Guidance: Exemptions – examples, and additional considerations

Overview

The Code of Federal Regulations identifies several different categories of minimal risk research as being exempt from the Common Rule, 45 CFR, Part 46.

This documents delves deeper into each category and provides examples and additional considerations.

Category #1: Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes:

(i) most research on regular and special education instructional strategies
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Guidance

Commonly accepted educational settings: include but are not limited to K-12 schools and college classrooms; after school programs; preschools, vocational schools, alternative education programs and other sites where educational activities regularly occur.

Normal educational practices include established teaching methods, curriculum content, commonly accepted classroom management techniques that are planned and implemented by the classroom teacher, and, on a case-by-case basis, projects conducted with teachers for professional development purposes. Normal educational practices are activities that would occur regardless of whether the research is conducted.

The IRB considers educational time to be a valuable commodity, and thus, the design of a research study that will be carried out in an educational setting should be developed with this in mind. At the minimum, the research should not waste student educational time, and may offer benefit to the individual and/or class-wide educational experience. The IRB will consider the proposed methodology for the study in light of both time requirements and likelihood of benefit in order to determine whether it qualifies as normal educational practice. In all cases, the IRB will need to assess risks to all proposed participants in the study to determine the level of review required. Thus, a study that evaluates a radically new instructional strategy or curriculum, or that randomly assigns students to different instructional strategies/curricula for

comparison, would probably not be exempt, since these are not "normal educational practices." Studies that involve surveys and interviews with minors that are outside of "normal education practices" also do not qualify for exemption.

Examples

- Evaluating the use of accepted or revised standardized tests
- A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practices.
- A study comparing two curricula that are currently being implemented in a school. Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials (but not about specific students).
- A study comparing driver's education curricula offered by area driving schools. The researcher will observe classes and compare group driving test scores at the end of the course.

Category #2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects; OR

(ii) Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or indirectly through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination requested by §46.111(a)(7).

Guidance

Information is gathered in such a manner that subjects cannot be identified, either directly (such as if you use photographs, video tapes, or voice recordings) or indirectly through identifiers (e.g., codes) linked to individuals; and Any disclosure of the subjects' responses

outside of the research will not be damaging to the subject in any way (i.e., subject them to criminal or civil liability, damage financial standing, reputation, etc.).

The information collected is not anonymous (because, for example, the researcher has a key linking respondents' names to coded identifiers), but the information is so innocuous that, in the event of disclosure outside of the research, there would be no significant detrimental consequences to the subject. The significance of "detrimental consequences" depends in part on context. For example, including a question about sexual identity in an interview study that investigates adults' plans to change careers could be non- controversial – and exempt – in some locales, but highly sensitive – and non-exempt – in other places.

Data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. If a study falls under one of these exemption category, a limited IRB review will be completed to determine there are adequate provisions for protecting subject privacy and maintaining confidentiality.

Sensitive survey research is not exempt. A sensitive survey is one that deals with sensitive or highly personal aspects of the subject's behavior, life experiences or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc. The principal determination of sensitivity is whether or not the survey research presents a potential risk to the subject in terms of possible precipitation of a negative emotional reaction. An additional risk consideration is, of course, whether or not there is risk associated with a breach of confidentiality should one occur. With respect to potential psychological risk associated with a survey, the presence or absence of subject identifiers is not necessarily a consideration since the risk may be primarily associated with the sensitive nature of the survey as opposed to being dependent upon confidentiality. Subject identifiers do, however, become a factor when confidentiality is an issue.

Research Involving Children

Research involving children can be classified as exempt under this category if the research involves only educational tests and/or observation of public behavior where the investigator does not participate in the activities being observed and meets the other conditions of the exempt category.

Examples

- Surveying teachers, nurses, or doctors about a technique or outcome
- Interviewing managers about a management styles or best practice
- A study involving an anonymous survey regarding workplace satisfaction at area firms.
- An observational study of pedestrians crossing a street; the researcher takes notes of what occurs, recording sex, race, and type of clothing of pedestrians, but does not interact with subjects.

- A study involving interviews with college seniors (age 18 and older) about their plans after graduation. The answers to questions asked would present no risks to subjects if divulged outside the research.
- A study involving focus groups with expectant mothers regarding their perceptions of parenting education.

Category 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR

(ii) Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review to make the determination requested by §46.111(a)(7).

Guidance

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Brief in duration is intended to refer to the intervention as opposed to the intervention and the data collection activities together. Thus, the data collection activities could proceed over a longer period of time without precluding the applicability of this exemption. If the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration. To meet the requirement of brief in duration, the benign behavioral intervention should last a few minutes to a few hours.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is

informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Examples

- Solving puzzles under various noise conditions. Study procedures take about 2 hours.
- Playing an economic game: having them decide how to allocate a nominal amount of received cash between themselves and someone else
- Being exposed to stimuli such as color, light or sound (at safe levels)
- Performing cognitive tasks
- Healthy adult subjects are asked to take part in two two-hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.

Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available; OR
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"
(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities.

Note: Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records, or existing repositories of clinical specimens. No contact between investigator and

subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another IRB review path will be required. Exemption Category 4(iii) only applies to the use of data (when HIPAA applies) and not to biospecimens.

