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

45 CFR 46.102

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

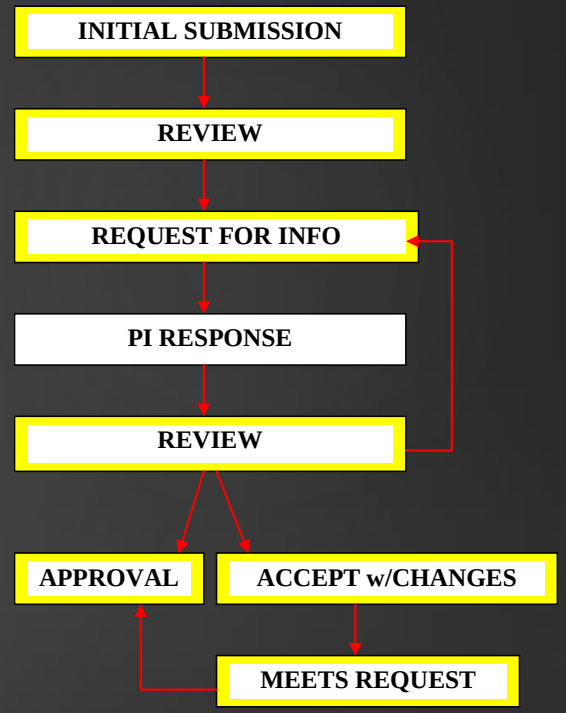
IRB Forms for Investigators

- 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)]

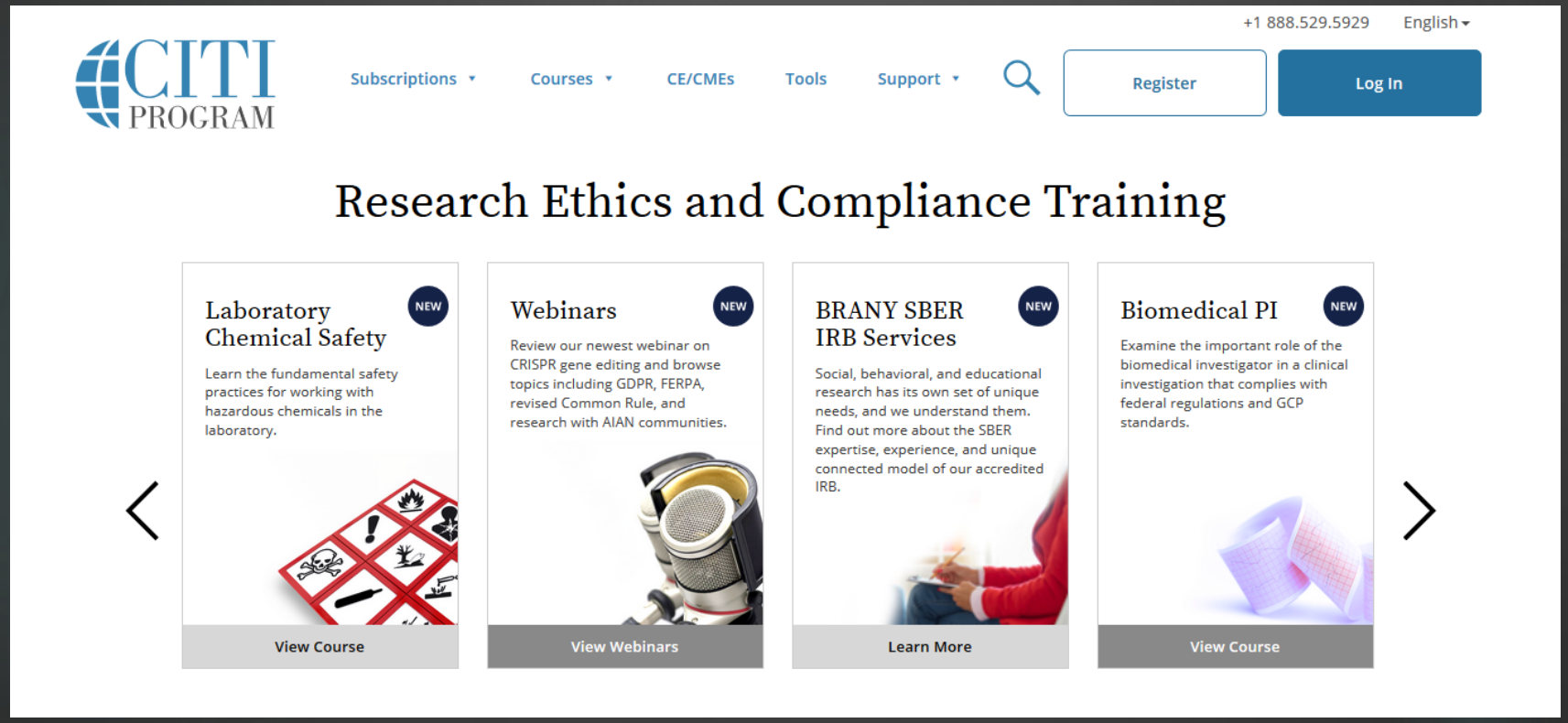
- Collaborative Institutional Training Initiative (CITI) – research ethics and compliance training
  - Free & accessible online to researchers
  - General & field-specific inquiry topics
  - Widely used by other organizations

