Title: PROGRESS REPORTS – CRITERIA FOR RENEWAL **Version No.:** 1.6

SOP No.: RR-411 **Effective Date:** August 18, 2025

1. Purpose

This policy describes the criteria for the renewal of IRB approved non-exempt human research that does not require a regulatorily mandated IRB continuing review as outlined in the below policy.

2. Policy

Unless the IRB determines otherwise, a progress report (in lieu of a continuing review report submission) is required in the following circumstances:

1. When research is eligible for expedited review in accordance with MSK IRB SOP RR-403.
2. When research has progressed to the point that it involves only one or both of the following, which are part of a non-FDA regulated IRB-approved study:
    A. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    B. Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

HRPP staff members conduct the progress report review at intervals not less than once every two years as determined by the IRB or HRPP.

During the review, HRPP staff determine that all applicable regulatory requirements, institutional requirements, and AAHRPP accreditation standards are met. In addition, during review, the HRPP reviewer 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 and/or HRPP review.

A study status update is required for exempt research including exempt research that was reviewed in accordance with a limited IRB review procedure. See IRB SOP FO-303.

3. Specific Procedures

3.1 Interval for Review for Purposes of Renewal

Per MSK, the HRPP must conduct review of protocols for purposes of renewal of the approval period, at intervals appropriate to the degree of risk, but not less than once every two years. “Not less than once every two years" means that the research must be reviewed on or before the two-year anniversary of the previous IRB or HRPP review date, even though the research activity may not have begun until sometime after granted approval. Risk level is determined at the initial review and may be revised by the convened IRB due to modifications to the protocol.

Principal Investigators are required to submit a Progress Report prior to the expiration of the study or as specified by the IRB or HRPP, but at least every two years.

3.2 Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of approval. If progress review and approval have not occurred as scheduled and 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 Progress 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 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 review process has been completed.

3.3 Criteria for Renewal

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

3.3.1 A copy of the protocol and consent, if appliable, will be available to the reviewer(s).

3.3.2 Progress Review: The HRPP reviewer(s) shall receive a Progress Report prepared and submitted by the Principal Investigator which, if applicable, includes:

- The number of participants accrued.
- A summary since the last IRB progress review of:
  - Participant withdrawals.
  - The reasons for withdrawals.
  - Complaints about the research.
  - 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 for:
  - 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 Progress Report Review

The HRPP will make one of the following determinations:

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

As an outcome of the progress report review, the HRPP may require that the research is sent to the IRB to assess if a continuing review report is required going forward because of identification of continuing non-compliance and/or safety concerns. The IRB will make the final determination for whether a progress report continues to be sufficient or if a CRR is required for future reviews. This may include the three determinations listed above or may require that the research be modified or suspended. The rationale for requiring a CRR will be documented in writing to the PI and within the IRB minutes.

4. Applicable Regulations and References

- 45 CFR 46.103
- 45 CFR 46.109

- MSK IRB SOPs FO-303, FO-304, RR-403, RR-405, RR-407, RR-408, RR-409, RR-410

Revision History

Revision	Effective Date	Reason for Change
1.0	01/21/19	NEW
1.1	11/23/20	2.0 Removed reference to degree of risk as Progress Reports would only be completed on low risk studies and/or at the time in which a greater than minimal risk study is closing 3.1. Clarified that risk level may be changed by the convened IRB due to modifications to the protocol 3.2 and 3.3 Minor corrections made to grammar and sentence structure
1.2	1/31/22	2 Grammatical updates 4 Updated to include MSK IRB SOPs referenced in this SOP
1.3	1/23/23	Minor editorial changes throughout 3.3 Updated to reflect what is submitted as part of CRR or PR review
1.4	11/6/23	3.2 Revised wording such that, if a PR 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. 3.3.2 Updated “deviations” to “Retrospective and Prospective deviations reported to IRB/HRPP”
1.5	1/21/25	Updated to reflect that progress reports are required on an annual or biannual (24 months) basis as determined by the IRB or HRPP.
1.6	8/18/25	3.2 Updated to include a reference to IRB SOP FO-304