Examples:

- A researcher is given two datasets that contain private, identifiable information. The researcher uses the identifiers to merge the two datasets but strips the resulting (merged) data of identifiers immediately after the merge and before conducting data analysis. The resulting data used for analysis is completely de-identified with no links to identifiers.
- A research study of treatment outcomes for a certain drug that involves the review of patient charts at a non-UC clinic. The researcher records patients age, sex, diagnosis, and treatment outcome in such a way that the information cannot be linked back to the patient.
- A student will be given access to data from their faculty advisor's health survey research project. The data consists of coded survey responses, and the advisor will retain a key that would link the data to identifiers. The student will extract the information she needs for her project without including ant identifying information and without retaining the code. The use of the data does constitute research with human subjects because the initial data set is identifiable (albeit through a coding system); however, it would qualify for exempt status.

Category 5: Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

(i) public benefit or service programs, including procedures for obtaining benefits or services under those programs,
(ii) possible changes in or alternatives to those programs or procedures, or
(iii) possible changes in methods or levels of payment for benefits or services under those programs.

Guidance

Exempt category 5 projects include, but are not limited to, internal studies by Federal employees, and studies under contracts of consulting arrangements, cooperative agreements, or grants.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category 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 Dept. of Agriculture

Guidance

Taste and food quality evaluation studies conducted under this exemption may not involve the consumption of any type or volume of food that would present any risk to the subjects and should fall into what would be considered reasonable eating behaviors by the subject.

The food must be “wholesome” (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA. Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for exempt status.

Examples

- A taste-test on different varieties of a fruit to determine consumer preference, when the fruits do not have any additives and subjects are asked to indicate which fruit they prefer.

Although the HHS IRB regulations list eight exemption categories, NU has opted to implement six of those categories at this time

Consent Process

The Belmont principle of respect for persons generally pertains to one's voluntary participation in a research study. Exempt protocols should have mechanisms in place to provide information so an individual may make a fully informed choice. The NU website provides a template for the participant information sheet. At a minimum, the following information is to be provided:

1. An explanation that they are being asked to participate in a research study.
2. The identity and affiliation of the researcher.
3. A clear description of the study procedures and how data will be used in the future.
4. A statement that participation in the research is voluntary.
5. Contact information for questions and concerns about the research.

Changes to exempt protocols

Modifications do not need to be submitted for exempt studies so long as the research remains minimal risk and stays within the boundaries of the exemption categories that the IRB found were applicable to the research.

Examples of when modifications are required include:

- Revisions to the consent process, or use of deception or incomplete disclosure.
- Significant changes to the recruitment procedures and additions of new data collection sites.
- Adding sensitive questions to a survey or interview process (e.g. questions regarding illegal activities; traumatic events such as childhood, sexual, or domestic abuse; suicide; or other probing questions that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation).
- Collection of new or additional identifiable information.
- add new types of participants to your study that include vulnerable populations (e.g., adding children, individuals with cognitive impairments, prisoners, etc.)
- Changes to the data storage plan which may affect confidentiality.

There are also instances where modifications will not impact risks to participants or impact exempt determination, however, must still be reported to the office. Examples of these include:

- change of Principal Investigator
- new data collection sites where a letter of support is required.
- Addition of external funding source.

Please contact the office if you have specific questions regarding when to report a modification to an exempt protocol.

IRB Authorization Agreements

An Authorization Agreement may be established when more than one institution is engaged in the same human subject research effort requiring IRB oversight. These agreements allow an IRB to exercise regulatory oversight over the actions of another institution's investigators. Studies that are determined to be exempt per the provisions at 45CFR46.101(b) are exempted from the regulatory oversight requirements. An IAA cannot be used if there is no oversight to exercise or cede. If all research activities are qualified as exempt, non-NU collaborating investigators will need to seek an IRB exempt determination from their home institution. In the event the non-NU collaborators are not affiliated with another institution, or with an institution with an FWA, a collaborative investigator agreement may be provided by NU. Please contact the NU HRPP for guidance, IRBreview@northeastern.edu.

Research that is not exempt:

Research that involves greater than minimal risk: Research eligible for exemption usually involves negligible risks to subjects. When reviewing an application for exempt status, the "minimal risk" definition is practiced. As defined in the federal regulations, minimal risk means, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Deception, manipulation or incomplete disclosure: Research that include any of these during the initial consent process are not eligible for exemption.

Research with vulnerable populations: Certain research activities are not eligible for exempt status because additional protection has been required by federal regulations for vulnerable populations.
Specifically, the following do not qualify for exempt status: (1) survey or interview of children; (2) observation of the public behavior of children when investigators interact with the children; (3) interactions with individuals with cognitive impairments; and (4) research involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Research regulated by the Food and Drug Administration (FDA): With the exception of Category 6, FDA-regulated research does not qualify for exempt status. In addition, research does not qualify for exempt status under Category 6 if there have been food and color additives incorporated into the food product and these additives are used in research with the intent to apply to the FDA for marketing of the additive.

Resources:

Federal Regulations, §46.104 Exempt research

Northwestern University

University of Connecticut

University of California – Berkeley

George Washington University

Colorado University – Boulder