Wayne State University Human Investigation Committee	
Subject	Expedited Review Procedures
Form Date	October 2003 (Rev. 7/12/10)
Approvals	11/19/03 Steering Committee, 9/30/10 Administrative Approval

Background

Expedited review can occur with (1) new protocols, (2) continuations of previously approved protocols, and (3) amendments to approved protocols. Protocols that may be eligible for expedited review are described in 45 CFR 46.110 and additional guidance published by the Office for Human Research Protection (OHRP) on August 11, 2003.

Please see Human Investigation Committee (HIC) Policy/Procedures "IRB Review of Initial Research Proposals", "Continuation/Renewal of Protocol", and "Amendments to the Research Protocols" specific guidance on expedited review within each procedure.

HIC Procedure

Categories of research that may be reviewed by expedited review procedures can be found in the HIC Policy /Procedure: "Types of Institutional Review Board (IRB) Review" at the www.hic.wayne.edu. Expedited review of research is not appropriate when a protocol is not found in the categories listed in 45 CFR 46.110 or when a proposal is more than minimal risk. Under this procedure, the research may be pre-reviewed by an experienced IRB member designated by the HIC Chairperson or IRB Chairperson. (Note: An experienced IRB member is one who has been an IRB member for at least six months and has participated in at least six IRB meetings.) The HIC Chairperson or IRB Chairperson will then review the medical research protocol, request modifications, provide administrative approval and report the status to one of the four IRBs.

Within these categories of research, the expedited reviewers may exercise all of the authorities of the IRB (45 CFR 46.111) except that they may not disapprove the research. The persons conducting the expedited review may either approve, require "specific minor revisions", or refer the research to the convened IRB for review in accordance with the non-expedited review procedures set forth in 45 CFR 46.108.

Expedited Review of Continuation Reports

Expedited review is usually not appropriate at continuation if the research proposal was reviewed by a convened IRB at the time of initial submission. However, the IRB is authorized to use expedited review procedures for continuations when the following circumstances are met:

a. where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
b. where no participants have been enrolled at a particular site and no additional risks have been identified by the IRB or investigator from any site or relevant source; or
c. where the remaining research activities are limited to data analysis.

Expedited review procedures are not to be used for research involving prisoners, cognitively impaired and mentally disabled participants.

The expedited review procedures may be used when informed consent is altered or waived as long as the regulations on informed consent are met (45 CFR 46.116(c).

Under an expedited review procedure for initial and continuing review, the HIC Chair, IRB Chair, or designee must review in-depth all of the applicable materials that the convened IRB would have received, including:

- Continuation/Renewal Form (including, but not limited to, the number of subjects/data/specimens accrued, racial and ethnic characteristics of participants, withdrawals of participants from the study, holds, audits, significant changes to risk/benefit ratio, etc.)
- Current copy of the Consent Form
- Initial Protocol Summary Submission Form
- Approved advertisements and recruitment material
- A brief summary of research methodology and procedures [VHA 1200.5.7.g(1)]
- Multi-center trial reports (if applicable)
- The number of vulnerable participants enrolled (VHA 1200.5)
- A summary of Adverse Reactions/Unexpected Events involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review
- A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review, and
- Any other relevant information, especially information about risks associated with the research

The reviewer will then document: (a) the categories justifying the expedited review and (b) actions taken by the expedited reviewer. These will be documented in the minutes of the IRB meetings each month and in the letters that are sent to the Principal Investigators.

Expedited Review of Amendments

For expedited review of amendments to the protocol, please see the HIC Standard Operating Procedure "Amendments to the Research Protocols and Informed Consent Documents".

Expedited Review Results – Notification to PI

The Principal Investigator will be notified in writing of all expedited review decisions. Please see the HIC Standard Operating Procedure “Notification of IRB Decisions to Principal Investigator and PI Response Requirements”.