University at Buffalo
The State University of New York

IRB Module Training Setup

MODULE DESCRIPTION:

The Click Portal IRB module provides a streamlined way for researchers to create and submit protocols for studies involving human subjects. It provides support for initial submissions, modifications, reportable new information, and continuing reviews. The module is designed to ensure compliance, meet AAHRPP accreditation standards, and reduce approval turnaround times.

UB's Human Research Protection Program protects the rights of research volunteers. The Institutional Review Board (IRB), comprised of faculty peers and community members, can approve, modify or reject proposed research based on its perceived risks and benefits to prospective subjects.

OBJECTIVES:

- Provide principal investigators, study staff, compliance and research administration staff an overview of the Safety module
- Demonstrate how to:
    - Create an IRB study and submit it for review
    - Manage the IRB review process
    - Create and convene IRB committee meetings
    - Communicate the committee's decision to the study team
- Allow the participants to practice with hands-on exercises
- Provide training materials and references that will provide assistance while using the IRB module

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TRAINING EXERCISES:

Safety Module Exercises	Role(s)
Navigation Exercises	
• Exercise 1: Log into the Click IRB Module	Any
• Exercise 2: Explore the Inbox	Any
• Exercise 3: Explore All Submissions	Any
• Exercise 4: Explore the Study Workspace	Any
• Exercise 5: Explore the SmartForm Pages	Any
Pre-Submission Exercises	
• Exercise 6: Create a New Study	Principal Investigator
• Exercise 7: Assign Additional Staff to a Study	Principal Investigator
• Exercise 8: Submit a Protocol to Review	Principal Investigator
Pre-Review Exercises	
• Exercise 9: Assign a Coordinator	IRB Coordinator
• Exercise 10: Request Pre-Review Clarification	IRB Coordinator
• Exercise 11: Respond to a Reviewer Request	Principal Investigator
• Exercise 12: Submit a Pre-Review	IRB Coordinator
IRB Review: Committee Review Exercises	
• Exercise 13: Assign Study to an IRB Committee Meeting	IRB Coordinator
• Exercise 14: Access Studies on the Meeting Agenda	IRB Committee Member
• Exercise 15: Locating Review Checklists	IRB Committee Member
• Exercise 16: Preparing Comments for a Meeting	IRB Committee Member
• Exercise 17: Convene a Meeting and Submit a Committee Review	IRB Coordinator
IRB Review: Non-Committee Review Exercises	
• Exercise 18: Send Study to Non-Committee Review	IRB Coordinator
• Exercise 19: Submit a Designated Review	IRB Committee Member
Ancillary Review Exercises	
• Exercise 20: Set Up Ancillary Reviews	IRB Coordinator
• Exercise 21: Submit an Ancillary Review	Ancillary Reviewer
Post-Review Exercises	
• Exercise 22: Finalize the Documents	IRB Coordinator
• Exercise 23: Prepare and Send Determination Letter	IRB Coordinator
Committee Meeting Management Exercises	
• Exercise 24: Create a New Meeting	IRB Coordinator
• Exercise 25: Run a Meeting	IRB Coordinator

TRAINING MATERIALS:

Safety Module Instructor

- IRB Module – Introduction PowerPoint
- Laptop or computer with hardwired Internet connection

Participants

- IRB Module – Exercises
- IRB Module – Sample Study
- Work Instructions:
  - Create and Submit a New Study
  - Create and Submit a Modification or Continuing Review
  - Clarifications, Modifications, and the Deferral Process
  - Reportable New Information

Equipment and Site Requirements

- LCD Projector
- Screen
- Laptops or computers with hardwired Internet connection (one per participant)

SYSTEM REQUIREMENTS:

User Accounts

Ensure that the following user accounts are created in the system with the necessary roles for training.

Role/User	User Name	Password
Principal Investigator	pi1 – pi25	1234
IRB Coordinator	irbc1 – irbc25	1234
Committee Member	irbchair1 – irbchair25 (chairperson) irbcomm1 – irbcomm25 (committee member)	1234
Ancillary Reviewer	anc1 – anc25	1234

Protocols

Create at least one IRB study that is in the review process. Ensure the study has gone through some reviews so these will appear on the Reviews tab.

Committee and Meeting

1. Log into the site as site administrator.
2. Click the **Meetings** link on the left.
3. Click **Create New Committee** and create the following committee and meeting:

Field Name	Setting
Committee Type:	Institutional Biosafety Committee
Name:	Biosafety Committee
Committee Administrators:	safety1-25
Committee Members:	chair1-25 (chairperson) comm1-25 (committee members)
Meeting Date and Start Time:	Any future date
Location:	University at Buffalo
Meeting Name:	Biosafety Committee Meeting

Library

Ensure that sample documents have been uploaded to the Library tabs for each document type.