

## IV. What Factors Influence the Successful Implementation of the Expedited Review Procedure?

The goal 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. Reaching this goal is not automatic, and depends on how the institution's expedited review procedure is implemented. Institutions can design and develop mechanisms to facilitate the processing of projects eligible for expedited review, such as the following<sup>11</sup>:

- Determining Eligibility. 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 to determine whether proposed activities fall under the authority of the Common Rule can also pre-screen proposals for expedited review.
- Deciding to Use Full Board Review. Institutions can identify a mechanism for ensuring that proposals that are initially assigned to the expedited review process and are later reassigned to full Board review are not unnecessarily delayed.
- Identifying Submission Requirements. Institutions can provide guidance for researchers preparing submissions for expedited review to ensure that they include all of the information needed by the reviewer(s) for applying the standard regulatory criteria for approval to proposed research activities.
- Appointing Reviewers. 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 at that institution. If the research activity involves prisoners, the IRB chair assigns a member who is a prisoner or prisoner representative to be a reviewer.
- Using Consultants. Institutions can arrange a system for making consultants available to the reviewing IRB members to facilitate the reviewers' access to useful information on an as-needed basis<sup>12</sup>. For example, each department at a college or university could identify an impartial expert in their discipline to serve as a consultant on projects submitted by people in that department.

11 These mechanisms are taken from a report of the Social and Behavioral Sciences Working Group on Human Research Protections titled "Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities" (2004), available at: <http://www.aera.net/aera.old/humansubjects/ExemptExpedited.doc>.

12 According to the regulations, "An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require special expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB." (45 CFR 46.107(f)).

The objective of the expedited review procedure is to enable institutions to optimize the use of institutional resources in the review of research activities to protect the human subjects of research. The expedited review procedure can provide appropriate review and oversight of many social and behavioral research studies involving only minimal risk, while allowing the institution to devote more of its resources to the review and oversight of research activities involving greater risks or more difficult ethical issues. Achieving that objective depends on the successful implementation of the expedited review procedure in the institution's human research protection program.

