# SOP-G-006: TC IRB Standard Operating Procedures (SOP) on IRB Reliance

## 1. Purpose

This SOP establishes the policies, procedures, and responsibilities governing IRB reliance at Teachers College (TC). It applies when TC is engaged in multi-site research, research involving external collaborators, or research under the jurisdiction of more than one IRB. The SOP is intended to ensure compliance with applicable federal regulations, protect the rights and welfare of human subjects, and provide a consistent, documented framework for establishing, maintaining, and concluding reliance arrangements.

## 2. Scope

This SOP applies to all investigators, key study personnel, and IRB staff performing or overseeing research under the auspices of the Teachers College IRB.

## 3. Definitions

- **Reliance Agreement (IRB Authorization Agreement):** A formal written document between a reviewing IRB and a relying organization that outlines the respective authorities, roles, responsibilities, communication protocols, and compliance expectations for IRB review.
- **Investigator Authorization Agreement (IAA):** A study-specific agreement executed when an external investigator affiliated with another institution will rely on TC IRB review (or vice versa) for a particular protocol. The IAA specifies roles, responsibilities, and reporting obligations for the specific study.
- **Letter of Agreement (LOA):** A streamlined written agreement used to document reliance between institutions when a full reliance agreement is not required or when the scope of collaboration is limited.
- **Individual Investigator Agreement (IIA):** An agreement used when an external researcher who either (a) does not hold affiliation with another institution, or (b) is collaborating on a TC-led project in a capacity unrelated to their institutional role, wishes to participate as a Co-PI or research team member. The IIA is completed by the TC PI and signed by the independent researcher and the TC designated signatory.
- **Memorandum of Understanding (MOU):** A formal, written agreement between two or more institutions used when sharing resources, facilities, data, property, or equipment, typically established when no other type of agreement applies. Outlines the intent to collaborate, defines roles and responsibilities, and is typically not legally binding unless specifically stated.
- **Data Sharing Agreement (DSA) / Data Use Agreement (DUA):** Agreements governing the access, use, and protection of data shared between institutions or researchers. These agreements are outside the scope of IRB review but are recommended when applicable. General Counsel should be consulted for execution.
- **Single IRB (sIRB):** A designated IRB responsible for the ethical review of a multi-site research protocol for all participating sites.


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- **SMART IRB:** A national platform that standardizes and facilitates reliance agreements and IRB reliance processes through a master joinder agreement.
- **Engagement in Research:** Activities conducted by an institution's employees or agents that make the institution subject to the requirements of the Common Rule or other applicable human research protection regulations. See OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008).
- **Site Permission Letter:** A document required when a TC PI plans to recruit from or access the population of another institution. TC provides a template that must be completed and signed by both the PI and the external site's authorized representative.
- **Local Context Review:** A structured assessment required for all sIRB protocols and for international research, conducted to ensure the reviewing IRB accurately accounts for site-specific ethical, legal, cultural, and institutional requirements before approving research at a relying site.
- **Reviewing IRB:** The IRB designated to conduct ethical review of a research protocol on behalf of one or more relying institutions.
- **Relying Institution/IRB:** An institution that has agreed to accept the review of an external IRB in lieu of conducting its own IRB review for a specific protocol.
- **TC Designated Signatory:** The institutional official authorized to execute reliance agreements on behalf of Teachers College. At TC, this is the Research Compliance Director or their designee, unless otherwise specified.

## 4. Roles and Responsibilities

*4.1 Research Compliance Director*

1. Serves as TC Designated Signatory for reliance agreements or designates an alternate.
2. Approves or declines requests for TC to serve as reviewing IRB or to rely on an external IRB.
3. Consults with the IRB Chair and institutional leadership as needed on reliance decisions.
4. Oversees compliance with all reliance agreements to which TC is a party.

*4.2 Reliance Agreement Specialist*

5. Evaluates reliance requests using the criteria specified in this SOP.
6. Coordinates communication between TC and external IRBs during reliance establishment.
7. Uses a standardized checklist to verify that reliance agreements address all required elements.
8. Manages SMART IRB platform submissions and correspondence on behalf of TC IRB.
9. Maintains a log of all active reliance agreements and their status.
10. Monitors ongoing compliance with reliance agreement terms and escalates issues to the Research Compliance Director.

