Issues to Address when Conducting Expedited Reviews

Definition

The Institutional Review Board (IRB) uses an expedited review process for initial review of studies that meet the expedited categories adopted by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), and that involve no greater than "minimal risk." Under DHHS revised Common Rule regulations, the research is deemed to be eligible for expedited review if the study involves activities on the list, unless the IRB reviewer determines and documents that the study involves more than minimal risk.

Expedited review procedures can also be utilized for exempt research requiring limited IRB review as a condition of exemption (i.e., exempt category 2 & 3) and for the review of *minor* revisions submitted for previously approved research during the period for which approval is authorized. (See Guidance on Expedited Review of Minor Changes in Previously Approved Research)

The expedited review process can be carried out by the Chair of the IRB or one or more experienced reviewers designated by the Chair from among voting members of the IRB. Federal regulations also dictate that when an IRB uses expedited review procedures, there must be a mechanism in place for advising all of the members of the IRB of the research procedures approved under this review process. The UK IRB meeting agendas serve this purpose.

Authority of an Expedited Reviewer

The expedited reviewer is responsible for ensuring that all of the information requested in the Expedited Review application is provided. The expedited reviewer make the final determination as to whether research activities meet the expedited review criteria as outlined in the section of this document titled, Definition of Minimal Risk and Guidance to PI and Reviewers.

The expedited reviewer also determines whether the research meets the federal criteria for approval. (See Criteria for IRB approval: Reviewer Checklist)

The expedited reviewer has the authority to approve a study or request additional information. The expedited reviewer does not have the authority to disapprove a study. (See Expedited Initial Review SOP)

Informed Consent

Expedited reviewers ensure that the investigator conducts the informed consent process and obtains documentation of informed consent, unless the IRB waives the requirements in accord with federal regulations. (See Informed Consent SOP)

When children are involved as research subjects, the expedited reviewer is also charged with ensuring that there are adequate provisions for obtaining assent from these children. (See UK IRB Policy on Children in Research)

Issues to Address when Conducting Expedited Reviews

Vulnerable Subject Populations

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects. The expedited reviewer also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during study participation. (See Protection of Vulnerable Subjects SOP)

Definition of Minimal Risk and Guidance to PI and Reviewers

Expedited procedures can only be used to review a study if the only involvement of human subjects fits one or more of the categories specified in the federal regulations, unless the reviewer determines and documents that the study involves more than "minimal risk."

The IRB reviewer confirms that **all of the research activities** fit in one or more of the expedited categories. If the research includes activities that do not fit in the categories, the study is not eligible for expedited review even if the research involves "minimal risk."

The Department of Health and Human Services defines *minimal risk* to mean "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102(j)].

Investigators are asked to provide a risk assessment, but it is the IRB reviewer's responsibility to determine whether the research meets the federal definition.

The IRB reviewer must consider two questions:

- Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?

- Is the magnitude of the harm or discomfort greater than that encountered ordinarily in the daily life or during the performance of routine physical or psychological examinations or tests?

If the answer is "yes" to either of these questions, then the research does not meet the definition of minimal risk. The IRB policy on risk assessment is included in the UK Assessing the Research Risk document, which is on the ORI website and in the IRB Survival Handbook.

Federal Expedited Review Categories

(A) The categories in this list apply regardless of the age of subjects, except as noted.

Issues to Address when Conducting Expedited Reviews

(B) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(C) The expedited review procedure may not be used for classified research involving human subjects.

(D) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   (b) From other adults and children[1] considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

   NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

3) Prospective collection of biological specimens for research purposes by noninvasive means*. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and

external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. **federal regulations interpret noninvasive as vaginal swabs that do not go beyond the cervical os; rectal swabs that do not go beyond the rectum; and nasal swabs that do not go beyond the nares.*

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (e.g., clinical care or academics) or material that was previously collected for research purposes, provided they were not collected for the currently proposed research (e.g., material previously collected at prior institution, or from previously conducted research, or from a research repository). To qualify for exemption 5, the proposed research objectives can be the same, similar, different (or any combination thereof) to the original research ***so long as*** the materials intended to be used in the proposed research include:

   a) materials that were **previously collected** for either non-research or research purposes provided that any materials collected for research were ***not*** collected for the currently proposed research;

   OR

   b) materials that **will be collected solely for non-research purposes**, such as a medical treatment or diagnosis.

   Studies of innovative treatments, unapproved products or prospective randomized treatments would not meet this category as the collection of material is for research purposes.
   (Note: Some research in this category may be exempt from the HHS regulations for the

Issues to Address when Conducting Expedited Reviews

protection of human subjects. 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.)

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
(Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.104(d)(2) and (d)(3). This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows:
   (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) Where no subjects have been enrolled and no additional risks have been identified; or
   (c) Where the remaining research activities are limited to data analysis.

9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but 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.