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June 10, 2021

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

Dear Dr. Ebekoziem:

SUBJECT: IRB EXEMPTION—NOT HUMAN SUBJECTS RESEARCH
Investigator: Osagie Ebekoziem, MD, MPH
Protocol Title: Reducing Inequities In Diabetes Technology Device Use

This letter is in response to your request for an opinion as to whether the above referenced research would constitute human subject research requiring IRB review.

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

We determined this study is exempt from IRB review because it does not meet the definition of human subject as defined in 45 CFR 46.102. Specifically, only aggregate-level patient data will then be analyzed to determine if the training impacts the use of pumps in certain patient populations. No patient-level identifying information is collected retained. The training of the medical staff is a not a research activity, as it is not a systematic investigation.

This 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 WCG IRB (such as an internal IRB) to make such determinations. WCG IRB 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 WCG IRB's determination.

WCG IRB's determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Please discuss with the local IRB authorities in the country where this activity is taking place to determine if local IRB review is required.

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 WCG IRB about the effect these changes may have on the status before implementing them. WCG IRB 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 Erin Brower, MS, C.I.P., at 919-595-0983, or e-mail RegulatoryAffairs@wirb.com.

EB:mr

NHS-Exemption-Ebekozen (06-10-2021)

cc: Ori Odugbesan, T1D Exchange
Saketh Rompicherla, T1D Exchange
WCG IRB Accounting
WCG IRB Work Order 1-1443077-1