# *Howard University Institutional Review Board*
# *Application (Protocol) for IRB Review (C-1)*
# *Minimal Risk and/or Student Research*

## Section One: Application Information

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|---|---|
| **PI/Faculty Advisor:** | |
| **Department:** | |
| **Title:** | |
| **Phone/Pager:** | |
| **Fax:** | |
| **E-mail address:** | |
| **Mailing Address**: | |
| **% Time/Effort** | |

| | |
|---|---|
| **Student Investigator:** | |
| **Department:** | |
| **Phone/Pager:** | |
| **Fax:** | |
| **E-mail address:** | |
| | |
| **% Time/Effort** | |
| | |
| **Student Investigator (if applicable):** | |
| **Department:** | |
| **Phone/Pager:** | |
| **Fax:** | |
| **E-mail address:** | |
| **Is this research for your thesis/dissertation?** | ☐ Yes |
| | ☐ No |

| **Title of Project** | **Purpose of Project (one or two sentences)** |
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| **Co-Investigators/Consultants, if any** | **Department or Institution** |
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| **Estimated duration of total project** | |
| **Estimated total number of participants (including controls)** | |
| **Age range of participants** | |
| **Gender of participants** | |
| **Where will study be conducted?** | |
| **Source of participants** | |
| **Experience of Principal Investigator:** Brief summary (also attach a CV or biographical sketch) | |

| **Source of Funding/Grant Support for Project (if any)** | **Commercial Support for Project (if any)** |
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## Section Two: Additional Howard University Regulatory Information

**Please answer each specific question and use additional sheets as needed. A response of "See attached project description or grant application" is not sufficient.**

1. **Background.** Provide a brief rationale for the project citing the pertinent scientific literature and the investigator's professional experience . *Use additional sheets as needed.*

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**2. The plan of study.** State the hypothesis or research question you intend to answer. Describe the research design, methods, interventions, and procedures (including standard or commonly used scales, instruments, interventions and/or procedures) to be used in the research. Identify any elements of the design that are innovative, unusual, or experimental. Where appropriate, provide statistical justification or power analysis for the number of participants to be studied. *Use additional sheets as needed.*

**3. Risks.** Indicate what you consider the risks to participants to be, and indicate the precautions to be taken to minimize or eliminate these risks. If any monitoring procedures are needed to ensure the safety of participants, describe them. *Use additional sheets as needed.*

## Section Three: Selection of Participants and the Informed Consent Process

**1.** Indicate whether this project involves any of the following vulnerable populations?

- ☐ Children (Children are defined by local law as anyone under age 18.)
- ☐ Prisoners
- ☐ Pregnant women
- ☐ Cognitively impaired or mentally disabled participants
- ☐ Economically or educationally disadvantaged participants

If you indicated any of the above, in the space below please describe what additional safeguards will be implemented to protect these populations from coercion or undue influence to participate. (Use additional sheets as needed.)

2. **Recruitment:** Describe how participants will be recruited and how informed consent will be sought from participants or from the participants' legally authorized representatives. If children are participants, discuss whether their assent will be sought, and how the permission of their parents will be obtained. Use additional sheets as needed.

3. **Compensation:** Will participants receive any compensation for participation in cash or in kind?

☐ Yes ☐ No

If participants receive any compensation, please describe amount or kind of compensation in the space below.

4. **Fees:** Will any finder's fees be paid to others?

☐ Yes *If so, please describe the amount below.*
☐ No

## Section Four: Privacy and Confidentiality of Data and Records

**1. Sensitive Information.** Will identifiable, private, or sensitive information be obtained about the participants or other living individuals? Whether or not such information is obtained, describe the measures you will take to protect the anonymity or privacy of participants, and to maintain the confidentiality of the data they provide. Use additional sheets as needed.

## Section Five: Conflict of Interest

**1. Conflict of Interest:** Do any investigators or co-investigators have a conflict of interest?

- ❑ Yes. If so, please explain below.
- ❑ No.

Note: A current Howard University Financial Conflicts of Interest Disclosure Form must be completed by each investigator and attached to this application. **Applications cannot be reviewed until signed forms are submitted for *all* investigators.**

☐ I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent document, and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study.

☐ I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

☐ I assure that the protected health information identified in the Authorization to Use and Disclose Health Information for Research (HIPAA) and the persons and entities that may use, give and receive protected health information is accurate, and reflective of the known use and disclosure for this human [clinical ] study.

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| _____<br>Printed/Typed Name of Investigator<br><br>_____<br>Signature of Investigator | _____<br>Telephone number<br><br>_____<br>Date |
| _____<br>Printed/Typed Name<br><br>_____<br>Signature of Department Chair | _____<br>Signature of the Dean<br><br>_____<br>Date |
| | |

<u>If more than one department or administrative unit is participating</u> in the research and/or if the facilities or support of another unit, e.g., nursing, pharmacy, or radiation therapy, are needed, then the chair or administrative official of each unit must also sign this application.

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|---|---|
| _____<br>Authorized Signature<br><br>_____<br>Title and Department | ☐ Approved<br>☐ Disapproved<br><br>_____<br>Date |
| _____<br>Authorized Signature and Title<br><br>_____<br>Title and Department | ☐ Approved<br>☐ Disapproved<br><br>_____<br>Date |
| _____<br>Authorized Signature and Title<br><br>_____<br>Title and Department | ☐ Approved<br>☐ Disapproved<br><br>_____<br>Date |

## Section Six: Attachments

The following documents are REQUIRED before the IRB can begin the review your research:

*Provide one copy of each of the following, and place them in the following order:*

- ☐ Signed copy of The Principal Investigator's Assurance Form
- ☐ Dissertation Committee Approval signature page
- ☐ Any recruitment notices or advertisements
- ☐ Informed consent document(s)
- ☐ Any survey instruments, psychological tests (other than standard, commercially available instruments), interview forms, or scripts to be used in the research
- ☐ Formal research protocol or dissertation proposal, if available.
- ☐ Grant application, if applicable.

**FOR ALL INVESTIGATORS:**

- ☐ Investigator's CV or biographical sketch (for all research staff including students)
- ☐ Conflict of Interest Forms (for Principal Investigators only)
- ☐ Certificate of completion of education in the protection of human research participants (required) (CITI for PI and staff / CITI and RCR for all students)

**FOR EXEMPTION OR EXPEDITED REVIEW**

- ☐ Request for Expedited Review. Typed letter on letterhead signed by the PI.
- ☐ Request for Exemption (Form D-1) *instead* of Form A-1, B-1, or C-1.

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Applications/Protocols are to 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.

The Office of Regulatory Research Compliance does not accept electronic submissions at this time, should you have any questions, you may e-mail: theorrc@howard.edu or call the ORRC at (202) 865-8597.