

# **Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities**

Social and Behavioral Sciences Working Group  
On Human Research Protections

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Institutions carrying out research activities under the *Federal Policy for the Protection of Human Subjects* (also known as the Common Rule<sup>1</sup>) 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 report'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.

## **I. 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 has discretion in determining 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, and this may delay 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

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<sup>1</sup>The Common Rule refers to the part of the Code of Federal Regulations for the Protection of Human Subjects adopted by 17 federal agencies.

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. Institutions should establish policies regarding when and how people who are planning data or information collection activities should consult with these officials about whether a formal decision is warranted regarding whether a planned activity should undergo IRB review.

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 to forward a proposed activity was appropriate and consistent with institutional policy. The process could involve sending appeals to the IRB chair, or to some other qualified official with the designated authority to overturn or uphold decisions.<sup>2</sup>

### Recommendation

Institution policy should be designed to 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>3</sup>
- Research activities that are exempt from the Common Rule but which the institution has elected to review nonetheless.
- Activities involving human subjects that are carried out in preparation for research, such as training exercises for students or prospective research staff.

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<sup>2</sup> This appeal process is distinct from appealing a decision of the IRB where, according to the regulations, any appeals board that has the authority to reverse a negative decision of an IRB must itself be a properly constituted IRB.

<sup>3</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.”

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, for example, students are involved as researchers—may be handled too slowly. With research-related activities, the IRB may be unaware of additional nonresearch objectives that should be considered as part of the successful design; for example, a research 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 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 humans. 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 institution, for example, individual or committee review of some exempt research activities can operate successfully at the Department level.<sup>4</sup> Similarly, oversight of the training of students or staff for fieldwork assignments could be carried out by a person or committee based in the specific research field<sup>5</sup> who is familiar with the research methods, ethical codes, 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 and oversight of research and research-related activities involving humans.

### **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 still apply to research activities involving human subjects lying 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,

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<sup>4</sup> Conflicts of interest need to be considered at all levels of review, including the Departmental level where there are overlapping and dual relationships. Scrutiny for conflicts of interest and the appearance of conflicts of interest is essential.

<sup>5</sup> Departments and other degree-conferring academic units are constituted by disciplines (e.g., psychology, anthropology) or interdisciplinary fields (e.g., child development, education research) and thus are guided by one or more ethical codes in considering research and research-related activities involving humans.

different ethical standards may apply. Falling outside of the Common Rule's requirements for ethical conduct does not mean falling outside of ethical standards of conduct.

The standards of conduct in such research activities should depend upon the nature and purpose(s) of the given activity. Even if a proposed activity is exempt from the Common Rule, it may still be important to 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. Appropriate standards may also vary according to the professional and training standards of the relevant research community, presumably due to the nature of the research involved. For example, in areas of social and behavioral science research that rely more heavily on field studies than on laboratory experiments, researchers may find that subjects wish to have their contributions to the research publicly recognized and thus should consider these wishes as part of the informed consent process.<sup>6</sup>

#### Recommendation:

Oversight mechanisms for reviewing exempt or not-covered research activities involving human subjects should establish clear, public criteria for the review of proposed activities. These criteria should be appropriate to the nature of the activity and 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.<sup>7</sup> The first condition is that the proposed research activity may involve no more than "minimal risk" to the

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<sup>6</sup> In all research involving human subjects there is a presumption that, unless otherwise specified, all private information and personal identifiers will be treated as confidential. In circumstances when subjects wish to have their contributions to research publicly recognized, it is necessary for the researcher to define, in consultation with the subjects, exactly what information is to be publicized and the methods for such publication. Care must be taken to assure that the subjects freely gave their informed consent to such plans and that they are fully aware of the possible consequences. Care must also be taken to respect the wishes of the communities (or other collectives) represented by the subjects when there is cause to believe that the interests of such collectives might be jeopardized by identifying their individual members.

<sup>7</sup> The regulatory requirements for expedited review are provided in "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" (November 9, 1998, Federal Register (63 FR60364-7), at: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm> The Office of Human Research Protections also provides a guidance document called "Guidance on the Use of Expedited Review Procedures" at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/exprev.htm>

research subjects, as defined by the Common Rule.<sup>8</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.<sup>9</sup>

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>10</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>11</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)]

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<sup>8</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>9</sup> The Social and Behavioral Sciences Working Group on Human Research Protections also provides a report called “Risk and Harm,” at <http://www.aera.net/humansubjects/index.htm>

<sup>10</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>11</sup> These illustrations assume that appropriate provisions can be made for protecting the confidentiality of the information.

- 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.<sup>12</sup> [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 risk" to proposed research projects, and how to determine whether projects fall within the list of categories for expedited review.

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

### Background

The 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 are not 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 proposals as to 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

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<sup>12</sup> In its guidance document, "Guidance on the Use of Expedited Review Procedures," the Office of 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.

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 college or 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.