OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

Office for the Protection of Research Subjects (OPRS)
Institutional Review Board
FWA# 00000083

201 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-1711
Fax: 312 413-2929
http://research.uic.edu/human-subjects-irbs/

Expedited Review Process

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Approved by: Human Protections Administrator and Director of OPRS
AAHRPP REF #: 127
AAHRPP Elements: II.2.E., II.2.E.1. - 3.

POLICY:

I. Expedited review refers to the review of a limited class of research outside of a convened IRB meeting by one or more experienced IRB members. Initial review, continuing review, amendments to previously approved research, post-approval reporting, and final reports may be reviewed by this process when they meet the criteria specified by federal regulations.

II. Expedited review is conducted by the Chair or an experienced IRB member designated by the Chair (refer to UIC HSPP policy *IRB Composition and Membership* for a description of the selection and documentation process).

III. The IRB may require review by the convened IRB for submissions meeting the criteria for expedited review.

IV. The expedited reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. If the reviewer finds that the research should not be approved, the research must be referred to the convened IRB for a final determination.

V. Review materials, criteria for approval (45 CFR 46.111 or 21 CFR 56.111), and requirements for informed consent (or its waiver or alteration) are identical for research reviewed by the convened IRB or expedited process.

VI. IRB members are informed through the agenda for the convened IRB meeting of initial reviews, continuing reviews, amendments of previously approved research, post-approval reports, and final reports approved by expedited procedures and conditions required to secure approval met and confirmed by the Chair (or designee) since the last IRB meeting.

VII. Protocols are eligible for the expedited review process at initial or continuing review if they meet (or continue to meet) the following two criteria:
   A. protocol does not involve more than minimal risks to subjects, as assessed by the reviewer; AND

B. procedures are limited to one or more of the activities described in Expedited Review Categories 1-7 (categories in this list apply regardless of the age of subjects, except as noted):

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); or
   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 from:*
   a) 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) 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.
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.

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 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. 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;* AND
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*.

C. Two additional categories are eligible for the expedited process at continuing review.
   1. *(*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***

2. (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 risk.***

D. The activities listed in categories 1-7 should not be considered minimal risk simply because they are included on this list. Their inclusion merely means that the activity is eligible for review through the expedited review process when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

E. If a research protocol meets the requirement of minimal risk, but includes activities outside of the expedited review categories 1-7, then the protocol must be reviewed by the convened IRB. The convened IRB may opt to make the determination that the research does not involves more than minimal risk and, therefore, may be reviewed under expedited review in the future (i.e., at time of continuing review, thus meeting the criteria for expedited category 9). This determination can only be made by the convened IRB at the time of initial or a subsequent continuing review.

F. Expedited review procedure may not be used where identification of 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, educational advancement, 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. Expedited review procedure may not be used for classified research involving human subjects.

VIII. Amendments to research previously approved by the convened board or expedited review are also eligible for the expedited review process when the proposed changes are minor. Criteria defining a minor change and examples of minor changes are provided in the UIC HSPP policy *Amendment to Previously Approved Research*. In addition, a proposed change to an expedited approved protocol is eligible for expedited review if the proposed change in the research involves no greater than minimal risk and the research continues to meet the expedited review criteria.

PROCEDURES

I. Application Materials

A. Materials required for submission are outlined on the Initial Review Checklist, Continuing Review Checklist, and Amendment Checklist and Instructions located on the UIC OPRS website.

II. Submission Procedures

A. Investigators make the initial determination of whether the submission qualifies for expedited review during the submission process, based on the criteria provided.
B. No submission deadlines exist for expedited review proposals.
C. Assignment of Submissions to an IRB
    1. Submissions for expedited review are assigned to an IRB based on:
        a. type of research (Health and Biological Sciences [IRBs 1 or 3] or Social, Behavioral, or Educational Sciences [IRB 2]),
        b. expertise of expedited reviewers,
        c. IRB conducting the initial review, as continuing reviews and amendments are typically assigned to the same IRB that conducted the initial review, and
        d. performance site (i.e., CHAIRb when research conducted at CAPriCORN institutions).
        e. Protocols may be transferred to another board due to considerations of expertise and workload, with agreement of both IRB Chairs.
    2. A protocol that has been disapproved by one IRB may not be submitted or transferred to another IRB.

