Howard University Institutional Review Board
Request for Exemption (D-1)

(Please type this form)

Principal Investigator:	Date:
Title of Protocol:	

The human participants regulations (45 CFR Part 46) define **research** as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)]. A **human participant** is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information" [45 CFR 46.102(f)].

Section One: Application Information

PI/Faculty Advisor:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
Mailing Address:	
% Time/Effort	

Student Investigator:	
Department:	
Phone/Pager:	
Fax:	
E-mail address:	
% Time/Effort	
Student Investigator (if applicable):	
Department:	
Phone/Pager:	
Fax:	
E-mail address:	
Is this research for your thesis/dissertation?	☐ Yes
	☐ No

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

Co-Investigators/Consultants, if any	Department or Institution

Estimated duration of project	
Identify what is to accessed:	
Estimated total number of specimens, Charts, records, datasets:	
Indicate whether identifiers will be or have stripped.	
Where will study be conducted?	
Requesting exemption according to what Code of Federal Regulation #	
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 Two: 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.

1. **Background.** Provide a brief rationale for the project citing the pertinent scientific literature and the investigator's professional experience . *Use additional sheets as needed.*

2. 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 scales, instruments, interventions and/or procedures) to be used in the research. Identify any elements of the design that are innovative, unusual, or experimental. Where appropriate, provide statistical justification or power analysis for the number of participants to be studied. *Use additional sheets as needed.*

☐ I certify that the information furnished concerning the procedures to be taken is correct. I will seek and obtain prior approval for any modification in the protocol.

☐ 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 _____ Signature of Investigator	_____ Telephone number _____ Date
_____ Printed/Typed Name _____ Signature of Department Chair	_____ Signature of the Dean _____ 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.

_____ 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

Section Three: Attachments

Please attach the following items in order for the review your research:

Note: provide the original plus 2 copies of all materials for review.

- ☐ Request for Exemption (Form D-1) (always required)
- ☐ Request for Expedited Review (cover letter request on letterhead)
- ☐ Signed copy of The Principal Investigator's Assurance Form
- ☐ Signatures of your Dean and Chairman on the appropriate page
- ☐ Certificate of completion of education in the protection of human research participants (CITI for Principal Investigators and CITI and RCR for students) (required)
- ☐ Instrument(s), if applicable
- ☐ Investigator's qualifications (CV, biographical sketch)
- ☐ Formal research protocol or dissertation proposal, if available.
- ☐ Grant application, if applicable.

Applications/Protocols are to be delivered to the Office of Regulatory Research Compliance, located in the HU Research Building-1, 1840 Seventh Street, N.W., Suite #309, Howard University, Washington, DC 20001.

The Office of Regulatory Research Compliance does not accept electronic submissions at this time, should you have any questions, you may e-mail: theorrc@howard.edu or call the ORRC at (202) 865-8597.

* * *

Subpart A	**Basic HHS Policy for Protection of Human Research Subjects**
	Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b).
	Source: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[1] Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. 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.