DATE: August 23, 2023

TO: UTMB Researcher

FROM: Anne Clark, BA, CIP
Director, Human Research Protection Program

RE: IRB Acknowledgement of Not Human Subject Research
Title: Secondary Analysis of data from TriNetX

Utilization of data from the TriNetX database UTMB IRB 20-0085 titled Deidentified Collections of Electronical Medical Records For Internal(I2B2) and External (TriNetX) Access does not require UTMB IRB review as it is secondary analysis of existing data, does not involve intervention or interaction with human subjects an is de-identified per the de-identification standard defined in Section 164.512(a) of the HPAA Privacy Rule. The process by which the data is de-identified is attested to through a formal determination by a qualified expert as defined in Section 164.514(b)(1). Therefore, the data does not meet the definition of a human subject as outlined at 45 CFR 46.102 and is deemed not human subject research which does not require IRB review and/or approval.

If you have any questions related to this project or the IRB, you may telephone me, at 409-266-9434.