2.7 Continuing Review of Research

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for continuing review of approved research

2.0 Policy

It is the policy of the Organization that:

- 2.1. Non-exempt research which is subject to the Common Rule or FDA Regulations shall undergo continuing review at intervals appropriate to the degree of risk, but not less than once per year, except as allowed under 45 CFR 46.109(f).
- 2.2. Non-exempt research which is not subject to the Common Rule or FDA Regulations shall undergo continuing review at intervals appropriate to the degree of risk.

3.0 Continuing Review Frequency

- 3.1. Non-exempt research which is subject to the Common Rule or FDA Regulations shall undergo continuing review at intervals appropriate to the degree of risk, but not less than

once per year, except as described in section 3.3 below.
    - 3.1.1. The IRB may determine that continuing review is required more often than annually, as described in HRPP policy 3.1 (Assessing the Need for Increased Monitoring, Interim Continuing Review, and Verification from Sources Other than the PI).
    - 3.1.2. Unless the IRB specifically determines at the time of initial review or continuing review that a protocol should be reviewed less often than annually, the research will be subject to review annually
- 3.2. Non-exempt research which is not subject to the Common Rule or FDA Regulations shall undergo continuing review at intervals appropriate to the degree of risk.
- 3.3. Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:
    - 3.3.1. Research not subject to FDA regulations which underwent expedited review in accordance with 45 CFR 46.110 after January 20, 2019.
    - 3.3.2. Research not subject to FDA regulations which was approved after January 20, 2019 and has progressed to the point that it involves only data analysis, including analysis of identifiable private information or identifiable biospecimens.
    - 3.3.3. Research not subject to FDA regulations which was approved after January 20, 2019 and has progressed to the point that it involves only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

  Note: For the purposes of this policy, if a particular procedure is specified in the research protocol to occur at a specific time then that procedure is considered a research procedure, and not a procedure "that subjects would undergo as part of clinical care."
    - 3.3.4. If the IRB determines that continuing review is required for research in any of the above categories, the rationale will be recorded in accordance with 45 CFR 46.115(a)(3).
    - 3.3.5. Non-exempt research approved prior to the effective date of the Revised Rule requires continuing review as per sections 3.1 and 3.2.
- 3.4. Unless the ORA determines otherwise, continuing review is not required for exempt research.
    - 3.4.1. If the ORA determines that continuing review is required for a specific research protocol which was eligible for exemption under categories 2 and 3 (45 CFR 46.104(d)(2) and (3)) and had initially undergone limited IRB review after the effective date of the Revised Rule, the rationale will be recorded in accordance with rev 45 CFR 46.115(a)(3).

  Note: The Organization will not utilize exempt categories 7 and 8 (45 CFR 46.104(d)(7) or (8)).

4.0 Criteria for Review

- 4.1. The criteria for continuing approval of all human subject research (either by full board or by expedited review) are described in HRPP policy 2.5 (Criteria for IRB Approval).

- 4.2. In addition to the criteria in HRPP policy 2.5 (Criteria for IRB Approval), during continuing review by the full IRB or by expedited review, the IRB or the expedited reviewer must also determine:
  - 4.2.1. Whether the research requires continuing review more often than annually as appropriate to the degree of risk. In making this determination, the IRB might consider the nature of risks posed by the research, the degree of uncertainty regarding the risks involved, the vulnerability of the participants, the experience of the investigator, the IRBs previous experience with that investigator or sponsor, the projected rate of enrollment, and/or whether the study involves novel therapies.
  - 4.2.2. Whether the research need verification from sources other than the PI that no material changes have occurred since the previous IRB review as required 45 CFR 46.108(a)(3)(ii)), or 21 CFR 56.108(a)(2).
  - 4.2.3. Whether the current consent form is still accurate and complete.
  - 4.2.4. Whether the research should have a third party observe the consent process.
  - 4.2.5. Whether the research requires an audit of research records in accordance with HRPP policy 1.21 (Post Approval Monitoring of Research) and HRPP policy 8.4 (Review of Noncompliance Involving the PI and Study Personnel).
  - 4.2.6. 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.
  - 4.2.7. Whether subject accrual is adequate to achieve the scientific goals of the study.
  - 4.2.8. 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.
- 4.3. During continuing review by an expedited reviewer, if the reviewer believes any of the situations in section 4.2.1 thru 4.2.8 apply, the protocol will be referred to the full IRB.

5.0 Investigator Responsibilities

- 5.1. If continuing review is required (as per section 3.3 above), a continuing review application must be submitted thru RSS prior to expiration date of the approved protocol.
- 5.2. The investigator must update the record in Clinicaltrials.gov as applicable, per HRPP policy 1.29 (Clinicaltrials.gov Reporting).
- 5.3. If the research is completed, the investigator will be responsible for the activities described in HRPP policy 2.9 (Closure of On-Going Research).
- 5.4. If the research is closed because an investigator does not submit a continuing review or a Demographics Reporting form, the investigator will be responsible for the activities described in HRPP policy 2.9 (Closure of On-Going Research).