*4.3 IRB Chair*

11. Provides input on reliance decisions as requested by the Research Compliance Director.
12. May serve as a point of escalation for disagreements between TC and external IRBs on review determinations.


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*4.4 IRB Office Staff*

13. Processes reliance-related submissions through Mentor IRB.
14. Verifies CITI training, COI review, and other applicable requirements for external investigators.
15. Maintains reliance documentation in study records.

*4.5 TC Principal Investigator*

16. Initiates reliance requests as early as possible in the grant or contract process.
17. Submits all required documentation to TC IRB via Mentor IRB.
18. Complies with the policies and procedures of the reviewing IRB, regardless of which IRB serves as IRB of record.
19. Reports changes, unanticipated problems, noncompliance, and other required events to both the reviewing IRB and TC IRB in accordance with this SOP and applicable reliance agreement terms.
20. Ensures all study team members complete required training and COI disclosures.

## 5. Policy

*5.1 Applicability*

TC enters into reliance arrangements for protocols reviewed at the Full Board or Expedited review level. Exempt protocols are generally not subject to IRB reliance procedures, with the following exception: when exempt research requires limited IRB review pursuant to 45 CFR 46.104(d)(2)(iii) or (d)(3)(i)(C), reliance procedures apply if the research is part of a multi-site collaboration or involves external investigators engaged in human subjects research at their own sites.

The addition of external researchers or establishment of any collaborative agreement triggers reliance procedures only when the external researcher is engaged in human subjects research (i.e., recruiting, consenting, collecting, or analyzing identifiable data). If external researchers will access only de-identified data, the IRB should consider whether the data can be readily re-identified (e.g., through a master list linking codes to identifiable information) before determining whether reliance is required.

*5.2 Federalwide Assurance (FWA) Requirements*

When TC serves as the reviewing IRB for an external institution engaged in HHS-funded human subjects research, that institution must hold a valid FWA with OHRP, or must obtain one prior to the initiation of research activities. TC IRB will verify the status of the external institution's FWA during the reliance evaluation process. If an external institution's FWA lapses during an active reliance arrangement, TC IRB will suspend review activities for that site until the FWA is reinstated or an alternative arrangement is established.

*5.3 General Principles*

When engaged in multi-site research, research involving external collaborators, or research otherwise under the jurisdiction of more than one IRB, TC acknowledges that each organization is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. TC may choose to review the research in its entirety, review only those components of the research in which TC is engaged, rely on the review of another qualified IRB, or make other arrangements to avoid duplication of effort. When TC is the prime awardee on an HHS grant, it will ensure that at least one IRB reviews the research in its entirety.


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When relying upon another IRB or serving as the reviewing IRB for an outside organization or investigator, a formal relationship must be established through a Reliance Agreement, IAA, LOA, or other written agreement as described in this SOP. The written agreement must be fully executed before TC will accept any human research proposals from the outside organization or investigator, or before TC investigators may submit research to an external reviewing IRB.

IRB reliance agreements establish the authorities, roles, and responsibilities of the reviewing IRB and the relying organization. The procedures for reliance, including communication, information-sharing, and reporting, may be outlined in the reliance agreement itself, in SOPs, or in other written materials. The Reliance Agreement Specialist uses a standardized checklist to ensure that all agreements address the required elements and are consistent with TC standards.

Requests for TC to either rely upon an external IRB or to serve as the IRB of record for an external organization or investigator should be submitted as early as possible in the grant or contract process.

TC IRB has signed the SMART IRB joinder agreement. When participating organizations are signatories to the joinder agreement, IRB reliance may be requested and documented through the SMART IRB platform. In collaboration with participating organizations, TC IRB will determine on a study-by-study basis whether SMART IRB SOPs or alternative procedures will be used.

