



Quality Life Through Research

# Federation of American Societies for Experimental Biology

## Member Societies

- The American Physiological Society
- American Society for Biochemistry and Molecular Biology
- American Society for Pharmacology and Experimental Therapeutics
- American Society for Investigative Pathology
- American Society for Nutrition
- The American Association of Immunologists
- American Association of Anatomists
- The Protein Society
- Society for Developmental Biology
- American Peptide Society
- Association of Biomolecular Resource Facilities
- The American Society for Bone and Mineral Research
- American Society for Clinical Investigation
- Society for the Study of Reproduction
- Teratology Society
- The Endocrine Society
- The American Society of Human Genetics
- Environmental Mutagen Society
- International Society for Computational Biology
- American College of Sports Medicine
- Biomedical Engineering Society
- Genetics Society of America
- American Federation for Medical Research

Representing over 100,000 biological and biomedical researchers.

### President

William T. Talman, MD  
9650 Rockville Pike  
Bethesda, MD 20814  
Tel 301.634.7090  
Email wtalman@FASEB.org  
Web www.FASEB.org

University of Iowa  
Carver College of Medicine  
Professor of Neurology and Neuroscience  
200 Hawkins Drive  
Iowa City, Iowa 52242  
Tel 319.356.8752  
Email william-talman@uiowa.edu

September 9, 2010

Georgina Verdugo  
Director, Office for Civil Rights  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
Room 509F, 200 Independence Avenue SW  
Washington, DC 20201

**Re: RIN 0991-AB57**

VIA ELECTRONIC SUBMISSION TO: <http://www.regulations.gov>

Dear Ms. Verdugo:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to submit comments on the Department of Health and Human Services (HHS) Notice of Proposed Rule Making (NPRM) regarding “Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act.” We are particularly grateful that HHS is taking the opportunity to improve the workability and effectiveness of HIPAA, and below we offer specific comments in response to the proposals related to compound authorization and authorization of future research. We would also like to take this opportunity to comment on the HIPAA Privacy Rule research provisions more broadly and to encourage HHS to create an exemption within the Rule for research.

FASEB appreciates that a goal of HIPAA is to ensure privacy for patients involved in clinical care. We are concerned, however, that the implementation of the Privacy Rule has had an adverse impact on medical research aimed at improving human health. A recent report conducted by the Institute of Medicine concludes that the Rule has made it more difficult to design consent forms that participants can understand, increased the cost and time associated with recruiting research subjects, caused delays in institutional review board (IRB) approval, and contributed to selection bias, among other impediments to research. Such obstacles slow the progress of research critical to developing treatments for human illness and disease. While the proposed modifications outlined in the NPRM may ameliorate some of the Rule’s detrimental effects, we believe that the collective interests of the research community and study participants could best be served by exempting research from the Privacy Rule, extending the Common Rule—which currently provides mechanisms to protect research participants—to non-federally funded research, and strengthening data privacy and security measures. FASEB recognizes that such broad changes are beyond the scope of this rule-making process. However, we hope that you will consider these comments as you explore ways to facilitate biomedical research and strengthen the privacy and security of protected health information (PHI).

With regard to the specific suggestions made in the NPRM, FASEB supports the proposal to amend the Privacy Rule to allow a covered entity to combine conditioned

and unconditioned authorizations for research. We agree that the authorization should clearly differentiate between the conditioned and unconditioned research components and allow individuals the option to opt in to the conditioned research activities. To distinguish between conditioned and unconditioned research components, we recommend developing forms that provide complete explanations of the conditioned and unconditioned authorizations in separate sections and requiring patients to sign off on each of those sections. This change will facilitate the research authorization process and minimize the confusion that results when patients are presented with multiple authorization forms for a single study.

FASEB also agrees that HHS should modify its interpretation that the Privacy Rule requires authorization for future research to be study-specific. We favor an interpretation that would permit an authorization for future use and disclosure of PHI for research purposes, so long as the intent to use PHI for diverse future research needs, each of which will require approval by an IRB, is clearly conveyed in the authorization. We do not support requiring a description of future research activities in the authorization as it is not possible to predict all future research needs. Nor do we favor certain disclosure statements on the authorization in cases where future research may encompass sensitive research activities. While we appreciate that research participants may have heightened sensitivity to their PHI being used for certain purposes, the nature of these concerns is likely to vary among individuals and change over time with advances in research, refinement of data security measures, changing attitudes toward research, and so forth. As such, it would be difficult if not impossible to ascertain in advance which research areas should require additional disclosures.

We would also like to take this opportunity to comment on the de-identification standards under the Privacy Rule. For PHI to be considered de-identified, the current standards require the removal of so much important health information that the utility of the data for many research projects is diminished. Moreover, the de-identification process does not guarantee that individuals cannot be re-identified, and advancements in technology and the availability of large public data bases are likely to make re-identification even easier. We encourage HHS to create a modified de-identification standard for research purposes that is more closely aligned with the Common Rule. We would especially urge HHS to eliminate service dates from the list of identifiers that have to be removed under the safe harbor method in order for PHI to be considered de-identified. Removal of service dates is particularly problematic for researchers studying health issues for which information about treatment dates is important (e.g., seasonal influenza).

Thank you for considering these comments. Please feel free to contact me if I can provide you with any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "William T. Talman". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

William T. Talman, MD  
FASEB President