HOWARD UNIVERSITY

Office of Regulatory Research Compliance

EXEMPT REVIEW CHECKLIST

Principal Investigator:

IRB #:

Study Title:

If the ONLY involvement of human subjects will be in one or more of the following categories AND all the answers in one or more categories is 'True' (except as noted in statements 7 and 11 below), the research may be eligible for exemption. However, the research must be declared EXEMPT by the HU IRB on the basis of the following answers, and responses on the HU IRB application form.

Checklist Statements	True	Not True	Regulation
[ ] Category 1 For Educational Settings:			
1 The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.)	☐	☐	45 CFR 46.101(b)1(i)
2 The research will involve only 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.	☐	☐	45 CFR 46.101(b)1(ii)
3 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	☐	☐	45 CFR 46.303(c)
4 The research is not subject to FDA regulations.	☐	☐	
[ ] Category 2 For Educational Tests, Surveys, Interviews, Public Behavior Observation:			
5 The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.	☐	☐	45 CFR 46.101(b)2
Address statement 6 only if the research will involve children as participants. If children will NOT participate, check N/A and continue with statement 7. 6 The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed.	☐ ☐ **N/A**	☐	45 CFR 46.401(b)
7 The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects. ***'True' to <u>either</u> statement 7 or 8 will qualify for exemption provided that statements 9 and 10 are true.***	☐	☐	45 CFR 46.101(b)2(i)
8 Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	☐	☐	45 CFR 46.101(b)2(ii)
9 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	☐	☐	45 CFR

			46.303(c)
10 The research is not subject to FDA regulations.	☐	☐	
[ ] Category 3 **For Educational Tests, Surveys, Interviews, Public Behavior Observation of Public Officials:**			
11 The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND the human subjects are elected or appointed public officials or candidates for public office. (Applies to senior officials such as mayor or school superintendent rather than a police officer or teacher.) ***'True' to <u>either</u> statement 11 or 12 will qualify for exemption provided that statements 13 and 14 are true.***	☐	☐	45 CFR 46.101(b)3(i)
Checklist Statements	**True**	**Not True**	**Regulation**
12 The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.	☐	☐	45 CFR 46.101(b)3(ii)
13 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	☐	☐	45 CFR 46.303(c)
14 The research is not subject to FDA regulations.	☐	☐	

[ ] Category 4 **For Existing Data, Documents and Specimens:**			
15 The research will involve only the collection or study of *existing* data, documents, records, pathological specimens, or diagnostic specimens. ("Existing" means existing before the research is proposed to the IRB to determine whether the research is exempt. All materials to be reviewed currently exist at the time of this exemption request.)	☐	☐	45 CFR 46.101(b)4
16 The sources of the existing data, documents, records or specimens are publicly available **<u>OR</u>** the information will be recorded by the investigator in such a manner that participants cannot be readily identified either directly or through identifiers (such as a code) linked to them.	☐	☐	45 CFR 46.101(b)4
17 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	☐	☐	45 CFR 46.303(c)
18 The research is not subject to FDA regulations.	☐	☐	
[ ] Category 5 **For Public Benefit or Service Programs (Federal):**			
19 The project is a research or demonstration project conducted by or subject to the approval of a (federal) Department or Agency head and which is 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 public benefit or service programs.	☐	☐	45 CFR 46.101(b)5

20 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	☐	☐	45 CFR 46.303(c)
21 The research is not subject to FDA regulations.	☐	☐	
22 The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).	☐	☐	
23 The research or demonstration project will be conducted pursuant to specific federal statutory authority.	☐	☐	
24 There is no statutory requirement that the project be reviewed by an IRB.	☐	☐	
25 The project does not involve significant physical invasions or intrusions upon the privacy of participants.	☐	☐	
26 The exemption has authorization or concurrence by the funding agency.	☐	☐	
[ ] Category 6 **For Taste and Food Quality and Consumer Acceptance Studies:**			
27 The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed **<u>OR</u>** (ii) food will be consumed that contains a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	☐	☐	45 CFR 46.101(b)6 21CFR 56.104(d)

Checklist Statements	True	Not True	Regulation
28 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	☐	☐	45 CFR 46.303(c)

[ ] Emergency Use of an Unapproved Test Article (i.e., a drug, device or biologic that is not FDA-approved)			
The activity involves emergency use of an investigational drug, device or biologic. Such an activity is not exempt from IRB review.	☐	☐	21 CFR 56.104(c)
The activity does not meet the DHHS definition of "research."	☐	☐	45 CFR 46.102(d)
[ ] Criteria that must be met for the research to be determined to be consistent with HU ethical standards			
The research holds out no more than minimal risk to subjects.	☐	☐	
Selection of subjects is equitable.	☐	☐	
If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.	☐	☐	
If there are interactions with subjects: There will be a consent process (and maybe some type of documentation) that will disclose such information as: ◆That the activities involve research. ◆The procedures to be performed. ◆That participation is voluntary. ◆Name and contact information for the investigator.	☐	☐	
There are adequate provisions to maintain the privacy interests of subjects.	☐	☐	

FOR THE IRB REVIEWER ONLY:

Is the activity exempt? YES ☐ NO ☐

Does the research meet the HU standards of ethical conduct? YES ☐ NO ☐

Which exemption category or categories apply to the activity? _____

Signature of IRB Reviewer:

Printed Name:

Date: