HOWARD UNIVERSITY

Office of Regulatory Research Compliance
Institutional Review Board



# FORM "A1"

## IRB Research Application (Protocol) for Funded and/or Drugs and/or Devices that are Greater than Minimal Risk

| | |
|---|---|
| **Principal Investigator:** | **Date:** |
| **Email:** | **Phone:** |
| **Title of Project:** | |

**Note:**
**Please consider using the ORRC consent template to enhance compliance with organization of the materials, context and new elements of the Revised Common Rule, Effective January 21, 2019**

# Form "A1": IRB Application Greater than Minimal Risk Research

## Section 1: Application Information

| | |
|---|---|
| **Principal Investigator:** | |
| **Department:** | |
| **Title:** | |
| **Phone/Pager:** | |
| **Email Address:** | |
| **% Time/Effort:** | |

| | |
|---|---|
| **Co-Investigator:** | |
| **Department:** | |
| **Title:** | |
| **Phone/Pager:** | |
| **Email Address:** | |
| **% Time/Effort:** | |
| | |
| **Co-Investigator:** | |
| **Department:** | |
| **Title:** | |
| **Phone/Pager:** | |
| **Email Address:** | |
| **% Time/Effort:** | |
| | |
| **Co-Investigator:** | |
| **Department:** | |
| **Title:** | |
| **Phone/Pager:** | |
| **Email Address:** | |
| **% Time/Effort:** | |
| | |

| | |
|---|---|
| **Other Members of the Research Team** | |
| **Name:** | |
| **Title:** | |
| **Phone/Pager:** | |
| **Email address:** | |
| **Research Nurse Assigned:** | |
| **Phone/Pager:** | |
| **Email Address:** | |
| **Study or Data Coordinator:** | |
| **Phone/Pager:** | |
| **Email address:** | |
| **Biostatistician (If study is Institutional)** | |
| **Phone:** | |
| **Email Address:** | |

# Form "A1": IRB Application Greater than Minimal Risk Research

| Title of Project | Purpose of Project (one or two sentences) |
|---|---|
| | |

| Additional Co-Investigators/Consultants, denote role in study | Department or Institution/Email |
|---|---|
| | |
| | |

| | |
|---|---|
| **Estimated duration of total project** | |
| **Estimated total number of participants (including control participants)** | |
| **Age range of participants** | |
| **Gender of participants** | |
| **Where will the study be conducted? (if outside of HU, please provide letters of support)** | |
| **Source of participants** | |
| **Experience of Principal Investigator:** Brief summary (also attach a CV, biographical sketch) | |

(NEED INFO IF MULTI-SITE and OTHER SITES IRB APPROVAL)

| **Source of Funding/Grant Support for Project (if any)** Please attach two copies of the Grant Application | **Commercial Support (if any) for Project** |
|---|---|
| | |

# Form "A1": IRB Application Greater than Minimal Risk Research

| **Source of Funding/Grant Support for Project (if any)**<br>Please attach two copies of the Grant Application | **Commercial Support (if any) for Project** |
|---|---|
| **Investigational New Drug (IND)**<br><br>☐ None<br>☐ IND: FDA #_____<br>☐ Drug Name:_____<br>☐ Drug Sponsor:_____<br>☐ Significant (SR)_____<br>☐ Non-Significant Risk (NSR)_____ | **Investigational Device Exemptions (IDE)**<br><br>☐ None<br>☐ IDE: FDA No.:_____<br>☐ Device Name: _____<br>☐ Device Sponsor: _____<br>☐ Significant (SR) _____<br>☐ Non-Significant Risk NSR)_____ |
| **If this project involves an FDA regulated drug or device, you must file an FDA Form 3455: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Please submit any communications from the FDA regarding IND: Form 1571: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf or for IDE, or humanitarian use applications related to this submission: http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm205697.htm** | |
| **Phase: I ☐ II ☐ III ☐ IV☐ Pilot ☐** | |

## Section 2: Additional Howard University Regulatory Information

2.1 Does this project involve the use of biohazardous materials, recombinant DNA and/or gene therapy? If so, Institutional Biosafety Committee (IBC) approval must be obtained. Contact the Office of Regulatory Research Compliance at (202)865-8597 for assistance.

☐ Yes ☐ No

Has the Institutional Biosafety Committee approved the protocol?

| | |
|---|---|
| ☐**Approved** | **Date Approved**: |
| ☐**Application Pending** | **Date Submitted**: |

2.2 Does this project include the use of byproduct materials? If so, all protocols must be submitted to the Office of Radiation Safety. Contact the Office of Radiation Safety at (202) 806-7216 for assistance.

