2.3 Expedited Review

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for using expedited review procedures for consideration of:

1. new research proposals;
2. continuing review of previously approved research;
3. minor changes in protocol;
4. minor complaints; and
5. non-serious noncompliance.

2.0 Policy

It is the policy of the Organization that

- 2.1. Expedited review will be conducted in accordance with HHS regulations at 45 CFR 46.110; FDA regulations at 21 CFR 56.110; and will satisfy the criteria for IRB approval described in HRPP policy 2.5 (Criteria for Approval) and in 45 CFR 46.111 and 21 CFR 56.111, as applicable.
- 2.2. Protocols initially reviewed and approved by the expedited method must:
  (1) be no more than minimal risk;
  (2) involve only activities listed in one or more of the categories specified in the OHRP Expedited Review Categories (63 FR 60364-60367, November 9, 1998); and
  (3) meet all the criteria specified in HHS regulations 45 CFR 46.111, FDA regulations at 21 CFR 56.111 (as applicable), the HIPAA Privacy Rule (as applicable), and UNMC HRPP policies.

- 2.3. Expedited review will not be used for initial or continuing review of:
  (1) classified research (per OHRP Expedited Review Categories (1998), section D); or
  (2) research involving prisoners.
- 2.4. Minor changes in IRB-approved research qualify for expedited review in accordance with HRPP policy 2.4 (IRB Review of Changes in Previously Approved Research).
- 2.5. Continuing review of research previously approved by a convened IRB where no subjects have been enrolled and no additional risks have been identified may undergo expedited review.
- 2.6. Continuing review of research which satisfies the requirements of OHRP Expedited Review Categories (1998) category 9 (“research not conducted under an investigational new drug application or investigational device exemption where {expedited} categories 2 through 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”) may undergo expedited review.
- 2.7. Continuing review of research which has been previously approved by the full IRB prior to the effective date for the Revised Rule, when the research meets the requirements of OHRP Expedited Review Categories (1998) category 8, is eligible for expedited review.
- 2.8. Complaints which are considered minor, unexpected incidents involving no more than minimal risk to subjects or others, and noncompliance which is neither serious nor continuing is eligible for expedited review in accordance with HRPP policies 8.2 (IRB Review of Study Related Complaints) and 8.4 (IRB Review of Noncompliance Involving the PI and Study Personnel).

3.0 Definitions

- 3.1. Expedited Review: review of research involving human subjects by one or more experienced reviewers designated by the Chair from among members of the IRB in accordance with the requirements set forth in 46 CFR 46.110; 21 CFR 56.110.
- 3.2. Minimal Risk: 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 (per 45 CFR 46.102(j)), and 21 CFR 56.102(i)).

4.0 Expedited Review Categories

- 4.1. The following categories of research may be eligible for review through the expedited review procedure. Research activities must be no more than minimal risk. For research subject to the Common Rule, inclusion of research activities on the list of OHRP Expedited Review Categories (63 FR 60364-60367, November 9, 1998) is presumed to mean that the activity is minimal risk (FR 82 (12):7206, 2017) unless the reviewer determines and documents the rationale for considering the activity greater than minimal risk.
    - 4.1.1. Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
        - 4.1.1.1. 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.
        - 4.1.1.2. Research on medical devices for which:
            - 4.1.1.2.1. An investigational device exemption application (21 CFR Part 812) is not required; or
            - 4.1.1.2.2. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
    - 4.1.2. Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
        - 4.1.2.1. 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
        - 4.1.2.2. From other adults and children, 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.
    - 4.1.3. Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.

      Note: Examples of such biological specimens include but are not limited to
      (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 scraping or swab, skin swab, or mouth washings;
      (j) Sputum collected after saline mist nebulization.

- 4.1.4. Category 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.
  Note: 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.
  Note: Examples of such non-invasive procedures include but are not limited to:
  (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.
- 4.1.5. Category 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 be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
- 4.1.6. Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.
- 4.1.7. 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. This listing refers only to research that is not exempt.
- 4.1.8. Category 8: Continuing review of research previously approved by the convened IRB as follows:
  - 4.1.8.1. 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
  - 4.1.8.2. Where no subjects have been enrolled and no additional risks have been identified; or
  - 4.1.8.3. Where the remaining research activities are limited to data analysis.
- 4.1.9. 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) above 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 Procedures

