To: Whom It May Concern

From: Sarah E. Nelson, PhD, IRB Chair
Erica Dwyer, MD, PhD, IRB Vice Chair

Date: December 10, 2021

Subject: Cambridge Health Alliance (CHA) Guidance: Use of Publicly Available, De-identified Data Sets for Research

As of the date of this memo, CHA has determined that IRB review for projects involving ONLY the use of publicly available, de-identified data sets for research will no longer be required, **unless** the individual requires an official IRB determination for their records. If you require an official IRB determination, please submit your request to the IRB via Cayuse **before** any research activities take place.

Use of publicly available, de-identified data sets for research does not meet the definition of research involving human subjects.

> According to 45 CFR 46.102(e), human subject means a living individual about whom an investigator (whether professional or student) conducting research:
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> > (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
> >
> > (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
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> De-identified means that all HIPAA or other identifiers have been removed from the data set. Please see CHA Policy A-COM-0004 for more information.

Note: Before initiating an activity, it is important to accurately determine if it is research that requires IRB review and oversight because Federal regulation does not give an IRB the authority to provide retrospective or retroactive approval. If a research project begins before IRB approval is obtained, it potentially jeopardizes not only the safety, welfare, and/or rights of participants, it also puts at risk the investigator's and/or the Institution's ability to conduct research and receive Federal funding. If you have ANY doubt, please contact the CHA IRB Office for guidance and help PRIOR to initiating the project.