

**Ethics and Law Subcommittee
of the Connecticut Stem Cell Advisory Committee**

Minutes of Friday February 8, 2008

In attendance: Audrey Chapman (UCHC); Anne Hiskes (UConn, Storrs, acting chair); Marianne Horn (CT –DPH); Ann Kiessling (Harvard and CT Stem Cell Advisory Committee, via telephone); Jeremiah Mahoney (Yale, via telephone); Lisa Newton (Fairfield University).

1.a. Approval of the minutes of October 12, 2007

It was agreed that the description of Dr. Green’s Nature paper in the submitted minutes should be revised. A. Hiskes will take care of this. The minutes were approved as amended.

b. Approval of the minutes of January 11, 2008.

It was noted that the reference to the NIH Guidelines on p. 2 should be changed to “NAS Guidelines”. The minutes were approved as amended.

2. Discussion of Regulation of iPS Cells.

a. The committee noted that one spin-off from the development of iPS cells is a required reconceptualization of the role of ESCROs. Initially ESCROs were formed to maintain respect for embryos, but now the question is whether oversight extends to pluripotent cells in general.

b. Jeremiah was asked to elaborate on the recent discussion by Yale’s ESCRO about the oversight of iPS cells. He noted that iPS cells were not substantially different from hESC, except for origins. The Yale ESCRO recognized that bench research was not problematic in general, and so they would not require that the ESCRO be notified of this research. They also recognized that there could be issues concerning the application of iPS and that new issues might emerge. One future issue could be the implantation of human cells into the mammalian brain, but Yale researchers are not yet involved in projects that raise questions in this area. The Yale IACUC has been brought into the discussion and will notify the ESCRO if it sees any projects that raise a red flag.

c. It was noted that iPS research is exploding, and that discussions with scientists would be valuable. Because the science is changing so fast it would be unwise to have a tight regulatory framework.

d. Ann Kiessling reported that the Harvard ESCRO has discussed the iPS issue. There is a tension between a desire not to burden researchers with the review of iPS and the need for some degree of oversight of an unknown area. George Daley has advocated for institutional oversight out of his concern that iPS have the capability to aggregate into a morula or blastocyst in a culture dish.

Harvard has developed the policy to report the research but not review because the potential for iPS to aggregate is unknown. If there is no reporting and no communication between scientists and the ESCRO, then the institution will never know what's going on.

The question is how similar these structures would be to a normal embryo. Jeremiah Mahoney stated that he believes that there may be blocks to continuing development.

e. There was some discussion about the future of ESCROs. As the research changes different kinds of issues of public concern may arise. Will the ESCRO be the group to discuss issues of public concern or some other group? Anne Hiskes noted that at some institutions, e.g. Wisconsin and UCSF, the ESCRO was a second generation oversight committee that had developed out of existing embryo and gamete research oversight committees. This pattern could continue.

The Ethics and Law subcommittee members agree that institutions must be able assure the public that the institution is on top of its research. Oversight committees exist to protect both the science and the researchers.

3. Discussion of the next Connecticut Inter-institutional ESCRO workshop.

Given the previous discussion, there was consensus that the next ESCRO workshop should include discussions of the scope and mission of ESCROs in general and also oversight of iPS. Other issues may be included. Lisa Newton's paper "Dance of the Overseers" will be distributed as a discussion point.

Possible dates are Friday March 7 or Friday March 14. The workshop will replace the regularly scheduled March meeting of the Ethics and Law Subcommittee.

Possible expert consultants to invite are George Daley and Bob Truog (Chair of Harvard's ESCRO). Other suggested invitees are Michael Snyder, Paula Wilson, Hai-fan Li, and the ESCRO from Yale, and the stem cell IRB panel from UConn.

Anne Hiskes and Audrey will organize and host the workshop at UConn.

4. Update on StemCore.

Marianne Horn reported that she has been unsuccessful in contacting the StemCore CEO Allen Sugar even with repeated attempts. She will continue her efforts. She noted that we are interested in talking to StemCore because if the State funds private companies, it will be useful to know about the available ESCRO services.

5. Update and discussion of the State Stem Cell Initiative.

a. **Awards:** The peer review committee is scheduled to submit its reports at the end of February. The advisory committee is tentatively scheduled to meet to determine awards on March 31 and April 1, 2008.

b. Contract Group: At the last Stem Cell Advisory Committee meeting Steve Latham raised the issue whether the contract group should merge with the Ethics and Law subcommittee. The issue wasn't discussed, but is on the agenda for the March meeting. A major issue will be royalties and intellectual property in contracts with private industry.

c. ESCRO review for private companies: The subcommittee discussed the issue of who might provide ESCRO review for private companies, whether it should be private for-profit ESCROs or perhaps university ESCROs. Jeremiah noted that initially private sector ESCROs looked like a good idea, but now there are doubts about them because of the experience with for-profit IRBs.

Committee members noted that universities may not want their ESCROs to provide services because of legal liability. IRBs are increasingly targets of law suits. Marianne noted that in California companies and small institutions may use ESCROs at larger institutions, and that a "hold harmless" document should be in place, particularly for any therapeutic applications.

Audrey asked whether the nature of the applicant (e.g. private industry versus university) was a factor in the award decision. The answer is "no". The state is interested in having private companies apply for funds.

Ann Kiessling suggested that as public research university with an outreach mission, UConn may have a special responsibility to provide ESCRO services to companies or small institutions. In Boston the teaching hospitals have their own ESCROs organized around the grant administration system.

This is an issue to take up with CURE.

6. Next Subcommittee Meeting.

The next subcommittee meeting is scheduled for April 11, 2008. There was discussion of moving the meeting time to the afternoon. A meeting time of 2:00 – 4:00 was agreeable with those present. All members will be polled on their availability.