

Human Subjects IRB Workshop

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IRB CO-CHAIR



Workshop Overview

- ▶ Thank you to the Office of Undergraduate Research & Creative Activity, the Honors College, and the Nationally Competitive Fellowship Office for sponsoring this workshop!
- ▶ Upon completion of this presentation, participants should be able to:
 - ▶ Define the Institutional Review Board and Human Subjects Research
 - ▶ Complete Required Training
 - ▶ Navigate the IRB-Human Subjects Website
 - ▶ Create an IRB application and be familiar with the IRB process

Institutional Review Board (IRB)



- ▶ An oversight committee charged with reviewing research involving human subjects
- ▶ Membership: faculty, staff, students, and community members
- ▶ Operates under federal regulations, state law and SU policy
- ▶ Authority to approve, require modification in, or disapprove research
- ▶ Human subjects research must be approved by the IRB before research begins

Human Subjects Research

- ▶ Federal Definition—

A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**

- ▶ Human Subject Defined—

an individual about whom an investigator conducting research obtains:

- ▶ Data through intervention or interaction with the individual
or
- ▶ Identifiable private information

Is it human subjects research?

- ▶ Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?
- ▶ Does the research involve obtaining information about living individuals?
 - ▶ Does the research involve intervention or interaction with the individuals?
 - ▶ If using existing data, is the information individually identifiable (i.e. subject identity may not readily ascertained by researcher)?
 - ▶ Is the information private (i.e. about behavior or provided for a specific purpose that occurs in a context in which an individual can reasonably expect it not be recorded and/or made public)?

Determining whether or not your project needs IRB review is not always obvious and often depends on the particularities of the specific project.
Seek Guidance!

Determine Level of Research Review

Full Board

- greater than minimal risk; e.g. drug study/involving minors
- reviewed by a full committee

Expedited (9 categories)

- no greater than minimal risk; e.g. blood draw/voice recordings
- reviewed by 2 board members

Exempt (6 categories)

- less than minimal risk; e.g. anonymous survey/de-identified data
- reviewed by chair/board member

Not Human Subjects Research

- doesn't meet federal definition of human subjects research

[Federal Guidelines](#)

Preparing Your Submission

The Principal Investigator

The PI is responsible for...

- ▶ The ethical performance of the project
- ▶ The protection of the rights and welfare of human participants
- ▶ Strict adherence to the study protocol and any stipulations imposed by the IRB
- ▶ Complying with applicable federal, state, and local regulations and SU policies
- ▶ Ensure key personnel are trained/qualified
- ▶ Obtaining legally effective informed consent

- ▶ Salisbury University Policy
 - ▶ Doctoral-level graduate students can serve as co-PIs
 - ▶ Master-level graduate & undergraduate students must be student researchers
 - ▶ Staff at the Assistant Director or higher level can serve as PIs

- ▶ Ethics training required for all researchers

- ▶ [Connect with OURCA!](#)

The Protocol

- ▶ To ensure compliance IRBs require that all investigators submit a standard set of documents designed to communicate all of the essential information about a particular study prior to the initiation of the research.
- ▶ All of the documents and materials that are submitted to the IRB are what constitute the **IRB protocol**.
- ▶ Spring 2019
 - ▶ Revised Common Rule Requirements
 - ▶ IRB launched new fillable form protocol & web resources
 - ▶ In development: eIRB system for review
- ▶ [IRB Website](#)

Protocol Development

- ▶ Researcher completes IRB application form
 - ▶ Identify researchers, project, timeline, collaborations, funding as applicable
- ▶ Protocol Components
 - ▶ Sampling and Recruitment
 - ▶ Informed Consent
 - ▶ Data Collection Procedures
 - ▶ Data Storage & Analysis
 - ▶ Risks/Benefits Analysis
 - ▶ Plan to Disseminate Findings

Sampling & Recruitment

- ▶ Describe—
 - ▶ Intended research site & involvement of external agency, if applicable
 - ▶ Target population
 - ▶ Estimated sample
 - ▶ Inclusion & exclusion criteria
 - ▶ Equitable selection of eligible participants
 - ▶ Recruitment methods
- ▶ Submission of recruitment materials

Informed Consent

- ▶ One of the primary ethical requirements foregrounding human subjects research
- ▶ Provide potential research subjects with all of the relevant information they need to make a fully informed, autonomous decision to participate
 - ▶ Ongoing process
- ▶ Researchers must:
 - ▶ Provide an adequate opportunity to the subject (legally authorized representative) to read the disclosure/consent form and ask questions
 - ▶ Minimize the possibility of coercion or undue influence
 - ▶ Obtain signed, written consent (oral/waiver of documentation)

