# TC IRB Standard Operating Procedure (SOP) on Training and Onboarding for TC IRB Staff and Members

## Purpose

This SOP outlines the training and onboarding process for new and existing Institutional Review Board (IRB) members and staff at TC to ensure compliance with regulatory requirements and ethical standards in human subjects research.

## Scope

This procedure applies to all newly appointed IRB members and IRB staff, as well as existing members and staff requiring ongoing training.

*Responsibilities*

- **Research Compliance Director:** Coordinates onboarding and training programs for IRB members and staff, ensuring compliance with this SOP; oversees the implementation of the training and onboarding policy for IRB staff under their supervision.
- **QA & Education Specialist:** Develops materials and resources that support the operational efficiency and professional development of IRB members and staff; supports the Director in enhancing the expertise and knowledge base of IRB members and staff; regularly reviews and updates this SOP to reflect current practices, changes in regulations, and feedback from IRB members and staff.
- **IRB Chair:** Oversees the implementation of the training and onboarding policy for IRB members.
- **IRB Manager:** Oversees the implementation of the training and onboarding policy for IRB staff under their supervision.
- **IRB Members and IRB Staff:** Participate in required training and onboarding activities.

*Procedure*

*IRB members*

1. **Initial Education:**

As part of their onboarding and initial education, new IRB members will be expected to complete the following:

A. Attend an orientation session with the Research Compliance Director. During this session, the roles of IRB membership, expectations, and your expertise and interests will be discussed.
B. Review training binders, complete online orientation modules in the New IRB Board Member Orientation, and review the Reviewer Orientation Manual.
C. Complete CITI Human Subject Protection (HSP) online training as per the designated role:
    i. IRB Chair: IRB Chair (**ID: 251087**) & IRB Members and Administrators (**ID: 48578**).
    ii. IRB member: IRB Members and Administrators (**ID: 48578**).

**Note these trainings are separate from the IRB Social and Behavioral Researchers (ID: 48577) course, which is a separate requirement for anyone involved in research with human subjects.*

D. Review and sign the IRB Member & Guest Confidentiality Agreement.
E. Provide the Research Compliance Director with a copy of your most up-to-date resume or curriculum vitae (CV). **Items A through E must be completed before moving to step F.*
F. Attend one or more full board meetings as an observer to understand the meeting process and to determine if IRB membership aligns with your interests and capabilities.


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G. Read the TC IRB Member Handbook.
H. Participate in mentorship with experienced IRB members and/or staff.
I. Receive training for specific reviewer roles (e.g., expedited and exempt review processes as applicable).

2. **Continuing Education:**
   - Subscribe and review email lists, presentations, and educational materials.
   - Re-certify in HSP training every three years via CITI.
   - Attend one national IRB meeting annually (supported by TC for IRB Chairs).
   - Upon request or as appropriate, the IRB presents training on selected topics at IRB meetings or IRB in-service programs. Additionally, TC IRB subscribes to and makes available applicable webinar presentations.
   - In addition to the above training, members have access to the following educational materials from the IRB website: the TC IRB SOPs, guidance, policies, educational materials, and forms.

*IRB staff*

3. **Initial Education:**

New IRB staff members will spend their provisional period of employment (three months) under the direct supervision of the Director and their assigned supervisor and will be oriented to the following:

- The Belmont Report;
- Federal Regulations (DHHS 45 CFR 46 and FDA 21 CFR 50 and 56);
- Exempt Review Process;
- Expedited Review Process;
- Full Board Committee Review Process;
- TC IRB Policies and Procedures;
- Job Description and Responsibilities;
- Performance Evaluation Process.

Overview of reference websites, which include the following:

- TC IRB
- Office for Human Research Protections.
- Food and Drug Administration.
- Health Insurance Portability and Accountability Act (HIPAA).
- Public Responsibility in Medicine and Research (PRIM&R).

New staff must also fulfill the following requirements:

A. Complete the New IRB Board Member Orientation.
B. Review the Reviewer Orientation Manual.
C. Complete the required HSP CITI training.
   - IRB Members and Administrators (**ID: 48578**).
D. Complete Office for Human Research Protections (OHRP) Human Research Protection Foundational Training and Considerations for Reviewing Human Subjects Research training.
E. Review and sign the IRB Member & Guest Confidentiality Agreement.