## 6. Teachers College Serving as Reviewing IRB

### *6.1 Evaluation Factors*

Generally, TC IRB does not serve as the IRB of record for an external organization unless TC is also engaged in the research or has a master agreement in place with the external organization. The Reliance Agreement Specialist evaluates the following factors, and others as appropriate, when considering a request for TC IRB to serve as the reviewing IRB:

1. The external organization's FWA status and terms.
2. Prior experience with the organization and its investigators.
3. The compliance history of the organization and investigators (e.g., outcomes of prior audits or inspections, corrective actions).
4. The accreditation status of the external organization's IRB or HRPP, if any, as one indicator of programmatic maturity.
5. The research activities to be conducted by or at the external organization.
6. The willingness of the external organization to accept TC's reliance terms and procedures.
7. The ability of the organizations to collaboratively provide meaningful oversight, taking into account:
    - The risks and procedures of the research.
    - The resources available at each organization for activities such as observing the consent process, performing compliance reviews, and conducting investigations of potential noncompliance.
    - The expertise and experience of the TC IRB with the proposed research, subject population, and applicable regulations.
    - The familiarity of the TC IRB with relevant local context considerations of the external organization.


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- The willingness of the external organization to provide information regarding investigator qualifications, conflicts of interest, institutional requirements, local context, and other matters that may inform IRB review.

*6.2 Procedures for Establishing Reliance*

The following steps apply when TC will serve as the reviewing IRB for an external institution or investigator:

1. The TC PI submits a protocol to TC IRB for initial review (Full Board or Expedited). The protocol and consent documents should reference the planned external collaboration, including the name of the external institution and investigators, if known at the time of submission.
2. Upon approval of the protocol, the TC PI submits a modification request via Mentor IRB to add the external collaboration. The modification request must include:
    a. The name of the external institution, the external Co-PI's name, their role, and a description of how they will engage in human subjects research.
    b. Revised protocol and consent documents reflecting the external collaboration, with tracked changes and final versions uploaded.
    c. The external PI's current human subjects training certificate (e.g., CITI).
3. The Reliance Agreement Specialist initiates a conversation with the external IRB to determine the reliance mechanism (SMART IRB, IAA, or LOA) and identify any documents the external institution may require (e.g., local context review).
4. For SMART IRB submissions, PIs must create an account on the platform prior to submission. The TC PI initiates the request, completes required information, and uploads required documents. TC IRB is notified once the TC PI completes their portion. Subsequent correspondence occurs primarily between the TC IRB and the external IRB.
5. For IAA or LOA submissions, the Reliance Agreement Specialist prepares the agreement using TC's standard templates and coordinates signature from the TC Designated Signatory and the external institution's authorized official.
6. All reliance requests must be accompanied by the approved protocol, consent form(s), and IRB approval correspondence.
7. The external institution conducts its local context review and provides results to TC IRB. TC IRB reviews the local context information and determines whether protocol modifications are required.
8. Once both institutions have communicated, reviewed study materials, and resolved any outstanding issues, the external institution confirms its willingness to rely on TC. The reliance agreement is fully executed once both designated signatories have signed.
9. Fully executed agreements are saved in the modification record, PI documentation, and the reliance agreement log. A copy is provided to the external IRB.
10. The TC PI receives email correspondence acknowledging the fully executed reliance agreement and approval of any revised study materials. Revised documents receive an updated approval stamp.

*6.3 Declining a Reliance Request*

If the Reliance Agreement Specialist or Research Compliance Director determines that TC should not serve as the reviewing IRB based on the evaluation factors in Section 6.1, the following procedure applies:


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1. The Research Compliance Director notifies the TC PI in writing of the decision and the reasons for declining.
2. The notification includes available alternatives, such as the external institution conducting its own IRB review or identifying a different reviewing IRB.
3. The TC PI may request reconsideration by submitting additional information addressing the identified concerns. The Research Compliance Director makes the final determination.

