Form "C1": IRB Application for Minimal Risk Research

HOWARD UNIVERSITY

Office of Regulatory Research Compliance
Institutional Review Board

PI/Faculty Advisor:	
Department:	
Title:	
Phone/Pager:	
Email address:	
Mailing Address:	
% Time/Effort	

Student Investigator:	
Department:	
Phone/Pager:	
Email address:	
% Time/Effort	

Student Investigator (if applicable):	
Department:	
Phone/Pager:	
Email address:	
Is this research for your thesis/dissertation?	◯Yes
	◯No

Co-Investigators/Consultants, if any	**Department or Institution**

Protocol Title

Note: Some of the New Changes to the Revised Common Rule

- **Pregnancy:** Is no longer considered a vulnerable by itself, especially for social-behavioral studies.
- **Economically disadvantaged population**: Is now considered vulnerable
- **Tribal Laws:** Must include consideration of Tribal laws in addition to consideration for Federal, State, Local and HU P & P.
- **Burden Reducing Provision - Continuing Review:** May not be required for certain minimal risk studies and or certain approved studies in which active intervention no longer occurs (Please check the expiration date on your approval letter and consent document. An expiration date/stamp mean a continuing review is required, and must be submitted annually)
- **Limited Review:** Mean full-board review may not be required
- **Broad Consent:** Check the HU Policy and Procedure for qualifying studies and conditions of approval.

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SECTION 1: Application Information

Brief Description of the Protocol

Estimated duration of total project	
Estimated total number of participants (including controls)	
Age range of participants	
Gender of participants	
Where will study be conducted? If study will be conducted outside of HU, please provide letters of support.	
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)

SECTION 2: 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.

2.1 Background. Provide a brief historical background of the project with reference to the investigator's personal experience and to pertinent scientific literature:

2.2 Benefits: Describe potential benefits, if any, to participants in this study. If there are none, state "none." (Note: compensation is not considered a benefit).

2.3 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 interventions or procedures) to be used in the research. Specifically, identify any interventions, procedures, or equipment that are innovative, unusual, or experimental. Where appropriate, provide statistical justification or power analysis for the number of participants to be studied.

2.4 Risks. 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.

SECTION 3: Selection of Participants and the Informed Consent Process

Inclusion/Exclusion Criteria: Describe how you will screen for eligibility, and the criteria that will be used to define who will be included or excluded in the study sample.

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3.1 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"]** **(Please note that pregnancy "by itself" is no longer considered vulnerable, especially in of behavioral studies)**
- ◯ 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 in place to protect these populations from coercion or undue influence to participate.

3.2 Recruitment: Describe how participants will be recruited and how informed consent will be sou from participants or from the participants' legally authorized representative. If children are participar discuss whether their assent will be sought and how the permission of their parents will be obtained. Please also describe methods that will be used to identify potential subjects.

3.3 Describe materials that will be used to recruit participants

3.4 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:

3.5 Fees: Will any finder's fee be paid to others?

Yes *if so, please describe the amount below.*
No

SECTION 4: Privacy and Confidentiality of Data and Records

4.1 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 provisions to protect the privacy of participants and to maintain the confidentiality of data. Use additional sheets as needed.

4.2 Data and Specimen Storage. If data and/or specimens will be stored for future use, please describe: 1) where data will be stored; 2) how long will data be stored; 3) how will data/specimen be accessed; and 4) by whom.

SECTION 5: REVISED COMMON RULE and NEW ELEMENTS of INFORMED CONSENT (Mostly Medical Sciences). Please respond to the questions below (also provide details in the consent document if applicable)

Biospecimens		
No	**Yes**	Are you collecting biospecimens?
No	**Yes**	Do you plan to de-identify the biospecimen?
No	**Yes**	Do you plan to use the biospecimen (***whether de-identified or not***) for future research or shared with other investigators [46.116 (b)(9)] ?
Commercial use of biospecimen		
No	**Yes**	Do you plan to use the subject's biospecimen for commercial purposes/profit?
No	**Yes**	Will subjects share in the commercial profit [46.116 (c)(7)]?
Disclosure of Research Results		

◯ **No**	◯ **Yes**	Do you plan to disclose clinically relevant research results, including individual research results, to subjects, and if so under which conditions [46.116 (c)(8)]?
Genome Sequencing		
◯ **No**	◯ **Yes**	Will the research include (if known) or might include whole genome sequencing [46.116 (c)(9)]?

SECTION 6: Conflict of Interest

6.1 Conflict of Interest: Do any investigators or co-investigators have a conflict of interest?

◯ Yes. If so, please explain below.

◯ No.

Note: A copy of each investigator's and co-investigators' current Howard University Financial Conflicts of Interest Disclosure Form must be attached to this application.

SECTION 7: Certification

◯ 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.

_____ **Printed/Typed Name of Investigator**	_____ **Date**
_____ **Signature of Investigator**	

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_____ **Printed/Typed Name** _____ Signature of Department Chair	○ Approved ○ Disapproved _____ **Date**
_____ **Printed/Typed Name** _____ **Signature of Dean**	○ Approved ○ Disapproved _____ **Date**

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

_____ **Authorized Signature** _____ **Title and Department**	○ Approved ○ Disapproved _____ **Date**
_____ **Authorized Signature and Title** _____ **Title and Department**	○ Approved ○ Disapproved _____ **Date**
_____ **Authorized Signature and Title** _____ **Title and Department**	○ Approved ○ Disapproved _____ **Date**

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IMPORTANT
SECTION 8: Attachments That Must be Included with This Application

Please attach the following items in order for the review your research:
Provide one copy of all materials for review.

- ☐ Request for Expedited Review. Typed letter on letterhead signed by the PI.
- ☐ Conflict of Interest Forms for all Investigators
- ☐ Certificate of completion of education in the protection of human research participants – www.citiprogram.org
- ☐ RCR certificate for student researcher- if your department did not participate in the RCR workshop then students may complete the RCR module via CITI.
- ☐ Informed consent document(s) or Preamble. Assent Documents should be submitted if children will be included.
- ☐ Signed copy of The Principal Investigator's Assurance Form (signed by the PI)
- ☐ Any recruitment notices or advertisements- flyers, radio ads, phone script, posters, etc.
- ☐ Any survey instruments, psychological tests (other than standard, commercially available instruments), interview forms, or scripts to be used in the research
- ☐ All investigators qualifications (CV, biographical sketch)
- ☐ Formal research protocol, if available.
- ☐ Thesis/Dissertation Proposal and Committee Signature Page
- ☐ Grant application, if applicable.

***** VERY IMPORTANT**

If your study include Vulnerable Populations, you MUST complete the relevant supplemental form. The forms are available on our website. Please see the list below:

- ☐ Children (45 CFR 46 Subpart D:) (Children are defined by local law as anyone under the age of 18.) **[If so, please complete Supplemental Form "J"].** May visit**:** http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- ☐ Prisoners (45 CFR 46 Subpart C) **[Does NOT qualify for Minimal Risk Research). [Complete Supplemental Form "I" as needed].** May visit**: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc**
- ☐ Pregnant women/Neonates/Fetuses (45 CFR 46 Subpart B) **[If so, please complete Supplemental Form "H"].** May Visit**:** http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
- ☐ Cognitively impaired or mentally disabled participants
- ☐ Economically or educationally disadvantaged participants

Applications/Protocols should be submitted via the online portal on our website www.howard.edu/orrc
Should you have any questions, you may email theorrc@howard.edu
or call the HUIRB office at (202) 865-8597.