working with the National Institutes of Health (NIH) to extent that they can prepare for a different future.
- CAMR focus groups suggest public can also distinguish between value of iPS cells and hES cells; we may have overreacted to the reports.

- IASCR role in coordinating among states is extremely valuable and needs to continue.
- Translate what you are funding and why for the patient advocates; need to have more lay translation of research to help public understand value of work.
- Speak with one voice, particularly about new science breakthroughs.

Michael Manganiello, New York Stem Cell Foundation (NYSCF)

- Patient and patient advocacy groups are critical to the enterprise; they need to be communicated to, reinforcing Amy's point. Don't forget the patients – they are the reason we are all doing this.
- Dickey-Wicker amendment is not going away
- First goal of NYSCF was to create “safe haven” space for derivation.
- NYSCF also established a fellowship program to train young scientists. Also working on public education.
- Funding mechanisms tend to support established institutions and researchers (NIH peer review model). Is there any way to think out of the box?
- We should try to engage NIH with IASCR.

Kevin Casey, Harvard University

- Massachusetts strategic problem of regulating somatic cell nuclear transfer (SCNT) first, then funding; result was major constraint on certain hES cell research activities (such as payment to egg donors) with no funding.
- New Governor announced \$1 billion life sciences research bill, but not stem cell specific; created confusion around research / banks. Win-win with a central stem cell bank for Massachusetts (at University of Massachusetts Medical School), Harvard could deposit its lines. Problem is legislature thought the bank was a research program.
- Legislative entanglements in regulations and needing to have a legislative process to “fix” or amend as a discrete issue. Creating problems for researchers and resulted in going out of Massachusetts to do research, which creates another set of issues.
- Need to move away from current patchwork of regulations.

Mark Kirk, University of Missouri

- Have Washington University, University of Missouri, and Stowers Institute.
- There are still efforts to ban SCNT in Missouri. Currently have a state law that allows derivation and use of hES cells, although this barely passed and is under court challenge. Efforts to reverse gains creating demands in Missouri.
- Needless to say, Missouri scientists have no state funding and there are worries that Missouri will not be able to attract scientists into the state because of the uncertainty.

Robert Goldstein, Juvenile Diabetes Research Foundation (JDRF)

- 35% of JDRF budget goes outside the United States, so managing variation in rules (regulations and guidelines) has been an on-going major exercise for JDRF.
- Silence can be a virtue in the absence of scientific context. Regulations may obstruct collaboration and it may be best to be silent on some issues at least until they become real.
- Preimplantation genetic diagnosis (PGD), SCNT, and iPS represent key developments to derive disease-specific cell lines.
- What about the products of cell lines? What will the Food and Drug Administration (FDA) do with products derived from “illegal” cell lines? They have said they don't want to deal with origins, but will that always be true?
- Reducing barriers for collaboration may address some problems regarding peer review.

- JDRF would like to partner with the states, will put up funding for beta cell experts if can pair them with stem cell experts willing to work on Type I diabetes. IASCR states could also look for other foundations to partner in this way.
- Stem cell banks popping up everywhere, but very little conversation on banks for disease-specific cell lines. Also not a lot of discussion on the ethical issues surrounding these.

Summary of Other Discussions:

Noteworthy Items:

1. CIRM meeting on Stem Cell and Predictive Toxicology in July
2. STEMConn 09, March 2009: suggestion that we have another IASCR meeting there at the same time
3. MSCRF.ORG Maryland WEB site
4. December 3 Maryland stem cell research symposium
5. Maryland is conducting a survey of facility/infrastructure needs
6. NAS Workshop on Clinical Trials & Clinical applications in the November time frame.
7. Canada's Stem Cell Network Centre of Excellence has created a for-profit commercialization arm, Aggregate Therapeutics Inc., which represents stem cell technologies from 16 Canadian institutions.

Presentation on state regulations applicable to informed consent and “acceptably derived” language: Geoff Lomax presented a comparative analysis of jurisdictional requirements for areas such as informed consent, payment restrictions, and permissible types of research. Discussion revealed some of the similarities and differences in approaches as well as challenges in comparing jurisdictions, given different terminology and definitions. Participants commented during the course of the meeting on the unique value of interstate dialogue to help clarify and foster understanding of these issues.

