



American Society for Investigative Pathology
Investigating the Pathogenesis of Disease

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Stephen Rosenfeld, MD, MBA.
Chair, Secretary's Advisory Committee on Human Research Protections (SACHRP)
Quorum Review IRB
c/o Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Jerry Menikoff, MD, JD
Executive Secretary, SACHRP
Director, Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Drs. Rosenfeld and Menikoff:

The American Society for Investigative Pathology (ASIP) is a nonprofit educational 501(c) 3 organization primarily representing the academic pathology research community. We are a society of biomedical scientists who investigate disease, linking the presentation of disease in the whole organism to its fundamental cellular and molecular mechanisms. Our members use a variety of structural, functional, and genetic techniques, seeking to ultimately apply research findings to the diagnosis and treatment of patients.

New Provisions in Common Rule: ASIP has deep concerns regarding the provisions in the final Common Rule requiring that federal agencies and departments re-examine the meaning of "identifiable biospecimen" within one year and at least every four years thereafter.¹ With the release of the final Common Rule, a new provision was added (§____.201(e)(7)) requiring federal departments and agencies implementing the Common Rule to "...regularly, upon consultation with appropriate experts, re-examine the meanings of the terms... "identifiable biospecimen.""² This effort will take place every four years, include consultation with appropriate experts and include "an assessment as to whether there are analytic technologies and techniques that should be considered by investigators to generate identifiable private information or identifiable biospecimens."³ Should a determination be made that particular analytic technologies or techniques when applied to biospecimens that are not identified, do lead to the generation of identifiable information, those technologies are techniques will be "placed on a list of technologies and techniques satisfying that determination, and recommendations might accordingly be made with regard to relevant issues related to consent

¹ Federal Register, Vol. 82, No. 12, January 19, 2017, pgs. 7169 and 7260.

² Fed Reg., p. 7169

³ Fed Reg., p. 7169

and privacy and data security protections.”⁴ The final Common Rule clearly states that whole genome sequencing will be one of the first technologies to be evaluated.

ASIP Recommendations:

- The use of a particular technology during research does not render a biospecimen identifiable. It is the conduct of a researcher in pursuing the research that may render the biospecimen potentially identifiable. ASIP recommends that researchers pursuing genetic, proteomic, or other identifiable data sign an agreement that they will comply with existing HIPAA regulations and have no intent to identify an individual’s identity, regardless of the technologies that are used in the research.
- Similar to the significant consequences that a health care professional may face for violating confidentiality and privacy requirements, the conduct of researchers should be the focus. Severe consequences should exist for those misusing research information in an attempt to re-identify an individual. A particular technology used during the course of research is not what renders a biospecimen potentially identifiable. There should be significant consequences for researchers violating the trust and confidence of research participants – regardless of whether the specimen was meant to be identified or de-identified when donated. These consequences should be similar to those incurred when violating HIPAA regulations.
- Give careful consideration to Recommendation 4 in the recent report of the National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century*, which states “regulations and their enforcement should take into account the risk of malfeasance and the overall cost of compliance.... Actions need to be targeted where transgressions occur.”⁵

Examples of problems with §____.201(e)(7) as proposed:

- During the process of conducting research on lung cancer, whole genome sequencing is performed on both de-identified normal and cancerous cells. Only the information that differs between the two cell types is retained; all other information is deleted from the records as the goal is to study the genomic differences between the two cell types. While whole genome sequencing was used as a cost-effective strategy for identifying genomic changes, the results of whole genome sequencing were never retained. There is little risk of re-identifying the individual from the data used in the research. The research process used a potentially problematic technology but did not retain any of the data generated by that technology. Would researchers be restricted from using one methodology for analyzing nonidentified specimens (whole genome sequencing and then pruning of the data) in favor of another mechanism that might be more costly? Less accurate? Less complete?
- A technology is developed during the course of a research study that uses nonidentified specimens and this new technology is adopted as a better method than that previously proposed. The technology is subsequently determined via §____.201(e)(7) to be on a list that renders the specimen identifiable and therefore requiring consent. What is to become of that research?

⁴ Fed Reg., p. 7169

⁵ Committee on Federal Research Regulations and Reporting Requirement; Committee on Science, Technology, and Law; Board of Higher Education and Workforce: Policy and Global Affairs; National Academies of Sciences, Engineering, and Medicine. *Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century*. National Academies Press. DOI: 10.17226/21824. 2016. p. 15

- A researcher has collected over 200 samples, all nonidentified, of a rare blood disorder; some of these samples are over 20 years old. When studying these samples, may a researcher use any technologies deemed to render a specimen identifiable? If they are prohibited from using archived collections of specimens without informed consent, does this not nullify the value of longstanding, nonidentified specialty tissue collections, especially for rare disorders?

ASIP is committed to supporting the ethical treatment of human subjects as it conducts pathology research. We strongly believe that there are fundamental flaws with the portion of the Common Rule (§____.201(e)(7)) that might render a specimen “identifiable” based on the technology used. As the administration proceeds with implementing this aspect of the Common Rule, ASIP requests that consideration be given to the issues raised above. ASIP appreciates the opportunity to raise our concerns with SACHRP and we hope that our comments may further refine the ongoing discussions. We would gladly participate in those discussions if given the opportunity.

Should you have questions or concerns, please feel free to contact Mark E. Sobel, MD, PhD at 240-283-9700 or mesobel@asip.org.

Sincerely yours,



Mark E. Sobel, MD, PhD
Executive Officer