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RE: Requirements for IRB Review Use of PHIS Datasets

This letter is to confirm that the CHOP IRB does not consider research that involves receipt and analysis of data from the Physician Health Information System (PHIS), maintained by the Child Health Corporation of America to meet the definition of human subjects research.

PHIS data sets are derived from over forty hospitals representing the entire nation, the data are coded using enrcrypted medical record numbers and the included identifiers are consistent with those defining a limited data set. The IRB does not consider the receipt or use of these data to meet the definition of human subjects research at 45 CFR 46.102(f) because the participants are not readily identifiable.

"…OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, OHRP does not consider research involving only coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

> *(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and*
>
> *(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:*
>
> > *(a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances…"*

A data use agreement must be in place between the provider of the data (CHCA) and CHOP to ensure to satisfy the requirements of HIPAA and to ensure that the investigator will not seek to re-identify the participants.

It is the policy of the CHOP IRB to permit investigators to determine whether or not proposed research meets the definition of human subjects research; the IRB does not mandate prior review.

Sincerely,

Mark Schreiner, MD.

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