#  Howard University

**Office of Regulatory Research Compliance (ORRC)**

**NOTIFICATION OF EXCLUSION FORM**

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|  | **SECTION ONE: Investigator Data** |  |
| **Principal Investigator (Faculty Mentor):** | **Telephone Number and HU Email:**  |
| **College/School:**  | **Department/Unit:**  |
| **Student Investigator:**  | **Telephone Number and HU Email:**  |
| **Title of Project:**  |

**SECTION TWO: Certification**

**For Students Selecting the NON-THESIS (EXAMINATION ALONE) Option:**  Students who are selecting the non-thesis (examination alone) option, please complete sections “1” and “3” only

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| --- | --- | --- |
|  | YES | NO |
| * Does the project/study involve humans as research subjects?
 |[ ] [ ]
| * Does the project/study involve secondary data analysis?
 |[ ] [ ]
| * Do you plan to access or use identifiable private information (e.g. names, DOB, SS#, driver license #, address, etc.)?
 |[ ] [ ]
| * Does the project/study involve the use of vertebrate animal subjects?
 |[ ] [ ]
| * Does the project/study require the use of human or non-human primate tissues, body fluids, and/or primary or established cell lines?
 |[ ] [ ]
| * Does the project/study require the use recombinant or synthetic nucleic molecules?
 |[ ] [ ]
| * Do you plan to use genetically modified organisms including viruses, bacteria, fungi, animals or plants?
 |[ ] [ ]
| * Do you plan to use recombinant DNA or genetically modified plants or organisms?
 |[ ] [ ]
| * Does the study require the use of biohazards or infectious material?
 |[ ] [ ]
| * Does the project/study involve the receipt of or transfer of biological material (Material Transfer Agreement required)?
 |[ ] [ ]
| * Does the project/study require the use of ionizing or non-ionizing radiation?
 |[ ] [ ]
| * Will the project/study require the receipt or transmission of classified information or materials including encryption technology?
 |[ ] [ ]
| * Does the project/study involve nuclear or defense materials/technology?
 |[ ] [ ]
| * Does the project/study involve the use of technology, a product, material or data owned, or to be provided by, a third party?
 |[ ] [ ]

To determine eligibility for exclusion, please answer Yes/No to the above questions. If during review, the ORRC determines that your project does not meet the exclusion criteria, you will be asked to submit a NEW STUDY application to the appropriate regulatory compliance committee.

**Whereas, the student involvement in this protocol is acknowledged, however, please note that students are not recognized as PI on research protocols, but rather must work under the supervision of the faculty mentor.**

If you have responded **“NO”** to all of the above statements, then your application qualifies for an exclusion.

If you have responded **“ YES ”** to any of the above statements, then your application does not qualify for an exclusion.

If you are completing **COMPREHENSIVE EXAMINATION ONLY**, then no further action is required. Please sign this form and return to the ORRC for the records.

# SECTION THREE: Type of Research, or Graduation/Program Requirement

[ ]  Qualifying/Comprehensive Examination “ONLY”

[ ]  Thesis/Dissertation

[ ]  Non-Thesis Option Paper [ ]  Capstone Project

[ ]  Other:

**PLEASE NOTE:** Applications that do not meet the criteria for review by one of the regulatory research compliance committees are considered to meet the exclusion threshold. If your project has been determined to be excluded from review, you will not be required to submit an application to the ORRC. ***Please return your completed form and project summary to the ORRC;* via Email:** **exclusions.orrc@howard.edu****, Phone: 202-865-8597.**

# In the instance that your project is not eligible to be excluded, please submit an application to the appropriate regulatory committee for review; i.e., IRB, IACUC and/or IBC, along with all supporting documents.

* **Please attach a summary of your project which outlines the methods for the gathering of data.**
* **Notification of Exclusion is based on the information provided on this form and the accompanying project summary. If any of this information changes, a new notification of exclusion form must be submitted for review.**

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| **RESEARCH EXCLUSION CERTIFICATION SIGNATURES** |
| Student’s Signature:  | Date:  |
| (Comprehensive Examination Only) |  |
| Principal Investigator’s Signature: | Date: |
| (Others) |  |

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| **REGULATORY RESEARCH COMPLIANCE OFFICE USE ONLY** |
| APPROVED: [ ]  | DENIED: [ ]  |
| ORRC Staff Reviewer: |
| Name:  | Signature: | Date: |

**Website**: [WWW.Howard.Edu/ORRC](http://WWW.Howard.Edu/ORRC)

Telephone: 202-865-8597

Revised: 07/16/15