*6.4 Alternative Procedures*

When TC IRB serves as the reviewing IRB for another organization, the requirements and procedures outlined throughout TC's SOPs apply unless an alternative procedure has been agreed to in the reliance agreement or outlined in a companion document. Alternative procedures may address any of the following:

1. Management and documentation of scientific review, ancillary reviews, and institutional permissions.
2. Training requirements and verification of qualifications and credentials for external investigators and staff.
3. For-cause and not-for-cause compliance reviews.
4. Disclosure and management of conflicts of interest. In all cases, COIs and conflict management plans identified by the relying organization will be communicated to TC IRB. TC IRB will determine the acceptability of the plan in accordance with its policies and procedures.
5. Review and management of site-specific consent language, HIPAA authorizations/waivers, noncompliance, unanticipated problems, and federal reports.
6. Ensuring concordance between any applicable grant and the IRB application or protocol.
7. Procedures for and type of IRB review (e.g., expedited, convened) when adding sites after the protocol is approved.
8. Procedures for submission and review of interim reports and continuing review materials.
9. Communication of IRB determinations and other information to external investigators and organizations.

## 7. External IRB Review of TC Research

*7.1 General Requirements*

All non-exempt human subjects research (or exempt research requiring limited IRB review pursuant to 45 CFR 46.104(d)(2)(iii) or (d)(3)(i)(C)) in which TC is engaged must be reviewed and approved by the TC IRB or by an external IRB that TC has agreed to rely upon. Research must not be initiated until the reliance agreement is fully executed and the reviewing IRB has issued approval. See OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008) for information regarding engagement.

Research meeting the above criteria must be registered with TC prior to submission to the external IRB, following the procedures in Section 7.3.

TC may also enter into an agreement to rely upon an external IRB when required as a condition of a grant or contract. Investigators should submit reliance requests as early in the grant or contract process as possible.

*7.2 Evaluation Factors*

TC IRB evaluates the following factors, and others as appropriate, when considering a request to rely upon an external IRB:

1. The federal IRB registration and organizational FWA, as applicable.
2. The compliance history of the proposed IRB (e.g., outcomes of prior audits or inspections, corrective actions).
3. Prior experience with the proposed IRB.
4. The accreditation status of the proposed IRB, if any, as one indicator of programmatic maturity.
5. The expertise and experience of the proposed IRB with the type of research, procedures, and subject population(s).
6. The research activities that will be conducted at or by TC.
7. The risks and complexities of the proposed research.
8. The proposed reliance terms and procedures, including procedures for collaborative management of conflicts of interest, noncompliance, unanticipated problems, and federal reports.
9. The plan for review and incorporation of site-specific consent language.
10. The plan for incorporating other relevant local requirements or context in the review process.

Depending on TC's familiarity with the proposed IRB and the risks of the research, the evaluation may also consider:

- A statement of assurance from the proposed IRB that its review will be consistent with applicable ethical and regulatory standards, and that it will report any regulatory investigations, citations, or actions.
- An attestation about, or summary of, any quality assessment of the reviewing IRB (e.g., external consultant evaluation, self-evaluation using recognized assessment instruments).
- The willingness of the external IRB to provide relevant minutes and records of the proposed study, and to copy TC's IRB office on determination letters, suspension notices, and termination notices.
- The willingness of the external IRB to allow a representative of TC to serve as a consultant or observer during review of the proposed study.
- An assessment of the external IRB's policies and procedures.

*7.3 Procedures for Establishing Reliance*

The following steps apply when TC will rely on an external IRB:

1. The external PI submits the protocol to the external (reviewing) IRB.
2. The TC PI registers the study with TC IRB by submitting a protocol through Mentor IRB:
    d. Select "delegate to external" as the review category.
    e. Upload all study materials (protocol, consent forms, recruitment materials, etc.).
    f. Upload the external PI's current human subjects training certificate.
3. TC IRB staff review the registration submission, verify CITI training, and any other applicable requirements, and identify local context information that must be relayed to the reviewing IRB.


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4. The Reliance Agreement Specialist coordinates with the external IRB to determine the reliance mechanism (SMART IRB, IAA, or LOA) and communicates any local context information or additional requirements.
5. For SMART IRB submissions, the reviewing IRB's PI typically initiates the request. Once the request is forwarded to TC IRB, the Reliance Agreement Specialist reviews:
   g. The approved protocol document.
   h. Approved consent forms.
   i. IRB approval correspondence (documenting level of review).
6. If TC IRB agrees to rely on the external IRB, the TC Designated Signatory signs the agreement and returns it to the reviewing IRB for full execution.
7. TC IRB obtains a fully executed copy. Agreements are saved in the study record and PI documentation, and the reliance agreement log is updated.
8. The TC PI receives email correspondence acknowledging the fully executed reliance agreement. TC IRB notifies the TC PI that they are cleared for submission to the external IRB (or, if already submitted, that the reliance is now in effect).
9. Once the external IRB issues approval, the TC PI submits a copy of the approval notice and any approved consent documents to TC IRB via Mentor IRB. If the protocol was modified during external review, the approved version of the protocol must also be submitted.

