

**Institutional Review Board**

***HIPAA Waiver of Authorization Form***

Principal Investigator:

Study Title:

***Under the federal privacy rule, ‘HIPAA’, research use or disclosure of an individual’s protected health information (PHI) requires the individual’s authorization, unless the use or disclosure is determined by the IRB to qualify for a waiver***. (See [SACHRP Recommendations on Interpretation and Application of the "HIPAA Exemption"](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-december-12-2017/index.html))

**I.** List, in detail, the health information that is to be collected for the research activity, and explain why this health information is the minimum necessary to meet the research objectives. Use the attached form (page 3) to view the 18 specific HIPAA identifiers of an individual and list which will be recorded.

**II.** Identify the source of the health information (e.g., medical record etc). Note that the source (‘entity’) must be able to account for disclosures made under this waiver.

**III.** The use or disclosure of PHI for this research activity must involve no more than minimal risk to the privacy of individuals, based on the presence of the following 3 elements:

a. An adequate plan to protect the identifiers from improper use and disclosure. Describe this plan and indicate where PHI will be stored, and who will have access (this list must include all of the entities that might have access to the PHI, such as student researchers, hospitals, study sponsor, IRB, OHRP, FDA, data safety monitoring boards). **The plan is:**

b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is required by law. **The plan (including HOW the identifiers will be destroyed, e.g., shredding documents etc.) is**:

c. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for other research which would be specifically approved by the Hanover College IRB and would qualify for a waiver of authorization. *Principal investigator submission of this document signifies assurance of compliance with this requirement.*

d. Adequate written assurances that the purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. *Principal investigator submission of this document signifies assurance of compliance with this requirement.*

**IV.** The research cannot practicably be carried out without the waiver. **Explain why:**

**V.** The research could not practicably be conducted without access to, and use of, the PHI. **Explain why:**

My submission of this form assures that the PHI obtained as detailed above will not be reused or disclosed to any other person or entity, except as required by law, or for other research specifically approved by the Hanover College IRB (and again, qualifying for a waiver of authorization).

**If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval from Hanover College IRB.**

Researcher Signature Date

Name typed/printed

The following is a list of the eighteen specific identifiers of the individual or of relatives, employers, or household members of the individual:

**45CFR164.514(b)(2)(i):**

**(A)** Names.

**(B)** All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

**(C)** All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

**(D)**  Telephone numbers.

**(E)** Fax numbers.

**(F)** Electronic mail addresses.

**(G)** Social security numbers.

**(H)** Medical record numbers.

**(I)** Health plan beneficiary numbers.

**(J)** Account numbers.

**(K)**  Certificate/license numbers.

**(L)** Vehicle identifiers and serial numbers, including license plate numbers.

**(M)**  Device identifiers and serial numbers.

**(N)** Web Universal Resource Locators (URLs).

**(O)** Internet Protocol (IP) address numbers.

**(P)** Biometric identifiers, including finger and voice prints.

**(Q)** Full face photographic images and any comparable images.

**(R)** Any other unique identifying number, characteristic, or code, except as permitted by paragraph (C) of this section.