

Policy Number: 13

Title: IRB Review of Human Subjects Research – Expedited

Date of Last Revision: 08/10/05; 10/05/10; 05/04/12; 05/29/13; 06/05/13; 01/09/15, 06/01/16, 09/07/17, 01/25/18, 10/16/18, 01/31/19

**Policy:**

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the expedited categories described in the Federal regulations.

**I. Expedited Eligibility**

- A. Federal regulations (45 CFR 46.110 and 21 CFR 56.110) allow the IRB to review certain applications on an expedited basis if they meet specified criteria (i.e., research activities that present no more than minimal risk to human subjects).
- B. All approved expedited protocols are reviewed by the IRB at least once per year, unless granted an extended 3 year IRB approval.
- C. Additionally, the standard requirements for informed consent (or its waiver or alteration) apply to all IRB approvals regardless of the type of review - expedited or full Committee.
- D. Minimal risk is defined by the federal regulations as "*...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.*" As written, the definition of minimal risk in federal regulations provides an ambiguous standard by which risks involved in a research study are compared to those encountered in daily life. The ambiguity lies with whether the definition applies to those risks found in the daily lives of *healthy individuals* or in the daily lives of the *potential research participants*. The UCI IRB, wanting to afford greater protection to human research participants, has adopted an absolute standard of minimal risk; therefore, UCI's working definition of minimal risks includes the phrase, "*in daily lives of the general population.*"
- E. An expedited review consists of a review of research involving human subjects by the appropriate IRB Committee Chair, his/her designee(s) or an HRP Staff Reviewer. In reviewing the research, the reviewer(s) may exercise all of the authorities of the full Committee except that the reviewer(s) may not disapprove the research. **Disapproval is only determined by the full IRB Committee.** Additionally, the reviewer(s) may refer the application to the full Committee for review as warranted.
- F. General Restrictions on Expedited Review
  - 1. Expedited review procedures may not be used for initial review of research involving intervention or interaction with prisoners.
  - 2. Expedited review procedures may not be used for classified research.
  - 3. Expedited review procedures 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.

- G. Appropriate Use of Expedited Review Procedures for Initial Review of Research: The IRB may use an expedited procedure to conduct initial review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and involve procedures listed in one or more of the following categories:
1. 45 CFR 46.110(F)(1)/21 CFR 56.110(F)(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 increase the risks or decrease 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;
      - (1) An investigational device exemption application (21 CFR Part 812) is not required; or
      - (2) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
  2. 45 CFR 46.110(F)(2)/21 CFR 56.110(F)(2): Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    - a. From healthy, non-pregnant 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, when 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 are considered. For these participants, 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. Children are defined in the federal regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" [See 45 CFR 46.402(a)].
  3. 45 CFR 46.110(F)(3)/21 CFR 56.110(F)(3): Prospective collection of biological specimens for research purposes by noninvasive means. For example:
    - a. Hair and nail clippings in a non-disfiguring 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 scrapping or swab, skin swab, or mouth washings; and/or
    - j. Sputum collected after saline mist nebulization.

4. **45 CFR 46.110(F)(4)/21 CFR 56.110(F)(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 include:
  - 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. **45 CFR 46.110(F)(5)/21 CFR 56.110(F)(5)**: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). **NOTE**: Some research in this category may meet exemption under 45 CFR 46.101(b)(4); this listing refers only to research that is not exempt.
  - a. **Retrospective chart review - evaluates patient data that is existing at the time the protocol is initially approved by the IRB.** This type of chart review uses information that has usually been collected for reasons other than research, such as administrative data and medical records. Therefore, the outcome of interest has already occurred by the time the study is started.
  - b. **Prospective Chart Review** – evaluates patient data that **does not yet exist** at the time the protocol is approved by the IRB for initial review. The protocols are designed before any information is collected. Study subjects are identified and followed forward to see if the outcome of interest happens over time.
6. **45 CFR 46.110(F)(6)/21 CFR 56.110(F)(6)**: Collection of data from voice, video, digital, or image recordings made for research purposes.
7. **45 CFR 46.110(F)(7)/21 CFR 56.110(F)(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 meet exemption under 45 CFR 46.101(b)(2); this listing refers only to research that is not exempt.