Data Collection, Storage, Analysis

- ▶ Explain process for all sources of data being collected
 - ▶ Methods for obtaining the data
 - ▶ Timeline & duration for data collection
- ▶ Describe the plan for handling, storing, and analyzing the data
 - ▶ Individuals with access & role
 - ▶ Use of any technology platforms/cloud storage
 - ▶ Timeline and method for disposal of data
- ▶ Measures in place to monitor participant safety/confidentiality throughout research

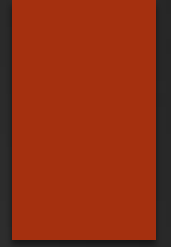
Risks/Benefits Analysis

- ▶ Discuss anticipated benefits, if any, for participation & research
- ▶ Discuss any potential risks & safeguards for minimizing them
 - ▶ Examples:
 - ▶ Loss of confidentiality
 - ▶ Social discomfort answering interview questions
 - ▶ Physical discomfort after exercise
 - ▶ Negative affective states from survey questions

Dissemination plan

- ▶ Describe intentions for disseminating findings through publications, presentations, reports, etc.
- ▶ Indicate the measures in place to maintain the confidentiality of participants
 - ▶ Aggregate vs individual findings
 - ▶ Descriptions of participants/direct quotes

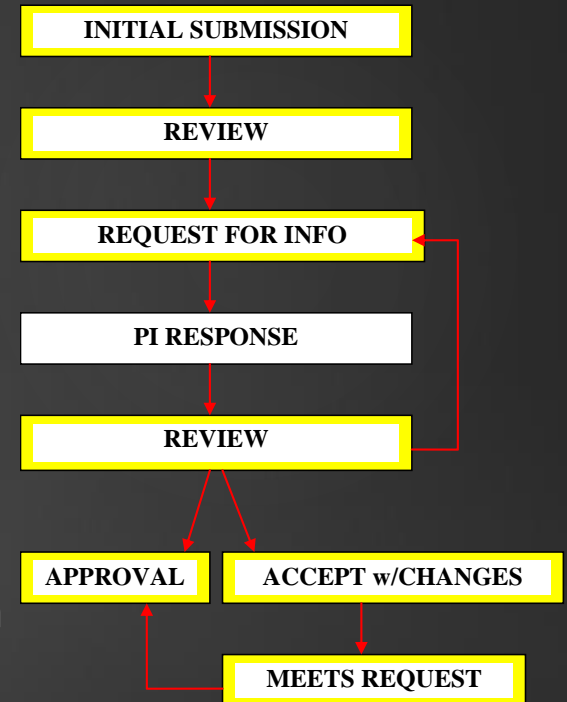
IRB Forms for Investigators



- ▶ Templates
 - ▶ Recruitment flyers/scripts
 - ▶ Disclosure/consent forms
 - ▶ Parental permission
 - ▶ Minor assent
 - ▶ Letter of Collaboration
 - ▶ Amendment Request
- ▶ [IRB Website](#)

Protocol Review Process

- ▶ Researcher submits application and attachments to department/program chair and then IRB
 - ▶ 15 business days for initial review once received
 - ▶ Committee / Committee member review
 - ▶ Decision in writing
 - ▶ Full Committee
 - ▶ Attendance at monthly meeting required
- ▶ IRB approval must be obtained prior to initiation of research activities



Source: UC Davis, Office of Research



Break

AFTER BREAK: REQUIRED RESEARCHER CITI TRAINING

Required Researcher Training

- ▶ Who is part of the research team?
 - ▶ Anyone who **intervenes or interacts** with **living individuals** for **research purposes**; or obtains **individually identifiable private information** for research purposes [45 CFR 46.102(f)]
- ▶ Collaborative Institutional Training Initiative (CITI) – research ethics and compliance training
 - ▶ Free & accessible online to researchers
 - ▶ General & field-specific inquiry topics
 - ▶ Widely used by other organizations

