Notes from January 11 meeting (As amended and approved on Feb. 8, 2008)

Present were: Chelsey Sarnecky of CT Innovations. Audrey Chapman, Lisa Newton, Warren Wollschlager, Stephen Latham, Julius Landwirth, Jeremiah Mahoney, Ann Hiskes, Marianne Horn.

Latham "volunteered" to take notes.

No approval of October minutes, since Latham has lost them.

Update on 2008 proposals from Chelsey Sarnecky:

There were 87 submissions, requesting $41.2 million. 50 were seed grants, 24 established investigator, 7 group, and 6 core. 38 were from UCHC, 19 from UConn, 7 from Yale Medical School, 14 from Yale, 9 from seven private firms. 8 more were ruled, one by its own withdrawal, 6 from an ineligible foundation in Nevada, and one from the University of Hartford, which requested funding exceeding the limit set for its category. As to the Nevada cases: some spending of grant monies out of state is permissible, but the actual research funded must take place in Connecticut.

The question was raised how ESCRO oversight should be managed for commercial grant recipients. Are commercial ESCROs acceptable? Might CURE start its own in-state ESCRO? A recent Hasting Center article has reviewed commercial IRBs and questioned the stringency of their review. Does the RFP require any stated plan for ESCRO oversight? Some firms, like Advanced Cell Technologies, have their own in-house ESCROs—is this acceptable? Chelsey will look to determine what requirements are in place for ESCRO oversight. Commercial grant recipients will also need special contract terms relating to indemnification and commercial property; perhaps federal or New Jersey contracts can supply relevant or useful terms.

Alan Sugar cancelled the planned StemCore talk, so that agenda item cancelled. Committee will attempt to find out what they do via electronic communication. What volume of cases have they handled? From where? Do they do revisions? What are their criteria and procedures?

Questions about ESCRO jurisdiction: suppose an investigator uses Induced Pluripotent Stemcells purchased from Japan? Yale ESCRO believes it has no jurisdiction, as no embryo was involved in the cell-line's creation. The IACUC will oversee if the cells are placed in SKID mice. The ESCRO would take jurisdiction over PGD-type cell-line derivation. What about Chimeras? We should seek uniformity of ESCRO approaches to these problems across the state.

Anne Hiskes proposed a number of topics for another seminar, like the one recently hosted by Yale, on these issues. Scope of ESCRO review? Chimera issue? Commercial ESCROs? Jeremiah mentioned issue of limits of ESCRO oversight over embryonic stem

cell derivatives (neurons, myocites). Molecules from embryonic cells remain subject to Bush guidelines (nucleic acids, etc.). What about molecules from de-differentiation?

Marianne Horn reviewed the proposed changes to the stem cell law (including Julius's change clarifying that not every ESCRO function needs to follow NAS guidelines as they are amended from time to time).

Marianne Horn reported on the IASCR:

Broad participation is anticipated, e.g., from the Stowers Institute of Kansas City, from all the funding states, from Brock Reeve at Harvard, from Johns Hopkins. The meeting will be April 9 and 10 in DC. IASCR website is up.

End of formal agenda.

Audrey raised a recent Stanford meeting and the Greeley et al. paper on poor SCRO performance in dealing with serious ethical issues.

Warren will be attending a Bio 2008 session on what happens to stem cell research after the presidential elections.

Audrey noted an upcoming April 10 meeting through which FDA hopes to develop a policy on use of embryonic stem cells in human subjects. Geron and ACT have pending applications for such use.