



**IRB Member Initial Training Completion Form**

In your role as a member of the NIH IRB, your primary responsibility is to protect the rights and welfare of research subjects. To ensure that you can effectively perform your responsibilities as a Board Member, you will become familiar with the following topics that will be covered during your IRB Member Training & Orientation:

- The Belmont Report and the ethical principles applicable to research with human subjects
- Health and Human Services (HHS) Regulations
- Food and Drug Administration (FDA) Regulations
- OHSRP Policies and Procedures
- NIH Policies
- Our eIRB system PROTECT

In conjunction with your initial appointment to the Board, the IRB office will provide you with the following training. Please indicate the date the training was completed and initial each item confirming that you participated in that training.

Training	Date Completed	Confirming Initials
<b>IRB Board Member Training &amp; Orientation:</b> <ul style="list-style-type: none"> <li>• Overview on topics including Informed Consent, Risk/Benefit Assessments, Approvability Criteria, and Privacy/Confidentiality</li> <li>• Information on how IRB members should conduct protocol reviews</li> </ul>		
<b><u>CITI Biomedical 101</u></b>		
<b>PROTECT Training (occurs during IRB Member Training)</b>		
<b>Observe a NIH IRB convened meeting (as guest)</b>		

Your signature below verifies that you received training in all the above areas. This form will be kept in your NIH IRB member file with your other credential information.

\_\_\_\_\_  
IRB Member Printed Name

\_\_\_\_\_  
Signature

**Eligibility for Voting Membership:**

\_\_\_\_\_  
Tiffany Gommel, MS, CIM, CIP  
Director, Office of IRB Operations

\_\_\_\_\_  
Date

## Board Member Initial Training Syllabus

### 1. IRB Member Training & Orientation

- a. New Member trainings occur at an ad hoc basis throughout the year. New board members are informed of dates to ensure attendance.
  - i. Please email [Mollie Fraser](#) to inquire on training dates/times.
- b. Review of OHSRP Policies and Procedures
  - i. Please refer to the “Education and Training” area of OHSRP website for additional IRB Board member resources regarding policies and guidance. These sections of the website include other educational materials and relevant articles and presentations.
    1. [IRB Members Presentations & Reference](#)
    2. [OHSRP Policies & Guidance](#)
- c. Board member responsibilities reviewed
  - i. Monthly attendance at meetings with a minimal number of absences. Please reach out to [Mollie Fraser](#) if any conflicts come up.
  - ii. Preparation to participate in the meeting by reviewing materials in advance of the meeting. Please have your review submitted 24 hours before the start of the meeting.
    1. Example: If you have the Wednesday 10 AM meeting, submit your review before Tuesday at 10 AM.
  - iii. Being an active contributor during the meeting.

### 2. CITI Training

- a. If you are an **Affiliated** member please visit the IRBO website and select “Education & Training” to access the CITI Training Portal.
  - i. [NIH CITI Training](#)
- b. If you are **Unaffiliated** member, please contact [Margaret Sanders](#) to obtain CITI log-in credentials

### 3. PROTECT Training

- a. An overview is provided during your IRB Member training with Nicole Grant.
- b. IRB Member PROTECT Review Guides can be found here:
  - i. [IRB Member Review Guides](#)

### 4. Observe one IRB meeting as Convened Guest

- a. Please email [Mollie Fraser](#) with the date/time you would like to attend. Mollie will inform the Analysts assigned to the meeting, and you will be sent the Zoom link. You are welcomed to observe more than one meeting if preferred.
  - i. Refer to the [NIH IRB Meeting Calendar](#) to determine a date/time of attendance.