

IRB Reliance Process and Single IRB (sIRB)

I. Purpose

To describe policies and procedures for deferring oversight of human research conducted by WCM investigators to external Institutional Review Boards (IRBs) and for WCM IRB to serve as the IRB of Record.

II. Revisions from Previous Version

Restructuring for clarity of research and institution responsibilities.

III. Definitions

Reliance Agreement: A formal, written arrangement between institutions allowing one institution to rely on the IRB of another institution for review of human research that documents respective authorities, roles, responsibilities, and communication between institutions.

Individual Investigator Agreements (IIA): a written agreement to extend an assured institution's Federalwide Assurance (FWA) to cover a collaborating individual investigator.

Institutional Official (IO): The individual who is legally authorized to act for the institution and, on behalf of the institution, approves the Reliance Agreement.

Local Context Review: An abbreviated review by the relying institution that provides the reviewing IRB with the following:

- **Local Research Context:** Knowledge of the institution and community environment in which human research will be conducted (e.g., research injury policy, state specific laws, mandatory reporting of diseases, abuse, etc.).
- **Local Context Language:** Language specific to the conduct of human research at the relying institution (e.g., research injury language, HIPAA authorizations, genetic testing language, etc.).
- **Local Ancillary Reviews (Auxiliary Reviews):** Institution specific reviews that must be completed prior to initiation of a study at that site (e.g., Institutional Biosafety, Conflict of Interest Committee approvals, etc.).

The purpose of the review is to determine local context issues including, but not limited to, local and state laws, institutional policies, community standards, researcher credentials, COI disclosure and management plans, resources to ensure safety and welfare of participants (such as adequate facilities and equipment, staff training, medical or psychosocial resources), demographics/cultural issues of the local population, and applicable ancillary reviews.

Relying Institution: The institution that relies on another institution's IRB for review of human research or independent investigator for a specific study, group of studies, or for all human research conducted by the other institution/investigator.

Reviewing IRB: The IRB that assumes IRB responsibilities for another institution. When multiple institutions conduct the same study and one IRB will conduct the review for all study sites, the Reviewing IRB may be called a Single or Central IRB (collectively, "sIRB").

External IRB: An IRB that is external to WCM. This IRB may be another institution's IRB or a commercial IRB. All IRBs must comply with the same federal regulations governing human research.

Letter of Support (LOS): The Letter of Support (LOS) confirms the willingness of an institution to rely on another IRB for the review of the human research activities.

NIH "Multisite" Research: A study in which the same non-exempt human research procedures (i.e., protocol) are

being conducted at two or more U.S. sites. This may also be called multicenter.

Cooperative Research: A study involving two or more U.S. sites where each site is conducting a different part of a research protocol under the direction/control of the lead Principal Investigator. This may also be called collaborative research. An example is a study where WCM researchers are conducting the interaction/intervention with participants, but the analysis of identifiable data/biospecimens is being done by an external institution/collaborator.

IV. Policy

WCM may enter into a reliance agreement for IRB oversight, whereby WCM will provide IRB review for other institutions or will rely on an external IRB. Reliance can be for a single study or series of studies. Reliance requests are considered on a case-by-case basis and final determinations on reliance is at the discretion of the WCM Reliance Team. For any collaboration, reliance staff will evaluate the activities of the WCM affiliated researcher to determine if those activities engage WCM in human research. If the activities engage WCM in non-exempt human research, the researcher's involvement in the collaboration may not begin until the WCM IRB has approved the research or until an agreement to rely on another IRB is negotiated and that reviewing IRB has granted final approval.

All federally-funded multisite projects involving non-exempt human research at U.S. sites are required to utilize a sIRB for the review of human research protections. For federally-funded cooperative research (multisite or multicenter) WCM IRB prefers that participating sites use the [SMART IRB Master Agreement](#) for establishing reliance unless a separate master agreement is already in place.

Sites are expected to utilize sIRB but may conduct reviews in accordance with National Institutes of Health (NIH) policy. In certain cases, it may be inappropriate to utilize sIRB. Exceptions to this policy are requested according to [NIH Guidance on Exceptions to the NIH Single IRB Policy](#) and are documented in the proposal (or award) documents through the Office of Sponsored Research Administration. Only the IRB review functions will be handled centrally. Awardee organizations are responsible for ensuring authorization agreements are in place and that documentation is maintained. Related local functions (e.g., ancillary committee review, conflict of interest (COI) disclosure, other required institutional approvals) remain with the individual participating institutions, unless otherwise specified. The conduct and reporting of the research remain the project team's responsibility. For federally funded multisite projects, WCM researchers must contact the WCM Reliance Team or submit the reliance request to begin discussion prior to grant proposal submission to determine which IRB should serve as the sIRB and to discuss researcher responsibilities (see below).

An external IRB may also be used to provide oversight of human research that the WCM IRB does not have the appropriate expertise to review.

