STANDARD OPERATING PROCEDURES
for
New Submissions

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I. OVERVIEW:

All individuals at Howard University, seeking to conduct research involving human participant(s), as defined in 45 CFR 46.102 (d)(f) and 21 CFR 50.3 (c)(g), must first have their research proposals approved by the Howard University Institutional Review Board (HUIRB) prior to the initiation of the study. The HUIRB operates in compliance with the Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP) regulations for the protection of human research participants, including 45 CFR 46, 21 CFR 50 and 21 CFR 56, which govern human participant research as amended to include the Common Rule (FR 56, No. 117, 28002). The HUIRB operates under the Federal Wide Assurance No. 00000891 which expires February 17, 2012.

The HUIRB will review and oversee all research involving human participants at the University and is authorized to inspect research facilities, obtain records, observe the consent process, suspend or terminate research, and take other actions as necessary to comply with federal regulations. The HUIRB is also responsible for providing assurance to the federal government that Howard University is in compliance with federal regulations. Further detailed instructions regarding HUIRB responsibilities, procedures and regulations can be found in this website at: "Ethical Principles & Responsibilities."

Research activity MUST NOT PROCEED UNTIL: 1) The University's IRB has reviewed and approved the research proposal; 2) An official letter has been issued to the research investigator by the Chairman or designee of the Board; and/or, 3) the research investigator is in possession of IRB-approved

consent documents as well as any accompanying recruitment materials, if applicable.

In the event that research is undertaken without the intention of involving human participants, but it is later proposed to involve human participants in the research, the above review and approval procedures must be followed prior to instituting the human participant research.

NOTE: All research that is conducted involving human participants must be reviewed by the HUIRB. Although some types of research on human participants may be eligible for an exemption, under federal regulations. Such exemptions can only be determined by the HUIRB.

II. ACCESS THE APPLICATIONS:

The Applications for Projects Involving Human Participants are located in this website at: "Applications and Instructions."

III. APPLICATIONS AND INSTRUCTIONS:

Select the type of Application to be completed.

A. Instructions for Applications to Federal Agencies:
The actual application signed by the authorized university official(s) that is submitted to the agency must be forwarded to the HUIRB for its review. In addition Application A-1 must be completed and signed by all appropriate officials. Include consent document(s) for each participant population, support documents, and advertisements, as appropriate. A Principal Investigators Assurance Form must be signed and included in all applications.

B. Instructions for Applications to Non-Federal Agencies:
These are proposals submitted to private grantors such as foundations, volunteer health agencies (e.g., the American Heart Association), and other non-federal grantors that support scholarly activities that involve human participations. The actual application, signed by the authorized university official(s) that is submitted to the grantor must be forwarded to the HUIRB for review. In addition Application A-1 or Application C-1 (whichever is appropriate) must be completed.

Include consent document(s) for each participant population, support documents, and advertisements, as appropriate. A Principal Investigators Assurance Form must be signed and included in all applications.

C. Instructions for Applications to Clinical Research Protocols Sponsored by the Pharmaceutical Industry:

The actual protocol developed by the industry sponsor and signed by the authorized university official(s); two (2) copies of he sponsor's Investigator's Brochure; a copy of a clinical research agreement (if required) by the Howard University General Counsel Office. In addition to this information, Application A-1 must be completed and signed by all appropriate officials. Include consent document(s) for each participant population, support documents, and advertisements, as appropriate. A Principal Investigators Assurance Form must be signed and included in all applications.

D. Instructions for Applications to Agencies which do not have a standard application format:

All protocols must be typed in a font size no smaller than 12 points. If the project involves drugs and/or devices or if the project involves greater than minimal risks, Application A-1 is to be completed and signed by all appropriate University officials prior to submission. If the project involves minimal risks or is a student project, Application C-1 is to be completed and signed by all appropriate University officials prior to submission. A Principal Investigators Assurance Form must be signed and included in all applications.

