| Expedited Review Procedures | Effective: | 6.25.2013 |
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| | Revised | 1.21.2019 |

**1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for recognizing and reviewing human subjects research that meet the federal criteria for expedited review.

**2.0 Research Protocols Affected:**

2.1 Human research activities submitted for review and approval by the UMCIRB that:

2.1.1 Meet the federal definition of "minimal risk" (See Section 4.1 below); and

2.1.2 Meet federal criteria defined in §45 CFR 46 Part 110 (See Section 4.2 below).

**3.0 SOP:** Expedited review is the mechanism in which the federal regulations allow for the review to be conducted by one experienced member of the IRB. At ECU, it has been determined that the UMCIRB Chairperson or his/her designee will serve in this capacity. Expedited review procedures may be used for initial review of proposed human research activities, continuing review of ongoing, currently approved human research, minor revisions of currently approved human research and some reportable events.

The UMCIRB has the authority to refer proposed new studies, continuing reviews, or requested minor revisions to the convened UMCIRB for review, even if it qualifies under the federal regulations for expedited review. This decision can be made by UMCIRB office staff or the UMCIRB Chairperson or designee and the reason will be documented.

**4.0 Definitions:**

4.1 **Minimal Risk** means the probability and magnitude of harm or discomfort anticipated for individuals participating 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.

4.2 **Expedited Review** is a review mechanism that allows for one or more experienced IRB members to conduct the review for the following:

4.2.1 Some or all of the research appearing on the Federal Register list and found by the reviewer(s) to involve no more than minimal risk;

4.2.2 Minor changes in previously approved research during the period for which approval is authorized, (i.e. an amendment to a currently approved study);

4.2.3 Research for which limited IRB review is a condition of exemption.

4.2.4 The expedited review procedure may not be used:

4.2.4.1 Where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than those encountered in everyday life;

4.2.4.2 For classified research involving human participants, i.e., research classified by the federal government, state legislature, or institutional policy to be considered sensitive in nature.

4.2.4 Standard requirements for informed consent (or its waiver, alteration, or exception) still

apply when a study or amendment qualifies for expedited review.

4.3 **Expedited review categories** are outlined by federal regulations as follows:

- 4.3.1 Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met
  - 4.3.1.1 Condition (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 its use is not eligible for expedited review)
  - 4.3.1.2 Condition (b): Research on medical devices for which an investigational device exemption application (§21 CFR Part 812) is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling
- 4.3.2 Category 2: Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
  - 4.3.2.1 From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times a week
  - 4.3.2.2 From adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the less or 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times a week
- 4.3.3 Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
  - 4.3.3.1 Hair and nail clippings in a nondisfiguring manner
  - 4.3.3.2 Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
  - 4.3.3.3 Permanent teeth if routine patient care indicated a need for extraction
  - 4.3.3.4 Excreta and external secretions (including sweat
  - 4.3.3.5 Uncannulated salvia collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
  - 4.3.3.6 Placenta removed at delivery
  - 4.3.3.7 Amniotic fluid obtained at the time of rupture of the membrane prior to or during delivery
  - 4.3.3.8 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
  - 4.3.3.9 Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
  - 4.3.3.10 Sputum collected after saline mist nebulization.
- 4.3.4 Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures which involve x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (i.e., 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)

4.3.4.1 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 participant or an invasion of the participant's privacy

4.3.4.2 Weighing or testing sensory acuity

4.3.4.3 Magnetic resonance imaging

4.3.4.4 Electrocardiography, electroencephalography, thermography, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, echocardiography, and detection of naturally occurring radioactivity

4.3.4.5 Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate give the age, weight, and health of the individual

4.3.5 Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.) The UMCIRB has also determined that secondary uses of specimens previously collected under an IRB approved research protocol may also be eligible for expedited review under this category, even if the specimens were originally collected for research purposes. For example, if tissue collected under a more than minimal risk study by muscle biopsy is not completely used by that research study, an investigator may be permitted to seek its use for a second research study under this category even thought it was previously collected for research purposes.

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

4.3.7 Category 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) . This listing refers only to research that is not exempt.)

4.3.8 Category 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.

4.3.9 Category 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.

**5.0 Responsibilities:**

**5.1** The Principal Investigator/Study Team Members will:

5.1.1 Provide accurate and complete information to the UMCIRB within the electronic application and attach all supporting documents (protocol, consent form, recruitment material, etc.).

