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 and modifications to secure IRB procedures 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 board 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, it must be referred to the full Committee for a final determination.

V. Review materials, criteria for approval (45 CR 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, and modification to secure approval approved by expedited procedures 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 poses no 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, electoretinography, 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. 45 CFR 46.101(b)(4)). This listing refers only to research that is not exempt)*;

6. **Collection of data from voice, video, digital, or image recordings** made for research purposes; **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 at continuing review for the expedited process.

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. Subsequently, the convened IRB may opt to make the determination that although the research includes activities outside of the categories eligible for expedited review, the research involves minimal risk and 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, 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 Amendments to *Previously Approved Research*.

IX. **Expedited Review of Modifications Stipulated by the Convened IRB to Secure Approval**

A. The convened IRB may designate the use of an expedited review process by the Chair (or other designee) for review of modifications to secure approval. This action may occur with initial reviews, continuing reviews and amendments to previously approved research when the convened
IRB requires specific changes or information that do not preclude the IRB from making all of the determinations required for approval (under 45 CFR 46.111 and, if applicable, subparts B, C, or D).

B. In contrast when the IRB action is a deferral, the changes or clarifications are substantive and not prescriptive, determinations for approval cannot be made and any revisions of the protocol or consent documents must be reviewed at a convened meeting of the IRB.

C. Approval with conditions at the time of continuing review is similar to modifications in that the IRB is able to make all of the determinations required for re-approval (under 45 CFR 46.111 and, if applicable, subparts B, C, or D) and further review of the research by the convened IRB is not necessary.

D. UIC HSPP Policy IRB Review of Research by the Convened IRB further describes these review actions.

PROCEDURES

I. Application Materials
A. The materials received for expedited initial reviews, continuing reviews and amendments are the same provided for convened IRB review.

B. Materials required for submission for expedited review of research are outlined on the Initial Review, Continuing Review, Amendment and JBVAMC checklists located on the UIC OPRS website.

II. Submission Procedures
A. Investigators make the initial determination of whether the submission qualifies for expedited review based on the criteria provided in the initial review, continuing review or amendment application.

B. No submission deadlines exist for expedited review proposals.

C. Submission Intake by OPRS: The OPRS intake staff reviews protocols at the time of submission to ensure that they are complete. The OPRS Check-In Process checklists guide this review. Any deficiencies identified are corrected by the researcher before the submission is formally accepted by OPRS.

D. Assignment of Submissions to an IRB
1. Submissions for expedited review are assigned to an IRB based on:
   a. type of research (biomedical [IRBs 1,3 or 4] or social behavioral [IRB 2,4],
   b. expertise of expedited reviewers,
   c. board workload,
   d. IRB conducting the initial review (i.e., for continuing review or amendments), and
   e. Performance site (i.e., IRB 4 when Jesse Brown VAMC is involved).
2. Continuing reviews and amendments are typically assigned to the IRB that performed the initial review. However, protocols may be
transferred to another board due to considerations of expertise and workload with agreement of both Chairs and the Executive Chair

III. IRB Staff Pre-Review
A. After acceptance of the submission, IRB staff performs a pre-review. The pre-review is guided by the UIC OPRS Pre-Review Checklist, and serves the following functions:
   1. confirms that all documents required by the IRB have been submitted by the investigator;
   2. determines whether the proposal may qualify for expedited review;
   3. determines whether supplemental reviews from other committees are required and their status (refer UIC HSPP Policy IRB Review of Research by the Convened IRB - Procedure section III.E. Committees Supplementing the IRB Review);
   4. (at continuing review) confirms that the informed consent documents, recruitment material and protocol submitted by the investigator matches the current IRB-approved documents; and
   5. aid the IRB in identifying important issues and concerns that the IRB may wish to consider.
B. The IRB staff assigns the proposal to the Chair (or designated experienced IRB member) based on expertise. If warranted due to the focus or complexity, a second reviewer or ad hoc consultant may be assigned.
C. The IRB staff in consultation with the Chair 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 IRB staff in consultation with the Chair 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 promptly notified of the IRBs decision.

IV. IRB Member Review
A. The IRB Chair (or designated experienced IRB member) is provided the completed pre-review checklist and appropriate review guide(s).
B. Reviewer is expected to perform an in depth review of the complete set of documents submitted by the investigator (i.e., comparable to the primary reviewer at a convened meeting). The review includes but is not limited to the following, when applicable: complete protocol with any IRB approved amendments incorporated, Investigator’s Brochure (when applicable), federal grant or contract, any appendices to the IRB application, DHHS approved consent templates and protocols, current consent and recruitment documents, UIC IRB Initial Review, Continuing Review and Amendment applications and appendices.
C. The reviewer confirms on the review guide that they have no conflicting interest and have the appropriate experience to review the research.
D. The reviewer documents in writing whether the proposal meets the eligibility criteria for expedited review on the Expedited Addendum review guide (UIC HSPP Document #516) for initial and continuing reviews and Amendment review guide (UIC HSPP Documents #519 & 536-JBVAMC) for amendments to currently approved research.