Criteria for Determining Reviewing IRB

1. Requests for IRB reliance should be made via the [WCM Reliance Request Form](#).
2. Decisions on whether to rely on an external IRB or serve as the sIRB for multisite projects will be based on funding, the location and experience level of the principal investigator, the risk level of the research, the location of the participant population, the extent of the procedures performed at WCM, the IRB policies and procedures at the collaborating institution(s), and the scope of existing agreements. The WCM Reliance Team and External IRB(s) will jointly determine who will serve as the IRB of Record for any given collaboration.
3. In most instances, the WCM IRB can serve as the reviewing IRB if the study is federally funded, minimal risk, and includes 2-3 non-WCM engaged US sites. The WCM IRB will assess and confirm its ability to serve as the reviewing IRB in other instances, on a case-by-case basis.
4. The WCM Reliance Team will confirm that the reviewing IRB has relevant expertise to review the project. The following criteria must be met:
 - a. The institution whose IRB will serve as IRB of record has a current Federalwide Assurance (FWA) with OHRP.
 - b. The IRB is in good standing with OHRP (no recent warning letters, no open investigations).

- c. The IRB conducts its review consistent with applicable ethical standards, laws and regulations. The policies and procedures of the IRB will be reviewed to determine compliance with the regulations, as appropriate.
 - d. IRB Authorization Agreement (IAA) or SMART IRB Master Agreement must be in place.
5. The WCM Reliance Team is responsible for facilitating and maintaining IRB reliance agreements, in consultation with the Institutional Official (IO) or designee as needed.

V. Procedure

External IRB Serving as Reviewing IRB

1. Once a decision has been made that an external IRB will serve as the reviewing IRB, the external IRB becomes the IRB of Record and is responsible for initial review, reviews of amendments, continuing reviews/progress reports, adverse events, and other reportable information. WCM is responsible for ensuring the project's continued compliance with the IRB requirements and institutional COI requirements related to human research for WCM affiliated researchers. The reliance agreement outlines the duties and responsibilities of both the relying institution and the reviewing IRB.
2. After a reliance agreement has been executed, the WCM Principal Investigator (PI) or designee should submit a "Non-WCM Review and Approval (Central IRB or Single IRB)" application in WRG-HS. The submission should include the executed reliance agreement, protocol (or proposal), and project team listed in WRG-HS that lists current CITI certificates and verification of COI disclosure for each WCM project team member. The protocol or proposal must clearly specify each site's role in the project. Note that the IRB Review Application (IRA) is not required for this type of submission. Additional documents may be requested.
3. The PI or designee should include in the WRG-HS submission the reviewing IRB approved documents, such as approval letter including waivers of consent or HIPAA authorization if applicable, approved protocol, approved consent and HIPAA authorization documents(s) expected to be signed by WCM participants, and other documents as applicable. It is preferred that these documents be included with the initial submission.
4. The WCM Reliance Team or designee will perform an administrative review of the research materials, known as local context review (see definitions for more information). Upon completion of this review, the WCM Reliance Team will complete relevant local context forms or memos and post in WRG-HS. The researcher is responsible for submitting the completed local context forms to the reviewing IRB.
5. When a project team member has a COI related to the research, deferral arrangements will not be finalized until a decision memo or management plan has been approved by the WCM COI Committee. This memo and/or plan must be provided to the reviewing IRB. WCM reserves the right not to rely on an external IRB when a COI management plan or other stipulations are required.
6. Should the reviewing IRB have questions about local context review, the WCM Reliance Team will communicate with them as necessary.
7. WCM retains the right to revoke a reliance agreement at any time in order to conduct its own IRB review. Additionally, WCM reserves the right to suspend or terminate the research activity or request additional protections at WCM at any time.
8. In most instances, documents submitted will not receive a WCM IRB stamp. Studies must use reviewing IRB approved study documents.
9. After the reviewing IRB has approved the WCM research, the researcher will upload documentation in WRG-HS, an acknowledgement letter will be issued.
10. Study expiration dates will reflect those issued by the reviewing IRB.
11. A Post Approval Monitoring Annual Report (PAMAR) submission must be submitted to the WCM IRB after the reviewing IRB has re-approved the study regardless of expiration date, an acknowledgement letter will be issued.
12. Any changes proposed to the protocol must be submitted to the Reviewing IRB for review and approval prior to implementation unless such a change is necessary to avoid immediate harm to the participants.
13. A change in PI must be submitted to both the WCM IRB and the Reviewing IRB. Any other changes in key personnel must be submitted to the WCM IRB.

14. Only amendments that impact or alter the risk level at WCM should be promptly submitted WCM for acknowledgement. (i.e., addition of a new vulnerable population, substantive protocol changes, or changes that increase risk level, changes that may require local ancillary reviews, study status changes, funding source changes, etc.). All other minor changes can be submitted at annual review (examples of minor changes: addition of procedure that do not increase risk, addition of, or changes to, recruitment materials, addition of non-sensitive survey or interview questions, etc.)
15. Any additional correspondence (e.g., noncompliance, adverse events, etc.) from the reviewing IRB must be submitted to the WCM Reliance Team through WRG-HS for acknowledgement and local context review when appropriate.
16. Upon completion of the study locally, the WCM researcher is responsible for submitting a closure with all relevant documentation via WRG-HS. This submission should include confirmation that the reviewing IRB has removed WCM as a site. Once a study is closed, the researcher is responsible for properly storing and disposing of specimens and data according to relevant agreements (e.g., DUAs, IRB requirements, etc.).

