TC IRB Researcher Guidance for External Collaborations

Purpose: This guide aims to provide a foundational understanding of external collaborations involving human subjects research. Always consult with your institution's IRB and legal counsel to ensure compliance with all applicable regulations and policies.

1. Determining Engagement in Human Subjects Research

Before initiating any collaboration, assess whether external collaborators are "engaged" in human subjects research. According to the Office for Human Research Protections (OHRP), an institution is considered engaged when its employees or agents:

- Interact or intervene with human subjects for research purposes.
- Obtain identifiable private information or biospecimens for research.
- Obtain informed consent from human subjects for research.

If collaborators are engaged, IRB oversight is typically required. If not, they may not need IRB review, but other agreements (e.g., Data Use Agreements) might still be necessary. Please refer to the TC IRB Engagement Determination Checklist for External Collaborators for more information.

2. Reliance Agreements (IRB Authorization Agreements)

a) When Is a Reliance Agreement Needed?

A reliance agreement allows one IRB to oversee research activities across multiple institutions, streamlining the review process. Situations requiring a reliance agreement include:

- Collaborative non-exempt human subjects research involving multiple institutions.
- Federally funded multi-site studies, as mandated by the NIH Single IRB policy.
- When an external collaborator's institution cedes IRB review to another institution.

For example, Teachers College requires reliance agreements for collaborative human subjects research but does not enter into such agreements for exempt research or when collaborators are not engaged in human subjects research.

b) When Is a Reliance Agreement Not Needed?

A reliance agreement may not be necessary when:

- The research is exempt under federal regulations.
- Collaborators are not engaged in human subjects research.
- Each institution prefers to conduct its own IRB review.

However, it's essential to consult with your institution's IRB to determine the appropriate course of action.

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3. CITI Training and TC Affiliation

All collaborators who are engaged in human subjects research must complete CITI training. **By default, external collaborators are expected to complete CITI training through Teachers College** and affiliate with "Teachers College – Columbia University" in the CITI Program.

However, CITI training completed at another institution **may be accepted on a case-by-case basis**, provided that:

- The collaborator's institution has an active FWA.
- The training is equivalent in content and recency to TC's required modules.
- Documentation of completion is submitted to the TC IRB.
- Prior confirmation is obtained from the TC IRB.

Researchers should contact the IRB early to confirm whether their external collaborators can rely on their home institution's training or will need to complete TC-specific modules. Please refer to the TC IRB Training and Certification for more information.

4. Data Use Agreements (DUAs)

DUAs are legal contracts that outline the terms and conditions for sharing research data between institutions, ensuring compliance with privacy laws and institutional policies. A DUA is typically required when:

- Sharing data containing Protected Health Information (PHI) or Personally Identifiable Information (PII).
- Transferring a limited data set under HIPAA regulations.
- The data provider requires a DUA as a condition for data sharing.

Teachers College uses the HIGHQ – Thomson Reuters Contract and Legal Matters Management Platform to manage all contract-related processes, including Data Use Agreements (DUAs). The IRB does not process or approve these agreements directly. To initiate a DUA:

- Access the HIGHQ system via the **OGC Contracts Portal**.
- Complete the required Contract Training Module before submission.
- Ensure your name is added to the QUIS list (Qualified Users for Institutional Submissions).
- Upload draft agreements and route through the platform for review and signature.

Questions about **HIGHQ access or routing**? Visit the General Counsel's Contracts Portal.

5. System Access for Unaffiliated Collaborators

If your collaborator is not affiliated with Teachers College but requires access to TC platforms (e.g., Mentor IRB, Google Drive, Box), the following steps are required:

a) **Submit a request to Human Resources** to create a temporary TC-affiliated profile.

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b) **Coordinate with TCIT** to grant specific system access once the profile has been activated.
c) **Ensure CITI training is complete and linked** to the TC profile before the collaborator logs into Mentor IRB.

Note: System access is typically time-limited and must align with the duration of the research collaboration.

6. Grant-Funded Collaborators and the Role of the Office of Sponsored Programs (OSP)

Researchers should ensure OSP records clearly list all external collaborators and their institutions during the grant submission phase to streamline access and compliance. For more information, please contact the **TC Office of Sponsored Programs (OSP)**.

7. International Research Requirements

When collaborating with international sites or participants, researchers must address the following:

- Local Context Review: Use TC's Local Context Review Template to describe site-specific regulatory, linguistic, or cultural factors.
- Translation Verification: Submit the Translation Verification Form if study materials are translated from English.
- Data Privacy Compliance:
  - GDPR (European Union/EEA)
  - PIPL (People's Republic of China)

Refer to TC IRB International Research Guidance Hub for other resources, consent requirements, and risk mitigation strategies.

8. Steps for Initiating External Collaborations

a) **Assess engagement**: Determine if external collaborators are engaged in human subjects research using the TC IRB Engagement Determination Checklist for External Collaborators or the OHRP engagement guidance. If engaged, IRB oversight and/or reliance agreements may be required.

b) **Consult the IRB early**: Reach out to the TC IRB at the planning stage to determine whether reliance, data sharing, or international considerations apply. Do not wait until submission to clarify requirements.

c) **Complete CITI training**: Ensure all external collaborators complete **CITI training** in human subjects research.

d) **Initiate reliance or sharing agreements as applicable**: For identifiable or coded data/material transfers, initiate a DUA via the OGC contracts portal. First-time users must complete the HIGHQ training and be added to the system.

e) **Prepare international research materials** (if applicable).

f) **Submit to Mentor IRB**: Once all collaborators are confirmed, training is complete, and agreements are in progress or finalized, proceed with IRB submission in Mentor IRB.

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g) **Request system access (if needed)**: If collaborators require access to TC systems (Mentor IRB, shared Google Drive, Box, etc.).

9. Resources

- TC IRB Engagement Determination Checklist for External Collaborators
- **OHRP Engagement Guidance**: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html
- **SMART IRB Platform**: https://smartirb.org/
- **NIH Single IRB Policy**: https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm
- TC IRB Training and Certification
- CITI's How to add/change your affiliated institution or transfer completions

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