- H. Appropriate Use of Expedited Review Procedures for Continuing Review of Research: The IRB may use an expedited procedure to conduct continuing review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and involve procedures listed in one or more of the following categories:
1. Research procedures that meet the criteria for initial review of research by an expedited procedure; or
  2. **45 CFR 46.110(F)(8)/21 CFR 56.110(F)(8)**: Continuing review of research previously approved by a full IRB Committee as follows:

- a. Where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
  - b. Where no subjects have ever been enrolled (at UCI performance sites) and no additional risks have been identified; or
  - c. Where the remaining research activities are limited to data analysis; or
  - 3. 45 CFR 46.110(F)(9)/21 CFR 56.110(F)(9): Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened full IRB Committee meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- I. Extended 3 Year IRB Approval
- 1. UCI's Federalwide Assurance (FWA# 00004071) allows some flexibility in applying human subjects federal regulations to non-federally supported research.
  - 2. Studies Eligible for the Extended 3 Year IRB Approval:
    - a. Research that involves no more than minimal risk to participants (as defined by 45 CFR 46.102) or
    - b. Research that is not subject to federal oversight.
  - 3. Studies Not Eligible for the Extended 3 Year IRB Approval:
    - a. Research Subject to Federal Oversight:
      - (1) Projects that receive federal support, projects implemented at the direction of federal agencies, or otherwise subject to federal oversight are excluded from this policy.
      - (2) Examples of Federal oversight include: Federal sponsorship, directly or indirectly, including federal training and program project grants, student projects when the faculty sponsor uses federal funding for the student's project, Federal no-cost extensions, studies seeking or obtaining Certificates of Confidentiality (which are granted by NIH) and studies where the UCI IRB is serving as the IRB of record for an institution that applies the federal standards to all research regardless of source of funding.
    - b. Studies that involve greater than minimal risk
  - 4. The UCI IRB reserves the right to make exceptions to this policy, and inclusion/exclusion of any research project under this procedure will be at the IRB's discretion.
  - 5. If the UCI IRB determines that the study is eligible for the Extended 3 Year IRB Approval, the determination will be inserted on the UCI IRB approval letter. Further the IRB approval period will be set of a period of 3 years. Studies that are granted an extended approval period will continue to have the same post-approval submission requirements. LR must continue to be responsible for submitting:
    - a. Modifications to the study, which must receive IRB approval before they are implemented;
    - b. Reports of adverse events, protocol violation/incidents, and other safety information meeting HRPP reporting criteria;
    - c. A continuing review submission at least 4-6 weeks prior to the study's expiration date, if the study is still active; and
    - d. A closeout report when the study is complete.
  - 6. If the study becomes ineligible for an extended approval period because of new federal funding or other changes, the lead researcher is responsible for notifying the IRB of this change via the submission of a formal modification to the study protocol. Further, an application for continuing review must be submitted to the IRB for renewal

so that the study can be re-reviewed and re-set on a 1 year (no more than 365 days) approval cycle.

J. Collecting Human Blood in a Non-Clinical Setting

All researchers conducting the collection of human blood samples in a non-clinical / non therapeutic setting for research purposes must abide by the following minimal standards. For researchers who cannot meet the following standards, the UCI Institute for Clinical and Translational Science nursing staff provide blood collection services for a fee.

- a. **Training and Competency:** It is the responsibility of the Lead Researcher (LR) to ensure that all personnel listed on an IRB application have the appropriate training and experience to perform their assigned duties. Collection of blood for research purposes must be performed by California licensed physicians, nurses or clinical lab scientists, or other licensed professionals where phlebotomy is in their scope of practice, or by certified phlebotomists able to provide documentation of competency.
- b. **Risk to Subjects:** The blood collection procedure in non-clinical setting must present no more than minimal risk to human subjects. Collection can be by finger stick, ear stick, or venipuncture from healthy, non-pregnant adults who weighs at least 110 pounds. The amounts drawn may not exceed 100 ml (~ 7 tablespoons) in an 8 week period and collection may not occur more frequently than 2 times per week.
- c. **Adverse Event Management Plan:** The LR must provide a safety management plan explaining how the research team will prevent and manage an adverse event (e.g., fainting, vasovagal response) including an emergency situation (cardiac arrest). Consideration should be made to ensuring that subjects are afforded a controlled environment.
- d. When the institutional requirement in an emergency is to call 911, the expectation is that at least two research team members are California licensed physicians or nurses, or individuals who hold current CPR certification through the American Red Cross or American Heart Association and that these members must be present at the time of the blood draw.
- e. **Environmental Health And Safety (EH&S) Employee Safety Requirements:**
  - (1) UCI employees handling human material must complete the Bloodborne Pathogens Training course ([www.uclcl.uci.edu](http://www.uclcl.uci.edu)) within 7 days of their assignment; before collecting blood. The Bloodborne Pathogens Training must be completed annually.
  - (2) The LR must ensure that a Bloodborne Pathogens Exposure Control Plan (ECP). (<http://www.ehs.uci.edu/biosafe.html>) has been completed and reviewed by all applicable employees. The ECP must be on file and a hard copy or electronic copy must be readily available.
  - (3) The employee must be offered the Hepatitis B vaccine or titer.
  - (4) Universal precautions must be used to prevent contact with blood or other potentially infectious materials (OPIM) at all times which includes utilizing engineering and work place practices and wearing appropriate personal protective equipment to limit exposure.
  - (5) All incidents/exposures must promptly be reported to the LR and the incident reporting system, <https://www.ehs.uci.edu/apps/hr/index.jsp>.
  - (6) **EH&S Institutional Biosafety Review (IBC) Registration:** Collection of blood for analysis in a UCI laboratory requires IBC

