



May 21, 2014

Laura Brass, PhD
TriNetX, Inc.
c/o MPM Capital
Hancock Tower 54th Floor
200 Clarendon Street
Boston, MA 02115

Dear Dr. Brass:

SUBJECT: IRB EXEMPTION—REGULATORY OPINION
Protocol Title: The TriNetX Network: A federated, searchable database of de-identified patient information.
Investigator: Laura Brass, PhD

This letter is in response to your request for an opinion as to whether your research “The TriNetX Network: A federated, searchable database of de-identified patient information,” 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 de-identified information in research without intervention or interaction with humans does not involve human subjects and thus is not research requiring 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.

This research does not involve human subjects. The Phase I aggregate count data will be collected in a way so that the subjects cannot be identified, directly or through identifiers linked to the participants. Therefore WIRB has determined this is not research involving “human subjects.”

Western Institutional Review Board®

1019 39th Avenue SE Suite 120 | Puyallup, WA 98374-2115

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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.

If you have any questions, or if we can be of further assistance, please contact Viveca Burnette, B.A., at 360-252-2880, or e-mail RegulatoryAffairs@wirb.com.

Sincerely,

A handwritten signature in black ink that reads "Amy A. Larson for". The signature is written in a cursive, flowing style.

Viveca Burnette, B. A.
IRB Chair

VDB:dao
NHS Exemption- Brass (05-21-2014)
cc: WIRB Accounting
WIRB Work Order #1-834667-1