General Discussion:

- State legislation vs. Administrative regulation vs. contract: New York is finding the contract approach to work well for them. While sometimes necessary, legislation and regulations provide less flexibility than is likely to be needed in this rapidly evolving field. Connecticut also has tried to use contracts to move quickly.
- NYSCF and American Museum of Natural History have public education exhibit.
- Maryland mentioned benefits of review, Dan emphasized that folks are overloaded.
- NIH funding, will there really be more money in NIH budget for stem cell research in the future?
- Maryland included translation criteria in the review, so translation is part of the review, but they are having problems with reviewers who are not familiar with criteria for this.
- Is there a model that will serve everyone better for peer review? A third-party that could perform the reviews for states? National Academies review proposals for several of Ohio's Third Frontier Program components.
- Should iPS cells be an issue? NAS and ISSCR are contemplating amending their guidelines to take these into account.
- Guidelines are needed to protect against unintended use; but you do not want to look back, rather look forward.
- What if Federal standards are more restrictive than states and states feel trumped by Federal rules? Federal rules could create “default” standards that states will feel compelled to adopt?

- CAMR does not have a systematic way of getting information about legislation; let them know about any state legislative efforts.

Issues Identified by Panel:

- Intra-state consortia being built to support research; stem cell partnerships to be elevated at the state level.
- Grant review demands are increasing and there is nothing in it for the reviewers. Most states will not allow money to be spent in other states. Scientists who do the reviews want to get something out of it.

Major Themes and Topics Identified for Future Consideration:

Based on the jurisdictional updates and presentations by invited organizations, a number of themes and topics emerged. These topic areas are candidates for further research and or focused presentations at future IASCR meetings.

1. Stem Cell Banks and Registries: There is a proliferation of stem cell banks and registries. Participants felt the need to understand the developmental status of different banks and registries to evaluate how they might be linked to their existing programs.
 - ▶ ISSCR is currently developing a stem cell registry and conducting an in-depth survey of current registry programs. ISSCR representatives will present this information to the group. Geoff Lomax and Heather Rooke agreed to work on this.
2. Chimeras: NAS and ISSCR offered to organize a panel of scientists and representatives from their respective guideline committees to describe the importance of chimera work for the IASCR participants and explain the basis of the considerations made in formulating the specific chimera provisions of the guidelines. Fran Sharples and Jonathan Auerbach agreed to work on this. What is the FDA framework?
3. Cord Blood Banks and Research: There is interest in many states in promoting cord blood research and banking. Connecticut just completed a report on cord blood banking and many other states (outside the IASCR network) are considering funding in this area. There is a need to share information about policies to support cord blood research.
 - ▶ Connecticut (Warren Wollschlager) and Rhode Island (Adriana Thomas) will develop a short fact sheet providing a basic overview of state efforts to support cord blood research and banking. IASCR will also respond to queries from other states interested in developing programs.
4. Translational Research and Private Sector Funding: Many state programs extend beyond basic-research. There is interest in funding translational research and the private sector. During initial efforts, potential applicants have expressed concerns that the review process (particularly in states with annual applications) tended to be oriented toward basic research (e.g., NIH-like) reviews. States are interested in how the request for application (RfA) and review process can be designed to support translational research and other critical developmental pathways.
 - ▶ Bring together different funding organizations (states and federal agencies and foundations) to consider how best to support translational research and moving products to the private sector.

5. Scientific Reviews / Capacity Concerns: States are concerned about being able to perform scientific reviews of grant proposals. There are increasing demands (growth in state programs) on a limited pool of reviewers (specialized field). Further, reviewers from states without programs are asking “what is in it for me.” Reviewers have limited opportunities to receive funding if they are from outside the granting state.
 - ▶ Consider opportunities for collaboration among different funding organizations to support collaborations. For example, JDRF’s interest in providing funds that could link an outside researcher with a state-funded researcher.
6. Use of Gametes / iPS cells: Are current policy frameworks sufficient for addressing the use of gametes, particularly in iPS cell research?
 - ▶ Review any future amendments to NAS guidelines, and have NAS brief IASCR group.
 - ▶ Egg sharing: Are any jurisdictions other than the UK considering this?

The consensus of the group was that we should take up the banking and registries and chimera topics for the next meeting.