E. Instructions for Applications for Theses and Dissertations Proposals:

The actual document, approved by the candidate's committee is to be submitted for HUIRB review on behalf of the candidate by the candidate's faculty advisor (FA). All protocols must be typed in a font size no smaller than 12 points. Protocols may only be submitted by a HU faculty member/advisor (FA) who will serve as the Principal Investigator (PI). The PI bears direct accountability and responsibility for the proper conduct of the project or activity described in the proposal and approved by the HUIRB. Application C-1 is to be completed and signed by all appropriate officials prior to submission to the IRB. A copy of the Dissertation/Thesis Committee's Approval

Sheet must accompany all submissions. A Principal Investigators Assurance Form must be included which has been signed by the FA and the Student Investigator.

F. Request for Exemptions:

Research which involves the collection or study of existing or archival data, documents, records, pathological specimens, or diagnostic specimens or research which does not contain identifiable information which can be linked to participants may be exempt based upon the Code of Federal Regulations (45 CFR 46.101). **The determination of the exempt status of a project is the responsibility of the HUIRB.** Application D-1 is to be completed.

NOTE: The HUIRB ONLY accepts protocols from Howard University faculty members. Students, staff, or other non-faculty investigators must identify a Howard University faculty member who agrees to be responsible for oversight of the research protocol.

IV. PROTOCOL INFORMATION:

One (1) original and two (2) copies of the completed protocol (including attachments and instruments) should be forwarded to the HUIRB Office located in the HU Research Building-1, 1840 Seventh Street, N.W., Suite #309.

It the protocol involves drugs and/or devices or if the protocol involves greater than minimal risks, it will be forwarded to the Board for review. Under normal circumstances the HUIRB reviews protocols every first and third Wednesday of every month except December. The deadline for submissions is the preceding Wednesday at 5:00 p.m. (Consult web page for the IRB meeting schedule). Minimal risks projects and student projects may be reviewed by officers of the IRB. Generally a response is available in one to two weeks.

V. VOTING OPTIONS

APPROVE: Recommended when protocols meet all qualifications for compliance.

APPROVE WITH MINOR OR ADMINISTRATIVE REVISIONS:

Recommended when slight modifications or clarifications are required to bring the protocol into compliance. May be handled administratively upon a satisfactory written response by the PI to the Board's critique.

REVISE: Recommended when major modifications are required that will result in alteration of protocol content. Only the requested revisions are necessary. Must be submitted to the full Board for consideration.

DEFER: Recommended when additional information is required for a more accurate determination or if information is missing or not enough information was included to make an accurate determination. Must be resubmitted to the full Board for consideration.

DISAPPROVE: Recommended when the proposal has significant deficiencies and does not meet the requirements for compliance. A new protocol must be submitted for full Board consideration.

EXEMPT: Recommended when the protocol does not involve human participants except as unidentifiable chart or record review(s).

Submission of requested revisions - provide three (3) copies of the revisions, (2 copies should be highlighted and/or underlined as appropriate), unless otherwise instructed in the letter requesting revisions. **The entire application is not required unless requested.** In addition, a cover letter signed by the PI/FA should accompany all revisions.

The request for approval of modifications should be detailed in a cover letter signed by the PI/FA whose name appears on the originally approved IRB application. In the case where the original PI/FA has left the University, the Dean's signature would be required on the cover letter. One (1) original and two (2) complete copies must be submitted.

Slight modification(s) or clarification(s) should be detailed in a letter to the IRB Chairman. The letter then becomes an addendum to the original application.

VI. OTHER OPTIONS:

ADMINISTRATIVE REVIEW:

Recommended when there is an urgent request for review. The determination is made on an individual basis at the Chairman's discretion.

NOTE: Drug studies can <u>not</u> be administratively reviewed.

EXPEDITED REVIEW:

Recommended when the PI/FA forwards a written request to review outside of the normal review process with an appropriate explanation and/or justification.

NOTE: Drug studies can <u>not</u> be expedited reviewed.