



Federation of American Societies for Experimental Biology

— Quality Life Through Research —

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The American Physiological Society
American Society for Biochemistry and
Molecular Biology
American Society for Pharmacology and
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Genetics
Environmental Mutagen Society
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Computational Biology
American College of Sports Medicine
Biomedical Engineering Society
Genetics Society of America
American Federation for Medical
Research

President

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January 5, 2010

Michael A. Carome, M.D.
Captain, U.S. Public Health Service
Office for Human Research Protections
1101 Wootton Parkway Suite 200
Rockville, MD 20852

SUBMITTED ELECTRONICALLY TO: <http://www.regulations.gov>.

Dear Captain Carome:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the Office for Human Research Protections' (OHRP's) draft *Guidance on IRB Continuing Review of Research* and *Guidance on IRB Review of Research with Conditions*. Both documents address important components of the review process, and we appreciate OHRP's effort to help investigators better understand their responsibilities under these regulatory requirements. In this regard, we generally find the drafts to be quite useful and consistent with our members' experiences with institutional review board (IRB) procedures. We are dismayed, however, that they do little to alleviate the significant administrative burden that the review process places on researchers and reviewers. Of particular concern to FASEB is the compounding nature of the workload associated with continuing review, which hampers the progress of research and discourages service on IRBs. We offer the following suggestions for easing this burden and facilitating the review process for both investigators and IRB members.

FASEB encourages OHRP to provide additional guidance as to how IRBs could reduce the number of protocols assigned to individual reviewers. One suggestion we have is to encourage IRBs to delegate to separate teams or committees the responsibility of reviewing new and continuing protocols. New IRB members could begin their service on the new protocol committee. After reviewing a set number of active protocols, they would transition to service on the continuing review committee where they would be assigned some protocols for which they had been responsible for initial review and some that are new to them. After reviewing a fixed number of continuing protocols, reviewers would rotate off the IRB. In addition to reducing the workload of reviewers, this method may improve the quality of review insofar as continuing reviewers would be familiar with some of the protocols for which they are responsible.

For investigators, a major challenge of continuing review is aggregating the information required by the IRB and completing and submitting the requisite forms. This process is even more time consuming for investigators who are obligated to report this information separately to other oversight bodies (e.g., Food and Drug Administration, funding agencies, clinical and translational science centers). OHRP

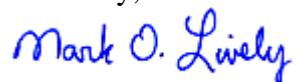
could facilitate this reporting by developing templates that investigators could use as a guide for reporting protocol and personnel changes, subject enrollment and withdrawal tallies, adverse event summaries, and other information necessary for continuing review. FASEB also recommends that OHRP work with other organizations to promote adoption of these templates so as to streamline reporting procedures as much as possible.

Section B-3 of the draft guidance on continuing review, “Evaluating the Adequacy of the Informed Consent Process,” indicates that, when appropriate, subjects must be provided with information on significant new findings that may impact their willingness to continue participation in the study. FASEB agrees that such notification is important. We are concerned, however, that the draft does not provide sufficient detail to help IRBs and investigators decide what type of information should be disclosed to participants after initial consent. We recommend that OHRP provide more detailed guidance, including specific examples, regarding the circumstances under which investigators are required to provide subjects with this information.

FASEB agrees that there are circumstances in which continuing review should be conducted more than once per year, and we appreciate that section F in the continuing review document, “Determining the Frequency of Continuing Review,” describes factors that IRBs should consider when deciding on the frequency of review. We believe this guidance could be made more useful with the addition of specific examples as to how these and other factors should impact an IRB’s determination of the appropriate interval.

On behalf of FASEB, our 23 member societies, and the more than 90,000 scientists they represent, thank you for considering this feedback. Please feel free to contact me if I can provide you with any additional information.

Sincerely,



Mark O. Lively, Ph.D.
FASEB President