# HIPAA Identification Authorization Form

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects my individually identifiable health information (protected health information). The privacy law requires me to sign an authorization (or agreement) in order for researchers to be able to use or disclose my protected health information for research purposes in the study entitled *[insert title of study/protocol/project].*

I authorize *[name of investigator]* and his/her research staff to use and disclose my protected health information for the purposes described below. I also permit my doctors and other health care providers to disclose my protected health information for the purposes described below.

## My protected health information that may be used and disclosed includes:

* *[List all of the protected health information\* to be collected for this protocol/study such as demographic information, results of physical exams, blood test, X-rays, and other diagnostic and medical procedures as well as medical history.]*

## The Investigator, (name of researcher) may use and share my health information with:

* Hanover College’s (IRB) when the researcher or the research site is undergoing Higher Learning Commission or accreditation reviews.
* Government representatives, when required by law
* *[List any collaborators, outside laboratories or research sites, etc.]*
* *[If applicable -- list the sponsor's name]*
* *[List any other groups with whom the information may reasonably be shared]*

**The Investigator, (name of researcher) intends to use or disclose my health information for the purposes of:** *[As required by 45 CFR 164.508(c)(1)(iv), describe each purpose of the requested use or disclosure of the protected health information]*

Once my health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

The investigator(s) (researcher) and *[list sponsor's name if applicable]* agree to protect my health information by using and disclosing it only as permitted by me in this Authorization and as directed by state and federal law.

## I do not have to sign this Authorization. If I decide not to sign the Authorization:

* It will not affect my treatment, payment or enrollment in any health plans nor affect my eligibility for benefits.
* I may not be allowed to participate in this research study.

## After signing the Authorization, I can change my mind and:

* Not let the researcher disclose or use my protected health information (revoke the Authorization).
* If I revoke the Authorization, I will send a written letter to: *[name and contact information of research advisor]* to inform him/her of my decision.
* If I revoke this Authorization, researchers may only use and disclose the protected health information **already collected** for this research study.
* If I revoke this Authorization my protected health information may still be used and disclosed should I have an adverse event (a bad effect, or experience something unanticipated).
* If I change my mind and withdraw the authorization, I may not be allowed to continue to participate in the study.

*Optional item: It has been explained to me that I will not be allowed to review the information collected for the research until after the study is completed. When the study is over, I will have the right to access the information again.*

This Authorization does not have an expiration date.

## If I have not already received a copy of the Privacy Notice, I may request one by contacting the IRB Chairperson. If I have any questions or concerns about my privacy rights, I should contact Hanover College, IRB Chairperson.

**I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.**

Signature of subject or \*research Date subject's legal representative

Printed name of subject or Representative's relationship to

\*research subject's legal representative research subject

\*Please explain Representative's relationship to patient/subject and include a description of Representative's Authority to act on behalf of

Patient:

\*Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Device Identifiers, Biometric Identifiers, any other unique code.

# HIPAA IRB WAIVER OF AUTHORIZATION\*\*\*

IRB#

Project Title:

1. The use or disclosure of Protected Health Information (PHI)\* involves no more than a minimal risk to the privacy of individuals. Explain why. Include a detailed list of the PHI to be collected and a list of the sources(s) used/accessed for the PHI.
2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access (researchers must list all of the entities that might have access to the study's PHI such as student advisors, hospitals, private clinics, FDA, and any others given authority by law);
3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is (explain below):
4. The research could not practicably be conducted without the waiver because (explain below):
5. The research could not practicably be conducted without access to and use of the PHI because (explain below):
6. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also accountable for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

The information listed in the waiver application is accurate and all research staff\*\* will comply with the HIPAA regulations and the waiver criteria. I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law.

## 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.

Principal Investigator Signature Date

Name typed/printed

\*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.

\*\*Note: *Research staff* is defined as ALL study personnel (including PI) that is involved in the research.

\*\*\*HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.

# HIPAA DE-IDENTIFICATION CERTIFICATION FORM

*DO NOT COMPLETE IF AUTHORIZATION WILL BE OBTAINED OR WAIVER OF AUTHORIZATION IS REQUESTED*

IRB# PI Name:

Title:

Research which involves the use of "de-identified" protected health information (PHI)\* is exempt from HIPAA requirements. To be exempt from HIPAA, none of the following subject identifiers can be reviewed (accessed) or recorded by the research team.

* + Names (individual, employer, relatives, etc.)
	+ Address (street, city, county, zip code - initial 3 digits if geographic unit contains less than 20K people, or any other geographical codes)
	+ Telephone/Fax Numbers
	+ Social Security Numbers
	+ Dates (except for years)
		- Birth Date
		- Admission Date
		- Discharge Date
		- Date of Death
		- Ages > 89 and all elements of dates indicative of such age (except that such age and elements may be aggregated into a category "Age>90
	+ E-mail Addresses/URLs
	+ Medical Record Numbers
	+ Health Plan Beneficiary Numbers
	+ Account Numbers
	+ Certificate/License Numbers
	+ Vehicle Identifiers and Serial Numbers (e.g., VINs, License Plate Numbers)
	+ Device Identifiers and Serial Numbers
	+ Biometric Identifiers (e.g., finger or voice prints or full face photographic images)
	+ Any other unique identifying number, characteristic, or code

I certify the protected health information (PHI)\* received or reviewed by research personnel for the research project referenced above does not include any of the 18 identifiers listed above.

Principal Investigator Signature: Date: