HOWARD UNIVERSITY

Office of Regulatory Research Compliance
Institutional Review Board

FORM "D1": Exempt Review Application

FORM "D1"

IRB Application for Exempt Review

Title of Project:Click here to enter text.	
Submission Date	Click here to enter text.
Principal Investigator:Click here to enter text.	**Department**:Click here to enter text.
	Email:Click here to enter text.
	Phone: Click here to enter text.
Co-Investigator:Click here to enter text.	**Department**:Click here to enter text.
	Email:Click here to enter text.
	Phone: Click here to enter text.
Student Investigator: Click here to enter text. Is this a Thesis?: No:__ Yes:__ Is this a Dissertation?: No:__ Yes:__	**Department**:Click here to enter text.
	Email:Click here to enter text.
	Phone: Click here to enter text.

Note - Under the Revised Common Rule:

- **Exempt Category #3**: Was replaced
- **Exempt Category #7 (New) -** Covers the **Storage or Maintenance** of identifiable private information or identifiable biospecimens for secondary research (Broad Consent)
- **Exempt Category #8 (New) -** Covers the **Secondary Research** for which BROAD CONSENT is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research. The following criteria are met.

Note: **The Revised Common Rule includes some changes to each of the categories of exemption *except for category #7* that remain unchanged.**

For Additional Details: Please see the revised IRB Policy and Procedures on the ORRC website at www.howard.edu/orrc

HU IRB FORM D1: Exempt Review Application

1.	STUDY INFORMATION
	Is the research federally funded, supported, or regulated?
	Click here to enter text.

2. Background: Describe (briefly) pertinent background information leading to the present proposal.

Click here to enter text.

3. Purpose: Describe the purpose or objectives and expected benefits of the study.

Click here to enter text.

4. Specific Aims:

Click here to enter text.

5. Describe Research Methods:

Click here to enter text.

6. Recruitment Methods if Applicable:

Click here to enter text.

7. DATA Collection

a. Data Collection Instruments to be Used:

- ☐ Interviews
- ☐ Educational tests
- ☐ Questionnaires/Surveys
- ☐ Observation
- ☐ Existing data

☐ Other sources of information – Describe:Click here to enter text.
What is the expected time it will take to complete:
Where will the procedure occur:
Check the applicable electronic data capture methods

	☐	Audiotape
	☐	Videotape
	☐	Digital recording
	☐	Photographed

8. Data Security and Confidentiality

How will the information obtained identified/recorded

	☐	No identifiers associated with the information
	☐	Identifying information is obtained but not shared with anyone except study staff
	☐	Identifying information will be obtained and potentially used in publications.

If applicable, what measures will you take to protect the confidentiality of the research subjects: Click here to enter text.

9. Risks: What are the potential risks (including breach of confidentiality) and or benefits to subjects or society? Minimal (*Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.)* or

Click here to enter text.

10. Plans for Reducing or Eliminating 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.

Describe: Click here to enter text.

11. Benefits. Please describe how society and investigators will benefit from the knowledge gained.

Click here to enter text.

12. 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, Do not qualify for Exempt]**

☐ **Pregnant women/Neonates/Fetuses [May qualify for exemption under certain circumstances: 45 CFR 46.101(b) (1) through (6)]**

Note:

a.) **If you indicated the inclusion of any of the above populations: In the space below, please describe additional safeguards for protection from coercion or undue influence to participate. You must also complete the relevant supplemental forms.**

b.) **For research involving prisoners, exemption of informed consent is DISALLOWED:**

Description of the vulnerable population to be included in your research: Click here to enter text.

13. Under which of the following categories are you seeking exemption? Please check whichever is applicable:

☐	**45 CFR 46.101(i)** **45 CFR 46.401(b)**	**Is the Human Subjects Research Eligible for Exemption?** **http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2**
☐	**CATEGORY 1** **§46.101(b)1**	**For Educational Settings:** **http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c3**

