DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the Assistant Secretary for Health

Office for Human Research Protections
Rockville, Maryland 20852

March 7, 2017

ICMJE Secretariat
c/o Christine Laine, MD, MPH
Editor in Chief,
Annals of Internal Medicine
Senior Vice President,
American College of Physicians
190 N Independence Mall West
Philadelphia, PA 19106

Dear ICMJE Secretariat:

You have provided the following information with some related questions about how the Common Rule applies to certain uses of data collected from prior research studies:

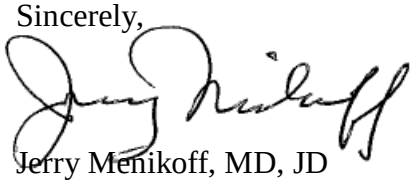
> "A researcher has completed an IRB approved interventional human research trial that was appropriately registered, reported and published. The consent form for the study makes no mention of the use of the data by other investigators. As part of that study, data (which may include genetic analysis of blood and tissue samples) were gathered on study participants and the data gathered have been de-identified. Does the OHRP consider it human subjects research for a third party, either related to or unrelated to the original researchers, to use those de-identified data for any or all of the following purposes?
>
> 1. Replication of the original published study results.
> 2. Use of the data to reproduce the general approach to the study, but using a different statistical approach.
> 3. Use of the data in an individual patient meta-analysis of a scientific question.
> 4. Use of the data for purposes unrelated to the original study goals, such as searching for interactions between treatments and outcomes or doing sample size calculations for a new study using similar patients.
> 5. Making the de-identified data available in a publicly accessible repository for any future analyses by parties not associated with the original research group."

In answering these questions, we first note that for the Common Rule to apply to an activity, it must involve, as you note, both "research" and "human subjects" (45 CFR § 46.101(a)). The term "human subject" is defined in section 102(f) to involve obtaining, about a living individual, either data through "intervention or interaction" with that individual, or "identifiable private information" about that individual.

In the five scenarios you describe above, the third party who is being given data is not interacting or intervening with the original research subjects. Accordingly, the only remaining issue with regard to whether there is any involvement of human subjects would be if the third party was provided with identifiable private information. Assuming that by the term "de-identified data" you mean data that would not constitute identifiable private information in the hands of the third party, as that term is defined in the Common Rule, then it would appear that the third party is not using human subjects, and that its activities would not be subject to the Common Rule.

We further note that OHRP has provided guidance indicating that under certain circumstances, data can even be released with a "code" in place, and the use of that data for research purposes by a recipient would nonetheless still lead to the conclusion that the recipient is not using human subjects. See *Coded Private Information or Specimens Use in Research, Guidance (2008)*, available at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html. Assuming that the conditions of that guidance document are met, then in your five scenarios the data could be coded, and the conclusion would still follow that the activities of the third party do not involve human subjects, and thus that the Common Rule does not apply.

Sincerely,



Jerry Menikoff, MD, JD
Director, Office for Human Research Protections