

DILLARD UNIVERSITY INSTITUTIONAL REVIEW BOARD
Request for Exemption

Principle Investigator:	
Title of Project:	

Some research involving human subjects may be exempt from IRB review. The categories below describe these exemptions. Please note that an exemption can be invoked **ONLY IF ALL COMPONENTS** of the research fit the category as described. To facilitate your decision, the DHHS decision charts found at the web site listed below may be helpful:

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

If you believe that your research may fall into one of the exempt categories, please indicate the relevant category in the appropriate space and the IRB Chairperson or designee will review your research to determine if an exemption can be granted. You will be notified in writing if your research has been approved for exemption.

NOTE: *If an exemption is granted, the principle investigator must notify the IRB if the research protocol changes in any way because the exemption may no longer apply; **AND** The IRB may request periodic follow-up; **AND** If an exemption cannot be granted, your exemption request will be returned to you with the rationale(s) for the decision and your research will automatically be submitted for review by the convened IRB.*

Section I

Categories eligible for Exemption (***Please indicate the category applicable for this project***)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - (a) Research on regular and special education instructional strategies, **OR**
 - (b) 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:
 - (a) When the subjects are ADULTS, information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects, **AND**
 - (b) When the subjects are ADULTS 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.

Note: This exemption also applies to research involving CHILDREN EXCEPT that (i) research involving survey or interview procedures with children is **NOT EXEMPT**, and (ii) research involving observation of the public behavior of children is **NOT EXEMPT** if the investigator(s) participate(s) in the actions being observed.

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:
- (a) the human subjects are elected or appointed public officials or candidates for public office; **OR**
 - (b) 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 of study of existing data, documents, records, pathological specimens, or diagnostic specimens (existing means research materials are already on the shelf or archived when the research is proposed; e.g. blood samples already taken from patients or subjects for other clinical or research projects) This exemption applies if:
- (a) These sources are publicly available **OR**
 - (b) The information is recorded by the investigator in such a manner that individual subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects that are designed to study, evaluate, or otherwise examine:
- (a) Public benefit service programs
 - (b) The procedures for obtaining benefits or services under such programs
 - (c) Possible changes in or alternatives to such programs or procedures; or
 - (d) Possible changes in methods or levels of payment for benefits or services under such programs

Note: This exemption applies **ONLY** to research and demonstration projects studying **FEDERAL** programs, and its use must be authorized by the Federal Agency supporting the research. Studies of state and local public service programs require IRB review. Waiver of informed consent is possible for such programs under 45 CFR 46.116(c).

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6. Taste and food quality evaluation and consumer acceptance studies, which meet any of the following conditions:

- (a) If wholesome foods without additives are consumed; OR
- (b) 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 FDA or approved by the EPA or the Food Safety and Inspection of the USDA.

Signature of Investigator

Date

Section II

Additional Materials

Please attach the following materials to this application:

1. Form IRB-A, Dillard University IRB Application (Protocol)
2. Informed consent document (if applicable)
3. Any survey tools and or questionnaires

Section III

FOR IRB USE ONLY

- Exemption Allowed (Category _____)
- Exemption Not Allowed (*See Comments Below*)

Comments:

Signature of IRB Chairperson

Date