



April 3, 2020

Osagie Ebekoziem, MD MPH CPHQ
T1D Exchange
11 Avenue de Lafayette
5th Floor
Boston, Massachusetts 02111

Dear Dr. Ebekoziem:

SUBJECT: IRB EXEMPTION—REGULATORY OPINION
Investigator: Osagie Ebekoziem, MD MPH CPHQ
Protocol Title: Surveillance of COVID-19 in Patients with Type 1 Diabetes

This is in response to your request for an exempt status determination for the above-referenced protocol. Western Institutional Review Board's (WIRB's) IRB Affairs Department reviewed the study under the Common Rule and applicable guidance.

We believe the study is exempt under 45 CFR § 46.104(d)(4), because the research involves the use of identifiable private information/biospecimens; and information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

This exemption determination 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 exemption determinations. WIRB cannot provide an exemption that overrides the jurisdiction of a local IRB or other institutional mechanism for determining exemptions. You are responsible for ensuring that each site to which this exemption applies can and will accept WIRB's exemption decision.

Please note that any future changes to the project may affect its exempt status, and you may want to contact WIRB about the effect these changes may have on the exemption status before implementing them. WIRB does not impose an expiration date on its IRB exemption determinations.

Western Institutional Review Board®

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If you have any questions, or if we can be of further assistance, please contact R. Bert Wilkins, J.D., M.H.A., C.I.P., at 360-252-2852, or e-mail RegulatoryAffairs@wirb.com.

RBW:mr

D4-Exemption-Ebekozi (04-03-2020)

cc: Nicole Rioles, T1D Exchange
Kelsie LaFerriere, T1D Exchange
WIRB Accounting
WIRB Work Order 1-1290115-1