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*F.* Provide the Research Compliance Director with a copy of your most up-to-date resume or curriculum vitae (CV). **Items A through F must be completed before moving to step G.*

G. Observe at least three IRB Committee meetings during the first three months of employment. The new staff member will then review the minutes from the committee meeting with the assigned IRB analyst.

After the outlined training procedures are completed, the Director and assigned supervisor determine whether the IRB staff member has obtained sufficient experience to work independently. This will be documented in the employee record.

**4. Continuing Education:**

IRB staff members are expected to take part in additional continuing education activities as follows:

- IRB staff members are expected to continue their education as part of their professional development. Each is offered the opportunity to attend local, regional, or national conferences in human subject protection during each year of employment. The office routinely subscribes to webinars for the staff and circulates continuing education opportunities at several time points throughout the year.
- Staff are encouraged to obtain the Certified IRB Professional (CIP) certificate as a long-term goal for all staff members. While not mandatory, achieving this certification is highly encouraged as a mark of professional development and commitment to ethical research practices.
    - Staff are encouraged to utilize the Professional Development (PD) fund provided by TC HR as part of their preparation for the CIP exam.
    - Recognizing that the PD fund may not cover all areas of the CIP exam, the IRB office commits to bridging the gap by providing additional resources and financial support. Resources may include study groups, access to practice exams, and mentorship from already certified staff members.
- Re-certify in HSP training every three years via CITI.

**5. Onboarding expectations:**

- New IRB staff members receive the IRB Staff Onboarding Checklist as a baseline orientation guide tailored to their specific roles.
- The IRB QA & Education Specialist and supervisory staff establish and implement a training plan for each new IRB staff member, which includes hands-on training by designated experienced staff members.
- Other internal training documents that may be disseminated to new staff include but are not limited to the IRB SOUP Manual.
- New IRB staff members review existing IRB standard operating procedures.
- TC IRB requires that all IRB staff be trained to protect human subjects. IRB staff fulfill this requirement by completing the CITI online HSP training program.

**6. Expectations for Review & Completion of Duties**

*6.1 Adherence to Regulations and Guidelines*

- Understand and apply relevant laws, regulations, and guidelines accurately, including but not limited to the Common Rule, FDA regulations, and any applicable local laws.


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- Ethical considerations should always be at the forefront, ensuring that research participants' rights, safety, and welfare are protected.

*6.2 Timeliness and Efficiency*

- Review submissions within the established timelines:
    1. Aim to complete pre-review for initial submissions, amendments, and continuing reviews within the predetermined timeframe:
        a) Initial: 7-10 business days from the assignment date
        b) Amendment: 5-7 business days from the assignment date
        c) Continuing review: 3-5 business days from the assignment date
- Promptly address any backlog of submissions to avoid unnecessary research process delays.
- Efficient communication with researchers to request any additional information or clarifications needed for review.

*6.3 Quality of Review*

- A comprehensive evaluation of all aspects of the submission, including the study protocol, consent forms, recruitment materials, and any measures for minimizing participant risks.
- Consistency in review standards, ensuring that all applications are evaluated fairly and thoroughly against the same ethical and regulatory standards.
- Critical thinking to identify potential risks or ethical concerns and suggest practical solutions or modifications.

*6.4 Protocol Resolution Timelines and Escalation*

- Pending PI Response – 30-Day Rule
    - When a reviewer identifies a deviation, issue, or missing information requiring PI input:
        - The reviewer will notify the PI and document the communication in the protocol record.
        - If no response is received from the PI within 30 calendar days:
            - For termination submissions, the reviewer may proceed with administrative closure, noting the lack of PI response in the final determination.
            - For other submissions, the reviewer must escalate to the IRB Manager or Research Compliance Director for further action.
            - The PI will be notified of the administrative action taken.
- Expired protocols following on-time PI submission
    - If the PI submits required materials on time, but the protocol expires while pending IRB staff review:
        - The reviewer must document the submission date and reason for delay.
        - The protocol may be processed post-expiration with written justification that the expiration resulted from internal queue delay—not PI inaction.
        - Patterns of delayed internal review must be reported to the IRB Manager for quality review and process improvement planning.
- Unresponsive reviewers on assigned consultations
    - When a staff member is assigned a protocol with a consult (e.g., with QA & Education Specialist), the primary reviewer must:
        - Initiate the consultation within 2 business days of assignment.