III. OPRS Staff Pre-Review
A. OPRS staff perform a pre-review as time permits. The pre-review is guided by a pre-review checklist, and serves as a mechanism to assist with the following functions:
    1. confirmation that all documents required by the IRB have been submitted by the investigator;
    2. assessment as to whether the protocol was submitted for the appropriate level of review;
    3. assessment as to whether supplemental reviews from other committees are required and their status*;*
    4. (at continuing review) confirmation that the approved documents (e.g., informed consent documents and protocol, when applicable) submitted by the investigator match the current IRB-approved documents; and
    5. identification of potential regulatory and/or administrative issues and concerns that the IRB may wish to consider.
B. The OPRS staff assigns the proposal to the Chair (or designee) based on expertise. If warranted due to the focus or complexity, a second reviewer or *ad hoc* consultant may be assigned.
C. The OPRS staff in consultation with the Chair (or designee) may also directly refer the proposal to the convened IRB when their evaluation indicates the eligibility criteria for expedited review are not met.
D. Conversely, when reviewing a proposal submitted for convened review, the OPRS staff in consultation with the Chair (or designee) may decide the proposal meets the criteria for expedited review and reassign it to this level of review.

E. With scenarios C and D, the investigator is notified of the IRB's decision through administrative communication by OPRS staff.

IV. IRB Member Review

A. The reviewer is notified of their assignment to an expedited submission via an email from OPRS Live. Within OPRS Live, the reviewer is provided with the complete submission, the completed pre-review, and appropriate review guide(s).

B. The reviewer is expected to perform an in-depth review of the complete set of documents submitted by the investigator via the OPRS Live system. Their review includes all materials submitted in conjunction with the IRB application and any additional materials obtained from the investigator by OPRS staff during the pre-review process.

C. By completing the review guide, the reviewer confirms that they have no conflicting interests and have the appropriate experience to review the research.

D. The reviewer evaluates whether the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111 and other protocol-specific determinations are met for initial and continuing reviews and for amendments when the changes affect a criterion for approval. The reviewer documents these determinations in writing on the designated review guide.

E. Evaluation of the requirements for the informed consent process and documentation (or waiver or alteration) is also provided in writing on the appropriate review guide (45 CFR 46.116 or 21 CFR 50.25).

F. The completed review guides serve as documentation of the expedited review process and are maintained with the protocol record.

G. The IRB reviewer indicates one of following actions:

1. Approve: Approve as submitted;
2. Conditions Required to Secure Approval: The research has met the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111; however, specific revisions or additional information is required to secure approval and the investigator's response may be reviewed by the Chair (or designee);
3. Refer for convened IRB review: Either the proposal does not meet the requirements for minimal risk, the expedited review categories, or minor change to previously approved research; the IRB reviewer(s) has concerns regarding the protocol and would like a convened review (e.g., complex design, involves a vulnerable population, approval criteria not met); or the IRB reviewer feels the research is not approvable.

H. The IRB reviewer may also document on the appropriate review guide that the protocol as submitted meets the criteria for one of the following:

1. Exempt: Refer to UIC HSPP policy *Exempt Review of Research*.

2. Not Research Involving Human Subjects: Refer to UIC HSPP policy *Determination Whether Activities Represent Human Subjects Research at UIC.*
3. Not Engaged in Human Subjects Research. Refer to UIC HSPP policy *Engagement of UIC in Human Subjects Research*.

I. When the IRB action is approval or conditions required to secure approval of an initial or continuing review submission, the reviewer must indicate whether further continuing review will be required as per the UIC HSPP policy *Continuing Review and Administrative Closure of Research*. If further continuing review will be required, the reviewer must indicate a review frequency appropriate to the degree of risk.

J. For protocols that are determined to require a continuing review, the procedures for determining the approval date and calculating the approval period are described in UIC HSPP policy *Approval Date and Approval Period*.

