New York State Bar Association
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COMMENTS SUBMITTED ON BEHALF OF THE HEALTH LAW SECTION COMMITTEE ON MEDICAL RESEARCH AND BIOTECHNOLOGY

On

The Proposed Revisions To The Common Rule "Federal Policy For The Protection Of Human Subjects" In The Notice Of Proposed Rulemaking (NPRM) Published In The Federal Register On September 8, 2015

Electronic Docket number is HHS–OPHS–2015–0008

Health #3 January 4, 2016

As members of the New York State Bar Association Health Law Section, Committee on Medical Research and Biotechnology, we are pleased to offer these comments on the proposed revisions to the Common Rule "Federal Policy for the Protection of Human Subjects" in the Notice of Proposed Rulemaking (NPRM) that was published in the Federal Register on September 8, 2015. (80 Fed. Reg. 53933).

The NPRM seeks to balance the protection of human subjects involved in research with efforts to conduct valuable research. To that end we raise the following comments for consideration to reduce the burden placed on investigators that may delay such research.

1) A Biospecimen Definition.

Developing a definition of the term "biospecimen" for insertion in Section _____.102" would be helpful as it is a key term in the proposed regulations. In the development of such new definition it should be understood that using nucleic acids as a defining parameter is not sufficient as protein polymorphisms, organic analytes and other future biochemical markers may emerge as new polymorphic systems that could be used to identify individuals and groups of individuals. This would require a definition that may be modified as new identifier technology is developed and could be updated in periodic guidance by the Office of Human Research Protection (OHRP).

2) Possible Waste of Resources and Need For Education.

Any modification to the Common Rule must be understood and adequately implemented by local Investigational Review Boards (IRBs) and protocol management review committees that protect human subjects. We are concerned that a study may be deemed exempt or excluded under the proposed changes to the Common Rule, may still be subject to an institutional full review due to a lack of familiarity with such changes. This may result in delays in protocol review and approval of protocols and reeducation of human subjects prior to approval. We request that the final regulations require education of local IRBs and other local protocol management review committees to ensure that the new regulations, meant to streamline the review process by excluding certain research from extensive internal IRB review, is implemented effectively.

There is a concern that a study may be deemed exempt or excluded under the proposed NPRM but may still be subjected to an institutional full review, resulting in non-peer lay review, delays, and reeducation of human subjects prior to approval.

3) Reliance on Investigators Regarding Exclusion Categories.

To facilitate the implementation of the modifications to the Common Rule, as well as the protocol review and approval process, it may be helpful to allow investigators to make self-determinations regarding the types of research activities covered in particular exclusion categories. At one New York medical institution, investigators fill out a brief questionnaire and follow a simple flow chart to determine whether or not their research study falls in an exclusion category. It would be helpful if the Office for Human Research Protections could develop a similar, brief template that IRBs could implement in their institutions.

4) Impediment of Genomic Research.

In describing the research to which the proposed changes to the Common Rule would be applicable, one alternative suggested by the NPRM is that certain research on genomic data would be considered human subject research under the Common Rule; all research on whole genome sequence data under Alternative A and, under Alternative B, research on any genomic sequence data combined with other information. A balance must be struck, however, between advancing research in the field of genomics and affording appropriate privacy protections for individuals from whom the data is derived. If research involving genomic data is deemed to be human subject research, as in Alternatives A and B, this may impede the progress of genomic research in the United States. Discoveries of new therapies using genomic science is largely dependent on researchers having access to a pool of genomic data from multiple prior studies. Such large pools of data are being created nationwide due to "next generation sequencing" technology that has allowed genomic sequencing to occur faster and at a lower cost than ever before. New possibilities in medical research are constantly opening as the data made available to researchers increases exponentially every year. One researcher has stated that within the next decade, genomics technology will generate somewhere between 2 and 40 exabytes of data per year.[1] Therefore, if access to data from multiple studies were inhibited, this would be a lost opportunity to advance science and medicine. Such new discoveries using genomic research is facilitated by allowing researchers to have access to the data generated from multiple, previous studies across large datasets of genomic information. The proposed Alternative A and B language may hinder future studies that seek to utilize past research. For example, a researcher may wish to query a database of genomic data that is derived from 15 previously conducted research protocols for a new study. If either

[1] Robert Gebelhoff , Washington Post, "*Sequencing the genome creates so much data we don't know what to do with it*" (July 7, 2015). Available at http://www.washingtonpost.com/news/speaking-of-science/wp/2015/07/07/sequencing-the-genome-creates-so-much-data-we-dont-know-what-to-do-with-it/.

Alternative A or B become part of the modified Common Rule, any such research could be considered human subject research. The study would then need an IRB to collect and review the relevant informed consents from all 15 prior protocols to confirm that such proposed research study on the previously collected genomic data would be permissible, even where the researcher would not have access to personally identifying information and only to the genomic sequence. This has the potential to slow down the progress of research in the area of genomics research, impeding scientific and medical advancement.

We thank you for the opportunity to submit these comments and look forward to a continued discussion.

Submission by the Committee on Medical Research and Biotechnology of the New York State Bar Association Health Law Section.

Committee Co-Chairs: Samuel J. Servello, Esq. and Alex Brownstein, Esq.