Title: IRB OF RECORD **Version No.:** 1.10

SOP No.: GA-106 **Effective Date:** January 20, 2026

1. Purpose

This policy defines the requirements when Memorial Sloan Kettering Cancer Center (MSK) elects to be the IRB of record for another institution or elects to cede IRB review to another entity.

2. Policy

It is the policy of MSK to enter into Institutional Review Board Reliance Agreements (IRB RA) whenever MSK elects to: (a) be the IRB of record for non-exempt human subjects research being conducted by the employees or agents of another institution; or (b) rely on another entity to be the IRB of record for non-exempt human subjects research being conducted by the employees or agents of our institution.

The Office for Human Research Protections (OHRP) requires single IRB review for non-exempt human subjects multi center domestic protocols that meet the following requirements:

- The study or a portion of the study is federally funded or supported
- Approved on or after January 20, 2020

For federally funded research, the reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance by the Federal department or agency supporting the research.

This policy currently aligns with NIH policy for single IRB review. The policy from the NIH stipulates that at the time of new and re-competing applications/proposals for funding, the primary Principal Investigator must indicate that single IRB (sIRB) will be applicable.

Approval by IRB Leadership or the HRPP Director is required prior to agreeing to be IRB of Record or to cede to another entity. MSK's Institutional Official (IO), or designee, retains final authority to determine whether MSK will enter into an IRB RA.

3. Specific Procedures

3.1 Scope

This policy applies whenever: (a) an institution requests MSK to be the IRB of record for non-exempt human subjects research to be conducted by the employees or agents of another institution; or (b) MSK would like to rely on another entity to be the IRB of record for non-exempt human subjects research to be conducted by the employees or agents of our institution. MSK may agree to be the IRB of record for another institution or agree to cede IRB review to another institution only if it is appropriate under the circumstances. If MSK agrees to be the single IRB for all sites participating in a multi-site research study, MSK may choose not to allow a site to rely on MSK IRB if not appropriate. An IRB RA must be fully executed, i.e., signed by MSK's IO (or designee) and the designated official from the other entity, before IRB approval can occur.

3.2 Definitions

Engaged Institution An institution whose employees or agents (i.e., individuals who act on behalf of the institution; exercise institutional authority or responsibility; or perform institutionally designated activities): (1) intervene or interact with human participants for research purposes; (2) obtain identifiable private information about human participants for research purposes; (3) obtain

the informed consent of human participants for research purposes and/ or (4) prime recipient of an award of federal funding to carry out the research.

Federal wide Assurance (FWA) A written document signed by an institution (not an IRB) outlining the institution's commitment to the Department of Health and Human Services (DHHS) that the institution will abide by 45 CFR 46, as well as the Terms of Assurance, when the institution becomes engaged in non-exempt human subjects research that is covered by the institution's FWA.

IRB Reliance Agreement (IRB RA) A written agreement that is entered into between an engaged institution and an institution operating an IRB when an engaged institution relies upon an IRB that is operated by another institution or organization for review of research covered by the engaged institution's FWA. The IRB RA outlines the IRB review relationship and includes a commitment that the IRB will adhere to the requirements of the engaged Institution's FWA. The IRB RA must be kept on file at both institutions/organizations and made available to OHRP or any U.S. federal department or agency conducting or supporting research covered by the FWA upon request.

IRB of Record The IRB responsible for the review and oversight of non-exempt human subjects research.

Local Context: Site-specific information such as applicable state or local laws, regulations, and institutional policies that relying sites need to provide to the IRB of record.

3.3 Procedures to be Followed When MSK is Asked to be the IRB of Record for Research Being Conducted by the Employees or Agents of Another Institution

1. Any requests for MSK to be the IRB of Record for review of research to be conducted by the employees or agents of another institution must be made to the HRPP Director (and/or designee).
    a. The HRPP Director (and/or designee) will review the request and make a recommendation to IRB Leadership as to whether the MSK IRB should be the IRB of record for the requested research. When making this recommendation, the HRPP Director (and/or designee) will consider the below items:
        i. Location of where the research will take place;
        ii. Type of research to be conducted, e.g., phase I, novel therapies, pediatric population;
        iii. Whether the IRB is designated to review the research being proposed;
        iv. Whether the site is Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accredited;
        v. Whether the IRB has the expertise to review the research being proposed;
        vi. Whether the IRB has the meeting space and sufficient staff (i.e., resources) to review the research being proposed in a timely manner taking into account IRB current workload, meeting schedule, etc.;
        vii. Whether MSK is affiliated or collaborates with the entity requesting IRB review; and
        viii. Any other relevant considerations.
2. IRB Leadership will make a decision as to whether our IRB will be the IRB of record for research to be conducted by the employees or agents of another institution. The HRPP Director (or designee) will communicate this decision to the individual requesting IRB review.
3. If IRB Leadership agrees to be the IRB of Record for research to be conducted by the employees or agents of another institution, the HRPP office will ensure a fully executed IRB RA (i.e., an IRB RA signed by the MSK IO (or designee) and the designated official from the

other entity) is in place. A fully executed IRB RA must be in place before granting IRB approval of IRB RA covered research.

