Introduction

As human subjects research has advanced over the last several decades, Federal guidelines and policies intended to protect those who volunteer as participants in Federally funded research have evolved. In 1991, these policies culminated in the *Federal Policy for the Protection of Human Subjects*, known as the Common Rule, now adopted by 17 Federal agencies that fund human subject research. By definition, the Common Rule applies to a wide range of human subject studies, including both biomedical research studies (e.g., interventional clinical trials), as well as social and behavioral research studies. A primary mechanism through which the Common Rule ensures that appropriate measures are taken to protect human subjects is the Institutional Review Board (IRB). It should be noted that the Common Rule exempts some biomedical and many social and behavioral research studies from its regulatory requirements, including the requirement of IRB review.[1]

Even before the widespread adoption of the Common Rule, researchers in the social and behavioral science research community expressed concerns regarding the impact of these regulations in their field. In contrast to the physical risks associated with biomedical research protocols, the risks associated with social and behavioral research are frequently limited to concerns of privacy or confidentiality, or subjects' reactions to questions about sensitive topics. While the importance of human subjects' protection in these areas cannot be minimized, the nature and assessment of risk is somewhat different. A National Academies report that focused on the protection of human subjects in social and behavioral sciences also recognized this issue, and highlighted the importance of appropriate review commensurate with level and type of risk.[2]

The Common Rule explicitly acknowledges the concept of "minimal risk" in certain categories of research, and allows for review of these types of studies without convening a meeting of the IRB, through use of expedited review. Ideally, expedited review is intended to enable institutions to conserve administrative resources, provide timely reviews, and focus the convened meetings of their IRBs on the review of research activities involving greater risks or ethical complexities. In practice, institutions supporting social and behavioral research have yet to fully utilize the expedited review option for a variety of reasons.[3] Many investigators are not certain if their protocols are eligible for expedited review, or may not know how to best demonstrate a study's potential eligibility in their IRB application. Guidance for investigators on expedited review varies widely in the level of explanatory detail at individual institutions, and IRB administrators and chairs may differ in their own interpretations of the scope of activities eligible for expedited review procedures. As a result, important research programs may experience unnecessary delays.

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1 45 CFR 46.101(b)(1-6)

2 Panel on Institutional Review Boards, Surveys, and Social Science Research, National Research Council of National Academies, *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (Washington: National Academies Press, 2003).

3 De Vries, R., DeBruin, D.A., and Goodgame, G. *Ethics review of Social, Behavioral, and Economic Research: Where should we go from here?* Ethics and Behavior 14(4), 351-368; 2004.

The purpose of this document is to improve clarity and provide suggestions regarding the expedited review of social and behavioral research studies, so that the benefits and use of expedited review can be maximized within the research community. The document addresses the following four questions, so that researchers, IRB administrators, and IRB members can share a common understanding of how those determinations are made:

- What is "expedited review"?
- What is "minimal risk"?
- What kinds of social and behavioral research studies are eligible for expedited review?
- What factors influence the successful implementation of the expedited review procedure?

In answering these questions, this document reviews the criteria for determining whether a proposed research activity is eligible for review under the expedited review procedure, and it identifies some strategies that institutional officials may adopt to improve the efficiency and quality of the expedited review process at their institutions.