E. The reviewer evaluates in writing on the appropriate review guide 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.

F. 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, 21 CFR 50.25).

G. The completed and signed review guides serve as documentation of the expedited review process and are filed with the protocol record.

H. The IRB reviewer indicates one of following actions:
   1. Approve: Approve as submitted;
   2. Modifications Required: Modifications or additional information required to secure approval and the investigators response may be reviewed through expedited review procedures; and
   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 member(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 member feels the research is not approvable.

A. When the IRB action is approval or modification (to secure approval) of an initial or continuing review submission, the reviewer must indicate a review frequency appropriate to the degree of risk, but not less than once per year.

B. The procedures for determining the approval date and calculating the approval period are described in UIC HSPP Policy IRB Review of Research by the Convened IRB - Procedure section IV.G. Approval Periods.

V. Post-Review Communications
   A. The IRB notifies the investigator in writing via both e-mail and campus mail concerning the IRB’s findings. The notification letter is prepared by the IRB staff based on the completed review guides. The staff may request the Chair or IRB member reviewer for their input.
B. The notification letter includes:
   1. date of review
   2. what was reviewed (i.e., protocol IRB number, title)
   3. process of review
   4. decisions of the IRB
   5. when the IRB requires modifications to the protocol/application or consent documents, further information or clarifications for approval (i.e., review action modification, deferral or approval with conditions):
      a) description of modifications, information requests or clarifications
      b) basis for requiring modification
      c) instructions for submitting written response
      d) process for IRB review of response
      e) notice that submission will be withdrawn in 90 days if no response
   6. review history for current submission
   7. when IRB approves submission
      a) approval date
      b) approval period (initial and continuing review only)
      c) rationale if approval period is less than a year
      d) amendment number (amendments only)
      e) amendment summary (amendments)
      f) approved number of subjects
      g) additional determinations for vulnerable groups
      h) performance sites
      i) sponsor (and grant or contract number for federal research)
      j) titles, version numbers and version dates of approved protocol, investigational brochure, informed consents and HIPAA authorizations,
      k) waiver or alteration of consent or waiver of documentation determinations,
      l) approved informed consent document(s) and recruitment material(s) stamped with the new approval period,
      m) approved HIPAA authorization stamped with the approval date,
      n) statement that only the most recent IRB-approved and stamped consent documents and HIPAA authorizations should be used to enroll subjects, and
      o) copy of investigator responsibilities poster.
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, and any recommendations for modifications, 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, i.e. Vice Chancellor of Research, Human Protections Administrator and Executive Chair are 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 for modifications. The IRB staff notes on the Pre-Review Checklist whether there are any issues with the response. The IRB Coordinator assigns the protocol to the appropriate Chair or designated member and informs them that the responses are ready for review and determination. Whenever possible, the responses are assigned to the expedited reviewer performing the original review.

F. Investigators are provided 90 days to respond to the IRB’s findings. UIC HSPP Policy Study Closure, Lapse in IRB Approval and Withdrawal of Research 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 Study Closure, Lapse in IRB Approval and Withdrawal of Research.

VI. Review of Research at the JBVAMC by the Convened IRB

Refer to UIC HSPP Policy Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4).

REFERENCES:

21 CFR 56.110
38 CFR 16.110
45 CFR 46.110
63 FR 60364-60367, November 9, 1998
OHRP Guidance on Written IRB Procedures, OHRP, DHHS, July 1, 2011
VHA Handbook 1200.05, vs. 10/15/2010, paras. 10, 22, 44
OHRP Guidance on Continuing Review of Research, OHRP, DHHS, November 10, 2010
OHRP Guidance on IRB Approval of Research with Conditions, OHRP, DHHS, November 10, 2010

REVISION LOG:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
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<tbody>
<tr>
<td>1.1, 12/23/08</td>
<td>1.0, 10/15/08</td>
<td>Inserted very specific language that the IRB</td>
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<tr>
<td>Date</td>
<td>Previous Date</td>
<td>Action</td>
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<tr>
<td>1.2, 3/13/09</td>
<td>1.1, 12/23/08</td>
<td>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.</td>
</tr>
<tr>
<td>1.3, 5/5/09</td>
<td>1.2, 3/13/09</td>
<td>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.</td>
</tr>
<tr>
<td>1.4, 9/17/09</td>
<td>1.3, 5/5/09</td>
<td>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.</td>
</tr>
<tr>
<td>1.5, 05/29/12</td>
<td>1.4, 9/17/09</td>
<td>Updated description of review process and removed material covered in other policies.</td>
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</table>