Dordt University HIPAA Authorization for Research

If you are collecting data from a covered entity or through a covered entity, then you must complete and submit this form. Covered entities are health care providers, health plan, or health care clearinghouse.

___ Have you attached your current certificate of completed HIPAA training?

___ Are you collecting PHI (protected health information)? Please check which of the following you are collecting from patients, their relatives, household members, or employers. If you say *yes* to any of the following, you are using PHI.

_____ Name
_____ Any geographic identifiers smaller than a state
_____ Dates except for years (including birth, admission, discharge, death)
_____ Social security numbers
_____ Telephone numbers
_____ Fax number
_____ Email address
_____ Medical record numbers
_____ Account numbers
_____ Health plan beneficiary numbers
_____ Certificate/license numbers
_____ Vehicle identifiers and serial numbers including license plates
_____ Web URLs
_____ Device identifiers and serial numbers
_____ Internet protocol addresses
_____ Full face photos and comparable images
_____ Biometric identifiers (i.e. retinal scan, fingerprints)
_____ Any unique identifying number or code
_____ None of the above

If you are not collecting any of the above, HIPAA Rules do not apply. Please indicate that in your proposal.

___ If you have met the criteria for HIPAA PHI, your consent for must be signed by an individual who is authorized under law to provide consent or permission to participation in the research.

An electronic signature is acceptable, but must be separate from the data

To be a consent form and HIPAA authorization, it must include the following additional elements to a consent form

Authorization core elements to be included in the text (45 CFR 164.508(c)(1))

___ A specific and meaningful description of the information to be used or disclosed
___ The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes
___ The name or identification of the persons or class of persons authorized to receive disclosures of the PHI and to use the PHI for research-related purposes
___ A research study specific description of the purpose of each use or disclosure
___ An expiration date or event, or a statement “end of research study” or “none” when appropriate (e.g., for a research database)

Authorization required statements (45 CFR 164.508(c)(2))

___ A statement that the individual may revoke the authorization to end the collection of data and how to do so. The investigator may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such authorization before it was revoked;
___ A statement that an individual’s clinical treatment may not be conditioned upon whether or not the individual signed the consent; however, participation in research may be conditioned on a signed consent.
___ A statement that information disclosed under the authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA.

If the researcher believes their study is appropriate for a HIPAA Authorization waiver, they should contact the chair of the IRB directly to discuss the requirements.

The researcher must maintain documentation for six years after close of study (45 CFR 164.530(j))

based on: https://irb.research.chop.edu/sites/default/files/documents/irbsop707_hipaa_1-22-19.pdf