

## 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](mailto: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)
- IRB Efficiency Initiative-Recordings and Documents
- IRB Overview Presentation
- Additional Topics
- Medical Ethics Advisor Newsletter

### Student PI Training Requirement (Full Recordings of HawkIRB Trainings)

These recordings are available, and strongly encouraged, for all UI researchers who use the HawkIRB system. They are not just for student Principal Investigators (PIs).

To satisfy the [Student PI Training Requirement](#), view the Part 1 and 2 recordings and pass the respective quizzes or attend the live Part 1 and 2 [HawkIRB trainings](#) (if offered).

1. [Get Started \(Mandatory reading to open HawkIRB Training, Part 1\)](#)
2. [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*)
3. [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*)
4. [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
5. [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
  6. [HawkIRB Training Part 5: New Project Form for Exempt Status](#)
    - Synopsis
    - HawkIRB Training, Part 5 – Recording (*No prerequisites*)
    - Slides
    - UI Exemption Tool (2022)

### IRB Efficiency Initiative

This section of the IRB ICON Course for Researchers provides brief tutorials and resources for new policies, procedures and HawkIRB enhancements associated with the [IRB Efficiency Initiative](#). Sponsored by the Office of the Vice President for Research, this organizational efficiency initiative focuses on streamlining processes for IRB review in an effort to remain competitive with application processing time with our peer institutions while maintaining regulatory compliance for the conduct of human subjects research. Visit the [IRB Efficiency Initiative](#) website for an executive summary, project updates, initiative timeline, and resources associated with the monthly information sessions that began in January 2024.

### IRB Overview Presentation

This is a recording of the general IRB overview presentation (2023). This presentation provides a good orientation to the UI IRB and the IRB approval requirements for human subjects research. It is an excellent supplemental lecture for any research methods or responsible conduct of research course. It is ideal for students/trainees doing research as a course requirement or as an honors, Master's or doctoral dissertation.

This presentation covers the following:

- Guidelines for human subjects research: why and when IRB approval is required
- Basic ethical principles for the conduct of human subjects research
- Student Principal Investigator (PI) training requirements
- What to expect from the IRB review process
- Research off campus or outside the United States
- Course-related student projects

### 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.

- Human Subjects Research Hot Topics & Updates Lectures (2021-2023)
- Ask if you Need IRB Approval (IRB/ICTS Lecture), December 2023
- Sticky Issues: Web-Based Data Collection for Human Subjects Research, November 2023
- Human Subjects Research at UI Health Care, November 2023
- Be Resourceful-Know the UI Research Resources that are Available to You (ICTS/IRB Lecture), October 2023
- Expanded Access of Emergency Use for Access to Investigational Medical Products
- Unlocking the Mystery of IRB Compliance Monitoring, September 2023
- The Single IRB Process: Navigating the Water, April 2023
- Casting the Net: Research Ethics in the Age of Social Media, April 2023
- ClinicalTrials.gov Reporting Requirements: Consequences of Noncompliance, April 2023
- Top 10 Reasons Researchers Come to Office Hours and the Guidance We Give, Feb 2023
- FDA Site Inspection Guide: Your Best Tool for Preparing, Feb 2023
- Make Effective Recruitment Plans (ICTS/IRB Lecture Series), December 2022
- A Deeper Dive into the Research Process (ICTS/IRB Lecture Series):
  - Create Informed Consent Documents, Aug 2022
  - Informed Consent Process, June 2022
  - Make a HawkIRB Application, May 2022
  - Recruitment Process, June 2022
  - Reportable Events Panel Discussion, July 2022
- Checklists and Guidance Documents Galore! October 2022
- HawkIRB Carousel Index, April 2022
- Single IRB Review Model for Federally Funded, Multi-Site Research, March 2022
- Clinical Trials.gov: Guidelines for Reporting Results, February 2022
- Exempt Application Updates, November 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

#### [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](#).