



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 125,000 Researchers

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Jerry Menikoff, MD, JD
Office of Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Comments submitted via www.regulations.gov: Docket ID No. HHS-OPHS-2015-0008

Dear Dr. Menikoff,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM), “Federal Policy for the Protection of Human Subjects.” FASEB comprises 27 member societies which collectively represent over 125,000 biological and biomedical researchers. The Federation recognizes the importance of protecting human research participants and commends the Common Rule agencies for attempting to update human research regulations to better reflect today’s quickly-evolving technologies and more engaged public. We believe proposals in the NPRM have the potential to both reduce burden on investigators and institutional review boards (IRBs) and better inform research subjects, provided they are implemented thoughtfully and with proper guidance from regulatory agencies. By-in-large, FASEB approves of the proposed revisions and has advocated some of them previously. Herein we offer comments on those issues of greatest interest to the biomedical research community.

Mandating Use of a Single IRB of Record for Multisite Studies

FASEB endorses the proposed mandate that all institutions in the United States engaged in cooperative, or multisite, research studies or clinical trials must rely on a single IRB of record for evaluating the protocol and the consent form. We previously supported such a policy in our responses to the [2011 Advance Notice of Proposed Rulemaking](#), “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” the [2013 National Science Board Request for Information](#), “Reducing Investigator’s Administrative Workload for Federally Funded Research,” and the [2014 National Institutes of Health Draft Policy](#) on the Use of a Single IRB for Multi-Site Research. The Federation feels that the efficiencies achieved by eliminating protracted negotiations concerning consent forms and institutional responsibilities will far outweigh any up-front costs incurred through implementation of this policy (Question 74). FASEB believes that this mandate is a realistic option at this time, as many institutions already use reliance agreements to facilitate single IRB use for multisite studies (Question 74). We further advocate a faster timeframe for compliance than the proposed three years from the time of final publication: one year for clinical trials and two years for research studies (Question 78).

To foster trust between institutions and maximize potential efficiencies of using a single IRB, adoption of and compliance with the provision at §_.103(e)—requiring a written agreement documenting specific responsibilities of participating institutions and the IRB—will be crucial. FASEB recommends that development of model agreements, if necessary, be left to organizations with a proven track record of

producing such documents, such as the Federal Demonstration Partnership or the Council on Government Relations, as opposed to a Federal agency or office (Question 75).

Expanding the Definition of Human Subject and Using Broad Consent

The biggest proposed change in the NRPM is extending the mantle of “human subject” to non-identified biospecimens. First and foremost, to help investigators, institutions, and IRBs begin to understand the implications of this potential revision, the Federation requests that Secretary of Health and Human Services provide a definition of “biospecimen;” there is simply too much uncertainty and room for interpretation without one (Question 2). There was extensive discussion among FASEB member societies about the inclusion of non-identified biospecimens in the definition of human subject. All share concerns about impacts of this change on the collection, storage, and secondary research use of biospecimens. However, while some societies feel that the initial hardships of implementation would ultimately be outweighed by increases in public trust and research participation, others fear that the stifling effects of categorizing non-identified samples as human subjects would decimate fields of research that rely on the use of biospecimens. FASEB, as a whole, does not support either of the alternative proposals for defining human subject as these would further the goal of increased autonomy for only a subset of research participants from whom biospecimens are collected (Question 4).

Adding biospecimens to the definition of human subject would necessitate obtaining informed consent for secondary research uses, a practice not currently required. Obtaining additional consent for storage and future use, and logging each response in some sort of central tracking system, would require relatively small efforts on a participant-by-participant basis, but these efforts would quickly add up to significant time and resources spent complying with this regulation (Question 5). Institutions would face enormous additional costs to implement consent procedures and systems to track consent responses, with small community and minority-serving institutions bearing an even greater burden (Question 5). We are further concerned that this could lead to an unintentional skewing of research results against minority populations.

FASEB welcomes the proposed use of broad consent for obtaining consent to store and use subjects’ biospecimens or identifiable private information for secondary research purposes. However, we take exception to the proposed 10-year collection limit for biospecimens or information collected in non-research settings (Question 61). This appears to be an arbitrary limit and goes against the logic behind using broad consent. It would add significantly to the costs and administrative burden of tracking and re-collecting participant consent responses, and would hinder work being done on chronic conditions. Additionally, FASEB strongly recommends the use of consent forms that allow participants to opt out of participation, rather than opt in. This would set the expectation that secondary research use with biospecimens or information is accepted practice while concomitantly allowing those who oppose such use to exercise their right to decline. Moreover, an opt-out system would be less onerous for institutions to implement, and would lessen the administrative burden imposed on investigators and staff.

Extending the Common Rule to all Clinical Trials

FASEB agrees with the premise that protections for human research participants must be in place regardless of how studies are funded. Currently, Common Rule protections apply to all research involving

human subjects directly conducted or supported by a Federal department or agency which has adopted the Common Rule. In addition, many institutions voluntarily extend Common Rule regulations to all human subjects research, regardless of the source of support. Gaps in coverage exist, however, because clinical trials may be supported by non-Common Rule entities. FASEB generally supports the proposal to extend the applicability of the Common Rule to all clinical trials conducted at domestic institutions receiving federal support for non-exempt, non-excluded human subjects research. We are concerned, however, that this proposal leaves open the possibility that some industry-funded clinical trials may be subject to oversight via both Common Rule and Food and Drug Administration regulations (Question 85). FASEB recommends, therefore, that all Federal agencies that support clinical trials or human subjects research should harmonize their human subject protection regulations, regardless of whether they are a Common Rule signatory.

Ensuring Appropriate Privacy Protections

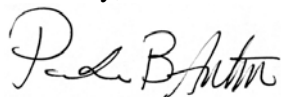
Under the current regulations, IRBs must evaluate the sufficiency of each research proposal's plan for protecting subjects' privacy and the confidentiality of their information, even though most IRB members are not data privacy and security experts. There are no standards set forth for what constitutes "adequate provisions" for protection, consequently different IRBs may have different definitions and standards. FASEB endorses the proposal at §.105 that investigators and institutions apply safeguards identified by Secretary of Health and Human Services as "necessary to protect the security or integrity of and limit disclosure of biospecimens and ...identifiable private information." We support the concept of calibrating safeguards to the sensitivity of the information but do not have sufficient expertise to comment on specific security requirements (Question 71).

Simplifying Continuing Review

Currently IRBs are required to revisit approved research on a yearly basis—at a minimum—throughout the life of the study, a process known as continuing review. FASEB supports the proposal to eliminate continuing review for minimal risk studies and studies for which data analysis and/or certain standard care procedures are the only remaining activities. These are common sense proposals that will reduce the burden on IRBs and investigators without compromising participant safety. However, we question the need for investigators to report that studies are on-going once they are closed for analysis; data analysis for clinical trials can take years, and dropping the requirement for this yearly "check-in" would further reduce administrative burden on investigators.

Thank you for considering FASEB's comments. Please do not hesitate to contact me if we can provide you with additional information.

Sincerely,

A handwritten signature in cursive script, appearing to read "P. B. Antin".

Parker B. Antin, PhD
FASEB President