

# Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities<sup>1</sup>

Institutions carrying out research activities under the federal policy for the protection of human subjects (a.k.a. the Common Rule) must agree to comply with the Common Rule's requirements and follow identified ethical principles to protect the rights and welfare of human research subjects. Institutions have considerable discretion in the procedural arrangements they may use to fulfill these responsibilities, particularly with regard to three kinds of activities: (1) Some activities do not fit the regulatory definitions of "research" involving "human subjects", and therefore do not fall under the Common Rule. (2) Some activities fit those definitions but may be judged "exempt" from the Common Rule's requirements. (3) Some activities are covered by the Common Rule, but are eligible for "expedited review." This document's purpose is to call attention to various options institutions may use to improve the effectiveness and efficiency of their procedures for reviewing these kinds of activities.

## 1. Who Should Decide Who Will Review What?

**Background.** Institutional Review Boards (IRBs) are the committees charged with reviewing research activities covered by the Common Rule. At many institutions, IRBs or IRB chairs assume the responsibility for deciding whether a particular proposed activity is covered by the Common Rule and needs review. The decision involves the proper application of the regulatory definitions of "research" and "human subject", and may also involve the application of six regulatory categories of exempt involvement of human subjects. Deciding that a given activity does not fit the two definitions, or else that it is exempt, means that the institution sets its own policy about if, when, and how the activity will be reviewed, and by whom.

Applying the definitions and exemption categories to a proposed activity can be a complicated task. Substantial time and effort may be involved in this decision, delaying the process. Investigators do not always provide complete and relevant information when requesting a decision about whether a proposed project requires review. IRB chairs may be busy with other responsibilities, and take some time to get to this task. If an IRB uses convened meetings to decide which projects need to be reviewed, and the meetings only take place at periodic intervals, decisions may be slowed by the IRB's schedule. Some institutions do not apply the exemptions, in part because applying them can be difficult, which results in an increase in the IRB's workload of projects to be reviewed for approval.

Alternative procedures could alleviate some of the delays caused by this institutional bottleneck. The regulations do not specifically identify who has the authority to decide which activities should undergo IRB review, but experience has shown that federal agencies will allow appropriate institutional officials other than IRBs or IRB chairs to make decisions about applying the Common Rule to a proposed activity. These officials should have three characteristics: First, they should have the institutional authority to represent the institution on these matters. Second, they should have no direct involvement in the proposed activity they are examining. Third, they should be thoroughly familiar with the Common Rule, their own institution's policies, and the nature of research, so that they can make sound judgments about the applicability of relevant policies to proposed activities.

Some institutions may find it worthwhile to include an appeal process in their procedural arrangements. An appeal process allows researchers and others to question a decision about forwarding a proposed activity to the IRB for review. An appeal process can serve as a quality control mechanism for checking whether a decision was appropriate and consistent with institutional policy. The process could

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<sup>1</sup> This paper was developed by the Social & Behavioral Science Working Group.

involve sending appeals to the IRB chair, or to some other qualified official with the designated authority to overturn or uphold decisions.

Recommendation. Institution policy should ensure that sound decisions about the need for IRB review are made promptly. Institutions should designate appropriate numbers of knowledgeable and disinterested representatives to make decisions regarding the applicability of the Common Rule and other relevant policies to proposed projects

## II. Who Should Review Exempt or Other ‘Research’ Activities?

Background. As a result of their implementation of the federal policy, many institutions charge their IRB(s) with the task of reviewing all research-related activities involving human subjects. IRBs review these activities regardless of whether or not they fall within the Common Rule’s definitions of “research” involving “human subjects”. IRBs review a range of research and research-like activities, some of which are not required by regulation to meet to the Common Rule’s criteria for approval. These activities include -

- Activities that do not fit the regulatory definitions of “research” or “human subject”, even though they are considered ‘research involving human subjects’ insofar as they collect or analyze information about people according to some conventional academic meaning of the terms.<sup>2</sup>
- Research activities that are exempt from the Common Rule but which the institution has elected to review nonetheless.
- Research-like activities that are carried out for purposes ancillary to research, such as training exercises for students or prospective research staff.