- 5.1. All IRB applications are submitted to the ORA and processed in accordance with HRPP policy 2.1 (Submission of Items for Review by the IRB).
- 5.2. Appointment of Designated Expedited Reviewers
  - 5.2.1. An IRB member may serve as an expedited reviewer once they have been judged by the IRB Executive Chair/designee to be sufficiently qualified and experienced. Specifically, the reviewer must have:
    - 5.2.1.1. An acceptable level of knowledge about the area of research under review.
    - 5.2.1.2. An understanding of the categories of research that qualify for expedited review.
    - 5.2.1.3. The ability to apply the IRB approval criteria and determine conditions required for IRB approval.
    - 5.2.1.4. An absence of a COI in accordance with HRPP policy 1.7 (IRB Member, Consultant, and Staff COI Identification & Management).
  - 5.2.2. An IRB Analyst who is also a voting board member may serve as an expedited reviewer, provided they meet the requirements above.
  - 5.2.3. Assignment of an expedited reviewer for a protocol will be made by the Executive Chair/designee. In the absence of a specific decision to the contrary the expedited reviewer will be the IRB Analyst responsible for the protocol, provided they meet the requirements above.
- 5.3. Expedited Review Procedures
  - 5.3.1. The expedited reviewer must be satisfied that they have sufficient information to make the determinations required for IRB approval in accordance with 45 CFR 46.111; 21 CFR 56.111, and HRPP policy 2.5 (Criteria for IRB Approval).
    - 5.3.1.1. The expedited reviewer must be satisfied that they have the appropriate expertise to review the protocol. If they do not, then the reviewer may request that a consultant with appropriate expertise be obtained, in accordance with HRPP 1.6 (IRB Composition, Leadership, Qualifications, and Responsibilities) section 3.1.3.
  - 5.3.2. The expedited reviewer is expected to consult the IRB study files in RSS (including but not limited to the IRB application, full protocol, investigator's brochure, questionnaires and surveys, recruitment and other subject facing materials, and consent documents), applicable regulations, and HRPP policies, as necessary during their review of the protocol.
- 5.4. Criteria for Expedited IRB Approval and Other Determinations
  - 5.4.1. The expedited reviewer must determine that the research falls into one or more of the categories described in section 4.1 above and is no more than minimal risk. If the expedited reviewer finds that the research falls into one of the above categories but constitutes greater than minimal risk the reviewer must document the rationale for considering the activity greater than minimal risk and for review by the

convened IRB.
    - 5.4.2. The expedited reviewer(s) must determine whether the criteria for IRB approval have been (or continue to be) met, per HRPP policy 2.5 (Criteria for IRB Approval).
    - 5.4.3. As appropriate and as relevant to the specific review (such as review of new protocols, continuing reviews, review of requests for change in protocol or ICF or other types of IRB reviews as described previously) the expedited reviewer must also determine:
        - 5.4.3.1. Whether continuing review is required, and if so, whether it is required more often than annually. In making this determination the expedited reviewer may consider factors including but not limited to the nature of the risks associated with the research; the degree of uncertainty regarding the risks involved; the vulnerability of the participants; the experience of the investigator in conducting the research; the IRB's previous experience with that researcher or sponsor); the projected rate of enrollment. If the expedited reviewer determines that continuing review is required, the rationale for conducting continuing review will be recorded in accordance with 45 CFR 46.115(a)(3).
        - 5.4.3.2. Whether the research should have a third party observe the consent process in accordance with HRPP policy 1.2, Section 2.7 (Authority Granted to the IRB by the Organization).
        - 5.4.3.3. Whether the research needs verification from sources other than the PI that no material changes have occurred since the previous IRB review, as required at 45 CFR 46.108(a)(3)(ii) and 21 CFR 56.108(a)(2).
        - 5.4.3.4. Whether the current consent form is still accurate and complete.
        - 5.4.3.5. Whether the research requires an audit of research records in accordance with HRPP policies 1.21 (Post Approval Monitoring of Research) and 8.4 (Review of Noncompliance Involving Risk to the Subject or Others).
        - 5.4.3.6. Whether there are any significant new findings that arise from the review process that might relate to a subject's willingness to continue participation in the study.
        - 5.4.3.7. When the PI is the lead researcher of a multi-site trial, whether the management of information to the protection of human subjects is adequate, such as reporting of unanticipated problems, interim results, and protocol modifications.

6.0 Expedited Review Actions

- 6.1. Approval; initiation of the research is authorized (when institutional requirements are satisfied).
    - 6.1.1. All of the criteria for approval are satisfied and no changes are required.
- 6.2. Conditional approval; final approval contingent upon Expedited Reviewer/designee review and acceptance of specified modifications and/or submission of additional

documents unrelated to the regulatory criteria for approval.
    - 6.2.1. All of the criteria for IRB approval are satisfied provided the investigator makes the specified changes and/or submits the specified documents. The requirements for final approval and release are considered minor and not substantive in nature.
- 6.3. Tabled; re-review required.
    - 6.3.1. The expedited reviewer requires additional information in order to determine whether the criteria for approval have been satisfied.
      Note: Prior to tabling a protocol, the expedited reviewer may continue communication with the investigator to resolve issues related to the protocol that prevent approval (for example that relate to the regulatory criteria for approval).
- 6.4. Refer to full IRB for review
    - 6.4.1. The expedited reviewer is unable to determine that the protocol satisfies the regulatory requirements for expedited review (for example, on closer examination it appears the protocol or the modification constitutes greater than minimal risk); or the expedited reviewer determines that the regulatory criteria for approval are not met; or the expedited reviewer considers the protocol has serious deficiencies which would merit disapproval; or the expedited reviewer believes the research would be more appropriately reviewed by the convened IRB.
      Note: The Expedited Reviewer may not disapprove research. Research which does not satisfy regulatory criteria for approval, or which has serious deficiencies which would merit disapproval must be referred to the full IRB.