registration. It is the responsibility of the LR to register the research with IBC prior to the initiation of the research procedures. See the [EH&S IBC web page](#) for more information.

- K. Expanded Category of Minimal Risk Research Procedures – Skin Punch Biopsy for Children and Adults
- a) **Applies to research that is not federally funded, not subject to FDA regulations.**
  - b) Category “13” allows for a skin punch biopsy of no greater than 2 mm for both children (minors under the age of 18) and adults. **There are limitations for children and adults. See below.**
    - (1) Placement of biopsy must be on the upper inner arm, upper inner thigh, or lower back/upper buttock below the pant line. The location must be agreed upon by the parent or legally authorized representative, the child subject or adult subject, in consultation with the lead researcher.
    - (2) The biopsy must be no greater than 2 mm.
    - (3) A biopsy greater than 2 mm requires full committee review for both children and adults.
    - (4) Additional Considerations for Children:
      - i. If the child is not affected by the condition under study, he/she must be age 7 and above to allow for assent. Parental permission is required.
      - ii. Greater than 2 mm skin biopsies on non-affected (healthy) children will require an additional review process (in addition to full committee review).
      - iii. If the child is affected by the condition under study, there is no age restriction. Parental permission is required.
  - c) Additional guidance for researchers (the following text may also be included in the IRB submission when describing the procedure):
    - (1) Use of EMLA or similar topical numbing cream should be used at least 2 hours in advance of the procedure for minors. Then, after selecting a biopsy site on the upper inner arm, upper inner thigh, or lower back/upper buttock the area will be cleansed with an antiseptic solution. Lidocaine or other local anesthetic will then be infiltrated into the biopsy area by injection to provide local anesthesia. A single 2 mm piece of skin will be removed via punch biopsy. A sterile gauze pad will be placed over the site to control bleeding, and the site will be bandaged. The biopsy site may be closed with a stitch if desired. The parents will be provided with post-biopsy care instructions.
    - (2) If multiple 2 mm skin punch biopsies are proposed, the IRB will consider whether the procedures in totality rise to a level greater than minimal risk on a case by case basis.
- L. Single-Patient Expanded Access Use:
- a) For an expanded access (compassionate) use of an investigational drug outside of a controlled clinical trial for a patient (with an IND), prospective IRB Chairperson approval is allowable through an expedited review process. See Policy # 41.
  - b) For an expanded access use request of an investigational device outside of a controlled clinical trial for a patient (with an IDE), prospective IRB Chairperson approval is allowable through an expedited review process. See Policy # 42.

