

DATE RECEIVED:

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**Howard University**  
**Office of Regulatory Research Compliance (ORRC)**  
**Regulatory Research Compliance Notification of Exclusion**

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

**NOTE:** 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.

**SECTION TWO: Certifications**

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

	Yes	No
<ul style="list-style-type: none"> <li>• This project will involve humans as research subjects or human data (including secondary data).</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require use of vertebrate animal subjects.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require use of human or non-human primate tissues, body fluids, and/or primary or established cell lines.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require use recombinant or synthetic nucleic molecules.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will use genetically modified organisms including viruses, bacteria, fungi, animals or plants.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>

<ul style="list-style-type: none"> <li>• This project will require use of recombinant DNA or genetically modified plants or organisms.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require use of biohazards or infectious material.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will involve receipt of or transfer of biological material. (Material Transfer Agreement required).</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require use of ionizing or non-ionizing radiation.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require use of biohazards or infectious material.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will require the receipt or transmission of classified information or materials.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will involve the use of technology, a product, material or data owned, or to be provided by, a third party.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• This project will involve the creation of software, drawings, written material or products for delivery to the sponsor (e.g., analysis, curriculum guidelines, and policy recommendations) other than common internal working documents, progress reports or publications.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>

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

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

### **SECTION THREE: Type of Research**

- 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 will be determined to be excluded. 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 the online portal at [www.howard.edu/orrc](http://www.howard.edu/orrc) or via Email: [theorrc@howard.edu](mailto:theorrc@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 methodology 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.

Principal Investigator Signature \_\_\_\_\_ Date \_\_\_\_\_

**Regulatory Research Compliance Office Use ONLY**

APPROVED \_\_\_\_\_ DENIED \_\_\_\_\_

\_\_\_\_\_  
ORRC Staff Reviewer

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date