7.0 Development of IRB Expedited Review and Final Approval Letters

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- 7.1. Expedited review letters, which reflect the deliberations and decisions of the expedited reviewer(s), are developed by the IRB Analysts, in consultation with the IRB Executive Chair and/or expedited reviewers as appropriate.
- 7.2. The IRB review letters will clearly document the determinations of the Expedited Reviewer and will include:
    - 7.2.1. The decision to approve, require modifications to secure approval, or table.
    - 7.2.2. List any modifications or clarifications required by the Expedited Reviewer.

8.0 Deadlines for PI Responses

- 8.1. The PI is given 60 days from the date of the IRB review letter to respond to the IRB's review by submitting appropriately revised documents. If no response is received by the end of the 60-day period, or by the expiration of an extension provided by the IRB Executive Chair/designee, the study may be withdrawn or closed.

9.0 Review of PI Responses

- 9.1. The IRB Analyst serves as the designated reviewer and is authorized to review and determine the acceptability of the PI's response, in consultation with the IRB Executive Chair, board members and/or other expedited reviewers as appropriate.
  - 9.1.1. If, on consultation with the Executive Chair, the IRB Analyst determines that the investigator's response to the review is inadequate, incomplete, or contains significant changes not initially reviewed by the IRB, the analyst may re-review (or refer back to another expedited reviewer for re-review) and further communicate with the investigator, or may refer the submission for review by the full convened IRB.

10.0 Final IRB Approval Letter

- 10.1. The IRB final approval letter will document the following determinations:
  - 10.1.1. Pertinent dates:
    - 10.1.1.1. Date of conditional approval by expedited reviewer
    - 10.1.1.2. Date all conditions set by the expedited reviewer were determined to be met and the study was granted final approval and release.
    - 10.1.1.3. Expiration Date (per section 11.0)
  - 10.1.2. Compliance with applicable HHS and FDA regulations
  - 10.1.3. Verification that the research is classified as minimal risk
  - 10.1.4. The applicable expedited review category or categories.
  - 10.1.5. Subpart B category for inclusion of pregnant women (as applicable)
  - 10.1.6. Subpart D category for inclusion of children (as applicable)
  - 10.1.7. Waiver or alteration of the requirements for informed consent (as applicable)
  - 10.1.8. Waiver of the requirement for documentation of informed consent (as applicable)

11.0 IRB Approval Periods

- 11.1. The approval period for protocols for which continuing review is required is based on the date that the expedited reviewer gave conditional approval of the research. Studies approved with annual continuing review are valid for 364 days from the date of conditional approval; the approval period expires on the 365th day.

12.0 Documentation of Expedited Review

- 12.1. The IRB Review Checklist: Full and Conditional Approval must be completed and maintained in the protocol file. This checklist will specify: a) the category or categories of research under which the protocol qualifies, b) the risk level as being no more than minimal risk, and c) the IRB approval criteria are satisfied.
- 12.2. IRB members and the IO are advised via email that minutes documenting all actions reviewed and approved by the expedited review procedure are available for review in RSS.
- 12.3. The full convened IRB retains the authority to require modification of the protocol and/or ICF(s) of research reviewed and approved under the expedited process, or to suspend the study or halt accrual if warranted.

13.0 Review by Other Organizational Committees

- 13.1. Before the IRB will grant final approval and release, the ORA must receive verification of approval or completion of review by components of the HRPP as described

in HRPP Policy 1.10 (Scientific and Other Committee Review of Research) and as required by the organization.

DOCUMENT HISTORY:

? Written: 4/11/2016 (Approved: 4/11/2016) - original author not recorded

? Revised: 6/13/2018 - revision not documented

? Revised: 3/17/2021 - Clarified that IRB administrator may re-review “inadequate or incomplete responses” by investigators (or refer back to the expedited reviewer for re-review) and further communicate with the investigator to seek modifications or clarifications; deleted regulatory references to pre-2018 Common Rule; deleted list of “other determinations (section 5.4) and referenced policy 2.2 instead; deleted list of other organizational committees (section 13.1) and referenced policy 1.10 instead.

? Revised: 9/16/2021 - Revised time allowed for investigator to respond (section 8.1) to match policy 2.2

? Revised: 8/4/2023 – generally revised for clarity and for consistency with HRPP 2.2; deleted reference to limited IRB review (section 2.4) since the Organization does not utilize limited IRB review, as per policy HRPP 2.8; revised section 5.3 to better describe Expedited Review Procedures; revised section 5.4 to more fully describe Criteria for Expedited IRB Approval and Other Determinations and to clarify requirement for expedited reviewer to determine and document if research needs continuing review; added description of items to be reviewed (section 5.3.2); simplified section 8.0 (Deadlines for PI Responses; clarified that expedited reviewer may refer a protocol to the convened IRB if they believe it would be more appropriately reviewed by the convened IRB (section 6.4.1); corrected typographic and grammatical errors. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 1/24/2024 – added section 5.4.1 {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Revision #13
Created 24 October 2019 21:26:10 by Autumn M Eberly
Updated 30 January 2024 21:09:09 by Robert A Lewis