Global Leader | Proven Expert

April 17, 2018

Paul M. Wax, MD
American College of Medical Toxicology (ACMT)
10645 N Tatum Blvd, Ste 200-111
Phoenix, AZ 85028

Dear Dr. Wax:

SUBJECT: REGULATORY OPINION—RESEARCH DOES NOT INCLUDE HUMAN SUBJECTS, IRB REVIEW NOT REQUIRED
Protocol Title: ToxIC Qualified Clinical Data Registry (TQCDR)
Investigator: Paul M. Wax, MD

This letter is in response to your request for an opinion as to whether your research, *"*ToxIC Qualified Clinical Data Registry (TQCDR)*"* would constitute human subject research requiring IRB review.

This opinion is based on federal regulation 45 CFR 46 and associated guidance.

In accordance with the regulation and guidance, the use of coded information is not research involving human subjects and thus does not require IRB review. The following is the basis for this opinion.

Federal regulation 45 CFR 46.102(f) defines a human subject as—

> Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
> (1) Data through intervention or interaction with the individual, or
> (2) Identifiable private information.

In guidance entitled, Guidance on Research Involving Coded Private Information or Biological Specimens, OHRP explains when research involving coded private information or biological specimens would not be considered to involve human subjects.

For example, OHRP does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

(a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, (note that HHS regulations do not require the IRB to review and approve this agreement);

(b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

(c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

This protocol meets these requirements. First, the information that would be involved in this research were not collected specifically for the currently proposed project; rather the information (clinical data) was collected for a national registry. Second, you have confirmed that the investigators and the holder of the key to the coded data have entered into an agreement prohibiting the release of the key to the investigators under any circumstances. Therefore WIRB has determined this is not research involving “human subjects”.

This determination that this research does not involve human subjects can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WIRB (such as an internal IRB) to make such determinations. WIRB cannot provide a determination that overrides the jurisdiction of a local IRB or other institutional mechanism for making such determinations. You are responsible for ensuring that each site to which this determination applies can and will accept WIRB’s determination.

Please note that any future changes to the project may affect its status as research that does not involve human subjects, and you may want to contact WIRB about the effect these changes may have on the status before implementing them. WIRB does not impose an expiration date on its determinations of research that does not involve human subjects.

You may address the Board in person or in writing regarding its action. If you wish to address the Board in person or if you have questions, please contact WIRB Regulatory Affairs at 360-252-2500, or e-mail RegulatoryAffairs@wirb.com.

AI:dao
Coded Data-Exemption-Wax (04-17-2018)
cc: Sharan Campleman, PhD, ACMT
WIRB Accounting
WIRB Work Order #