

Howard University Institutional Review Board
Application for Chart Review Request/HIPAA Waiver
(Form B-1)

(Please type form)

Principal Investigator: <div style="border: 1px solid black; height: 20px; width: 95%; margin-top: 5px;"></div>	Date: <div style="border: 1px solid black; height: 20px; width: 95%; margin-top: 5px;"></div>
Title of Project: <div style="border: 1px solid black; height: 30px; width: 100%; margin-top: 5px;"></div>	

Investigator Certification for Reviews Preparatory to Research

INVESTIGATOR'S REPRESENTATION

**REVIEW OF PATIENT INFORMATION FOR RESEARCH PREPARATION
PURPOSES**

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permits Howard University to make patient information available for review by an investigator for protocol development and research recruitment purposed, provided that the following representations are obtained from the investigator (45 C.F.R. § 164.512 (i)(1)(ii)).

1. Purpose(s) for which access to patient records maintained by Howard University is sought (**check all that apply**):
 - Research/data analysis
 - Protocol development *and/or*
 - Identification of potential research participants

2. Describe the nature and scope of the patient information to which access is sought. Be sure to specify the dates of the earliest and of the latest records you wish to review (e.g. records from 1/1/ 2010 to 12/ 31/ 2012).

(attach additional page(s), as needed).

3. Describe the purpose or objectives, and expected benefits of the study.

4. Specify the dates over which the investigators will complete the review of the charts:

BEGINNING DATE: ENDING DATE:

5. The Principal Investigator represents that:

- (a) access to the requested patient information is sought *solely* for the purpose(s) indicated above;
- (b) the requested patient information is *necessary* for the purpose(s) indicated above; and,
- (c) no individually identifiable patient information will be copied by the investigator(s) or removed from Howard University’s premises during [the course of] or following the review.
- (d) PI agrees to follow HUH procedures for protecting patient data as required by the HUH Compliance Office.
- (e) All investigators must complete the required HIPAA training through the HUH Office of Compliance. Please contact Meredith Harrison, JD, Chief Compliance Officer, HUH, for this information.

I agree to comply with all laws and regulations of the District of Columbia, the U.S. Department of Health and Human Services, the Office for Human Research Protections, the Food and Drug Administration, and the policies and procedures of Howard University/Howard University Hospital in the conduct of this research. I certify that all research personnel have been adequately trained to carry out their responsibilities, and will do so under my supervision.

Printed Name of Principal Investigator

E-mail Address and Date

Signature of Principal Investigator

Title and School/Department

Confidentiality

A. Participant Identifiers

To which of the following identifiers about participants (or their relatives, household members, or employees) *might* access be needed during the course of the proposed research?

B. Check all that apply:

- Names
- Geographic subdivisions smaller than state (e.g., street address, city, five digit zip code, county)
- Months or specific dates (e.g., birth date, admission date, month of discharge, date of death)
- References to age 90 or older *or* references to dates or years indicative of age 90 or older
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social Security numbers
- Medical record or prescription numbers
- Health plan beneficiary numbers
- Account numbers
- Medical device identifiers or serial numbers
- Biometric identifiers (e.g., finger or voice prints)
- Full face photographic images or comparable images
- Web Universal Resource Locations (URLs)
- Internet Protocol (IP) address numbers
- Certificate or license numbers (e.g., driver's license numbers)
- Vehicle identifiers or serial numbers (e.g., license plate numbers, VINs)
- Linkage codes (to permit re-identification or longitudinal tracking) derived from or related to any of the above

OR

By initialing here, I confirm that access to the identifiers listed above is not required or anticipated.

Please explain below how the anonymity of the patients and the confidentiality of their records will be protected and maintained. Include any measures that will be taken to strip identifiers from files used for data analysis, and specify where the records will be maintained and secured.

--

Identify all investigators who will have access to the charts and/or data files under your authority. Include their e-mail addresses (Howard/HUH email only):

Example: John Smith, MD

john.smith@huhosp.org

Applications/Protocols can be delivered to the Office of Regulatory Research Compliance, located in the HU Research Building-1, 1840 Seventh Street, N.W., Suite #309, Howard University, Washington, DC 20001 or submitted online at <http://www.howard.edu/orrc>

Should you have any questions, you may e-mail: theorrc@howard.edu or call the ORRC at (202) 865-8597.

B1-Checklist

- Original B-1 Form
- HUH HIPAA Certifications for all researchers
- CITI Certifications for all researchers
- CV/Bio for all researchers

rev 11/0/2012