



CITY OF PHILADELPHIA
Department of Public Health

InterOffice Memorandum

To: Thomas Storey, MD, MPH, Interim Chair, Institutional Review Board
Members, Institutional Review Board

From: Walter Tsou, MD, MPH, Commissioner

Date: August 2, 2001

Subject: Approved Expedited Review

In the past several years, the Philadelphia Department of Public Health Institutional Review Board has operated under policies prohibiting the use of Expedited Review. With this memorandum, I intend to relax this prohibition to allow the use of Expedited Review under the following limited circumstances:

1. Revisions submitted in response to specific changes in procedures or consent form requested by the IRB following full IRB review.
2. Changes submitted to the IRB for review which do not substantially change a study, which has previously been reviewed and approved by the full IRB. (e.g. change in Principal Investigator, change in address, etc.)
3. Update reports that are submitted in accordance with required IRB review schedule, which contain no substantial protocol changes or reported adverse events.

Expedited Review: The following requirements are necessary before expedited review can be allowed under the Federal Regulations:

- Studies can be no more than minimal risk and are in one of the following categories:
 - Clinical studies of drugs and medical devices where IND or IDE is not required or the device has been approved for marketing and is used as such (i.e. not experimental drugs)
 - Collection of blood samples by finger stick, heel stick, ear stick or venipuncture with restrictions on age, weight, and amount
 - Prospective collection of biological specimens for research purposes by noninvasive means
 - Collection of data through noninvasive procedures routinely employed in clinical practice
 - Research involving materials that have been collected or will be collected solely for non-research purposes
 - Collection of data from voice, video, digital or image recordings made for research purposes
 - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, etc.
 - Continuing review of research previously approved by the convened IRB with no further direct subject participation
 - Continuing review of research (not under IND or IDE) where the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified
- Anything not listed above must receive full board review and does not qualify for expedited review.

Expedited Review Procedures: (Reference is made to 45CFR46, Chapter 110)

1. In accordance with Chapter 110 (b), “review may be carried out by the IRB chairperson or by one or more experienced reviewers.” For our purposes, preference will be given to assigning a reviewer who has previously reviewed a study or who possesses knowledge or experience of relevance to the study.
2. In accordance with Chapter 110 (b) “A research activity may be disapproved only after review in accordance with the non-expedited procedures...” If the reviewer cannot recommend approval for a study, it will be referred for review by the full IRB membership.
3. In accordance with Chapter 110 (c) “Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure. In keeping with our existing procedures for activity, which occurs between meetings, these reviews shall be read during the subsequent IRB meeting. Any IRB member may request a copy of the study or a full IRB review of any issues addressed through expedited review.

WT/JSD