I. What is "Expedited Review"?

The Common Rule allows institutions to review certain kinds of research proposals under an "expedited review" procedure[4]. Expedited reviews are performed as an alternative to review by the full Institutional Review Board (IRB) at a convened meeting. The expedited review procedure is carried out by the IRB Chair, or by one or more experienced IRB members appointed by the Chair. The expedited reviewer(s) has all the same authorities as the full IRB to approve, modify, or attach conditions to proposed research activities, except the authority to disapprove a research activity[5]. Institutions using the expedited review procedure must have procedures for notifying IRB members of research activities approved under the expedited review. Expedited review involves applying the same criteria for approval of research activities that are required for review by the full IRB, as specified by the Common Rule[6].

Human subjects research activities covered by the Common Rule must satisfy two regulatory conditions in order to be eligible for expedited review. The first condition is that the proposed research activity involves no more than "minimal risk" to the research subjects. The second condition is that the proposed research activity must be included in a list of eligible research categories established by the Department of Health and Human Services and the Food and Drug Administration for this purpose[7]. Explained in detail in section III of this report, this list applies to proposed research activities supported or conducted by any of the Federal agencies that have adopted the Common Rule, and includes several categories that are directly relevant to social and behavioral research. Institutions have the option to use the expedited review procedure to review research studies that satisfy the two eligibility conditions, but they are not required to do so.

4 45 CFR 46.110. The regulations also allow using the expedited review procedure for the reviewing "…minor changes in previously approved research during the period …for which approval is authorized" (45 CFR 46.110(b)(2),) but this option is not the focus of this document.

5 In the event that a proposed research activity cannot be approved, modified, or amended to secure approval under the expedited review procedure, the proposed research activity may be disapproved only after review in accordance with the non-expedited review procedure of a convened meeting of the full IRB (45 CFR 46..110(b)(2).)

6 45 CFR 46.111.

7 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/ohrp/humansubjects/guidance/expedited98.htm*