5.1.2 Comply with all determinations and procedures as outlined in their approved submission application and IRB approval letter.

**5.2** UMCIRB Administrative Director or designee will:

5.2.1 Ensure compliance with and revise (as necessary) this SOP and provide training opportunities and resources;

5.2.2 Raise any applicable issues outside of the UMCIRB jurisdiction and communicate those issues to the investigator or appropriate institutional official;

5.2.3 Assist study team members and expedited UMCIRB reviewers as needed;

5.2.4 Keep UMCIRB members advised of expedited approvals by ensuring the are reported in the IRB minutes;

5.2.5 Not allow investigators to select or assign reviewers for their expedited review procedures;

5.2.7 Retain a copy of the research records on file for no less than 3 years after the study closure.

**5.3** IRB Chairperson or designee will:

5.3.1 Review, request necessary changes and approve research studies that are eligible for expedited review;

5.3.1.1 The reviewer may raise issues outside of the UMCIRB jurisdiction and communicate those issues to the investigator or appropriate institutional official.

5.3.2 Utilize reviewer checklists to make a determination for criteria for approval of expedited reviews;

5.3.3 Forward to the IRB committee any research study that the Chair or designee is uncomfortable with approving in an expedited fashion along with justification for the full committee review;

5.3.4 Recuse from reviewing any research study for which they have a conflict of interest and inform the UMCIRB Office staff of that decision;

5.3.5 Be a Biomedical Committee Chair or designee for review of "no more than minimal risk" research study eligible for expedited review that involves an FDA regulated test item.

**6.0 Procedures:**

**6.1** The investigator will submit all material for expedited review. All supporting and related material should be submitted for any expedited review. The UMCIRB recognizes that a research sponsor may require full UMCIRB committee review for new research or amendments to existing studies, even if the action would otherwise be in an exempt or expedited category. Expedited review occurs in the order a submission (whether initial, continuing, amendment, or final) becomes available to the UMCIRB staff and then the Chairperson (or designee) through the electronic IRB submission system.

**6.2** The UMCIRB staff will assign the expedited review to the UMCIRB Chairperson (or their designee from among the experienced members of the UMCIRB)

**6.2.1** For FDA regulated expedited studies, the approval period can be no greater than 365 days and will extend from the date final approvals in granted for the period set by

the UMCIRB Chairperson or designee. However, a Final Report will be required when the study is complete.

**6.3** The research project may be elevated from expedited to full UMCIRB review during or after initial approval, based on new information or regulatory guidance changes.

**6.4** The UMCIRB Chairperson (or designee) will either approve or request modifications to an expedited study.

**6.4.1** Changes needed for a study to be approved will be communicated to the study team via the electronic submission system

**6.4.2** Once the study team submits changes or answers to questions, the study will be sent back to the UMCIRB Chairperson (or designee) for confirmation that final approval can be granted

**6.4.3** An expedited study could only be disapproved by the convened UMCIRB.

**6.5** Expedited categories of research will have no set expiration date but will extend from the date final approval is granted by the IRB Chairperson (or designee) until the Expected End Date provided within the electronic IRB submission system by the study team.

**6.5.1** This does not prevent the IRB Chairperson (or designee) from requiring continuing review for an expedited studies with a documented rationale (see Continuing Review SOP).

**6.5.2** A Final Report would be required by the Expected End Date (see Study Completion and Closure SOP) or an Amendment would need to be submitted to change that date if the study was not yet complete.

**6.6** The UMCIRB office will communicate the Chairperson's (or designee's) decision to the investigator in writing, within three to five business days via the electronic submission system. The research cannot proceed until all requested modifications are met and the principal investigator receives an approval letter. The principal investigator is responsible for submitting all changes and reporting unanticipated problems and protocol deviations to the UMCIRB because they may result in an elevation in classification to require full UMCIRB review.

**Revision History:**

| Date | Change | Reference Section(s) |
|---|---|---|
| 6.25.2013 | Updated to stand-alone document. | All |
| 1.21.2019 | Updated definitions and procedures according to revised regulations. | 3.0-6.0 |

**References**

FDA. Code of Federal Regulations:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50 and
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Federal Register 63 FR 60364-60367, November 9, 1998.