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- If no activity occurs within 5 business days, the consult (secondary reviewer) may:
  - Escalate the delay to the IRB Manager or Director for reassignment or intervention.

*6.5 Communication and Feedback*

- Clear, constructive feedback to researchers on any aspects of the proposal that require revision or clarification.
- Responsive to inquiries from researchers, providing guidance and support throughout the review process.
- Maintain confidentiality of all research proposals and related communications.

*6.6 Professional Development and Training*

- Ongoing education on the latest regulations, ethical guidelines, and best practices in human subjects research.
- Participate in training sessions and workshops to continuously improve the quality of reviews and stay updated with the latest developments in research ethics and compliance.

*6.7 Documentation and Record-Keeping*

- Accurate and detailed documentation of all review activities, decisions, and research communications.
- Secure and confidential storage of all documents and records related to the review process.

*6.8 Collaboration and Teamwork*

- Work collaboratively with other IRB members and staff to ensure a thorough and fair review process.
- Contribute to the continuous improvement of the IRB processes and procedures.

*6.9 Conflict of Interest*

- Identify and disclose any potential conflicts of interest that might affect the review process, per the IRB's policies.

**Relevant Documentation:**

- TC IRB New Staff Onboarding Checklist
- TC IRB New Member Orientation Checklist

**Resources**

- Belmont Report
- DHHS Policy Index
- DHHS Decision Charts
- Expedited Review Categories
- Federal OHRP Educational Videos
- Title 21 CFR Part 50 (FDA)
- Title 21 CFR Part 56 (FDA)
- Title 45 CFR Part 46 (DHHS)


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# TC IRB New Staff Onboarding Checklist

To ensure all components of the revised onboarding checklist are completed within 3 months, the following sample timeline organizes tasks into weekly goals. This structure allows for a gradual increase in responsibility and understanding, with time allocated for learning, application, and reflection. The checklist should be tailored to the specific role as applicable.

## *Month 1: Foundation and Orientation*

### Week 1: Introduction to IRB and Initial Setup

- Day 1: Orientation meeting with supervisor; introduction to the team.
- Day 2: Access setup for all necessary software (Mentor IRB, Confluence, Jira); begin introductory tutorials.
- Day 3-4: Review Standard Operating Procedures (SOPs), focusing on areas that require clarification. Compile questions.
- Day 5: Introduction to IRB website and guides; start DEI (Diversity, Equity, and Inclusion) module.

### Week 2: Deep Dive into Policies and Procedures

- Day 1: Complete DEI training; discuss SOP questions with supervisor.
- Day 2-3: Detailed review of IRB submission procedures and consent processes.
- Day 4: Complete CITI training.
- Day 5: Feedback session on Week 1-2 learnings and adjustments.

### Week 3: Compliance, Safety, and Documentation

- Day 1: Attend the Research Safety Monitor Agreement review session.
- Day 2-3: Begin document review in Mentor IRB; identify areas for updates.
- Day 4: Review compliance and noncompliance issues; start drafting potential FAQs.
- Day 5: Professional development course or workshop.

### Week 4: Technology and Communication

- Day 1-2: Deep dive into Mentor IRB, Confluence, and Jira functionalities with practical exercises.
- Day 3: Set up and organize Google Drive and Confluence page.
- Day 4: Initial networking meetings with intradepartmental contacts.
- Day 5: Feedback session on Month 1 learnings; set goals for Month 2.

## *Month 2: Integration and Application*

### Week 5: Shadowing and Practical Application

- Shadow different staff members each day to understand their roles and contributions.
- Reflections and notes sharing with supervisor.

