NOTE: THIS GUIDANCE DOCUMENT CONSOLIDATES GUIDANCE REGARDING EXPEDITED REVIEW PREVIOUSLY FOUND IN THE FOLLOWING OHRP GUIDANCES: (1) "EXPEDITED REVIEW OF CERTAIN RESEARCH BY INSTITUTIONAL REVIEW BOARDS" (OPRR REPORTS, January 6, 1999) CLICK HERE AND (2) "EXEMPT RESEARCH AND RESEARCH THAT MAY UNDERGO EXPEDITED REVIEW" (OPRR REPORTS, May 5, 1995) CLICK HERE. THE GUIDANCE ALSO HAS BEEN UPDATED FOR FORMAT AND REFERENCES ADDITIONAL GUIDANCE ON EXPEDITED CONTINUING REVIEW.

Office for Human Research Protections (OHRP)
Department of Health and Human Services (HHS)

Guidance on the Use of Expedited Review Procedures

Date: August 11, 2003

Scope: The purpose of this document is to provide guidance on the use of the expedited review procedure by Institutional Review Boards (IRBs)

Target Audience: IRBs, sponsors, and investigators.

Regulatory Requirements: Expedited review procedures are described in HHS regulations at 45 CFR 46.110. Under an expedited review procedure, the IRB Chairperson, or one or more experienced reviewers designated by the Chairperson from among the members of the IRB, reviews the research protocol. The IRB shall adopt a method for keeping all IRB members advised of research proposals that have been approved under the expedited review procedure. In conducting expedited review, the IRB reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the nonexpedited procedure set forth in 45 CFR 46.108(b). Under 45 CFR 46.110(d), HHS may restrict an institution's or IRB's authority to use the expedited review procedure.

Guidance: The list of categories of research that may be reviewed by the IRB through an expedited review procedure was updated in 1998 and can be found at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm. Additions to, and extrapolation from, this list by the institution or the IRB are not appropriate. For example, it is inappropriate to use an expedited review procedure for the initial review of either research that involves minimal risk but does not appear in the categories of research published in the Federal Register or research that involves greater than minimal risk.

Institutions and IRBs are reminded that expedited review usually is not appropriate at the time of continuing review if the research required review by the convened IRB at the time of initial review (for information about expedited continuing review see OHRP Guidance at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/contrev2002.htm#WHEN MAY EXPEDITED REVIEW PROCEDURES BE USED).

Like review by the convened IRB, expedited review must fulfill all the requirements of review found at 45 CFR 46.111 and subparts B, C, and D, if applicable. IRBs are reminded that the requirements for informed consent (or for altering or waiving the requirement for informed consent) apply regardless of whether research is reviewed by the convened IRB or under an expedited procedure.

OHRP policy provides that any institution with an OHRP-approved Assurance may use expedited review for initial or continuing review of HHS-supported or conducted research and for review of minor changes in previously approved research as described in 45 CFR 46.110(b)(2).

Consultants may assist the IRB in the review of issues which require expertise beyond, or in addition to, that available on the IRB. Only the IRB Chairperson, or one or more experienced reviewers designated by the Chairperson from among members of the IRB, may carry out the expedited review. The person(s) conducting the expedited review may either approve, require modifications (to secure approval) or refer the research to the convened IRB for review in accordance with the non-expedited review procedures set forth in HHS regulations at 45 CFR 46.108(b).

Finally, OHRP recommends that:

> (1) documentation for initial and continuing reviews conducted under an expedited review procedure include: (a) the specific permissible categories justifying the expedited review; and (b) documentation of the review and action taken by the IRB Chairperson or designated reviewer and any findings required under the HHS regulations;
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> (2) written IRB procedures include a description of policies describing the types of minor changes in previously approved research which can be approved under an expedited review procedure in accordance with HHS regulations at 45 CFR 46.110(b)(2); and
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> (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.