New York Hospital Queens

Theresa & Eugene M. Lang Center for Research & Education

Exempt Application

Exempt means that the research will be reviewed for exempt status approval by the IRB Chairperson or designee, and will not be subject to continuing review under the federal regulations. The IRB must be notified of any changes to a protocol that has been given exempt status, as the changes may require the project to undergo IRB review.	
Protocol Title:	
Principal Investigator:	
Name of Person Completing this Form:	
Email:	**Phone #**

In order to qualify for exempt status, the research must fall into one of the following categories, as described in 45 CFR 46.101(b), 45 CFR 46.401(b), or 21 CFR 56.104. **Please select the category that describes your research:**

☐ 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.

☐ 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. **NOTE***: For research involving survey or interview procedures or observations of public behavior, this exemption category does not apply when the research involves children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.*

☐ 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.

☐ 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.

Did the data exist prior to the time the research was proposed?

- ☐ YES
- ☐ NO – If so, the research does not qualify for exempt status. Please complete the Application for Review of a Research Project and do not apply for exempt status.

☐ 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;

(a) the program under study must deliver 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);

(b) the research or demonstration project must be conducted pursuant to specific federal statutory authority;
(c) there must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB); and
(d) the project must not involve significant physical invasions or intrusions upon the privacy of participants (see 12/97 OPRR Guidance at http://www.dhhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm). This exemption is for projects conducted by or subject to approval of Federal agencies, and is most appropriately invoked with authorization or concurrence by the funding agency.

(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.

☐ 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.

☐ Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

☐ Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

Principal Investigator's Statement	
I understand studies that qualify as exempt are subject to the same regulations and ethical principles governing all research. I will inform the IRB of any changes in the research submitted with this application (e.g., study design, procedures, etc.), as the changes may necessitate IRB review.	
_____ Principal Investigator Signature	_____ Date
IRB Use Only	
Please check one: ☐ Project is **exempt** from IRB review. Please indicate the category # from item 3 above: _____ ☐ Project requires **expedited** IRB review. ☐ Project requires **full** IRB review. Please check one: ☐ HIPAA applies (if the data collected is **NOT** de-identified) ☐ HIPAA does not apply (if the data collected is de-identified)	
IRB Reviewer's Printed Name:	**Date**
IRB Reviewer's Signature	