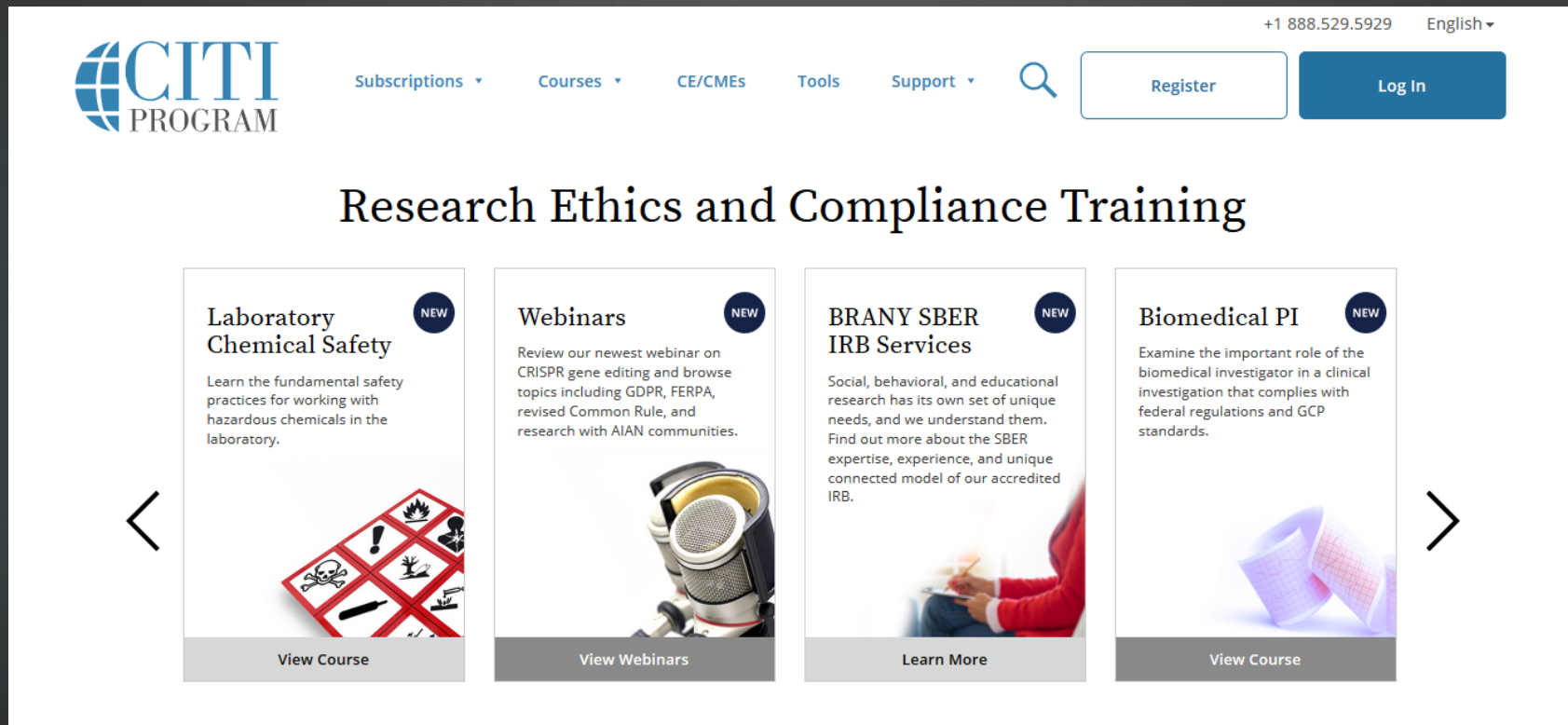


Training Requirement

- ▶ Human Subjects Protection Basic Course is required for all investigators
- ▶ 9 required modules
 - ▶ Overview of history, ethics, and federal regulations
 - ▶ Informed consent
 - ▶ Risk assessment and conflicts of interest
 - ▶ Privacy and confidentiality
- ▶ 9 Supplemental Courses
 - ▶ Examples: Internet-based research; research with children; introduction to community-engaged research
- ▶ NIH training (or related training from other institutions) may be submitted to satisfy this requirement.

Registering for CITI Training

- ▶ To create an account, visit:
<https://about.citiprogram.org/en/homepage/>
- ▶ Click on “Register” at top of screen



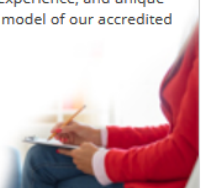
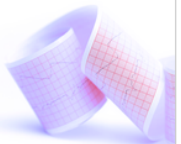


The screenshot displays the CITI PROGRAM website homepage. At the top right, there is a phone number (+1 888.529.5929) and a language selector (English). The navigation menu includes links for Subscriptions, Courses, CE/CMEs, Tools, and Support, along with a search icon. Two prominent buttons are labeled "Register" and "Log In". The main heading is "Research Ethics and Compliance Training". Below this, there are four featured course cards, each with a "NEW" badge and a "View Course" or "Learn More" button. The cards are: "Laboratory Chemical Safety" (with a hazard symbol image), "Webinars" (with a microphone image), "BRANY SBER IRB Services" (with a person writing image), and "Biomedical PI" (with a document image).

