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Federation of American Societies for Experimental Biology

----Quality Life Through Research----

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FASEB Comments on ISSCR *Guidelines for the Conduct of Human Embryonic Stem Cell Research*

The Federation of American Societies for Experimental Biology (FASEB) appreciates this opportunity to comment on the International Society for Stem Cell Research (ISSCR) draft *Guidelines for the Conduct of Human Embryonic Stem Cell Research*. As a coalition of 21 scientific societies representing more than 80,000 biomedical scientists and clinicians, FASEB believes strongly in reasonable and ethical oversight of biomedical research. We applaud ISSCR for your thoughtful, proactive effort to provide clear guidance to the international scientific community while addressing public concerns regarding human embryonic stem cell (hESC) research.

Generally, FASEB strongly supports the draft guidelines, and would very much like to see a coordinated effort between ISSCR and the United States' National Academies (NAS) to reconcile the two existing set of stem cell guidelines. We feel it is important to have one set of principles which can be adopted by funding entities, scientific societies, research institutions and other stakeholders concerned with hESC research, and would urge ISSCR to work with the new NAS oversight committee to reconcile the two sets of guidelines.

That being said, FASEB feels that the ISSCR draft guidelines are preferable to those of NAS in several areas. First, ISSCR has addressed issues related to harmonization of international laws and regulations regarding hESC research. While it is perhaps appropriate for the NAS guidelines to be more limited in scope, the truth is that biomedical research is a global, collaborative enterprise and it makes sense to approach ethical oversight from an international perspective. However, the question remains how best to do this; the ISSCR proposes 'concerted efforts to engage people throughout the world in honest and realistic conversations about the science and ethics of stem cell research'. FASEB thinks this is a laudable and necessary goal, but we wonder about the feasibility of such a dialogue and whether it is within the scope of a scientific oversight body. Nevertheless, we endorse the flexibility the ISSCR guidelines provide in creating an oversight mechanism at the 'institutional, local, regional, national or international level.' This allows both for compliance with varying international or local regulations, as well as providing for a greater pool of expertise to serve on an oversight body.

Secondly, FASEB thinks the categories of stem cell research outlined in the ISSCR guidelines are excellent, and would support their adoption over those of the NAS. We are particularly gratified to see discussion of clinical research involving hESC, which is conspicuously absent from the NAS guidelines. Moreover, while the NAS would allow no breeding whatsoever of chimeric animals, ISSCR allows for such provided there is strict oversight. Although FASEB agrees entirely that breeding of chimeric animals may be necessary to evaluate normal reproductive behavior or function, we would support further guidance on determining an allowable extent of cerebral cortex chimerism. Given public concerns about this area of science, leaving such decisions to local review may prove problematic. In addition, inclusion of specific examples for preventing the production of chimeric offspring while still maintaining the ability to assess some reproductive function, such as vasectomizing males, might be useful. FASEB would, however, support inclusion of such detailed information in the template documents discussed below, rather than in the guidelines themselves, if ISSCR thought such an approach might be more appropriate.

Finally, the inclusion of sample documents for informed consent, material transfer agreements, resources and documents to guide the Stem Cell Research Oversight (SCRO) committee provides an invaluable resource that serves to transform the ISSCR guidelines from abstract principles to a useable, practical oversight tool. FASEB believes the availability and distribution of such resources will facilitate the rapid adoption of oversight practices for hESC research.

FASEB has a few, relatively minor concerns with the ISSCR guidelines as currently written that we would respectfully request receive further consideration. First and foremost, FASEB fully concurs with ISSCR's dedication to 'the use of precise and accurate terminology in stem cell research.' As such, we think that it is critically important, in terms of oversight, to differentiate human or chimeric stem cell research from non-human stem cell research. It is our view that stem cell research using non-human stem cells and animal models, with no involvement of human cells or tissues, should not be subject to review by SCRO committees. Although this is fairly clear in the categories of research section of the guidelines, FASEB thinks it is important to not use the generic term 'stem cells' when the intent is to limit oversight to 'human stem cells.' For example, in section 2.1, in describing the mission of the task force in creating these guidelines reference is made to 'appropriate oversight of stem cell research' rather than 'appropriate oversight of human stem cell research.' FASEB would recommend ISSCR carefully review the guidelines to make sure such discrepancies are eliminated.

While the consent guidelines described in sections 11.2 and 11.3 are excellent and clearly understandable, we would ask there be added a 'grandfathering' provision to apply to existing stem cell lines or stages of derivation that might not meet these requirements, so as to minimize disrupting ongoing research.

In addition, in section 8.3a the ISSCR guidelines propose that the SCRO committees should assess the merit of proposals along with the scientific rationale, expertise, and ethical compliance. While it is appropriate for SCRO committees to review proposals for safety and ethical considerations, FASEB believes that the review of scientific merit falls outside the scope of this body. The granting institution will necessarily consider the scientific merit of proposals

as they go through the competitive grant review process and an additional level of meritorious review by the oversight committee is not necessary.

FASEB would like to extend our sincere gratitude to the task force and the ISSCR for undertaking this effort and its outstanding achievement in producing these guidelines. We look forward to seeing the next iteration and working with ISSCR and NAS in producing uniform guidance for adoption by the research community and policymakers.