HOWARD UNIVERSITY

Office of Regulatory Research Compliance

September 12, 2014

MEMORANDUM

TO: All Howard University Research Investigators

FROM: Thomas O. Obisesan, MD, MPH
Associate Vice President and Designated Institutional Official
Regulatory Research Compliance

RE: **INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECT REVIEW OF PROTOCOL FEE POLICY**

Effective immediately, the Howard University Office of Regulatory Research Compliance (ORRC) will begin charging an IRB review fee for industry sponsored protocols, and other specified human subject research studies; as defined in the policy "Academic and Research 100-005."

This policy applies to the entire University enterprise, and any affiliated entities including but not limited to Howard University Hospital, its faculty, staff, and students.

The following definitions shall guide the identification of relevant protocols:
Industry-Sponsored Protocols - When a commercial entity either: 1) contributes to the design or conduct of a study as evidenced by a sponsor's protocol, investigator's brochure, etc.; 2) coordinates the study as a multi-center trial; 3) reimburses the University or a University investigator for costs associated with conducting the trial; or 4) will have access to, publish or present the data gained from conducting the trial.

Others - Protocols submitted on behalf of non-Howard University organizations or non-Howard University employees including but not limited to federal agencies (e.g., an industry-sponsored protocol from a non-Howard University affiliated entity, requesting the service of the Howard University IRB).

It should be noted that Junior Investigators (Instructor or Assistant Professor), submitting industry-sponsored protocols for the first time are exempted from the fee, but must request a waiver. Please provide the fee schedule to the sponsor well in advance of contract negotiation or refer them to the Research Administrative Services.

For additional details, please review the attached policy "Academic and Research 100-005."

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HOWARD UNIVERSITY POLICY

Policy Number:	Academics and Research 100-005
Policy Title:	INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS REVIEW OF PROTOCOLS FEE POLICY
Responsible Officers:	Provost and Chief Academic Officer Associate Vice President for Research and Compliance
Responsible Offices:	Office of the Provost Office of Regulatory Research Compliance and Research Administrative Services
Effective Date:	September 12, 2014

I. POLICY STATEMENT

Howard University ("University") is committed to the highest ethical standards in the conduct of research, and specifically to its obligation of ensuring the rights and welfare of human research subjects. Human research protection is a shared responsibility involving the University, the Institutional Review Boards (IRBs), investigators, and research staff.

Any undertaking, regardless of funding source, in which a University faculty member, staff member, or student conducts research involving human subjects or a clinical investigation, requires IRB review and approval prior to initiation. To determine which activities require IRB review and approval prior to initiation, the Office of Regulatory Research Compliance (ORRC) and the IRB employ applicable federal definitions for "research", "human subjects", and "clinical investigation". These definitions are guided by the ethical principles of the Belmont Report, and in accordance with the Common Rule set forth by 45CFR46 Subpart A through D, and the FDA 21 CFR Parts 50 and 56.

This policy authorizes the ORRC and the IRB on Human Subjects Research ("the IRB") to charge a fee for reviewing certain research protocols as specified in this policy, and as permitted by federal regulation.

II. RATIONALE

To offset the increasing costs of IRB operation and research oversight not otherwise covered by the overhead assessment, the ORRC and IRB will charge for reviewing certain research protocols. The IRB fee will benefit the University research enterprise by generating additional resources for education and training of IRB members and researchers. Payment of the fee will not provide preferential review or faster response time, nor will it guarantee outcome of the review.

III. ENTITIES AFFECTED BY THIS POLICY

This policy applies to the entire University enterprise, and any affiliated entities including, but not limited to, Howard University Hospital, its faculty, staff, and students.

IV. DEFINITIONS

A. **Industry-Sponsored Protocols** - When a commercial entity either: 1) contributes to the design or conduct of a study as evidenced by a sponsor's protocol, investigator's brochure, etc.; 2) coordinates the study as a multi-center trial; 3) reimburses the University or a University investigator for costs associated with conducting the trial; or 4) will have access to, publish or present the data gained from conducting the trial.

B. **Others** - Protocols submitted on behalf of non-Howard University organizations or non-Howard University employees including, but not limited to, federal agencies (e.g., an industry-sponsored protocol from a non-Howard University affiliated entity, requesting the service of the Howard University IRB).

C. **Junior Investigator** – Instructor or Assistant Professor submitting industry-sponsored protocols for the first time are exempted from the fee, but must apply for a waiver.

D. **Indirect Cost** - Also known as Facility and Administrative Fees or Overhead Costs are costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity.

V. POLICY PROCEDURES

Effective with the promulgation of this policy, the ORRC and the IRB will charge for the review of the following types of research protocols: industry-sponsored protocols and other human subject research that is financially sponsored by industry or for-profit protocols, as defined in this policy.

There will be no charge for the review of Howard University investigator-initiated protocols funded by federal and state agencies, foundations, non-profit entities, or Howard University. Human subject research deemed to be "intellectual property" by the Howard University Intellectual Property Committee will be exempt from fees. In addition, protocols that fall under research-exempt, which do not require review by the full IRB, will not incur an IRB charge for review.

A. Charge Rates

In compliance with national standards, the following rates are in effect:

	Initial Review (Full Board)	Initial Review (Expedited)	Continuing Review (Full Board)	Continuing Review (Expedited)	Modification	Exempt Certification
Industry/Private Sponsored Protocols (institutional indirect costs are not included in this rate)	$2500	$1000	$1000	$500	No Charge	No Charge

Important Notes Regarding Charge Rates:

- There will be no charge for adverse event reports submitted to the IRB for review and processing.
- HU indirect cost will be added to the above cost for protocols submitted by outside agencies/entities.
- Continuing reviews occur at intervals defined by the ORRC/IRB. However, continuing reviews may occur more frequently in cases when the principal investigator submits a protocol amendment from the sponsor that includes major changes to the study, such as removing or adding a study arm. In such cases, the IRB can review the change at a convened meeting as required, and reapprove the study.
- To cover review costs, investigators should list the expenses for IRB review as a budget line item as part of the startup costs.
- Fees are refundable only if the research proposal is withdrawn prior to its review by the IRB. Fees are not refunded if the IRB reviews the research proposal and either does not approve it or requires modifications.

B. Charging Process

Investigators will be charged after a review has occurred.

1. University investigators will be charged through invoice and subsequent interdepartmental charge to their grants.
2. External investigators and industry sponsors will be directly invoiced.

C. Exemptions to the Charge

The fee for junior investigators (instructors or assistant professors) with industry-sponsored clinical trial research will be waived on the first submission. To receive a waiver, the junior investigator must submit a written request for an exemption attached to the application.

If an investigator not identified in this policy as eligible for an exemption believes there are special circumstances, he or she may request a waiver in writing. Approvals for such waivers will be rare and shall be approved by the Director, ORRC in consultation as needed with the Associate Vice President for Research.

D. How the Fee is Determined

The fee is determined by the ORRC, in consultation with the IRB, and informed by national standards and federal agencies.

VI. INTERIM POLICIES

There are no interim policies.

VII. SANCTIONS

The collection and management of fees under this policy shall be transparently applied. In the event that the charge is not paid, the Howard University IRB reserves the right to prevent future review of such protocols from investigators and sponsors who have not complied with the provisions of this policy.

VIII. HYPERLINKS

University:

www.howard.edu/policy

Office of Regulatory Research Compliance

References:

The Belmont Report

Code of Federal Regulations Title 45, Part 46 *Protection of Human Subjects*