4. For each relying site, the following documents must be submitted to the MSK IRB for review and approval.
    a. Relying site consent form, if applicable:
        i. The MSK IRB approved consent form must be used. Unless otherwise approved by the MSK HRPP Office due to local/state regulation (e.g. genetic research), only the below sections of the consent form can be revised to include local site information:
            1. Site logos in the header/footer
            2. Site PI and contacts
            3. Number of participants taking part in the study at the site
            4. Conflict of interest
            5. Costs
            6. Compensation for Injury, if applicable
            7. HIPAA language, if site is a HIPAA covered entity
    b. Other relying site documents, if applicable (e.g., participant facing documents)
    c. Local context form
5. The MSK IRB will follow its standard operating procedures when reviewing research covered by an IRB RA, with the following modifications:
    a. The HRPP Office or designees will:
        i. Promptly notify the investigator and the investigator's institution in writing of MSK IRB's decision to approve or disapprove the research or of modifications required to secure IRB approval of the research;
            1. The relying site must implement the approved changes within 30 calendar days of receipt of MSK approval.
        ii. Promptly notify the investigator and the investigator's institution whenever the following occurs in relation to reviewed research, as appropriate:
            1. Any unanticipated problem involving risks to participants or others;
            2. Any serious or continuing noncompliance with 45 CFR 46, 21 CFR 50/56/312/812 or the requirements or determination of our IRB; or
            3. Any suspension or termination of IRB approval.
        iii. Prepare and maintain for the relying institution the following documentation of IRB activities associated with the reviewed research:
            1. Copies of all IRB approved research documents;
            2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
            3. Records of continuing review activities;
            4. Copies of all formal correspondence between the IRB and the investigators;
            5. MSK IRB SOPs GA-106, FO-309, FO-310, RR-401, RR-404, RR-405, RR-407, RR-408, RR-409, RR-411, RR-412, SC-501, IC-701, IC-702, IC-703, IC-704, IC-705, IC-706, RI-804; and
            6. Statements of significant new findings provided to participants, as required by 45 CFR 46.116(b)(5) (45 CFR 46.115(a)).
        iv. Maintain documentation of IRB activities associated with the reviewed research for at least 3 years, and records relating to the reviewed research which is conducted for at least 3 years after completion of the research. All

records will be accessible for inspection and copying by the relying institution, as well as authorized representatives of, as applicable, FDA, OHRP and/or the funding department or agency at reasonable times and in a reasonable manner.

3.4 Procedures to be Followed When MSK Seeks to Rely on Another Entity to be the IRB of Record for Research Being Conducted by the Employees or Agents of Our Institution

1. Any requests for MSK to rely on another entity to be the IRB of Record for research being conducted must be made to the HRPP Director (or designee).
    a. The HRPP Director (and/or designee) will review the request and make a recommendation to IRB Leadership as to whether MSK should cede IRB review of the research to the IRB of another entity. When making its recommendation, the HRPP leadership will consider the following:
        i. Whether the IRB is appropriately registered with OHRP;
        ii. Whether the IRB is AAHRPP Accredited;
        iii. Type of research to be conducted, e.g., phase I, novel therapies, pediatric population;
        iv. Whether MSK is affiliated or collaborates with the entity requesting IRB review;
        v. Whether the IRB is approved to review the type of research being proposed;
        vi. Whether the IRB has the expertise to review the research being proposed;
        vii. Whether the IRB meets all IRB membership requirements outlined at 45 CFR 46.107/21 CFR 56.107;
        viii. Whether the IRB possesses sufficient knowledge of the local research context to be able to ascertain the acceptability of the proposed research in terms of MSK's mission, applicable law and standards of professional conduct and practice;
        ix. Any other relevant considerations.
2. IRB Leadership will make a decision as to whether MSK will cede IRB review of the research to the IRB of another entity, The IO has the final authority to determine reliance. the HRPP Director (or designee) will communicate this decision to the individual requesting to rely on the IRB of another entity.
3. If IRB Leadership agrees to cede IRB review of research responsibility to another entity, the HRPP Office will ensure a fully executed IRB RA (i.e., an IRB RA signed by the MSK IO (or designee) and the designated official from the other entity) is in place. A fully executed IRB RA must be in place before MSK will acknowledge the outside entity's IRB approval of IRB RA covered research.
4. Privacy Board Review at MSK is still required if MSK participants will be accrued on the study unless otherwise approved by the HRPP Director (and/or designee).
5. The MSK PI must follow all applicable IRB of record policies. In addition, the MSK PI must:
    - continue to report retrospective deviations, serious adverse events, unanticipated problems, and noncompliance for MSK participants in accordance with MSK IRB SOPs RR-407, RR-408, RR-409, and FO-309.
    - continue to report Amendments and Progress Reports to the HRPP for acknowledgment and filing in the regulatory binder, as per MSK IRB SOP FO-304.
    - consult with MSK HRPP (irbofrecord@mskcc.org) if the external IRB of record does not have a policy for which MSK does as MSK IRB SOPs may apply.
6. All external IRB of Record amendment approvals and corresponding updated documents should be submitted in PIMS to the MSK HRPP Office within 5 calendar days of receipt. The submission will be reviewed for 1) local context as defined in the MSK Boilerplate Language for External IRB of Record document and 2) MSK face sheet changes. The submission must be acknowledged/activated by MSK within 30 calendar days of receipt unless otherwise