IRBs’ capacity to perform appropriately thorough reviews of proposed activities may be hampered if such activities are added to the workload they have by virtue of the quantity of proposed projects they are required by regulation to review. Covered research activities involving significant levels of risk may receive less attention than they should. Activities that are not covered and whose timing is constrained by the academic calendar of the institution - because students are involved as researchers or as subjects - may be handled too slowly. The IRB may be unaware of additional nonresearch objectives that should be considered as part of the successful design of some research-related activities; for example, a training exercise may involve an inordinately intricate survey procedure, not because the responses are important, but rather because the trainee is learning about the challenges of administering complex surveys. The IRB might not give the activities the attention they deserve in a timely fashion.

IRBs do not have to be the only mechanism for institutional oversight of the entire range of institutionally supported activities involving the ethical treatment of human subjects. Other individuals or committees can perform this function as well or better than the IRB in some activities associated with an academic definition of research, but not the regulatory one. Likewise, other mechanisms may be used to review activities that meet the regulatory definitions of “research” and “human subjects”, but are judged to be exempt. For these projects, the person(s) or committees responsible for reviewing such projects can be people whose background and qualifications are more specifically suited to the particular projects in question, since they do not have to meet the compositional requirements of an IRB. At an academic university, for example, individual or committee review of some exempt research activities can operate

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<sup>2</sup> For example, an historian who interviews someone in the course of writing a biography about that person is engaged in an activity that does not fit the regulatory definition of “research,” even though they might consider the activity ‘research’ in the academic sense of the term. Similarly, a sociologist who passively observes people’s public behavior and records anonymous data about them is engaged in a research activity that involves collecting information about people, but this kind of involvement does not fit the regulatory definition of a “human subject”.

successfully at the Department level. Similarly, oversight of research-like activities such as the training of students for fieldwork assignments could be carried out by a person or committee based in the specific research discipline, who is familiar with that discipline's typical research methods, ethical code, and the educational objectives of the activity. These various review mechanisms can be coordinated with the IRB's operations, both to control and monitor the flow of work and to ensure that particular activities are promptly and properly assigned to an appropriate review mechanism.

Recommendation. Research institutions should distribute the review workload so that timely, informed, and appropriate reviews take place. Review mechanisms should be established so that appropriate IRB or non-IRB reviewers or review committees are set up to accommodate the review of research and research-related activities.

### **III. What Criteria Should Be Applied to Activities that are Not Covered or Exempt?**

Proposed activities that are not covered by the Common Rule or are judged exempt may still need to undergo some sort of review and approval process. The Common Rule represents the minimal ethical standards to be observed in covered research activities involving human subjects, but ethical standards may still apply to research activities outside of the federal requirements. For example, research involving interviews of public officials are exempt, but this does not mean that researchers should feel free to interview such people about sensitive topics under coercive or deceptive conditions. In other research-related activities, different ethical standards may apply. Avoiding the Common Rule's requirements for ethical conduct does not mean avoiding appropriate ethical standards of conduct entirely.

The standards of conduct in such activities should depend upon the nature and purpose(s) of the given activities. Even if a proposed activity is exempt from the Common Rule, a reviewing body may still insist that the risks to subjects of a given research activity be minimized, or that informed consent be obtained from the people who will provide information. In some cases, such as a proposed training exercise for research fieldworkers learning how to do interviews, some Common Rule approval criteria may apply while others do not: for example, the Common Rule's criterion for subject selection may be altered in this case, in keeping with the purposes of the training; however, the criteria regarding consent and confidentiality may be appropriate. Variations in the standards used by reviewing bodies should vary according to the professional and training standards of the relevant research community. Anthropologists and creative writing researchers should consider whether subjects should be recognized or given credit for the content of their contributions to research, for example, while psychologists should be more concerned about preserving confidentiality.

Recommendation. Oversight mechanisms reviewing research or research-related activities should establish clear, public criteria for the review of proposed activities. These criteria should reflect the ethical standards of the relevant research community regarding research, training, and related activities.

### **IV. What is Eligible for Expedited Review?**

Background. The regulations allow institutions to review certain kinds of research proposals under an "expedited review" procedure. In expedited reviews, the IRB chair or one or more experienced IRB members review the proposed activity instead of the full IRB at a convened meeting. The standards for approval or modification of research proposals under the expedited review procedure are identical to those of full IRB review. (Expedited reviewers cannot disapprove a proposed activity, however.)

