

Planning Meeting to Establish an Interstate Alliance for Stem Cell Research

Beckman Center, Back Bay Room
Irvine, CA
May 23-24, 2007

May 23

7:30 am Participants assemble in lobby of the Island Hotel for rides to the Beckman Center

7:45 am Breakfast, Beckman Center Dining Room

8:30 am Welcome and Introductions
Warren Wollschlager, Chief, Office of Research and Development, State of Connecticut and Alta Charo, co-chair, National Academies' Human Embryonic Stem Cell Research Advisory Committee

Introduction of other participants

The purpose of this meeting is to follow up on the preliminary discussions held at the StemCONN 07 Interstate Collaboration meeting on March 27. We need to discuss the goals and scope of an Interstate Alliance for Stem Cell Research.

8:45 am Overview of State Programs on Stem Cell Research: Summary of state statutes/regulations on the following: **Susan Stayn, Stanford University**

1. Legality and funding of research using cell lines from excess IVF embryos
2. Legality and funding of research doing new derivations from IVF
3. Legality and funding of research using cell lines from made-for-research embryos created either by IVF or SCNT
4. Legality and funding of new derivations by making IVF or SCNT embryos
5. Legality and funding of creation of hybrids
6. Legality and funding of creation of chimeras
7. Specific provisions for informed consent from (a) embryo donors and (b) gamete (especially oocyte) donors
8. Rules about payment for embryo and gamete donation
9. Donor control of downstream research
10. Conflict of interest provisions regarding doctors and investigators involved in embryo or gamete donation
11. Compensation for injury of gamete donors

Do the rules for 1-11 apply statewide or only to grantees of a specific funding program?

12. Specific state statutes/regulations on IP management
13. Specific state statutes/regulations on grants administration

- 9:45 am Potential Roles of States, National Academies, other national/international organizations (National Governor’s Association, National Conference of State Legislatures, Commission on Uniform State Laws, International Society for Stem Cell Research, et al.) – **Alta Charo, Mary Jo Waits, Pew Center on the States, and William Lensch, International Society for Stem Cell Research**
- 10:15 Break
- 10:30 Identification of areas where information exchange and harmonization could facilitate stem cell research: **Marianne Horn, Director of Legal Services, Office of Research and Development, Connecticut Department of Health**

In this preliminary discussion, we will identify the areas needing attention in an interstate forum. These areas may serve to define a set of topics that should be dealt with via plenary sessions or smaller working groups. This afternoon, we will form breakout groups to address each of the areas chosen in more detail and decide what issues need to be addressed and what approaches for each would be most workable. Candidate areas include, but are not limited to:

Information exchange mechanisms: where to go with questions, model forms and agreements on reciprocity, etc.

Establishing and operating grant-making programs: procedures, policies, fundraising

Oversight of stem cell research (ESCRO issues)

Materials sharing and IP: exchange of information and identification of best practices for stem cell research

Mechanisms for management and tracking of cell lines to increase reciprocity: provenance, characterization, banking

- 12:00 pm Lunch: Intellectual Property Issues and the CIRM Experience: **Mary Maxon, California Institute for Regenerative Medicine**
- 1:00 pm General principles and operational considerations for the Alliance: **Warren Wollschlager and Fran Sharples, National Academy of Sciences**

We should also discuss the more general terms of how the Interstate Alliance should operate. How many times a year should it meet? Where? Who is it open to? How should any working groups established interface with the plenary Alliance body? Should we attempt to use only a small number of face to face meetings each year and conduct

other business via e-mail and conference calls? Should the Alliance have a more substantive function, such as drafting model legislation, regulations, procedures, and consent forms that States can adopt where possible?

- 2:30 pm Formation of breakout groups: the number of breakout groups should reflect the areas chosen in the morning session for the Alliance to address
- 2:45 Breakout group discussions: Each group should define a list of issues under its main topic (e.g., grant-making programs, research oversight, etc.) that might be appropriate for an Interstate Alliance to address. The participants should then attempt to identify what information or actions might be needed to address these issues and develop suggested approaches (e.g., request assistance from one or more national/international organizations, form a working group, etc.) and a preliminary list of next steps.
- 4:15 pm Reconvene in Plenary: Needs of States not yet in the funding arena and lacking specific laws/regulations: **Warren Wollschlager**
- 5:00 pm Breakout group rapporteurs develop (with participant assistance) presentations for plenary session on Day 2
- 5:30 Adjourn for the day

May 24

- 7:30 am Participants assemble in lobby of the Island Hotel for rides to the Beckman Center
- 7:45 am Breakfast, Beckman Center Dining Room
- 8:30 am Breakout group reports to plenary session
- 10:00 am Break
- 10:15 am Wrap up: Summary of decisions and action items: **Warren Wollschlager and Alta Charo**
- 11:00 am Adjourn

Participants are welcome to stay for lunch in the Beckman Center Dining Room to continue their discussions on an informal basis.

**The Interstate Alliance for Stem Cell Research
Draft White Paper – Not for Distribution
May 22, 2007**

I. Mission

The Interstate Alliance for Stem Cell Research (IASCR) is a voluntary body whose mission is to advance stem cell research (human embryonic, adult, and other) by fostering effective interstate collaboration, by assisting states in developing research programs, and by promoting efficient and responsible use of public funds.

II. Goal

The goal of IASCR is to carry out its mission in consultation with private and public research program administrators, private and public researchers, ESCRO members, consumers, and other interested parties by (a) identifying and increasing opportunities for interstate collaboration; (b) identifying and decreasing obstacles to collaborative research across state lines; and (c) assisting states who wish to develop or improve upon public funding programs in this area.

III. Objectives

IASCR objectives include the development of mechanisms for data and material sharing, the provision of technical assistance, the identification of critical issues and strategic options, the provision of subject matter expertise to members, and the development of formal and/or informal state assistance and reciprocity agreements.

We should also discuss the more general terms of how the Interstate Alliance should operate.

1. How many times a year should it meet?

- Timelines
 - Meetings twice/year of Alliance
 - Location of meetings rotating amongst state capitols
 - Possible locales & dates:
 - Chicago; 5/08
 - Baltimore; 9/07

2. Where?

- NAS
 - Funding issues; Dr. Cicerone is proponent
 - States should assist with funding via Alliance membership
 - ~\$15K/state?
 - Other foundations that may benefit
- Point person needed
 - Warren "elected" to this position

3. Who is it open to?

- Open forum (fully public)
 - Taped transcripts?
 - Televised?
 - Posted on web?
- Not supported by this group
- FOIA

4. How should any working groups establish interface with the plenary Alliance body?

- Assignments for groups with deadlines & schedules

5. Should we attempt to use only a small number of face to face meetings each year and conduct other business via e-mail and conference calls?

- Virtual
 - Web page
 - Conference calls on scheduled basis
 - www.nationalacademies.org/stemcells
- Webmaster needed to control content, updating, etc.
 - NAS/BLS stem cell webpage can be used

6. Should the Alliance have a more substantive function, such as drafting model legislation, regulations, procedures, and consent forms that States can adopt where possible?

- Yes! Refer to breakout session product
- Consent forms
 - Each organization writes its own policy/legal language
 - Template needed
 - Common language preserves integrity of intent as well as stakeholder's interest
 - <http://www.isscr.org/guidelines/consent.htm>
 - <http://www.isscr.org/guidelines/mta.htm>