Title: CONTINUING REVIEW – CRITERIA FOR RENEWAL **Version No.:** 1.8

SOP No.: RR-405 **Effective Date:** August 18, 2025

1. Purpose

This policy describes the criteria for the continuing review and renewal of IRB approved human research.

2. Policy

The IRB conducts continuing review of non-exempt human research occurring within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year. Research requires a continuing review except as outlined in MSK IRB SOP RR-411.

During continuing review, the IRB determines that all regulatory requirements, institutional requirements, and accreditation standards are met. In addition, during continuing review the IRB determines which projects require verification from sources other than the investigator to ensure that no material changes in the research have occurred since the previous IRB review.

3. Specific Procedures

3.1 Interval for Review for Purposes of Renewal

The IRB must conduct continuing review of protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk, but not less than once per year. “Not less than once per year" means that the research must be reviewed on or before the one-year anniversary of the previous IRB approval date, even though the research activity may not have begun until sometime after IRB granted its approval. Risk level is determined at the initial review and may be revised at the time of continuing review.

Principal Investigators are required to submit a Continuing Review Report prior to the expiration of the study or as specified by the IRB, but at least annually.

3.2 Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. If Continuing Review and IRB approval have not occurred as scheduled and IRB approval expires, the investigator must stop all research interactions and interventions. Refer to MSK IRB SOP FO-304 for information on additional action taken if the Continuing Review Report is not approved by the anniversary date.

If the Principal Investigator believes that stopping research related interventions or interactions would adversely affect the safety of currently enrolled participants, the PI must immediately contact IRB Leadership to discuss the specific safety concerns. An IRB Chair (or Associate Chair) will determine whether it is in the best interest of individual participants to continue to receive research related interventions. During the lapse of IRB approval, new participants cannot be enrolled, prospective data cannot be collected, and no procedures that are only being performed for the protocol may be conducted until the continuing review process has been completed.

3.3 Criteria for Renewal

Continuing review must be substantive and meaningful. The criteria for approval of research detailed at 45 CFR 46.111 and/or 21 CFR 56.111, and all applicable regulatory subparts will be followed as outlined in MSK IRB SOP RR-401.

To determine the status of the study, the following will be revisited:

3.3.1 Consent document: The IRB shall review the currently approved consent document and ensure that the information is still accurate and complete. Any significant new findings that may relate to the research participant's willingness to continue participation should be provided to the research participant in an updated consent document (see MSK IRB SOP IC-701).

3.3.2 Protocol document: The IRB shall review the currently approved protocol document and ensure that the information is still accurate and complete. Amendments to the protocol since initial review are submitted to the IRB in real-time without waiting until the time of continuing review.

3.3.3 Continuing IRB review is required if individually identifiable follow-up data are collected on research participants enrolled in protocols unless stipulated in MSK IRB SOP RR-411. This remains the case even after a protocol has been closed at all sites and protocol-related treatment has been completed for all research participants. These renewal requests may qualify for expedited review.

3.3.4 Continuing Review: All IRB members shall receive a Continuing Review Report prepared and submitted by the Principal Investigator which includes:

- The number of participants accrued.
- A summary since the last IRB continuing review (or initial review if a continuing review hasn't occurred) of:
  - Participant withdrawals.
  - The reasons for withdrawals.
  - Complaints about the research.
  - Amendments or modifications.
  - Any relevant recent literature.
  - Any interim findings.
  - Any relevant multi-center trial reports.
  - The current risk-potential benefit assessment based on study results.
  - Audit summaries
- A summary for the lifetime of the study of:
  - Serious Adverse Events.
  - Unanticipated problems involving risks to participants or others.
  - Confirmation that adverse events have occurred at the expected frequency and level of severity.
  - Retrospective and Prospective deviations reported to IRB/HRPP.

3.4 Possible Outcomes of Continuing Review

As an outcome of continuing review, the IRB may require that the research be modified or suspended altogether. The IRB may need to impose special precautions or relax special requirements it had previously imposed on the research protocol, such as shortening the approval time frame.

In addition, the IRB may make one of the following determinations:

- Continue to enroll to participants
- Closed to accrual
- Closed – no further research (See MSK IRB SOP RR-410)

4. Applicable Regulations and References

- 21 CFR 56.108
- 21 CFR 56.109
- 45 CFR 46.103
- 45 CFR 46.109
- MSK IRB SOPs FO-304, RR-401, RR-407, RR-408, RR-409, RR-410, RR-411, IC-701

Revision History

Revision	Effective Date	Reason for Change
1.0	6/15/09	NEW
1.1	11/11/14	• Updated Signature Page, MSK branding, typos • Clarified the Principal Investigator's role throughout • Added the IRB determinations to section 3.4 • Added references to related SOPs (RR 405 and IC 701)
1.2	2/29/16	• Renumbered to RR-405 (formerly RR-404) • Updated Signature page, MSK branding, formatting. • 3.2 Updated text on Extensions of Approval Period • 3.3 Criteria for renewal references the regulatory requirements • 3.3.4 Detail on what must be included in the CRR/progress report
1.3	1/21/19	• 2 Added reference to IRB SOP RR-411 for exceptions to continuing review • 4 Updated to include IRB SOP RR-410 and IRB SOP RR-411
1.4	11/23/20	• 3.1 Revised length of approval period from 365 days to one year; clarified when risk level is determined and that it may change • 3.3.3. Added reference to IRB SOP RR-411 • 3.3.4. Added SAE to list of items summarized in the CRR
1.5	1/31/22	• 2 Grammatical updates • 4 Updated to include MSK IRB SOPs referenced in this SOP
1.6	1/23/23	• Editorial changes made throughout • 3.3.4 Updated to reflect the information included in a CRR report • 3.4 Updated to reflect that the timeframe for approval may be changed
1.7	11/6/23	• 3.2 Revised wording such that, if a CRR expires, any IRB chair or associate chair can determine whether it is in the best interest of individual participants to continue to receive research related interventions. • 3.3.4 Updated "deviations" to "Retrospective and Prospective deviations reported to IRB/HRPP"
1.8	8/18/25	• 3.2 Updated to include a reference to SOP FO-304