6.0 ORA/IRB Responsibilities

- 6.1. Continuing review, when it is required, is conducted by the convened IRB, except under the following circumstances where expedited continuing review is allowed:
  - 6.1.1. Research which satisfies the requirements of OHRP Expedited Review Categories (1998) and HRPP policy 2.3 (Expedited Review), expedited category 8 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 where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis, may undergo expedited continuing review.
  - 6.1.2. Research which satisfies the requirements of OHRP Expedited Review Categories (1998) and HRPP policy 2.3 (Expedited Review), expedited 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 continuing review.
  - 6.1.3. Research which underwent expedited review in accordance with 45 CFR 46.110 or 21 CFR 56.110 prior to January 20, 2019, may undergo expedited continuing review.
- 6.2. The ORA will send emails to the PI and the Lead Coordinator and/or Regulatory Contact at least 60 days and 45 days prior to the date of expiration.
- 6.3. Protocols initially approved by IRB-01 or IRB-02 will undergo continuing review at either the IRB-01 or the IRB-02 meeting.
- 6.4. Protocols initially approved by IRB-04 (Pediatrics) will undergo continuing review at the IRB-04 meeting. If the Executive Chair determines that earlier review is necessary to minimize risk or inconvenience to subjects, protocols can be reviewed at the IRB-01 or IRB-02 as a “Special Review Item”, provided at least one member of IRB-04 is present at IRB-01 or IRB-02 and can serve as primary reviewer.
- 6.5. Protocols initially approved by IRB-03 will undergo continuing review at the IRB-01 or IRB-02 meeting or at the IRB-04 meeting, depending on the nature of the research and the predominant subject population, at the discretion of the Executive Chair.
- 6.6. Protocols initially approved by IRB-05 (SIRB) will undergo continuing review at the IRB-05 meeting. If the Executive Chair determines that earlier review is necessary to minimize risk or inconvenience to subjects, protocols can be reviewed at the IRB-01 or IRB-02 as a “Special Review Item”, provided at least one member of IRB-05 is present at IRB-01 or IRB-02 and can serve as primary reviewer.
- 6.7. For continuing review by the convened IRB or by expedited review, IRB members (and alternates), or the expedited reviewer, will have access to, and are expected to review, IRB study files in RSS, including but not limited to the CR application (which includes a status report on progress of the research) and any newly proposed consent

forms. The primary reviewer for review by the convened IRB, or the expedited reviewer, is also expected the review any protocol modifications previously reviewed and approved by the IRB.

- 6.8. The expiration date of protocols for which continuing review is required is based on the date that the convened IRB 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.
- 6.9. If a protocol for which continuing review is required has not received full approval by the expiration date, the protocol is considered “expired”, and investigators are no longer authorized to conduct research activities or enroll subjects.
  - 6.9.1. Approval expiration is not study suspension, and the protocol is not subject to reporting as per HRPP policy 8.6 (Study Hold, Suspension, and Termination).
  - 6.9.2. The Investigator and the Lead Coordinator and/or Regulatory Contact will be notified by email or through the RSS Message portal that a study is expired and that investigators are no longer authorized to conduct research activities or enroll subjects.
  - 6.9.3. If the investigator believes that it would be in the best interest of a subject participating in an expired research study to continue research activities, the investigator may submit a “Request to Continue Treatment for Enrolled Subjects on Approval Expired Studies” form in RSS.
    - 6.9.3.1. The Executive Chair or designee has the authority to grant approval of the request for one or more subjects provided (1) the research interventions hold out the prospect of direct benefit to the subjects, or (2) withholding those interventions poses increased risk to the subjects.
    - 6.9.3.2. If the Executive Chair or designee decides that already enrolled subjects should continue to receive the interventions that were being administered to subjects under the research protocol, data collection (especially safety information) should also continue for such subjects.
  - 6.9.4. If the investigator does not respond to the “Approval Expired” notification from the ORA within 30 calendar days, the study will be considered closed.
- 6.10. The convened IRB will conduct continuing review as per section 4.0 above.
- 6.11. For research that requires FPBCC Scientific Review Committee (SRC) review, IRB continuing approval will be contingent of SRC review and approval.
  - 6.11.1. The IRB Continuing Review Analyst, or designee, in consultation with the IRB Executive Chair or designee will be responsible for assuring that no substantive changes have been made to the protocol or the consent forms by the SRC. If substantive changes have been made, re-review by the convened IRB will be required.
- 6.12. The expiration date for the next continuing review will be based on the date that the convened IRB gave conditional re-approval of the research (as per section 5.7 above)
- 6.13. The ORA will keep appropriate records of all continuing review activity in accordance with 45 CFR 46.115(a)(3).
- 6.14. For research that is exempt, or for which continuing review is no longer required per section 3.3, the investigator is required to complete a Demographic Recruiting Numbers form in RSS annually.
  - 6.14.1. If the investigator does not respond to the email requesting demographic information within 20 calendar days, the study will be considered closed. The investigator will be responsible for the activities described in HRPP policy 2.9 (Closure of On-Going Research).

DOCUMENT HISTORY:

? Written: 2/6/2018 (Approved: 2/6/2018) - original author not recorded

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? Revised: 1/29/2021 - Clarified “procedures that subjects would undergo as part of clinical care” per (45 CFR 46.109(f)(iii)(B)) (section 3.2.3); clarified which IRBs can perform continuing review (sections 5.2 thru 5.5); various minor clarifications and corrections

? Revised: 1/30/2023 – Revised to stress distinction between FDA regulated and non-regulated research; clarified process for submission of demographic information for research that is exempt, or for which continuing review is no longer required (section 6.1.4); deleted requirement that convened IRB be notified of Request to Continue Treatment for Enrolled Subjects on Approval Expired Studies; changed “20 working days” to “30 calendar days”; reformatted; various minor clarifications and corrections. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board notified: 1/31/2023

? Revised: 5/17/2023 - Corrected 6.14 to reflect accurate form name, corrected typo of 30 days to 20 days in 6.14.1 (Robert Lewis, IRB Assoc)

? Revised 1/12/2024 - Revised section 4.0 to clarify responsibilities of expedited reviewer; added section 6.1.3 to clarify research approved by expedited review prior to January 2019 may undergo expedited continuing review; revised section 6.7 to clarify materials available to, and expected to be reviewed by, the convened IRB or expedited reviewer; other minor stylistic changes. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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