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## **Summary of June 2005 COGR Meeting Session on Stem Cell Research**

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## SUMMARY OF JUNE 2005 COGR MEETING SESSION ON STEM CELL RESEARCH

### Stem Cell Panel Explores Current State of Federal and State Regulation

The topic of this panel was an examination of the experiences gathered by university representatives who have initiated stem cell research outside of the perimeters that currently apply to federally funded projects.

**Preparation of the Public** - Kevin Casey described the tremendous public education effort that accompanied the development of legislation in the State of Massachusetts. The question of who provides the approval for research protocols and the breadth of coverage were settled after lengthy debate, but changes may be expected once the discussion moves from the planning stage to the allocation of actual research funding. Like California, Massachusetts may also decide to establish a State Commission.

**Identification and Processing** - Ara Tahmassian described the careful system of identification of research projects and their processing at the University of California, San Francisco. The casework load for the Institutional Review Boards is much increased and the Biosafety Office's constituency was modified. New firewalls were established between the research and the financial office. A database which contains the approved protocol is searched every few months.

**Financial Issues** - Elizabeth Mora explained that Harvard University decided to operate under the premise that the stem cell projects should be administered just like any other research under Circular A-21. Cost allocation protocols use the common allocation scheme. Harvard hired outside counsel and developed a careful Q&A document which is now on the university's web page. While Harvard's experience was positive in its first year, during the second year work with derivatives proliferated, affected the University's space allocation and required adjustments. Ms. Mora emphasized that collaboration with hospital colleagues is especially important.

**Faculty Issues** - According to Anne Hannigan, Stanford University set a new policy to mandate training for faculty, oversight committees and identification of projects. Faculty are reportedly very anxious to comply because they are highly interested in the research. Since official NIH clarification of stem cell questions is still not available, the university is rather conservative.

**Intellectual Property Issues** - Revenue sharing is not mandated in the legislation in California. Wendy Streitz explained that the State of California sees the benefits of the research in the establishment of new companies, rather than in the development of a blockbuster new drug in the near term. Obviously, should that occur, there will be more discussions. The other contentious issue in California is the portability of drugs, which ties in with the question of reasonable pricing. The plan at present is to provide the drugs at cost.

**Use of Equipment** - Harvard University developed an elaborate color coding scheme identifying the nature of specific equipment as yellow, red or green, depending on whether there was federal funding and whether the equipment still had capacity. The

survey that preceded the identification was based on Harvard's requesting faculty to identify any type of equipment they would possibly be likely to use in the next five years. While most of the equipment cleared, some was placed in specific small service centers.

Towards the end, there was more discussion about the political sensitivity of research on stem cells. There was agreement that the best advocates are clearly the researchers, but that definitions are essential to the process as well as to communication and arriving at them is a difficult undertaking. The recent report by the National Academy of Sciences and its 23 recommendations were strongly recommended reading. Appendix A contains the key Sections. The panel agreed that if the recommendations were adopted by the higher education community, we might be better equipped to fend off further attacks.