

III. What Kinds of Social and Behavioral Research Activities are Eligible for Expedited Review?

The Common Rule references a list of nine categories of research involving human subjects that may qualify for expedited review⁹ which vary in applicability to social and behavioral research studies. The first four of the nine categories primarily pertain to biomedical research studies, and concern the use of drugs or medical devices, the collection of blood samples or biological specimens, or noninvasive procedures routinely employed in clinical practice. These will not be discussed here, nor will the last two categories, which concern the circumstances under which expedited review may be used for the continuing review of research activities originally reviewed by the full IRB at a convened meeting. Categories five, six and seven are most relevant to social and behavioral research studies, and are as follows:

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

These categories are relatively broad and potentially include a wide variety of different kinds of social and behavioral research studies. As noted, the categories also include some research studies that are exempt from the Common Rule, and do not require either expedited or full board review. Because the wording of the categories is not elaborate, it is not always obvious what kinds of research studies fall within each category. Some fairly common types of social and behavioral research activities do qualify for expedited review under one or more of these categories, assuming that they also meet the standard of minimal risk. A number of these types of research activities, accompanied by brief illustrative examples, are as follows⁹.

⁹ 45 CFR 46.110(a), and *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure*, Federal Register (November 9, 1998, Federal Register (63 FR60364-7), available at: <http://www.hhs.gov/obrp/humansubjects/guidance/expedited98.htm>.

- A. Secondary analyses of existing or future data sets, such as databases containing medical records, criminal justice system records, education records, or survey data. These analyses may include studies where one or more data sets are combined.

For example:

An analysis of student educational records to explore the relationship between student mobility from district to district and student academic achievement for students from various economic and ethnic backgrounds. [Category (5)];

A study of prison administration records to explore the relationship between inmates' individual background characteristics, type of criminal violation, and acquisition of a Graduation Equivalent Development (GED) credential¹⁰. [Category (5)];

A study of medical records and survey data to compare people's weight with the cultural attitudes of different subpopulations toward diet and exercise. [Category 5].

- B. Observational studies of human behavior and characteristics where personal identifiers are recorded and the data are not particularly sensitive in nature.

For example:

A study using video recordings to examine communication styles used by cooperating employees in a variety of business organizations. [Category (6)];

A laboratory study comparing patterns of eye movement and reading comprehension performance among novice and competent readers. [Categories (6) and (7)];

- C. Experimental studies of human behavior, attitudes, opinions, and decisions, where the experimental manipulation consists of subjects reacting to hypothetical or contrived situations that are not expected to have significant lasting effects on the subjects.

For example:

A study in experimental economics in which people play an economic game that involves offering and/or accepting amounts of cash provided as part of the experiment. [Category (7)];

A study of adults' ability to identify accurately the perpetrators of staged thefts. [Category (7)];

A study attempting to validate a previously tested measure of extroversion/introversion with members of a previously untested cultural group. [Category (7)].

¹⁰ In its guidance document, "Guidance on the Use of Expedited Review Procedures," the Office for Human Research Protections (OHRP) recommends that: "... (3) expedited review procedures NOT be used for research involving prisoners. However, if an IRB chooses to use expedited review for research involving prisoners, OHRP recommends that the prisoner representative of the IRB be one of the designated reviewers." Readers should note that this is a recommendation, not a requirement, and that OHRP clearly recognizes this in the second part of its recommendation, which is directed toward how expedited reviews should be carried out if the institution does elect to use the expedited review procedure.

- D. Survey research where the respondents are approached in a natural setting, either personally or through a communications medium (e.g., by mail, telephone, or the internet), and participation is voluntary. For example:

A research study using telephone surveys of persons who provide their names and information about their background characteristics, political beliefs, and voting behavior. [Category (7)];

An online internet study in which undergraduate students view a video clip about economic theory and then respond to computer-simulated scenarios about individual spending decisions. [Category (7)];

- E. Evolving research activities (such as ethnographic studies or focus group research) where the research activity is refined in various ways in response to earlier data collection, and the topics are not especially sensitive. For example:

An ethnographic field study using un-structured interviews to explore the interrelationship between family life and involvement in religious activities. [Category (7)];

An ethnographic study using participant-observation where the researcher participates in the subject's activities of daily life, such as an anthropologist studying an agrarian market place by sitting in the respondent's market stall, observing interactions and sometimes selling items to help out. [Category (7)];

A participatory action research project in which middle school teachers and students use group discussions, surveys, and interviews to evaluate the school's social studies curriculum and develop recommendations for improvements. [Category (7)];

The types of research activities listed above should not automatically be considered minimal risk simply because they are presented here. The presentation of these types of research activities only indicates that a significant portion of these types of research activities will be *eligible* for review through the expedited review procedure, depending on whether the specific circumstances of the proposed research activity involve no more than minimal risk to human subjects. Decisions regarding eligibility for expedited review must be made on a case-by-case basis.

It should also be noted that some research studies may not fit any of the types of research activities presented above, and yet still fall within the categories of the Common Rule's list of research activities eligible for expedited review. The variety of topics and research designs in social and behavioral research studies is substantial, and studies whose designs are unusual in some way may still qualify for expedited review. Here again, the decision must be made on a case-by-case basis.

In summary, a research activity must meet two qualifications in order to be eligible for expedited review: First, it must involve no more than minimal risk to the subjects, which means that the potential for negative effects of participating in the research activity must be no greater than the potential for negative effects of i) routine physical examinations or tests, or ii) routine psychological examinations or tests, or iii) daily life. One of these three standards may lend itself more readily than the other two to comparison with a particular social or behavioral research activity, depending on the nature of the activity and its potential for negative effects. That potential may be influenced by the characteristics of the specific population of research subjects,

and by features of the research activity that are designed to prevent or decrease the likelihood or seriousness of possible harm or discomfort. Second, the research activity must fit into one of the categories of research involving human subjects on the list approved by the Department of Health and Human Services and the Food and Drug Administration. Categories five, six, and seven on that list are especially germane to social and behavioral research activities. Because these categories encompass a range of different kinds of research activities, the reviewer needs to examine the particular research activity carefully to determine if it falls within one of those categories.