☐ Yes ☐ No

Has the Radiation Safety Committee approved your application to use byproduct materials at Howard University?

| | |
|---|---|
| ☐**Approved** | **Date Approved**: |
| ☐**Application Pending** | **Date Submitted**: |

2.3 Does this project involve the use of fetal tissue?

☐ Yes ☐ No

2.4 Do any investigators or co-investigators have a conflict of interest as defined in the Howard University Faculty handbook?

◯ Yes ◯ No

A copy of the current Conflicts of Interest Disclosure Form for each Investigator and Co-Investigator involved with this study must be attached to this application.

**THE FOLLOWING SECTIONS 3 to 5 SEEK to ESTABLISH COMPLIANCE with APPLICABLE FEDERAL REGULATIONS GUIDING CLINICAL RESEARCH: 45 CFR 46:**
Subpart A (§46.111, §46.116; and §46.117):
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta
Subpart B: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
Subpart C: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
Subpart D: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd

## Section 3: Information for Protocol Review

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

**3.1 Study Description** (summarize the protocol according to the following format in less than 2 total pages)

| |
|---|
| **Study Design** (for example, hypothesis, research question, standard and experimental procedures, special or unusual equipment or procedures) |
| **Rationale and justification for study** (for example, historical background, investigator's personal experience, pertinent medical literature): |
| **Primary study endpoint**: |
| **Primary objective**: |
| **Secondary objectives**: |
| **Treatment plan:** |
| **Statistical Considerations** (justification for sample size or "n", power or degree of change): |
| **Relative importance/value of the trial, considering "standard" therapy and competing trials**: |
| **Feasibility of study including projections for accrual of participants (Total and Howard University) and timeline for accrual:**<br>Anticipated Accrual for local site? _____<br>Overall Target Accrual? _____<br>How Long Will Study Be Open to Accrual?_____ month(s)<br>Duration of Study?_____ month(s) |

*3.2* **Use of Biospecimens and physiological data**: please provide details about biospecimen data collection, i.e. the use of the following urine, blood, saliva, hair, skin, nails, nasal swab, etc.) Additionally, please describe the storage, handling, transportation and disposal for all biospecimens to be used. *Please consult IRB policies and IBC for additional information on biosafety practices.*

**3.3 Risks**: Indicate what you consider to be the risks to participants **and** indicate the precautions to be taken to minimize or eliminate these risks. Justify the need for a placebo control group if one is included in this study. Where appropriate, describe the data monitoring procedures that will be employed to ensure the safety of participants. Use additional sheets as needed.

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

**3.5 Does a Data Safety and Monitoring Board exist?**

☐ Yes ☐ No

[A Data Safety and Monitoring Board, an independent group of experts, will review the data from this research throughout the study. Patients will be told about new information from this or other studies that may affect their health, welfare, or willingness to stay in this study.]

**3.6 Does this study include a Placebo?**

☐ Yes ☐ No

**3.7 Website Summary**: If this is an open clinical trial, recruitment material for clinical trials and information for sponsors about the type of research we do will be posted on the Clinical Trials website. Please create a brief summary, in Layman Terms (8th grade reading level) of 200 words or less for this protocol outlining the salient features that may be useful to public and health care professionals.

**3.8 Data Safety and Monitoring Plan**

**3.8.1 Assignment of Risk Levels** – Please select the risk level for your study and check the boxes that apply.

A Examples of procedures considered minimal risk:

| | | | |
|---|---|---|---|
| ☐ | Anthropomorphic evaluations | ☐ | DEXA scans |
| ☐ | Electrocardiograms (EKGs) | ☐ | Exercise testing |
| ☐ | All types of oximetry and Doppler studies | ☐ | Intravenous catheter insertion |
| ☐ | Magnetic resonance imaging (MRI) scans | ☐ | Observational studies |
| ☐ | Oral glucose tolerance tests | ☐ | Pathology slide review |
| ☐ | Special/prescribed diets | ☐ | Venipuncture |
| ☐ | Other non-therapeutic tests or studies. Please list: | | |

Note: *In the assignment of risk levels, a research survey may be considered more than minimal risk to participants if dealing with very sensitive information.*

**3.8.2 Adverse Events:** Plans for Reporting of Adverse Events Including the Death of a Participant:

Adverse events from this protocol will need to be reported to the HUIRB within 72 hours of its occurrence. Should a serious adverse event(s) occur that was not included in the risk statement in the protocol it must be immediately reported verbally and in writing. All serious adverse events, both related and unrelated to the research, should be reported. In the section below, please list other individuals and/or entities to whom adverse events will be reported.

| **Individual/Entity** | | |
|---|---|---|
| ☐ | Investigator | |
| ☐ | National Institutes of Health and/or | |
| ☐ | Food and Drug Administration (FDA) | |
| ☐ | Other agency or sponsor | Please specify: |

