

DEPARTMENT: Yale University Human Investigation Committee
POLICY NUMBER:
SECTION: Delegation of Authority
REVIEW RESPONSIBILITY: HIC Leadership Committee
ORIGINAL CREATION DATE: April 1, 2007
REVISION DATES: August 7, 2008

Yale University School of Medicine IRB Policy on the Delegation of IRB Chair Authority for the Review of Research Qualifying for Expedited Review:

I. Policy:

The IRB Chair may designate an experienced reviewer(s) from among the members of the IRB to carry out the Chair's authority to review and approve protocols under an expedited review process pursuant to 45 CFR 46.110(b) and 21 CFR 56.110(b):

“Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research,” in accordance with [45 CFR 46.108](#)(b) and 21 CFR 56.110(b).

II. Procedure:

In addition to the regulatory requirements of IRB membership, in order for an individual to be delegated authority by the Chair to conduct expedited review and to sign off on expedited protocol actions and actions deemed approvable by the fully convened IRB once specific minor revisions are completed, the following standards must be met:

1) A proficiency in reviewing protocol submissions for their approvability, as successfully demonstrated by:

- thorough working knowledge of ethical principles, federal regulations and guidance, and Institutional policies that support the proper conduct of human subjects research;
- thorough administrative reviews on all assigned protocols and full IRB-required revisions, which include but are not limited to,
 - the evaluation of the relative risks and benefits to participants given the research hypothesis and the proposed conduct of the study, and the ability to determine whether adequate provisions are in place to protect participants;
 - the determination as to whether further protections are required to ensure risks are minimized;

- the determination as to whether the selection of subjects is equitable given the purpose of the research;
- that determination that adequate provisions and findings are documented for research involving populations that may be considered vulnerable;
- the assurance that informed consent for research will be sought from each prospective subject or the subject's legally authorized representative or surrogate unless it is determined that it is appropriate to waive the consent because the use of the waiver does not adversely affect the rights and welfare of the subjects, it is not practical to obtain consent for the research, and provisions are in place to inform subjects of the information gained from the research, if appropriate;
- the determination that the research has adequate provisions to protect the privacy of subjects and maintain confidentiality;
- the determination that projects may require review more frequently than annually; and
- the determination when a research study requires verification from sources other than the investigator that no material changes have occurred since the previous IRB review;
- the ability to resolve minor discrepancies between requested revisions and investigator responses (consulting with Chair as necessary), and to negotiate their adequate resolution with the investigator, as well as the ability to identify substantive issues which must be resolved by the full IRB;
- high and consistent quality of work;
- accurate and timely review of protocol submissions; and
- the ability to prepare comprehensive approval and other action letters inclusive of all applicable regulatory findings and comments related to the action, accompanied by relevant documentation, with comprehensive copies retained for the file.

2) A minimum of one year's service either as full-time IRB staff or as IRB member, or the equivalent background and experience;

3) The Chair will make the delegation of authority for reviewing and approving expedited protocol actions and specific minor revisions to full IRB protocol actions in writing to the IRB member. Delegation will expire upon the end of the IRB member's term. A copy of the letter will be retained in the member's departmental file for reference.

References:

45 CFR 46.110

21 CFR 56.110

Appendices:

HIC Administrative Review Checklist

Reviewer Checklist

Vulnerable Categories

Sample letter of delegation

DATE:

TO: Committee Member

FROM: Maurice Jeremiah Mahoney, M.D., J.D., Chair, HIC II

Sandra L. Alfano, Pharm. D., FASHP, Chair, HIC I

SUBJECT: Delegation of Authority for the Review of Research Qualifying
For Expedited Review

This letter serves to document that you have successfully met the standards set forth in the HIC Policy on the Delegation of IRB Chair Authority for the Review of Research Qualifying for Expedited Review. Pursuant to 45 CFR 46.110(b) and 21 CFR 56.110(b), the delegation of my authority to you to review and approve expedited protocol actions and specific minor revisions to full Committee protocol actions is now effective. This delegation expires when your Committee membership ends.