ENDOCRINE SOCIETY
Hormone Science to Health

January 04, 2016

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

Dear Dr. Menikoff,

The Endocrine Society appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) for the Federal Policy for the Protection of Human Subjects (the Common Rule). We believe that the many of the proposed changes will reduce research-related administrative burden and clarify ambiguity while strengthening important protections for research participants. Several of these positive changes are highlighted in our comments. However, we are concerned about the proposal's intent to extend the definition of human subjects research to research involving human biospecimens.

Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. Our membership of over 18,000 includes clinical, translational, and basic scientists. Many of our members conduct research with human participants and use biospecimens in their research. As members of the Federation of American Societies for Experimental Biology (FASEB), we also endorse the Federation's letter submitted separately to regulations.gov. Our letter is intended to be complimentary to FASEB's letter and reflect our Society's strong translational and clinical research community.

Research Involving Biospecimens

Our principal concern is the proposed expansion of the definition of human subjects research to include research involving human biospecimens, and the proposed process for re-consenting human research participants. Our understanding is that information used to develop these changes to the Common Rule derives from small data sets. Therefore these changes may be premature. We note that many patients value the opportunity to contribute meaningfully to research studies and might view the re-consenting process as an additional burden, or source of psychological stress, that will limit their motivation to to fully contribute to research. The process of re-consenting patients might be impossible in some cases, for example due to death or relocation, thereby jeopardizing the entire research study. Additionally, the costs of re-consenting significant numbers of patients would introduce severe barriers, in particular for under-resourced institutions, possibly precluding their involvement in clinical research, thus limiting the generalizability of the data obtained from the research effort. Therefore, any proposed limits on broad consent should be informed by additional data on patient perspectives, and all data used to arrive at the proposed revisions should be provided to the biomedical research community so that we can understand and comment on the rationale for proposed limits on broad consent before they are enacted.

We contend that the proposed 10-year limit for broad consent for research involving biospeciments is arbitrary, and not a "sufficiently long enough time period to appropriately facilitate research using biospecimens and information." This limit would impose severe administrative and financial burdens on researchers and institutions. For example, studies that seek to examine the links between cancer initiation and genetics or environmental exposures might examine human biospecimens collected and stored for more than

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

10 years. We therefore request that the 10-year limit on broad consent for research involving biospecimens be eliminated from the update to the Common Rule.

Other Proposals in the NPRM

In our review of the proposed changes to the Common Rule, we identified several provisions in particular that, if implemented properly, will streamline review processes without negatively impacting patient safety. We ask that the following proposals be adopted in the final rule to reduce burdens for investigators and Institutional Review Board (IRB)s, and ensure that regulatory requirements are better harmonized across agencies.

- We are encouraged by the proposal to eliminate continuing IRB review for minimal risk studies and for studies that have progressed to the point of analyzing data or accessing follow-up data from standard clinical procedures. The Endocrine Society believes that IRB reviews and "check-ins" should be minimal for studies in which data collection has been completed or in which the only risk is privacy.
- We look forward to the proposed Secretary's guidance on how consent forms can be written to comply with new regulatory requirements. The Endocrine Society asserts that, where possible, consent forms should conform to a proposed length with standardized language.
- The proposal to exempt research studies begun before the new rule takes effect is absolutely necessary and should be retained. Without this exemption, the revisions to the Common Rule will generate substantial barriers to ongoing outcomes studies that are using samples that are collected and maintained over long periods. We recommend that this proposal be further clarified to avoid additional burdens on studies in progress.

In conclusion, the Endocrine Society views patient safety as a top priority in both the implementation of clinical studies and in the practice of patient care and strongly supports regulations that protect human research participants while not hindering the progress of clinical research. The Endocrine Society applauds the Department of Health and Human Services and Office of Science and Technology Policy in their efforts to revise the Common Rule to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. Thank you for considering the Endocrine Society's comments. If we can be of any assistance in your efforts, please contact Joseph Laakso, PhD, Associate Director for Science Policy at jlaakso@endocrine.org.

Sincerely,

Lisa H. Fish MD

Lisa Fish, MD
President
Endocrine Society