NOTE: THE INFORMATION IN THIS DOCUMENT RELATED TO EXPEDITED REVIEW IS OUTDATED AND HAS BEEN REPLACED BY OHRP'S AUGUST 11, 2003 GUIDANCE ENTITLED, "GUIDANCE ON THE USE OF EXPEDITED REVIEW PROCEDURES." CLICK HERE FOR THE AUGUST 11, 2003 GUIDANCE.

THE GUIDANCE INFORMATION IN THIS DOCUMENT RELATED TO EXEMPT RESEARCH REMAINS IN EFFECT.

Number 95-02

Human Subjects Protections

OPRR Reports

May 5, 1995

Subject: Exempt Research and Research That May Undergo Expedited Review

Dear Colleague:

The purpose of this letter is to assist Institutional Officials and Institutional Review Board (IRB) Chairs in interpreting the term "exempt" research and identifying research for which "expedited review" is appropriate.

Research activities involving human subjects that are **exempt** from IRB review are identified in 45CFR 46.101(b)(1)-(6). (Institutions and IRBs may not create new categories of exempt research under 45 CFR Part 46.) Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. OPRR advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.

Institutions may elect to review all research under the auspices of the institution even if the research qualifies for exemption under .46.101(b). An institution with a Multiple Project Assurance (MPA) or Cooperative Project Assurance (CPA) should indicate in its Assurance if and how exempt research is reviewed. It is incumbent on the institution to advise investigators and others involved in the conduct and administration of research involving human subjects of the institutional policies for reviewing exempt research.

Expedited review procedures are described in .46.110. In short, the IRB Chair or one or more experienced reviewers, designated by the Chair from among members of the IRB, review the research and approve it or refer it to the IRB for full IRB discussion. Attached is the list of activities that may be reviewed through expedited review procedures (**Federal Register 46**: 8392; Jan. 26, 1981). (Additions to, and extrapolation from, this list by the institution or the IRB are not appropriate.) To qualify for expedited review, an activity must: (1) involve no more than minimal risk **AND** be found on this list, **OR** (2) be a minor change in previously approved research during the period of 1 year or less for which approval is authorized by the IRB. It is OPRR policy that only institutions with MPAs or CPAs may use expedited review as in the condition of (1), above, if appropriate.

Consultants may assist the IRB Chair in making decisions in expedited review, but expedited review cannot be performed solely by persons who are not members of the IRB. 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 in accordance with the ordinary, nonexpedited procedure set forth in .46.108(b). The IRB shall adopt a method for keeping all IRB members advised of research proposals that have been approved under the expedited review procedure. The institution's Assurance should specify how expedited review will be carried out.

Institutions and IRBs are reminded that expedited review is not ordinarily appropriate at the time of continuing review when the research qualifies for full board review (see **OPRR Reports** 95-01).

The concept of **exempt** research and the practice of **expedited review** of research can come together, as some institutions choose to provide an additional measure of protection for human subjects by reviewing what would be exempt research under .46.101(b) in an expedited manner. This is acceptable, since expedited review of that which is exempt exceeds the minimum requirements for both in 45 CFR Part 46.

The categorization of human subjects research as "exempt" from IRB review or appropriate for "expedited" IRB review is intended to streamline IRB procedures with no diminution of protection for human subjects. Please employ these concepts in that spirit. OPRR's Health Research Policy Officer, Dr. Joan P. Porter, is available at 301-496-7005 (ext. 206) for any questions you may have.

Sincerely,

/s/

Gary B. Ellis, Ph.D.
Director
Office for Protection from Research Risks