**3.8.3 Adverse Events Reporting Structure:** Who is the individual/entity primarily responsible for AE and to whom they are primarily reported:

| **Name** | **Position** |
|---|---|
| | |

**3.8.4 Safety and Monitoring:** Plans for Monitoring the Progress of Trials and the Safety of Participants

**3.8.5 Safety tests.** In the section below, please indicate the summary of safety tests, particularly those that screen out ineligible research participants and those that monitor for toxicity and other adverse outcomes.

| |
|---|
| |

**3.8.6 Safety Contact Information:** In the section below, please include a description of who will manage the patients and be responsible for assessing participants' responses including potential adverse events during their participation in the protocol. Please provide 24-hour contact information of the PI or other responsible member of the study team.

| **Name** | **Role on the Project** | **Can be contacted 24X7?** | **Contact Information** |
|---|---|---|---|
| | | | Phone: |
| | | | Pager: |
| | | | E-mail: |
| | | | Phone: |
| | | | Pager: |
| | | | E-mail: |
| | | | Phone: |
| | | | Pager: |
| | | | E-mail: |
| | | | Phone: |
| | | | Pager: |

| | | | |
|---|---|---|---|
| | | | E-mail: |
| | | | Phone: |
| | | | Pager: |
| | | | E-mail: |

**3.8.7 Drug Dispensing**: Description of Individuals/Entities in Charge of Dispensing Drugs. In the section below, please include the description of individuals and/or entities in charge of dispensing the drugs:

| Name | Role on the Project | Contact Information |
|---|---|---|
| | | Phone: |
| | | Pager: |
| | | E-mail: |
| | | Phone: |
| | | Pager: |
| | | E-mail: |
| | | Phone: |
| | | Pager: |
| | | E-mail: |

**3.8.8 Safety Monitoring Methods and Intervals:** In the section below, please check all that apply:

| Data to be Evaluated | Interval/Frequency of Evaluation* |
|---|---|
| ☐ Age specific intervention(s) | |
| ☐ Clinical test(s) | |
| ☐ Participant interview and/or contact | |
| ☐ Participant's physical exam | |
| ☐ Participant's symptoms or performance status | |
| ☐ Participant's vital signs | |
| ☐ Other study parameters. Please list: | |

**3.8.9 Decision-Making Criteria and Stoppage Rules:** In the section below, please describe data safety monitoring criteria for decision-making regarding continuation, modification, or termination of the clinical study.

| |
|---|
| |

**3.8.10 Monitoring of the Study:** In the section below, indicate who will monitor the study and to whom the study will report. Describe the frequency of the monitoring. If a DSMB is required, describe the composition of the board, its role, and the frequency of meetings and methods of communications.

| |
|---|
| |

**3.8.11 Participant Withdrawals/Dropouts:** In the section below, please describe how participant withdrawals/dropouts prior to study completion will be reported. Include examples of reasons that may prompt participant withdrawals/dropout.

## Section 4: Selection of Participants and the Informed Consent Process

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

☐ 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"]**

☐ Prisoners (45 CFR 46 Subpart C) **[If so, please complete Supplemental Form "I"]** (Note: Subpart C is not applicable to research in the general population, that only incidentally include prisoners)

☐ Pregnant women/Neonates/Fetuses (45 CFR 46 Subpart B) **[If so, please complete Supplemental Form "H"]** (Though pregnancy is no longer considered a vulnerable state (especially for socio-behavioral studies, consideration for the fetus remains important in biological science research)

☐ Cognitively impaired or mentally disabled participants

☐ Economically or educationally disadvantaged participants (e.g. the homeless)

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. (Use additional sheets as needed.)

**4.2 Recruitment: Describe how you plan to inform participants about the purpose and procedures for this study.** Describe how participants will be recruited and how informed consent will be obtained from participants or from the participants' legally authorized representative (LAR), and by whom. If children are the participants, discuss whether their assent will be sought and how the permission of their parents will be obtained. Use additional sheets as needed. Include information pertinent to the inclusion criteria and the exclusion criteria to be used:

**4.3 Equity and Justice: Does the review of this protocol include evaluation of patient population that ensure women and minorities are included, if appropriate?**

☐ Yes. This study is open to both men and women, and to all racial/ethnic groups. Since there are no prior reasons to expect different effects of therapy in male and female patients, and in different racial/ethnic groups, this study will not have separate accrual targets for these groups. Subgroup analyses will be conducted to determine gender and race/ethnicity treatment effects and will document any interactions between treatment and these factors.

☐ No

Explain the rationale for excluding these populations in the space below:

**4.4 Other Exclusions**: Please check the corresponding box if any of the following populations is excluded:

☐ **HIV**
☐ **Pediatric**
☐ **Other** _____

Explain the rationale for excluding any sub-population populations in the space below.

