100 GD.9 Guidance on Exemption from IRB Review

Overview

Federal regulation and IRB policy acknowledge that certain categories of research pose little risk to participants and hence do not require continuing oversight by the IRB. Research which is limited to one or more of the exemption categories may be reviewed by the IRB and deemed exempt from full review and oversight by the IRB. Once the IRB has determined that a project qualifies for exemption, no additional oversight is required by the IRB except in cases where the study is to be modified in a way that would change the applicability of the exemption determination, or when there are unanticipated problems involving risks to participants or others. Exemption determinations rely on an understanding not only of federal regulation and university policy but also on current federal guidance and industry best practice standards; hence determinations of exemption status are made by the IRB. This document provides guidance on applying the exemption categories to human research. Additional federal guidance is available at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

45 CFR 46.101(b)(1) Educational Research

Educational research may qualify for exemption if the project meets all of the following criteria:

- The research is conducted in commonly accepted educational settings. Commonly accepted education settings include school class rooms, university class rooms, museums, educational centers such as nature centers or music schools. The location should be such that the participants are aware that learning occurs there.

- The research involves normal educational practices such as research on regular or special education instructional strategies or research on the effectiveness of, or the comparison among, instructional techniques. Normal education practices include lectures, seminars, didactic sessions, workshops, and standardized testing. The educational practices involved in the research, while they may be innovative, should not be outside the nature and/or scope of methods used in standard education.

- The goal of the research is to improve aspects of education such as improvement of student understanding, educational performance, ability to function productively in the class room, etc.

- The research is not regulated by the FDA and does not involve prisoners.

Investigators should also be aware that school based studies may also invoke other regulatory requirements. In particular, academic records are subject to the Family Educational Rights and Privacy Act (FERPA) which limits the ability of schools to release student records without appropriate authorization. The Protection of Pupil Rights Amendment (PPRA) requires parental consent for surveys involving sensitive topics such as sexuality, illegal behavior, and political affiliations.

45 CFR 46.101(b)(2) Educational Tests, Interviews, Surveys and Public Observation

Educational tests, interviews, surveys and public observation may qualify for exemption when the research meets the following criteria:

- The research is limited to:
  - educational tests including cognitive, diagnostic, aptitude and/or achievement, and/or
  - survey procedures, and/or
  - interview procedures and/or
  - observation of public behavior.
• The information collected is anonymous or, if identifiers are kept, the information collected does not pose a risk of criminal or civil liability or could be damaging to the participants' financial standing, employability, or reputation if the information was disclosed.
  o Note that these criteria allow sensitive information to be collected if the information can not reasonably be associated with the identities of participants. Ability to identify participants is determined based on the type and extent of information collected. For example, in a small population, a sufficient amount of demographic information even without name, social security number or address, may still be considered to be identifiable.
  o Also note that potential for disclosure includes both intentional disclosure by the investigator (e.g. publication) as well as unintentional disclosure such as a breach of data security. In this exemption, whether or not the data will be disclosed or protected from disclosure is irrelevant to the determination as to whether there is a risk of harm from such a disclosure.

• May involve children only if the research is limited to public observation and the investigator does not interact with the children.

• Is not regulated by the FDA and does not involve prisoners.

• Does not involve the psychology subject pool operated by Yale University.

• Research deemed exempt under this category must still conform to HIPAA requirements if the data is collected from a HIPAA covered entity or the research will be conducted by University personnel subject to HIPAA. In particular, note that the criteria for the ability to identify participants here does not require full de-identification under HIPAA. Research may still be considered “anonymous” and hence exempt under this category while including some of the HIPAA identifiers. Thus the researcher may be required to request that the IRB issue a waiver of HIPAA authorization when the data is deemed anonymous under the Common Rule but not de-identified in accordance with HIPAA.

45 CFR 46.101(b)(3) Educational Tests, Interviews, Surveys and Public Observation not Qualifying for Exemption (b)(2) but Involving Public Officials, Candidates for Office, or Statutorily Protected Information

Educational tests, interviews, surveys and public observation may qualify for exemption when the research meets the following criteria:

• The participants are limited to (i) elected or appointed public officials or candidates for office, or (ii) there are federal statute(s) which require without exception that the information collected will be maintained confidentially throughout the research and thereafter.

• The research is limited to:
  o educational tests including cognitive, diagnostic, aptitude and/or achievement, and/or
  o survey procedures, and/or
  o interview procedures, and/or
  o observation of public behavior.

• Is not regulated by the FDA and does not involve prisoners.
45 CFR 46.101(b)(4) Existing Publicly Available or Anonymous Data Sets or Specimens

Research involving existing data or specimens may be deemed exempt if the following criteria are met:

- Data are limited to data, documents, records, pathological specimens and/or diagnostic specimens which are currently in existence at the time the research is proposed. No additional future data or specimen collection may be involved in research qualifying for this exemption category.

- The data is either publicly available or the data will be recorded by the investigator such that participants can not be identified either through collection of identifying information or through a code linking the data to the participants’ identities. Data may be identifiable at the time of access but must be recorded by the investigator without inclusion of any identifiers.

- Is not regulated by the FDA.

- Does not involve prisoners, was not collected from individuals while they were imprisoned or include individuals known to currently be imprisoned.

- Research deemed exempt under this category must still conform to HIPAA requirements if the data is collected from a HIPAA covered entity or the research will be conducted by University personnel subject to HIPAA. In particular, note that the criteria for the ability to identify participants here is not the same as de-identification under HIPAA so exempt research may still require that the IRB issue a waiver of HIPAA authorization, if applicable.

45 CFR 46.101(b)(5) Public Benefit or Service Programs

The exemption for research and demonstration projects examining public benefit or service programs requires that the project meet the following criteria:

- The research is designed to study, evaluate or otherwise examine a public benefit or service program, such as:
  - The program itself, or
  - Procedures for obtaining benefits or services under the program, or
  - Changes or alterations to those programs, or
  - Changes in methods or levels of payment for benefits or services under the program(s).

- The program to be studied must deliver either:
  - A public benefit such as financial or medical benefits under the Social Security Act, or
  - A public service such as social, supportive, or nutrition services under the Older Americans Act.

- The research or demonstration project must be conducted pursuant to specific federal statutory authority, or if not a federally funded project, pursuant to specific authority of the funding source. In either case, the authority must concur with the exemption determination.

- There is not a statutory requirement for IRB review.

- The research does not include any significant physical invasions or intrusions upon the privacy of participants.

- The research does not propose to collect data in addition to that which is necessary for the study, evaluation or examination of the public benefit or service program.

- Is not regulated by the FDA.

- Does not involve prisoners.
45 CFR 46.101(b)(6) Taste and Food Quality

Studies evaluating taste and food quality or consumer acceptance studies of food and food products may be determined to be exempt if the following criteria are met:

- Only wholesome foods without additives are consumed, or
- The food to be consumed includes a food ingredient at or below the level and for a use found to be safe or includes an agricultural chemical or environmental containment at or below the level found to be safe by the Food and Drug Administration, Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.