*7.4 Declining a Reliance Request*

If TC IRB determines that reliance on a proposed external IRB is not appropriate, the Research Compliance Director notifies the TC PI in writing, provides the basis for the decision, and outlines available alternatives (e.g., TC conducting its own IRB review, identifying a different reviewing IRB, or seeking an exception to applicable sIRB requirements).

*7.5 Authority and Investigator Obligations*

External IRBs that serve as the IRB of record for TC research have the same authority as the TC IRB, and all determinations and requirements of the external IRB are equally binding. Investigators must be familiar with and comply with the external IRB's policies and procedures, as well as any additional requirements outlined in the reliance agreement or companion materials.

Regardless of which IRB is designated to review a research project, TC is responsible for the conduct of the research in which it engages. Research reviewed by external IRBs remains subject to applicable TC policies, procedures, and requirements, including those of the TC IRB.

TC will support compliance by providing investigators with information relevant to their responsibilities under reliance agreements, such as a copy or summary of the agreement, an information sheet, or reliance-specific SOPs.

## 8. NIH Single IRB (sIRB) for Multi-Site Research

*8.1 Policy Overview*

The NIH requires domestic awardees and domestic sites of NIH-funded multi-site research to use a single IRB for review of non-exempt human subjects research, unless an exception is granted (NOT-OD-16-094). The NIH sIRB policy does not apply to career development, research training, or fellowship awards, nor to

research sites outside the U.S. However, sIRB review may still be required for domestic sites under the Cooperative Research provisions of the revised Common Rule (45 CFR 46.114).

Exceptions to the NIH sIRB policy are rare. Information regarding exception requests is available on the NIH Single IRB Policy website.

*8.2 Selection and Designation of a sIRB*

TC investigators must plan for sIRB review when developing applications for non-exempt NIH-funded multi-site research and may request direct cost funding to cover additional costs related to sIRB requirements. The NIH requires that the name of the sIRB be provided at Just-in-Time (JIT) or, for delayed-onset research when an sIRB has not yet been identified, prior to initiating the non-exempt multi-site research. In all circumstances, the named IRB must have agreed to assume the reviewing IRB role in advance.

Requests for TC IRB to serve as the sIRB should be directed to the IRB office. The Research Compliance Director will consult with institutional leadership as needed. Requests for TC to rely on an external IRB as the sIRB should be submitted as early in the process as possible.

*8.3 Reliance Agreements for sIRB Studies*

A Reliance Agreement between the sIRB and each participating site is required. The agreement must document the respective authorities, roles, responsibilities, and communication procedures between the reviewing and relying organizations, including:

- Notifications of the outcome of regulatory review.
- Management of federally mandated reports (unanticipated problems, serious or continuing noncompliance, suspensions or terminations of IRB approval).
- Responsibility for meeting certification requirements when applicable (e.g., NIH Genomic Data Sharing).

The institution awarded the funding is responsible for maintaining all agreements and ensuring adequate communication channels between the sIRB and participating sites. Participating sites are responsible for maintaining copies of their site agreements in accordance with their FWA terms.

## 9. Local Context Review

*9.1 When Required*

A local context review is required for all sIRB protocols and for all international research. A local context review may also be requested by either party to a reliance agreement for any protocol where site-specific factors may affect the ethical review.

*9.2 Content*

The local context review must assess and communicate the following to the reviewing IRB:

1. Applicable institutional policies that may affect the conduct or review of the research.
2. Applicable local, state, or national laws or regulations.
3. Informed consent requirements or variations (e.g., language, cultural considerations, age of majority).
4. Population characteristics that may affect the risk-benefit analysis or the adequacy of protections.
5. Additional expertise that may be needed on the reviewing IRB for adequate review.
6. Institutional requirements for ancillary reviews (e.g., biosafety, radiation safety, conflict of interest).