WCM IRB Serving as the Reviewing IRB

1. In circumstances when the WCM IRB serves as the reviewing IRB, the WCM IRB becomes the IRB of Record and is responsible for initial review, reviews of amendments (local and study wide), continuing reviews, adverse events, and other reportable information. The WCM IRB reviews these studies in accordance with the review procedures described in the WCM IRB policies.
2. Individual institutions are responsible for ensuring the project has continued compliance with the WCM IRB requirements and institutional COI requirements related to human research for their researchers. The reliance agreement outlines the duties and responsibilities of both the relying institution and the reviewing IRB.
3. After a reliance agreement has been executed, the WCM PI is responsible for submitting the project to the IRB for review following WCM policies through WRG-HS. This submission must include the executed reliance agreement(s). This submission should include the IRA and all research specific documents. The IRA must contain a detailed description of each site's proposed activities.
4. The expected process is that the study is approved at WCM and then the WCM IRB approval is submitted to the relying IRB(s) for local context review (see definition for more information) using the WCM local context review form. Once local context review has been obtained from a site, the WCM PI should submit an amendment adding that site to the approved study. This amendment must include documentation of the completed local context review and any relevant study documents. Research activities cannot begin at the external sites until after the amendment is approved at WCM.
5. WCM will stamp approved documents according to the WCM IRB policies.
6. Upon completion of the study at all sites, the WCM researcher is responsible for submitting a closure with all relevant documentation via WRG-HS. Once a study is closed, the researcher is responsible for properly storing and disposing of specimens and data according to relevant agreements (e.g., DUAs, IRB requirements, etc.).

Researcher Responsibilities

1. The WCM researcher is responsible for knowing and complying with the policies and requirements of the reviewing IRB. Responsibilities include, but are not limited to, completing required human protections training, not enrolling participants until the reviewing IRB has approved the project, obtaining and documenting informed consent as required by the reviewing IRB, reporting unanticipated problems or noncompliance, deviations and participant complaints, complying with requirements for project amendments, continuing reviews, project closure, data security, data monitoring reports and record retention and responding to the reviewing IRB requests in a timely manner.
2. Researchers must also allow the reviewing IRB or WCM IRB staff to inspect research files for post approval monitoring activities.
3. The WCM researcher must provide the reviewing IRB local contact information for participant complaints and/or injury at local sites and any relevant COI management plans or stipulations.

4. The WCM PI must provide to the reviewing IRB contact information for individual site researchers to obtain answers to questions, express concerns, and convey suggestions related to the research.
5. The WCM researcher must be aware of any institutional requirements in addition to the approval from the reviewing IRB. The project may not begin until all approvals are obtained. Examples include approvals from ancillary committees, material transfer or data use agreements, or project contracts. Material changes related to COI specific to the project must be submitted according to WCM policy.
6. The researcher will provide to the WCM Reliance Team or the WCM IRB via WRG-HS all IRB related correspondence and study documentation (including but not limited to local and study wide approval letters, notices of suspension or termination, reportable events, etc.) and will submit an annual progress report to ensure compliance with institutional policy and federal regulations.
7. Additionally, the WCM PI must submit to the reviewing IRB a written plan in the protocol for the management of information that is relevant to the protection of human participants, such as reporting obligations (e.g., mandated reporting laws, unanticipated problems, etc.), protocol amendments, and interim results from all participating sites in addition to documentation from any local ancillary review (e.g. radiation safety, etc.).
8. The reviewing IRB will evaluate whether the management of information that is relevant to the protection of human participants is adequate.

Institutional Responsibilities

1. Institutional responsibilities regarding collaborative research are outlined in the reliance agreement signed by the participating parties.
2. In the case of serious and/or continuing noncompliance related to collaborative research, the IO has the authority to suspend the involvement of WCM and its researchers.
3. The institution will notify the reviewing IRB of any changes in local institutional policies or researcher status that impacts IRB review, including any suspensions, terminations, or information related to noncompliance.
4. Regardless of whether WCM IRB reviews the research or relies on an external IRB, WCM remains responsible for the safe and appropriate performance of the research conducted at WCM. WCM IRB staff may conduct quality assurance reviews to confirm that the project is being conducted in compliance with the protocol and the requirements of the reviewing IRB.

VI. References

- OHRP document "[Guidance on Engagement of Institutions in Human Subjects Research](#)"
- [Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research NOT-OD-16-094](#)
- <https://smartirb.org/agreement/>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html>
- [WCM SOPs](#)