### Week 6: Networking and Advanced Documentation

- Attend an IRB Board meeting and a Research Compliance and Safety Committee meeting.
- Continue document review and updates in Mentor IRB.

### Week 7: Submission Process and Professional Development

- Walkthrough of submitting a new protocol with a mentor; identify improvement areas.
- Enroll in another professional development course related to research ethics.

### Week 8: Team Building and Feedback

- Participate in or design a team-building activity.


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- A mid-onboarding feedback session will be held with the supervisor to discuss progress and areas of improvement.

*Month 3: Leadership, Innovation, and Professional Growth*

**Week 9: Leadership and Project Proposal**

- Propose a short-term project to improve or innovate within the IRB processes.
- Begin planning and initial steps for the project.

**Week 10: Read, Write, and Present**

- Choose a book for the Book Club and start reading.
- Draft a blog post or series outline for the IRB website or social media.

**Week 11: Professional Development and Review**

- Present on an IRB-related topic to colleagues or at a department meeting.
- Review and reflect on professional development course learnings; apply insights to daily work.

**Week 12: Finalization and Future Planning**

- Final feedback session with supervisor to review onboarding progress and project outcomes and set future goals.
- Prepare and share an onboarding reflection presentation with the team, highlighting learnings, challenges, and suggestions for improving the onboarding process.

Relevant Documentation:

- SOP: Training and Onboarding for TC IRB Staff and Members


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# TC IRB New Member Orientation Checklist

This checklist is designed to ensure a smooth and comprehensive introduction for new IRB members, outlining the necessary steps to become fully integrated and effective participants in the IRB process. Through this structured approach, we aim to familiarize you with the roles, responsibilities, and expectations of IRB membership, provide essential Human Subject Protection (HSP) training, and prepare you for active participation in board meetings and review processes. Additionally, this checklist includes ongoing education opportunities to enhance your knowledge and effectiveness in safeguarding the rights and welfare of research participants.

## *Initial Orientation and Training*

A. **Attend Orientation Session**
   - With the Research Compliance Director, discuss IRB membership roles, expectations, and how your expertise and interests fit.

B. **Complete Online Orientation**
   - Review training binders, complete online orientation modules in the New IRB Board Member Orientation, and review the Reviewer Orientation Manual.

C. **Complete CITI Human Subject Protection Training**
   - As applicable to your role:
     - IRB Chair: IRB Chair (**ID: 251087**) & IRB Members and Administrators (**ID: 48578**).
     - IRB member: IRB Members and Administrators (**ID: 48578**).

**Note these trainings are separate from the IRB Social and Behavioral Researchers (ID: 48577) course, which is a separate requirement for anyone involved in research with human subjects*

D. **Sign Confidentiality Agreement**
   - Review and sign the IRB Member & Guest Confidentiality Agreement.

E. **Submit Resume or CV**
   - Provide an updated resume or curriculum vitae to the Research Compliance Director. **Complete items A through E before proceeding to F.*

## *Integration into Board Activities*

F. **Observe Full Board Meetings**
   - Attend one or more meetings as an observer to grasp the process and assess alignment with your interests and capabilities.

G. **Review IRB Member Handbook**
   - Read through the TC IRB Member Handbook for comprehensive guidance.

H. **Participate in Mentorship**
   - Engage with experienced IRB members and/or staff for mentorship.

I. **Role-Specific Training**
   - Receive training tailored to specific reviewer roles, such as expedited and exempt review processes.

## *Continuing Education*


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J. **Stay Informed**
   - Subscribe to and review email lists, presentations, and educational materials.

K. **CITI HSP Re-certification**
   - Complete every three years to stay current with Human Subject Protection training.

L. **Attend an Annual National IRB Meeting**
   - Mandatory for IRB Chairs (supported by TC).

M. **Engage in IRB-Sponsored Training**
   - Attend training sessions on selected topics, in-service programs, and webinars as presented by the IRB.

N. **Access Educational Resources**
   - Utilize the IRB website for TC IRB SOPs, guidance, policies, educational materials, and forms.

Relevant Documentation:

- SOP: Training and Onboarding for TC IRB Staff and Members


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