Projects must satisfy two conditions in order to be eligible for expedited review. The first condition is that the proposed research activity may involve no more than "minimal risk" to the research subjects, as

defined by the Common Rule.<sup>3</sup> There appears to be considerable variation in the way IRBs apply the definition of “minimal risk,” and guidance may be needed regarding how this concept should be understood.

The second condition for expedited review is that the involvement of research subjects in the proposed activity must conform to the categories in a list established by the Department of Health and Human Services and the Food and Drug Administration. This list includes several categories particularly relevant to social and behavioral research, including

“(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).

(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.”<sup>4</sup>

The following examples illustrate fairly common forms of research activities that would qualify for expedited review under one or more of these categories<sup>5</sup>:

- A study in which undergraduate students view a video about economic theory and then respond to computer-simulated scenarios about individual spending decisions. [Category (7)]
- A field study using interviews and participant observation to study the interrelationship between family life and involvement in religious activities. [Category (7)]
- A laboratory study comparing patterns of eye movement and reading comprehension performance among novice and competent readers. [Categories (6) and (7)]
- A longitudinal study involving surveys of people’s background characteristics, political beliefs, and voting behavior. [Category (7)]
- A study of people’s ability to identify accurately the perpetrators of staged thefts. [Category (7)]
- A study of prison administration records to study the relationship between inmates’ individual background characteristics, type of criminal violation, and acquisition of a Graduation Equivalent Development (GED) credential. [Category (5)]
- A study attempting to validate a previously tested measure of extroversion/introversion with members of a previously untested cultural group. [Category (7)]

**Recommendation.** Institutions should develop guidance for researchers about project eligibility for expedited review. Guidance should explain how the IRB interprets the regulatory definition of “minimal

<sup>3</sup> The Common Rule defines “minimal risk” as follows: “*Minimal Risk* means that 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.” Section .102 (i).

<sup>4</sup> See *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure*, November 9, 1998, Federal Register (63 FR 60364).

<sup>5</sup> These illustrations assume that appropriate provisions can be made for protecting the confidentiality of the information.

risk” to proposed research projects, and how to determine whether projects fall within the list of categories for expedited review.

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## **V. How can Expedited Review Live Up to Its Name?**

**Background.** The ostensible purpose of the expedited review procedure is to provide for appropriate reviews of relatively low-risk research projects while avoiding an excessive expenditure of effort or time. In practice, however, expedited reviews aren’t always any faster or more efficient than full IRB review. Several factors may contribute to the problem: One factor is that questions may arise about whether the proposed research activity is exempt, or whether it is eligible for expedited review. Another factor is that researchers sometimes misunderstand what information needs to be provided for expedited review. Furthermore, the expedited reviewer(s) may be overburdened, or they may be unfamiliar with the field in which the particular research project is to be carried out.

Institutions can design and develop mechanisms for improving the processing of projects eligible for expedited review:

- Institutions can ensure that there is an efficient procedure for promptly determining whether the proposed project is in fact suitable for expedited review or whether it should be directed elsewhere. For example, an IRB administrator who is designated to review projects for whether they are covered research involving human subjects or not can also pre-screen proposals for appropriateness for expedited review.
- Institutions can identify a mechanism for ensuring that proposals that are initially routed through the expedited review process, turn out to be problematic in some way, and are re-directed for full Board review, are not unnecessarily delayed by having started out under the institution’s expedited review procedure.
- Institutions can provide guidance for researchers preparing submissions for expedited review to ensure that they include the information relevant to applying the standard regulatory criteria for approval of a proposed project.
- IRB chairs can appoint a sufficient number of experienced, qualified IRB members to perform expedited reviews. Where more than one IRB member is assigned to this task, chairs can appoint reviewers whose backgrounds and qualifications reflect the normal range of research projects eligible for expedited review that are submitted to the IRB.
- Institutions can arrange a consulting system for the reviewing IRB members to facilitate access to useful information on an as-needed basis. (For example, each department at a university could identify a faculty member to serve as a consultant on projects submitted by people in that Department.)

**Recommendation.** Institutions should develop guidance to improve researchers’ understanding of the information needed to accomplish expedited reviews of eligible research projects. Institutions should develop a system for prompt, efficient and thorough expedited reviews.