☐	**CATEGORY 2** **§46.101(b)2**	**For Educational Tests, Surveys, Interviews, Public Behavior Observation:** ***http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c4***
☐	**CATEGORY 3** **§46.101(b)3**	**Replaced**: Research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings (Applies to behavioral interventions only) ***http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c4***
☐	**CATEGORY 4** **§46.101(b)4**	**For Existing Data, Documents, and Specimens:** **http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c5**
☐	**CATEGORY 5** **§46.101(b)5**	**For Public Benefit or Service Programs (Federal):** ***http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c6***
☐	**CATEGORY 6** **§46.101(b)6**	**For Taste and Food Quality and Consumer Acceptance Studies:** **http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c7**
☐	**CATEGORY 7** 45 CFR 46.104(d)(7), 46.111(a)(8), and 46.116(d)	Covers the Storage or Maintenance of identifiable private information or identifiable biospecimens for secondary research (Broad Consent)
☐	**CATEGORY 8** 45 CFR 46.104(d)(8), 111(a)(7) and 46.116(d)	Covers the Secondary Research for which BROAD CONSENT is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research. The following criteria are met:

14. Do You Plan to Obtain Consent:
If SO, please describe: Click here to enter text.
If NOT, Please Justify: Click here to enter text.
If Waiver is required - please complete the appropriate Waiver Form: Click here to enter text.
If Waiver is NOT required, please JUSTIFY: Click here to enter text.

Please Note:

1) However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C.

2) The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Assurances and Signatures

LEAD RESEARCHER

- I certify that I am aware of and agree with the information provided in this application
- I understand that I am ultimately responsible for the conduct of this research, the protection of the human subjects, and for the work of those I hire or supervise (including the content and accuracy of any correspondence or materials that they provide to the Office of Regulatory Research Compliance (ORRC) on my behalf).
- I will comply with all applicable HU policies and procedures and federal and state regulations on human subjects engaged in research, including, but not limited to, the following:
  - This research will not begin until a determination is received.
  - The research personnel is qualified and appropriately trained.
  - Unanticipated adverse events related to the research will be reported to OHRP according to Federal Regulations.
  - A co-investigator will assume full responsibility for the research if I am unavailable to direct this research.
-

Click here to enter text.	Click here to enter text.	Click here to enter text.
Typed name	**Signature of Lead Researcher**	**Date**

STUDENT INVESTIGATOR

Students may be a Lead Researcher on a human subjects' research project only if they provide the following consent in addition to signing the Lead Researcher assurance (above). The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. By signing below, I hereby give my consent to the Howard University to disclose as necessary personally identifiable information from my education records, which are relevant to and may include my IRB application and my human subjects research. Howard University school officials, including but not limited to IRB members; representatives of relevant state and federal agencies, such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA); individuals, organizations, or agencies and others that are involved with this research; and individuals, organizations, or agencies filling a complaint with the IRB or any Howard University of Regulatory Research Compliance (ORRC). Such disclosures shall be for one of the following purposes: compliance with contractual obligations, funding-related obligations, and state and federal laws and regulations regarding human subjects research; to provide

research subjects with information on potential risks and benefits of my research; to investigate and or respond to any complaint or concern of non-compliance with Howard University policies and or procedures and or federal, state, and local regulations in conducting my human subjects research; to verify whether my research was approved by the IRB: and to confirm the approval of my research activities by the IRB. I agree that this consent shall remain in effect for as long as "this" IRB file is retained by the Howard University.

Click here to enter text.	Click here to enter text.	Click here to enter text.
Typed name	**Signature of STUDENT Lead Researcher**	**Date**

FACULTY ADVISOR of Student Researcher

- I am responsible for working with the Student Lead Researcher to ensure that this research is performed in a manner compliant with appropriate human subjects' regulations and with the information provided in this application.
- I have reviewed and agreed with all the elements of this research proposal.
- I will provide continued relevant oversight and guidance to the student on the research.
- When unavailable, I will arrange for an alternate faculty advisor to assume my responsibility

Click here to enter text.	Click here to enter text.	Click here to enter text.
Typed Name	**Signature of Faculty Advisor**	**Date**

DEPARTMENT OR DIVISION CHAIR, CENTER DIRECTOR of Lead Researcher

- I certify that the researcher has adequate resources and is qualified to conduct the research.
- I concur with the student's choice of an appropriate faculty advisor.

Click here to enter text.	Click here to enter text.	Click here to enter text.
Typed name	**Signature of Department Chair**	**Date**

DEAN of the SCHOOL/COLLEGE of Lead Researcher

- I certify that the researcher has adequate resources and is qualified to conduct the research.
- I concur with the student's choice of an appropriate faculty advisor.

Click here to enter text.	Click here to enter text.	Click here to enter text.

Typed name	Signature of Dean	Date

Applications/Protocols can be submitted online at http://www.howard.edu/orrc
Should you have any questions, you may e-mail: theorrc@howard.edu or call the ORRC at (202) 865-8597.