## II. Required Review

- A. Applications for expedited research are accepted on a rolling basis. The appropriately experienced IRB Committee Chair, his/her designee(s) for subcommittee or an HRP Staff Reviewer is required to review and approve research meeting expedited criteria.
- B. An experienced IRB member means a voting member or alternate voting member who has received training relative to the expedited review categories, and possesses the scientific expertise needed to review the proposed research. However, a Reviewer may request a second reviewer or refer the research to the full IRB Committee for further determination.
- C. The Reviewer may also request review of the research by an expert consultant for issues which require expertise beyond, or in addition to, that available on the Committee.
- D. When research is Department of Navy (DoN) sponsored, U.S. Navy-wide survey research requires additional Navy Survey Review and Approval. In addition to UCI IRB approval, the Navy Survey approval manager may require IRB approval by the DoN prior to granting approval.
- E. Research materials submitted include sufficient detail for the Reviewer to determine that the study meets criteria 45 CFR 46.111 and 21 CFR 56.111, if applicable, for approval:
  - 1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
  - 2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Reviewer should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The Reviewer should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
  - 3. Selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
  - 4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the Federal and State regulations and Institutional policies and procedures including the IRB;
  - 5. Informed Consent will be appropriately documented, in accordance with, and to the extent required by the Federal regulations and Institutional policies and procedures including the IRB;
  - 6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;
  - 7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
  - 8. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The Reviewer must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- F. Materials to be Reviewed - The following materials are provided to the Reviewer(s) for expedited review:
1. A completed "Application for IRB Review" with signatures
    - a. Investigator's Assurance document
    - b. Disclosure of Investigators' Financial Interest form
  2. Protocol Narrative
  3. Sponsor and/or Master protocol, if applicable
  4. Proposed informed consent document(s) including "Experimental Subjects Bill of Rights", as appropriate and/or Study Information sheet and/or informed consent script as appropriate;
  5. Copies of surveys, questionnaires, or videotapes
  6. Copies of letters of assurance or cooperation with research sites
  7. Investigator's brochure (if one exists)
  8. Advertising intended to be seen or heard by potential subjects, including e-mail solicitations
  9. DHHS-approved sample informed consent form, if applicable
  10. DHHS-approved protocol, if applicable
  11. DHHS grant application – human subjects section, if applicable and considered to be in a fundable range
- G. The Reviewer determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the last date of IRB approval. The IRB may review a protocol more often than annually when the following circumstances apply:
1. Studies conducted by researchers who have been determined to be in serious non-compliance in the past two years; and
  2. Other situations where the IRB believes that more frequent continuing review is required.
- H. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of the research must occur on or before the date when IRB approval expires.
- I. Approval Period for Expedited Research is assigned as follows:
1. For expedited research, the approval period starts on the date of the approval. The expiration date would be 365 days from the approval date, minus one. (For example, if the IRB approves the research on April 12, 2005 for one year, the approval period is April 12, 2005-April 11, 2006.)
  2. In all cases the expiration date (the last day the research is approved) is the last day of the approval period. Research may be conducted on the expiration date, but not after the expiration date without continuing approval. (For example, if the approval period is April 12, 2005-April 11, 2006, the expiration date is April 11, 2006.)
- J. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting criteria for approval under the expedited criteria.
- K. The full Committee is advised of research proposals/activities that have been approved under the expedited review procedure, including initial reviews, continuing reviews and reviews of modifications to previously approved research. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing expedited review procedures, a report documenting approval of research per expedited review procedures for the previous month is provided to the IRB Committee as a standing item on the IRB Committee meeting agenda.
- L. All research activities approved by expedited review are conducted in accordance with all applicable UCI IRB policies and procedures.
- M. Research cannot be disapproved by the Chair or his/her designee; only the full Committee can disapprove research.



**References:**

45 CFR 46.110

21 CFR 56.110

21 CFR 56.102(i)

45 CFR 46.102(i)

DHHS Federal Register Notice: November 9, 1998 (Volume 63, Number 216), "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure." <http://www.hhs.gov/ohrp/policy/63fr60364.html>

OHRP Guidance on the Use of Expedited Review Procedures, August 11, 2003.

<http://www.hhs.gov/ohrp/policy/exprev.html>

OHRP Guidance on Continuing Review, January 15, 2007.

<http://www.hhs.gov/ohrp/policy/contrev0107.html>

FDA, *IRB Information Sheets: Continuing Review After Study Approval*, September 1998.

<http://www.fda.gov/oc/ohrt/irbs/review.html>

DoD: SECNAVINST 3900.39D, para. 6e

OPNAVINST 5300.8C

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**Procedure Number: 13.A**

**Title: Procedure for IRB Review of Human Subjects Research – Expedited**

**Procedure:** This procedure provides guidance for the review of human subjects research activities that qualify for expedited review under the Federal regulations.