V. Post-Review Communications

A. The investigator is notified in writing that a review determination has been made. A letter detailing the IRB's findings is sent to the investigator as an e-mail attachment. The notification letter is prepared by the OPRS staff based on the completed review guide. The staff may request the reviewer to provide their input on the letter.

B. The notification letter includes:
   1. date of review
   2. relevant submission information (i.e., IRB protocol number, protocol title, submission type)
   3. process of review
   4. decisions of the IRB
   5. when the IRB requires revisions to the protocol, application, and/or consent documents, and/or further information or clarifications for approval (i.e., conditions required to secure approval) the following is included:
      a. description of required revisions, information requests or clarifications
      b. instructions for submitting written response
      c. notice that submission will be withdrawn in 90 days if no response
   6. when the IRB approves a submission, information relevant to the submission as prompted by the notification template is included.

C. When the proposal is referred to the convened IRB for review, the letter describes the reason for referral, the date of the convened IRB meeting if known, and any recommendations for revisions, clarifications or additional information prior to convened IRB review.

D. Reporting Findings to Organization
   1. The investigator's department head and, if applicable, faculty sponsor are copied on all communications.

2. The Institutional Official is informed of the IRB's review actions through the IRB minutes.

E. Review of Investigator's Responses to the IRB
   1. The IRB Coordinator or Assistant Director reviews responses from investigators and notes their pre-review comments with the response as time permits. The response is then assigned to the appropriate Chair (or designee). Whenever possible, the responses are assigned to the expedited reviewer who performed the original review.

F. Investigators are provided 90 days to respond to the IRB's findings. UIC HSPP policy *Administrative Withdrawal of Research and Submissions* describes the policy and procedures related to withdrawal of research due to a failure to respond.

G. The consequences of a failure to obtain continuing review approval by the expiration date are described in UIC HSPP policy *Lapse in IRB Approval.*

VI. Review of Research by the CHAIRb

A. CHAIRb follows the policies and procedures regarding the expedited criteria and review process as stated within this document.

B. CHAIRb protocols are submitted and reviews are completed via the CHAIRb Portal.

C. Additional post-review procedures are outlined in the *CHAIRb Operations SOP.*

REFERENCES:

21 CFR 56.110, 21 CFR 56.111, 21 CFR 50.25
45 CFR 46.110, 45 CFR 46.111, 45 CFR 46.116
63 FR 60364-60367, November 9, 1998
Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs. OHRP, HHS, FDA, May 2018
OHRP Guidance on Expedited Review Procedures, OHRP, DHHS August 11, 2003
FDA Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval. US FDA, DHHS, February 2012
OHRP Guidance on Continuing Review of Research, OHRP, DHHS, November 10, 2010

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 12/23/08	1.0, 10/15/08	Inserted very specific language that the IRB Chairs had designated through a form that all IRB Assistant Directors have the capacity to perform expedited review. Previously, the policy had general language as to the designation.

1.2, 03/13/09	1.1, 12/23/08	Inserted language to indicate that policy covers expedited review for continuing review. Revised Initial and Continuing Review Procedure Section V to include the review of HHS grant, contract, or cooperative agreement materials.
1.3, 05/05/09	1.2, 03/13/09	Inserted language to indicate that eligibility for expedited review is considered on a protocol by protocol basis, emphasizing that changes in key research personnel and adding a local site may in some circumstances constitute a more than minor change. Provided examples to illustrate this idea.
1.4, 09/17/09	1.3, 05/05/09	Added language as to the process by which IRB members with a conflict of interest are identified. Described to whom IRB members report a conflict of interest when they are assigned to review a protocol in which they have a conflict of interest.
1.5, 05/29/12	1.4, 09/17/09	Updated description of review process and removed material covered in other policies.
1.6, 10/12/16	1.5, 05/29/12	Further removed material covered in other policies. Provided clarification regarding “conditions required to secure approval”. Removal of JBVAMC, addition of CHAIRb.
1.7, 01/21/19	1.6, 10/12/16	Revision of policy to ensure compliance with 2018 Common Rule Requirements. Editorial revisions to remove material covered in other policies and to ensure consistency between policies.