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

☐ Yes ☐ No

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

**4.6 Waiver of Documentation Informed Consent (45 CFR 46.117) Are you requesting a waiver of documentation (signed) informed consent?:**

◯ Yes ◯ No

If yes, will the only record linking the participant and the research be the consent document and the primary risk to participant would be breach of confidentiality?

Explain how you plan to obtain consent, please justify:

**4.7 Alternatives to participation:**

Describe alternative treatments if participant declines participation:

## Section 5: Privacy and Confidentiality of Data and Records

**5.1 Confidentiality and Data Security**: Will **identifiable, private, or sensitive information be obtained** about the participants or other living individuals? Whether or not such information is obtained from a covered entity (HUH), describe the provisions to protect the privacy and confidentiality of participants and secure research data. If the information does come from a covered entity, please attach a copy of the completed appropriate HIPAA General Authorization Form or Request for Waiver. Use additional sheets as needed. For HIPAA compliant forms, please refer to the Chief Compliance Officer, Howard University Hospital at (202) 865-5266.

# Form "A1": IRB Application Greater than Minimal Risk Research

| Section 6: Questions on NEW ELEMENTS of INFORMED CONSENT (Medical Sciences) Remember to describe the details in the consent document – Must match your responses here (See consent template) | | |
|---|---|---|
| **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)]? |

◯ 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.

# Form "A1": IRB Application Greater than Minimal Risk Research

☐ I assure that the protected health information identified on the "Medical Records Release and General Authorization to Use and Disclose Health Information for Research" 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.

| | |
|---|---|
| _____<br>Printed/Typed Name of Investigator<br><br>_____<br>Signature of Investigator | _____<br>Date |
| _____<br>Printed/Typed Name<br><br>_____<br>Signature of Department Chair | ☐ Approved<br>☐ Disapproved<br><br>_____<br>Date |
| _____<br>Printed/Typed Name<br><br>_____<br>Signature of Dean | ☐ Approved<br>☐ Disapproved<br><br>_____<br>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, are needed, then the chair or administrative official of each unit must also sign this application.

| | |
|---|---|
| _____<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 |

# Form "A1": IRB Application Greater than Minimal Risk Research

## IMPORTANT

## Section 7: Attachments That Must be Included with This Application

Please attach the following items in order for the HUIRB to review your research.

**A copy of the Following for Full Board review:**

- ○ IRB Application form (Form A-1)
- ○ Informed Consent Document(s)
- ○ Signed copy of The Principal Investigator's Assurance Form
- ○ Any recruitment notices or advertisements
- ○ Any research survey instruments, psychological tests, interview forms, or scripts to be used
- ○ HIPAA Authorization or Request for Waiver*
- ○ Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.

**A copy of the Following for Full Board review:**

- ○ Investigator's Brochure from the sponsor, if applicable**
- ○ Research protocol and sample consent document from the sponsor or Cooperative Group, if applicable
- ○ Grant application, if applicable

**A Copy of the following forms for Principal Investigator and ALL Co-Investigators:**

- ○ Certificate of Completion for HIPAA training and HIPAA forms if completing a chart review.*
- ○ Conflict of Interest or Financial Disclosure Form
- ○ Certificate of Completion of Education in the Protection of Human Research Participants (CITI)***
- ○ Investigator's qualifications (NIH biographical sketch)
- ○ If this project involves an FDA regulated drug or device, FDA form 3455

* **HIPAA Training**

All persons listed on the IRB application, Co-Investigators Page, Investigator's Agreement or 1572 of any research protocol will need to have completed the HIPAA training module for Researchers in order to secure HUIRB approval. Additionally, Investigators will need to assure that all key personnel involved in the research, especially personnel with data access and patient contact, have completed the HIPAA training module for Researchers. For more information and to download forms, please refer to the Chief Compliance Officer, Howard University Hospital at (202) 865-5266.

** **Investigator's Brochure (where applicable)**

The Investigator's Brochure must contain the following information. If it does not contain the information, then please attach a separate sheet of paper to address the item.

- Name of drug under study.
- Source of the drug.
- Experience with the drug in humans, including doses tested, toxicity observed, minimal toxic dose, pharmacokinetic data (absorption, elimination, metabolism, etc.).
- Description of toxicity in humans.
- Procedures for minimizing adverse reactions and dealing with those that might occur.

# Form "A1": IRB Application Greater than Minimal Risk Research

*** **Information on Human Participants Protection in Research Training: The ORRC**

*** **VERY IMPORTANT: As noted in Section 4, 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) **[Complete Supplemental Form "I"].** May **v**isit**:** **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