**I. Lead Researcher (LR) Responsibilities**

- A. The IRB Application is completed in its entirety and electronically submitted to the HRP staff for processing.
- B. A Protocol Narrative is completed in its entirety and uploaded as part of the IRB Application submission.
- C. If applicable, an Investigator's brochure and Sponsor's protocol is submitted.
- D. A signed version of the IRB Application is required. Signatures must be provided from the Lead Researcher, Department Chair, and Faculty Sponsor, if applicable.
- E. The Informed Consent form(s) or Study Information sheet may be written using the template consent document, as guidance.
- F. Studies that include vulnerable populations are submitted with applicable appendices demonstrating added protections and a rationale as to why these populations are to be included in the proposed research.
  - 1. Vulnerable Population Appendix B for pregnant women, human fetuses, and neonates.
  - 2. Vulnerable Population Appendix C for prisoners.
  - 3. Vulnerable Population Appendix D for children.
  - 4. Vulnerable Population Appendix E for cognitively impaired individuals.
- G. The LR replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable, and provide an explanation if the requested revisions are not made.
- H. If an LR disagrees with any IRB comments and/or requests for revisions, the researcher should provide written justification for his/her position for review by the original IRB subcommittee. If after review, the subcommittee determines that the revisions/clarifications are allowable per federal regulations, state statutes, or UC/UCI policies and procedures, the changes will be required prior to granting IRB approval.
- I. Any proposed changes to IRB approved documents are submitted to the IRB using the electronic "Modification Request" process. The Investigator must receive written IRB approval before implementing any changes to the research study.
- J. All unanticipated problems to participants or others are submitted to the IRB using the electronic "Unanticipated Problems" (UP) Report.

**II. IRB Committee Responsibilities**

- A. Review of New Protocols and Continuing Review of Protocols
  - 1. Applications for new expedited research are accepted on a rolling basis and are reviewed weekly by the appropriately experienced IRB Committee Chair, his/her designee(s) for subcommittee or an HRP Staff Reviewer (**Tier 1**).
  - 2. Applications for continuing review of expedited research protocols are reviewed weekly by the appropriately experienced IRB Committee Chair, his/her designee(s) for subcommittee or an HRP Staff Reviewer (**Tier 1**). Refer to Policy # 18 for exceptions.
  - 3. In considering a new expedited protocol, an experienced Reviewer means an IRB voting member or alternate voting member who has received training relative to the

- expedited review categories, and possesses the scientific expertise needed to review the proposed research.
4. Delegation is provided in the HRP Staff Reviewer Delegation of Authority document maintained on the HRP WIKI page – and signed by the IRB Chairs for A, B and C, as well as the Executive Director of Research Protections.
  5. As noted, HRP Staff may serve as reviewers of expedited research with some exceptions. An HRP Staff Reviewer is defined as follows:
    - a) **HRP STAFF REVIEWER:**
      - (1) **Tier 1:** Administrator or above, CIP or CCRP certified and appointed as IRB members or alternate members may review and approve transactions related to exempt and expedited level protocols. Exceptions are noted as applicable.
  6. An HRP Staff Reviewer (**Tier 1 only**) may review and approve expedited protocols **except under the following conditions:**
    - a) Category 1: Clinical studies of drugs and medical devices
    - b) Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from
      - (1) pregnant women (where they are the focus of the research)
      - (2) children
      - (3) individuals with cognitive or medical impairments
    - c) Category 3: Prospective collection of biological specimens for research purposes by noninvasive means from
      - (1) pregnant women (where they are the focus of the research)
      - (2) children
      - (3) individuals with cognitive or medical impairments
    - d) Category 4: Collection of data through noninvasive procedures routinely employed in clinical practice from
      - (1) pregnant women (where they are the focus of the research)
      - (2) children
      - (3) individuals with cognitive or medical impairments
    - e) Categories 6 & 7, *if the research involves*
      - (1) direct interaction/intervention with vulnerable populations e.g.,
        - (a) pregnant women (where they are the focus of the research)
        - (b) prisoners
        - (c) children
        - (d) individuals with cognitive or medical impairments
    - f) Expedited applications that involve a disclosure of financial interest
  7. The Reviewer(s) is required to review and approve research meeting expedited criteria. Research may involve/ represent one or more approvable categories of research.
  8. The Reviewer(s) assigned will have expertise in the area of the research adequate to the scope and complexity of the research. If a Reviewer has a conflict of interest, the Reviewer will be recused from the review. A Reviewer may request a second reviewer, request review by an expert consultant to the IRB, or refer the study to full IRB Committee for determination. However, the determination of disapproval can only be made at full Committee.
  9. The Reviewer(s) reviews the “Application for IRB Review” and validates or declines the researcher’s claim for review under the expedited category. When declined, the Reviewer(s) refers the study to full Committee.