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



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.

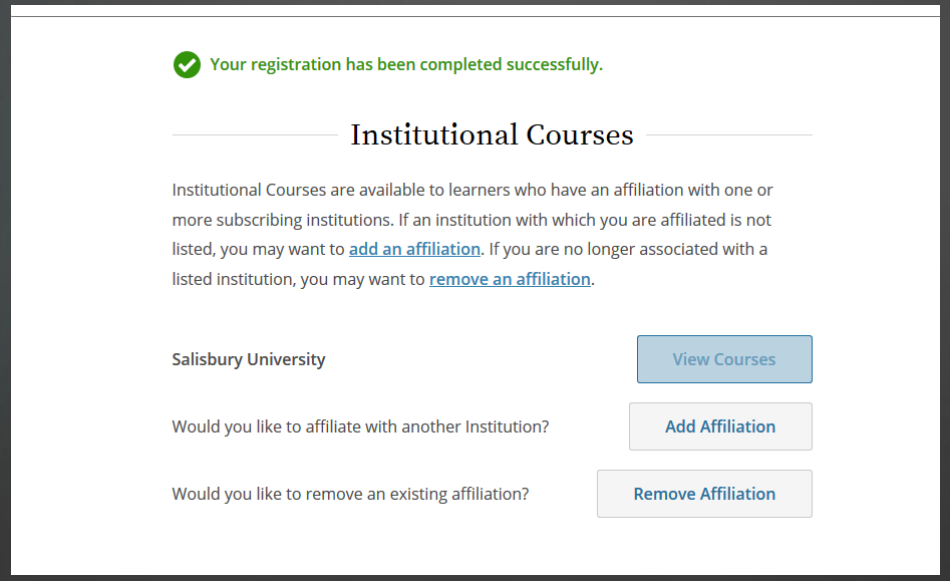
4. Select your country of residence (United States).

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.

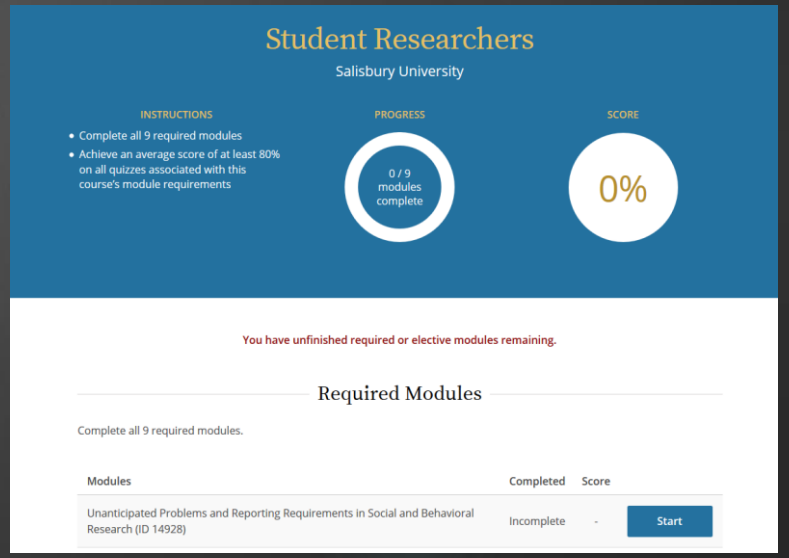
Register for Training Modules

- 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"



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



Workshop

Protocol & CITI Training

Q & A

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