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*9.3 Process*

1. The Reliance Agreement Specialist provides the local context review form or template to the relying institution (or completes it when TC is the relying institution).
2. The relying institution completes the review and returns it to the reviewing IRB.
3. The reviewing IRB incorporates the local context information into its review. If the review surfaces issues requiring protocol modifications for a specific site, the reviewing IRB communicates the required changes to the relying institution.
4. The local context review is documented in the study record. A new or updated local context review may be required at continuing review, when protocol modifications affect site-specific factors, or when there are changes in applicable local laws or institutional policies.

## 10. Other Agreements and Collaborative Arrangements

*10.1 Individual Investigator Agreement (IIA)*

An IIA is used when an external researcher who is either unaffiliated with another institution or whose role on the TC-led project does not contribute to their institutional role wishes to collaborate as a Co-PI or research team member.

1. The agreement is completed by the TC PI and signed by the independent researcher and the TC Designated Signatory.
2. CVs are requested for Co-PIs.
3. Independent researchers must affiliate with TC through CITI and complete the "IRB Social and Behavioral Researchers Basic" training course. Proof of completion must be submitted to TC IRB.

*10.2 Memorandum of Understanding (MOU)*

An MOU is a formal, written agreement between two or more institutions used when sharing resources, facilities, data, property, or equipment, typically when no other type of agreement applies.

1. Outlines the intent to collaborate, defines roles and responsibilities of each party.
2. Typically not legally binding unless specifically stated but sets a framework for cooperation.
3. Used when establishing long-term or strategic partnerships (e.g., ongoing joint research programs).

*10.3 Site Permission Letter*

A Site Permission Letter is required when a TC PI plans to recruit from or access the population of another institution. TC provides a template that must be completed and signed by the PI and the external site's authorized representative. The letter may be amended to meet the external site's requirements provided the TC researcher can still carry out their research as planned. The fully executed document must be submitted to TC IRB for approval.

*10.4 Data Use and Data Sharing Agreements*

DUAs and DSAs are outside the scope of IRB review. However, these agreements are recommended when applicable to protect data accessed or shared between institutions or researchers. General Counsel should be consulted for execution. The IT department may also need to be consulted when agreements involve data storage or transfer on institutional servers.

## 11. Maintaining Reliance Compliance


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### *11.1 Where TC Is the Reviewing IRB*

The TC PI is expected to provide the following to TC IRB on an ongoing basis:

1. Updated IRB correspondence, including continuing review and modification approval correspondence.
2. Newly approved or updated study materials (including new data sets, changes in risk level, etc.).
3. Notification of any changes at the external institution that may affect the reliance arrangement (e.g., changes in institutional officials, FWA status, or key personnel).

The Reliance Agreement Specialist monitors active reliance agreements and contacts external institutions at least annually to confirm that the terms of the agreement remain in effect and that no material changes have occurred.

### *11.2 Where TC Is the Relying IRB*

The TC PI is required to update TC IRB with any changes or updates to the research project via a modification submission through Mentor IRB.

1. TC IRB may contact the external reviewing IRB for additional information as needed.
2. Upon completion of TC IRB's review of the modification, the TC PI receives acknowledgment correspondence.

If TC IRB becomes aware that the external reviewing IRB has suspended or terminated approval of the protocol, lost its FWA or IRB registration, or had its accreditation revoked, TC IRB will take the following steps:

1. Notify the TC PI immediately and instruct them to suspend all research activities at the TC site.
2. Assess whether TC can assume review of the protocol or whether an alternative reviewing IRB must be identified.
3. Document the situation and all actions taken in the study record.
4. Notify relevant institutional officials and, if applicable, the funding agency.

## 12. Post-Approval Requirements

Investigators approved through external IRB review must still report the following to the TC IRB office via Mentor IRB, in addition to reporting to the external reviewing IRB:

1. Local unanticipated problems, complaints, and noncompliance (see Unanticipated Problems, Noncompliance, and Complaints SOPs). Copies of reports submitted to the external IRB are generally acceptable; additional information may be requested.
2. Continuing review reports.
3. Updated protocols and consent forms.
4. Study closures and corresponding IRB approval or acknowledgment.