10. The Reviewer(s) assesses the protocol for both scientific and scholarly merit in relationship to the level of risk.
11. The Reviewer(s) reviews the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111 and if applicable, FDA 21 CFR 56.111 for approval. In order to provide written documentation of these criteria, the Reviewer(s) complete the "Reviewer's Checklist" detailing how each of these criteria is met.
12. The Reviewer(s) completes any Supplemental Checklists, as applicable. The Reviewer(s) determines the review interval appropriate to the degree of risk, but not less than once per year. The Reviewer(s) may request that the study be approved, minor modifications required, tabled for re-review by subcommittee, tabled for review by full Committee, or request administrative hold.
13. When revisions are requested, the modified documents are re-reviewed and, if acceptable, approval is granted.
14. The Chairperson or his/her Designee verifies and signs the "Reviewer's Checklist."
15. HRP staff prepares the IRB Approval Letter.

B. Review of Minor Modifications

1. Minor modification requests are accepted on a rolling basis and are reviewed weekly by appropriately experienced IRB Committee Chair, his/her designee(s) for subcommittee or an HRP Staff Reviewer (**Tier 1** and **Tier 2**).
2. An experienced Reviewer is an appropriately experienced IRB Committee Chair, his/her designee(s) for subcommittee or an HRP Staff Reviewer (**Tier 1** and **Tier 2**) who has received training relative to the expedited review categories and HRP SOPPs, and possesses the scientific expertise needed to review the research. HRP Staff Reviewers are delegated the authority to approve modifications related to expedited level research activities.
3. HRP Staff Reviewers are defined as follows;
  - a. **HRP STAFF REVIEWER:**
    - (1) **Tier 1:** Administrator or above, CIP or CCRP certified and appointed as IRB members or alternate members may review and approve transactions related to exempt and expedited level protocols. Exceptions are noted as applicable.
    - (2) **Tier 2:** Analysts or above, CIP or CCRP certified may review and approve transactions related to exempt and expedited level protocols. Those without current CIP or CCRP have been designated by an IRB Chair or the Executive Director of Research Protections to have the appropriate experience to review transactions related to exempt and expedited protocols. Exceptions are noted as applicable.
4. An HRP Staff Reviewer (**Tier 1** and **Tier 2**) may review and approve modifications to expedited protocols **except as noted in Policy #17.**
5. The Reviewer(s) is required to review and approve modifications meeting expedited criteria.
6. The Reviewer(s) assigned will have expertise in the area of the research adequate to the scope and complexity of the research. If the Reviewer has a conflict of interest, they will be recused from the review. A Reviewer may request a second reviewer, request review by an expert consultant to the IRB, or refer the study to full IRB Committee for determination. However, the determination of disapproval can only be made at full Committee.

7. The Reviewer(s) reviews the submitted materials and validates or declines the researcher's claim for review under expedited review criteria. When declined, the Reviewer(s) refers the study to full Committee.
8. The Reviewer(s) assesses the protocol for both scientific and scholarly merit in relationship to the level of risk.
9. The Reviewer(s) reviews the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111 and FDA 21 CFR 56.111 as applicable for approval. In order to provide written documentation of these criteria, the Reviewer(s) complete the "Reviewer's Checklist" detailing how the criteria have been met.
10. The Reviewer(s) completes any Supplemental Checklists, as applicable.
11. The Reviewer(s) determines the review interval appropriate to the degree of risk, but not less than once per year.
12. The Reviewer(s) may request that the study be approved, minor modifications required, tabled for re-review by subcommittee, tabled for review by full Committee, or request administrative hold.
13. When revisions are requested, the modified documents are re-reviewed and, if acceptable, approval is granted.
14. The Chairperson or his/her Designee verifies and signs the "Reviewer's Checklist" or response/ submitted materials.
15. HRP staff prepares the IRB Approval Letter.

### III. IRB Analyst or Higher Responsibilities

- a. The Analyst conducts a pre-review for studies submitted requesting expedited review. The Analyst determines whether the application includes all information required and requests additional information, if needed, from the LR, to assist the Reviewer in making a determination.
- b. E-mails recommending pre-review changes may be sent by the Analyst to the LR.
- c. The Analyst prepares the "IRB Reviewer Checklist" and any Supplemental Checklists for the Reviewer(s).
- d. When consultants to the IRB are utilized, the Administrator obtains a signed Consultant's standards document which includes a description of Disclosable Conflict of Interest and a statement of confidentiality.
- e. The Analyst assembles and prepares for distribution of review materials.
- f. Letters requesting revisions from the Reviewer and approval letters are drafted using the appropriate template which includes a citation to the specific permissible category or categories justifying the expedited review.
- g. New approvals, modifications, and continuing reviews are processed according to corresponding IRB policies and procedures.
- h. Appropriate database entries in HPS are completed.
- i. Approved documents are processed.
- j. The Protocol File is collated and filed.