dictated by the external IRB of Record's policy or unless an exception has been granted by the HRPP Office.

7. For studies relying on the National Cancer Institute (NCI) CIRB, the MSK Additional Information sheet must be used to provide any required local information to MSK participants that CIRB does not allow to be embedded in the CIRB consent form. The Additional Information Sheet must be reviewed and approved by the MSK IRB/PB along with the CIRB consent form.

4. Applicable Regulations and References

- 45 CFR 46.114
- 21 CFR 56.114
- FDA Information Sheets: Non-Local IRB Review
- OHRP Guidance on IRB Knowledge of Local Research Context
- National Institute of Health (NIH) Policy on the Use of a Single Institutional Review Board for Multi-Site Research, NOT-OD-16-094
- Determination of Exception for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements
- MSK IRB SOPs RR-407, RR-408, RR-409, FO-309, FO-304, CO-602, IC-701

Revision History

Revision	Effective Date	Reason for Change
1.0	2/29/16	NEW
1.1	1/25/18	• Updated naming convention of agreements • Added NIH policy requirements for S-IRB • Updated staff titles • Added MSK PI requirements to MSK HRPP/IRB when they cede IRB review to another entity
1.2	1/20/20	• Updated per OHRP policy requirements for sIRB
1.3	5/11/20	• 3.3,1a Added AAHRPP accreditation • 3.3, 6ai1 Section added to specify timeline for notifying sites of MSK IRB approvals and for sites to activate the approval • Former 3.4, 2 removed as information is already included in 3.4, 1 • 3.4, 6 Clarified that Privacy Board at MSK is required unless otherwise approved by the HRPP Director (and his/her designee). • 3.4, 8 Section added to specify timelines for acknowledgment/activation of external IoR amendments • Terminology and acronyms updated for consistency throughout
1.4	11/23/20	• 2 Revised per updated NIH regulations to remove requirement to delegate the IoR in grant applications/proposals • 3.4, 7 Updated to include that MSK PI must follow all applicable IRB of record policies; updated to note that MSK IRB SOPs may apply if the external IoR does not have a policy for which MSK does

1.5	7/28/21	• 3.3, 6 Section added to outline the relying site documents that must be submitted to the MSK IRB for review and approval. • 3.4, 8 Updated to note that submissions will be reviewed for 1) local context as defined in the MSK Boilerplate Language for External IRB of Record document and 2) MSK face sheet changes; Removed language regarding a study being subject to Administrative Hold for submission not acknowledged/activated within 30 calendar days; • 4 Updated section to include reference to MSK IRB SOPs
1.6	1/31/22	• Removed gendered language • 2 Added: For federally funded research, the reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance by the Federal department or agency supporting the research • 3.2 Updated the definition of engaged institution to include prime recipient of an award of federal funding to carry out the research. • 3.3, 2 Replaced individual staff titles with IRB Leadership • 3.3, 4 and 3.3, 7aiii1 and 3.4, 5 Simplified language • 3.3, 7aiii5 Replaced written procedures with list of MSK IRB SOPs relying sites must follow • 3.4, 9 Added to describe the MSK Additional Information Sheet used for CIRB trials
1.7	1/23/23	• Minor grammatical edits
1.8	2/5/24	• Minor grammatical edits
1.9	1/21/25	• 2 Clarified that MSK's Institutional official or designee retains final authority to determine whether MSK will enter into a reliance agreement. • 3.1 Updated to clarify that MSK may choose not to allow a site to rely on MSK IRB if not appropriate. • 3.3 Updated to clarify the procedures followed when MSK is asked to be the IRB of Record for another site. • Section 3.3 5ai: Removed the 2-business day timeframe for staff to send MSK IRB approvals to the relying site and replaced with direction to promptly notify. • 3.4: Updated to clarify the procedures followed when MSK seeks to rely on another IRB. • Editorial changes.
1.10	1/20/26	• 3.2 Updated to include the definition of local context • 3.3 Removed the need for submission of a relying site face sheet • 3.3 Added the local context form to list of submission requirements • Editorial updates