CITI PROGRAM Subscriptions ▾ Courses ▾ CE/CMEs Tools Support ▾ 🔍 Register Log In

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Research Ethics and Compliance Training

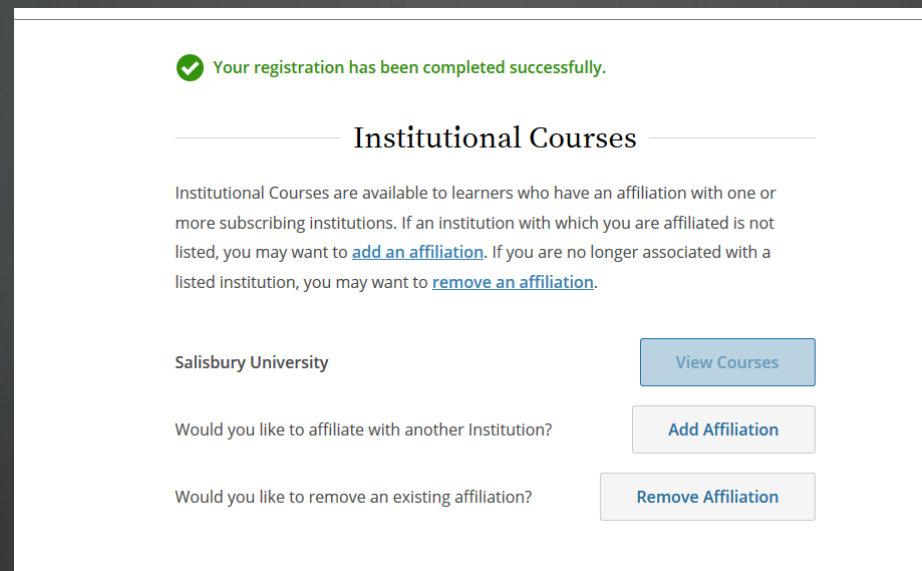
- Laboratory Chemical Safety** NEW
Learn the fundamental safety practices for working with hazardous chemicals in the laboratory.

View Course
- Webinars** NEW
Review our newest webinar on CRISPR gene editing and browse topics including GDPR, FERPA, revised Common Rule, and research with AIAN communities.

View Webinars
- BRANY SBER IRB Services** NEW
Social, behavioral, and educational research has its own set of unique needs, and we understand them. Find out more about the SBER expertise, experience, and unique connected model of our accredited IRB.

Learn More
- Biomedical PI** NEW
Examine the important role of the biomedical investigator in a clinical investigation that complies with federal regulations and GCP standards.

View Course

Setting Up Your Profile

1. Type “Salisbury University” in the fillable box under “Select your organizational affiliation” and agree to the terms of service.
2. Enter your personal information (Note: an SU email address is not required).
3. Create a user name and password.
4. Select your country of residence (United States).
5. Select “yes” or “no” if your module completion also serves a need for continuing education and complete the remainder of the questions.
6. Set your language preference & complete the SU requested information.

Register for Training Modules

- ▶ Under Curriculum Selection:
 - ▶ Skip Question 1 (unless it applies to your research)
 - ▶ Choose your learner group for Question 2
 - ▶ Questions 3-8 optional, recommended at your discretion of needs
- ▶ Click “Complete Registration” and then select “Finalize Registration”



✔ Your registration has been completed successfully.

Institutional Courses

Institutional Courses are available to learners who have an affiliation with one or more subscribing institutions. If an institution with which you are affiliated is not listed, you may want to [add an affiliation](#). If you are no longer associated with a listed institution, you may want to [remove an affiliation](#).

Salisbury University [View Courses](#)

Would you like to affiliate with another Institution? [Add Affiliation](#)

Would you like to remove an existing affiliation? [Remove Affiliation](#)

Student Researchers Basic Course

- ▶ Navigate to your course menu
- ▶ Select “Start” and choose your preferred delivery format (AV or text)
- ▶ Review the content and complete module quiz
- ▶ Work at your own pace (2-6 hours)
- ▶ Must obtain 80% or higher score for certificate
 - ▶ Once complete, retain a copy of your certificate for records & submission
 - ▶ Certificate valid for 3 years

Student Researchers
Salisbury University

INSTRUCTIONS

- Complete all 9 required modules
- Achieve an average score of at least 80% on all quizzes associated with this course's module requirements

PROGRESS
0 / 9 modules complete

SCORE
0%

You have unfinished required or elective modules remaining.

Required Modules

Complete all 9 required modules.

Modules	Completed	Score
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID 14928)	Incomplete	-

Start

Workshop

Protocol & CITI Training

Q & A

Institutional Review Board

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