Changes in PI and the addition of research team members must be submitted to the IRB office via Mentor IRB prior to the new PI or team member assuming study responsibilities. The IRB office must verify CITI training, COI review, and any other applicable requirements.

Notices about and reports from external monitors, auditors, or inspectors must be provided to the IRB office as described in the Quality Assurance SOP.


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The following must be reported immediately (as soon as possible once aware) to TC IRB by phone or email:

1. Any negative actions by a government oversight office, including OHRP Determination Letters.
2. Restrictions placed on IRBs or investigators, and corresponding compliance actions under non-US authorities related to human research protections.
3. Any litigation, arbitration, or settlements related to human research protections.
4. Any press coverage of a negative nature regarding TC's IRB.

See the Investigator Responsibilities SOP for additional information. Other TC reporting requirements (e.g., Compliance, Privacy) remain applicable in addition to IRB reporting requirements.

## 13. Termination and Withdrawal of Reliance Arrangements

### *13.1 Grounds for Termination*

A reliance arrangement may be terminated under any of the following circumstances:

- Completion of the research protocol and all associated reporting obligations.
- Mutual agreement of both parties.
- Material breach of the terms of the reliance agreement by either party.
- Loss, suspension, or revocation of the FWA, IRB registration, or accreditation of either party.
- Determination by TC that continuing the arrangement would compromise the protection of human subjects.
- Withdrawal by either party with written notice, subject to the provisions below.

### *13.2 Procedures*

1. The party initiating termination provides written notice to the other party, specifying the reason for termination and the proposed effective date.
2. For active protocols, both parties collaborate to ensure continuity of oversight until an orderly transition can be completed. This may include:
    a. Transfer of review responsibilities to another IRB.
    b. Suspension of enrollment at the affected site pending transfer of review.
    c. Completion of ongoing participant activities under the existing arrangement if a transition would create greater risk to participants.
3. The Reliance Agreement Specialist documents the termination in the reliance agreement log and notifies all affected investigators.
4. Copies of the termination notice, and any transition documentation are retained in the study record.

### *13.3 Effect on Active Research*

Termination of a reliance agreement does not automatically terminate IRB approval for the underlying protocol. The reviewing IRB retains authority over the protocol until review responsibilities are formally transferred or the protocol is closed. Investigators may not conduct research activities at the affected site without valid IRB oversight.

## 14. Conflict Resolution

If a disagreement arises between TC and an external IRB regarding a review determination, required modification, noncompliance finding, or other matter under a reliance arrangement, the following process applies:

1. The Reliance Agreement Specialist documents the disagreement and facilitates communication between the parties to resolve the issue informally.
2. If the issue cannot be resolved at the staff level, the Research Compliance Director and the corresponding official at the external institution attempt to reach agreement.
3. If the disagreement remains unresolved, the IRB Chairs of both institutions (or their designees) confer to identify a resolution.
4. If no resolution is reached, either party may terminate the reliance arrangement for the affected protocol in accordance with Section 13, and each institution will resume independent review.

Throughout the resolution process, the more restrictive determination or requirement governs the conduct of the research to protect human subjects.

## 15. References

- 45 CFR 46, Subpart A (2018 Common Rule), including 46.104, 46.114
- NIH Single IRB Policy (NOT-OD-16-094)
- OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008)
- SMART IRB Master Common Reciprocal Reliance Agreement
- SOP-R-002_TC IRB Standard Operating Procedures (SOP) on Investigator Responsibilities
- SOP-R-003_TC IRB Standard Operating Procedures (SOP) on Unanticipated Problems Involving Risks to Subjects or Others
- SOP-R-005_TC IRB Standard Operating Procedures (SOP) on Noncompliance
- SOP-A-009_TC IRB Standard Operating Procedures (SOP) on Quality Assurance & Post-Approval Monitoring
- SOP-R-009_TC IRB Standard Operating Procedures (SOP) on Complaints from Research Subjects or Others


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