**FORM “B1”**

**IRB Application for Medical Records Review Request**

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| --- | --- |
| **Principal Investigator**:Click here to enter text. | **Date**:Click here to enter text. |
| **Email**:Click here to enter text. | **Phone**:Click here to enter text. |
| **Title of Project**:Click here to enter text. | |

***(Please, complete by typing on to the form)***

**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 purposes, 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

1. **Category of Review.** Check one of the following:

**Retrospective Chart Review**- data is already in existence when the project is submitted to the IRB for initial review – EXEMPT REVIEW

**Prospective Chart Review**- data is not in existence when the project is submitted to the IRB for initial review –EXPEDITED REVIEW

**BOTH** Retrospective/Prospective Chart Review – EXEDITED REVIEW

**Definitions*:***

***Exempt Review:*** Study procedures involving de-identified data or health information (usually one-time chart collection.)

***Expedited Review:*** Study procedures involving identifiable data or health information (usually done for longer-term studies that involve tracking or follow-stages.)

1. **Background.** Describe (briefly) pertinent background information leading to the present proposal.

Click here to enter text.

1. **Purpose.** Describe the purpose or objectives, and expected benefits of the study.

Click here to enter text.

1. **Patient Information.** Describe the nature and scope of the patient information to which access is sought: i.e., inclusion/exclusion criteria and age range. Provide the date range of the chart review (if this is a retrospective chart review, the end date must come before the IRB submission date): (e.g. records from 1/1/ 2010 to 12/ 31/ 2012).

Click here to enter text.

1. **Source of Medical Information.** Check all that apply:

Complete Medical Record

Laboratory Results

Pathology Records/Reports

Radiology Records

Other (describe):

1. **Summary of Activities.** Specify the dates over which the investigators will complete the review of the charts:

BEGINNING: \_\_/ \_\_/\_\_\_\_ ENDING: \_\_/\_\_/\_\_\_\_

1. **Statistical Considerations.** Please provide the proposed Sample Size:

|  |  |
| --- | --- |
| Proposed Sample Size: | Click here to enter text. |

**Confidentiality**

1. **Sensitive Information.** Will identifiable, private, or sensitive information be obtained about the participants or other living individuals?

Explain 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.

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| **If any personal identifiers will be recorded or linked by a code (or master list) to the research data, please list all of these identifiers and clarify how long you will keep the link/record:**Click here to enter text. |

1. **Participant Identifiers**

What data items will be collected/Recorded for research purposes?

**Check all that apply:**

|  |  |  |
| --- | --- | --- |
| **Accessed** | **Recorded** | **Recommends that you only record what is needed for your research** |
|  |  | 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 |
|  |  | Email 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 |
|  |  | Other (describe): |

***OR***

**If you will not record identifiers:** Please initial below to confirm that you will not record any of the identifiers listed above, and complete **Supplemental Form “G”** Initial: \_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_

1. **Risks.** The use or disclosure of PHI must not involve more than minimal risk to the privacy of individuals. What are the potential risks (including breach of confidentiality) and/or benefits to subjects or society?

Minimal (*Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.)* or

More than Minimal

Indicate what you consider to be the risks to participants and indicate the precautions to be taken to minimize or eliminate these risks. If any data monitoring procedures are needed to ensure the safety of participants, describe them.

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| Click here to enter text. |

1. **Benefits.** Please note that the subjects’ whose charts are reviewed are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.

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| Click here to enter text. |

1. **Vulnerable Populations:** Indicate whether this project involves any of the following populations?

**Children** (Children are defined by local law as anyone under the age of 18.) **[If so, please complete**

**Supplemental Form “J”]**

**Prisoners** **[If so, please complete Supplemental Form “I”]**

**Pregnant women/Neonates/Fetuses** **[If so, please complete Supplemental Form “H”]**

**Cognitively impaired or mentally disabled** participants

**Economically or educationally disadvantaged** participants

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| **Note:**   1. **If you indicated the inclusion of any of the above populations: In the space below please describe additional safeguards for protection from coercion or undue influence to participate. You must also complete the relevant supplemental forms.** 2. **For research involving prisoners and some children, waiver of an informed consent is disallowed:** [**http://answers.hhs.gov/ohrp/categories/1568**](http://answers.hhs.gov/ohrp/categories/1568)   **Please direct your remaining questions to the IRB.** |
| **Description of the vulnerable population to be included in your research:**Click here to enter text. |

1. **Consent.** Describe the type of consent to be obtained and justification for the choice **[written, waiver, or verbal]**.

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| **Note: For chart reviews, if you plan to collect/record identifiers, you are conduction human subject research, and therefore, must obtain consent or request and justify waiver of consent. For retrospective chart review, if you are not recording identifiers, then consent is not needed. To request waiver of informed consent, please complete Supplemental Form “E”. For more information click on the link below:** [**http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1**](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1) **(Charts 1, 2 and 5)** |
| **Describe type of consent to be obtained:**Click here to enter text. |

1. Identify all investigators who will have access to the charts and/or data files under your authority. Please include their email addresses:

|  |  |
| --- | --- |
| **Name(s)/Role** | **Email Address** |
| Click here to enter text. | Click here to enter text. |
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1. The Principal Investigator represents that:
   1. Access to the requested patient information is sought ***solely*** for the purpose(s) indicated above;
   2. The requested patient information is ***necessary*** for the purpose(s) indicated above; and,
   3. 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.
   4. PI agrees to follow HUH procedures for protecting patient data as required by the HUH Compliance Office.

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.

\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_

Printed Name of Principal Investigator Title and School/Department

\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date

Applications/Protocols can be submitted online at <http://www.howard.edu/orrc>

Should you have any questions, you may email: [theorrc@howard.edu](mailto:huirb@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

**Supplemental Form E**- “Waiver of Informed Consent”

**Supplemental Form G**- “HIPAA De-Identification Certification,” if applicable.

rev 8/27/2014