IRB ICON Course for Researchers – Content Outline

The content outline provides an overview of this ICON course that is available to anyone with a HawkID. If you have questions or suggestions for additional topics to cover in this course, contact the IRB Education and Outreach Program at irb-outreach@uiowa.edu or 319-335-6564.

Course Overview

A brief description of what you will find in each of the following sections.

- Student PI Training Requirement (Full Recordings of HawkIRB Trainings)
- HawkIRB Training Quick Tutorials
- Additional Topics
- Medical Ethics Advisor Newsletter

Student PI Training Requirement (Full Recordings of HawkIRB Trainings)

To satisfy the Student Principal Investigator (PI) Training Requirement, student PIs must view the Part 1 and 2 recordings and pass the respective quizzes or attend the live Part 1 and 2 HawkIRB trainings.

- Get Started
  (Mandatory reading to open HawkIRB Training, Part 1)

HawkIRB Training, Part 1: How to Complete a HawkIRB New Project Application

- Synopsis
- HawkIRB Training Video 1 – Recording
  (View entire recording on regular speed to access the Part 1 quiz)
- Slides
- HawkIRB Inbox Handout
- Part 1 Quiz
  (Pass with 80% correct to access the Part 2 recording)

HawkIRB Training, Part 2: How to Complete a HawkIRB New Project Application

- Synopsis
- HawkIRB Training Video 2 – Recording
  (View entire recording on regular speed to access the Part 2 quiz)
- Slides
- Part 2 – Quiz
  (Pass with 80% correct to complete the Student PI Training Requirement)

HawkIRB Training Part 3: Forms Submitted After IRB Approval (Modifications, Continuing Reviews, Reportable Event Forms and Project Close Forms)

- Synopsis
- HawkIRB Training Video 3 – Recording *(No prerequisites)*
- Slides

HawkIRB Training Part 4: Submissions for the Single IRB Model – Form submission for Lead and Relying Sites

- Synopsis
- HawkIRB Training Part 4 – Recording *(No prerequisites)*
- Slides

HawkIRB Training Part 5: New Project Form for Exempt Status

- Synopsis
- HawkIRB Training, Part 5 – Recording *(No prerequisites)*
- Slides
- UI Exemption Tool (2022)

HawkIRB Training Quick Tutorials

This module consists of a series of short recordings for each section or feature of the eResearch system, HawkIRB. The application has changed some since these tutorials were recorded in 2010, but they still provide section-specific guidance.

- HawkIRB Inbox/Carousel
- New HawkIRB Application, Index & Help Messages
- HawkIRB - Section I – Project Introduction
- HawkIRB - Section II – Research Team
- HawkIRB - Section III – Funding/Other Support
- HawkIRB – Section IV – Project Type
- HawkIRB – Section V – Other Committee Review
- HawkIRB – Section VI - Subjects
- HawkIRB – Section VII.A – VII.E Project Description
- HawkIRB – Section VIII - Risks
- HawkIRB – Section IX - Benefits
- HawkIRB – Section X – Privacy & Confidentiality
- HawkIRB – Section XI – Data Analysis
- HawkIRB – Section XII – Future Research
- HawkIRB Attachments Page
- HawkIRB Workflow System
- HawkIRB Project Summary Page
- HawkIRB Modifications
- HawkIRB Continuing Review
- HawkIRB Reportable Event Form
- HawkIRB Project Closure Form

Additional Topics

Each semester, staff from the Human Subjects Office offer presentations on human subjects research-related topics. Information about presentations for the current

semester can be found on the Education and Training page of the HSO website. This module contains recordings of past presentations in reverse chronological order.

- Single IRB Review Model for Federally Funded, Multi-Site Research, March 2022
- Human Subjects Research Hot Topics and Updates, March 2022
- Clinical Trials.gov: Guidelines for Reporting Results, February 2022
- Exempt Application Updates, November 2021
- Human Subjects Research Hot Topics and Updates, October 2021
- Research Billing Compliance (RBC), September 2021
- Human Subjects Research Hot Topics & Updates, July 2021
- Understanding the External IRB Process
- Student Principal Investigators (PI) and Faculty Advisors (FA): Know Your Responsibilities
- Boomerang Application: Best Practices for Managing Workflow Questions and Requests
- Getting on the Same Page: Submission and Review of Human Subjects Research Applications (A 3-part Lecture Series), Spring 2021
    - Part 1.Getting on the Same Page, Form Submission
    - Part 2.Getting on the Same Page, Case Examples
    - Part 3.Getting on the Same Page, Budget Best Practices
- Data Security Mystery Machine: Study Data, Where Are You?
- Use of eConsent: A Look at the Regulatory Guidance
- FDA Site Inspection Guidance
- Data Use and Transfer Agreements
- Off-Campus Research
    - Off-Campus Research - IRB-01
    - Off-Campus Research - IRB-02
- Regulations, Policies and Best Practices
- Reportable Events and Unanticipated Problems
- UIHC Research Record of Consent, HIPAA and HITECH
- International Research and Collaboration with Non-UI or Non-VA Researchers
- Waivers of Consent
- Cash Handling Policy: Research Subject Compensation
- IRB Review Types
- Creating an Informed Consent Document
    - Creating an Informed Consent Document
    - Elements of Consent
- Conflict of Interest in Research
- Additional Protections for Vulnerable Subjects
- The New HawkIRB Carousel Index: What the IRB Asks for and Why
- Children in Research Panel Discussion
- Informed Consent and Assent

- Human Subjects Protections – IRB Overview

Medical Ethics Advisor Newsletter

The UI IRB subscribes to this monthly newsletter as a resource for the UI research community. We typically spotlight one or more articles in each issue of the IRB Connection Newsletter.