FLORIDA STATE UNIVERSITY

Study Coordinator Lunch and Learn Bootcamp 101

Presented By

The Office for Clinical Research Advancement (OCRA)

FSU Office for Human Subjects Protection (OHSP)

Learning Objectives

- Gain a greater understanding of basic terminology and essential documents needed to manage Human Subject research activities.

Presenters:

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  - OHSP Assistant Director
- Sharon Liebrich, MSN, CCRC
  - OCRA Clinical Research Program Director

This session will be recorded via ZOOM and published on the Lunch and Learn Series Website for future reference. For our ZOOM participation, please post questions in the CHAT.

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ⓘ Start presenting to display the joining instructions on this slide.

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How many years of study coordinator experience do you have?

ⓘ Start presenting to display the poll results on this slide.

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What type of research are you working with?

ⓘ Start presenting to display the poll results on this slide.

Definitions and Key Terminology

Clinical Trial:

- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Human Subject as Defined by DHHS:

- A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject as Defined by FDA:

- An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

Research as Defined by DHHS:

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

Research as Defined by FDA:

- Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following: Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Additional Definitions at the link below:

https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/FUC26GOCNFO458JE1OBERD0H79/HRP-001%20-%20SOP%20-%20Definitions.pdf

A.L.C.O.A-C

Attributable

- Who did what? From documentation to events, all items should be traceable to a person, visit, date, and time.

Legible

- Easy to read and identifiable
- Single Line Cross-out any changes
  - Initial and Date the cross-out

Contemporaneous

- Document as it occurs
- “Late Entry” is acceptable if it is defined and justified

Original

- Original Source Documents MUST be maintained (maybe a sticky note)

Accurate

- Real and Consistent Representation of the Facts

Complete

https://www.fda.gov/media/85183/download

https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/research-information-security/

Decision Trees and Algorithms

What activities require IRB review?

- **Engagement** algorithm to find out.

Review Process:

- Follow OHSP's **Review Pathway for Human Research** for a high-level overview of key IRB decision points.

HIPAA Privacy Rule and Research:

- **HIPAA Privacy Rule & Research Requirements** algorithm to see what requirements apply to the use or disclosure of health information.

Clinical Trials:

- Specific legal requirements apply to clinical trials (evaluating effects of interventions on biomedical or behavioral health-related outcomes); refer to our draft **Clinical Trials/Human Research Workflows** algorithm to learn more.

FDA-regulated Products and Test Articles:

- FDA **Drug**, **Device**, and Dietary Supplement algorithms for special requirements for research using drugs, devices, including software considered a "device," biological products, or dietary supplements.

Link to all Decision Trees and Algorithms

- https://www.research.fsu.edu/research-offices/ohsp/decision-trees/

Standard Operating Procedures

Why are SOPs needed?

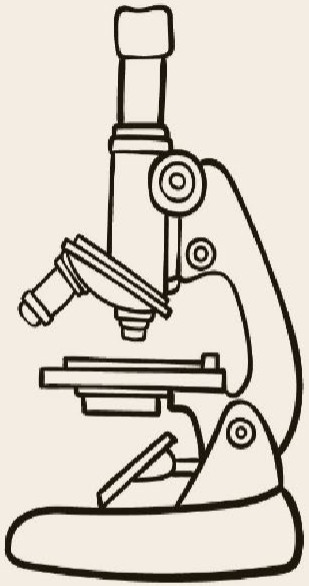
- The key purpose of research SOPs is to help you and your research department stay in compliance with regulations and maintain good clinical practices (GCPs): an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

What SOP may apply?

- Office of Human Subjects Protection SOPs
- Your Research Lab/Department
- FSU ITS
- Funding agencies SOP

Pre IRB Approval

Premise



Research+

Human subject

= IRB review

Best Practices Summary

DO—	DO NOT—
✓ Use and follow the templates; refer to checklists IRB uses	x Underestimate risks or discomforts to participants
✓ Upload materials participants will read, hear, see or complete	x Mislocate study-related materials in RAMP IRB
✓ Complete CITI training [link] & CAMS [link]	x Omit required information, forms or materials
✓ Adhere to external requirements	x Overstate expected benefits
✓ Check IRB schedule, turnaround	x Exceed participants' readability: target ≤ 8th grade

Review Types:

Examples

Not Human Research	Exempt	Non-Committee

• QI, program evaluation
• Class projects
• Case studies
• De-identified information or biospecimens (no linkage)
	• Surveys, benign behavioral interventions: *adults;* non-sensitive; identifiers removed
	• Secondary studies: publicly available; identifiers removed; other protection
		• Minimal risk activities
		  • no FDA IND/IDE
		  • prospective collection of biospecimens
		  • non-invasive procedures sensors (no x-rays, no sedation)
		  • MRI, EEG, EKG
		  • moderate exercise

Otherwise, IRB review at convened monthly meeting

Study Team Members

Ensure proper training is completed:

- **CITI**
  - Human Subjects Research (HSR)
  - Good Clinical Practice (GCP)
    - https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/citi-training-requirements/
- **Bloodborne Pathogens-**
  - https://safety.fsu.edu/sections/biotraining.php
- **Biomedical Waste Training-**
  - https://safety.fsu.edu/sections/biotraining.php
- **Dry ICE-**
  - https://www.facilities.fsu.edu/ehs/sections/trainingonline-dryice.php
- **Hazardous materials DOT/IATA-**
  - https://safety.fsu.edu/safety_manual/Hazardous%20Materials%20Shipping%20Training.pdf
- **Radiation Safety**
  - https://safety.fsu.edu/sections/radsafety.php
- **Study Specific Training** (an ongoing process, not stagnant)
  - Protocol
  - Consenting
  - Debriefing
  - SOPs related to your work flows

FDA Guidance: The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks, and identify the dates of involvement in the study.

ICH E6 Good Clinical Practice: The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

DOA https://files.nccih.nih.gov/s3fs-public/CR_Toolbox/Delegation_of_Authority_Log_ver2_07.17.2015.docx

steps and phases

1. CITI, Conflicts of Interest (COI)
2. Committee, faculty advisor
3. Protocol (RAMP)
4. IRB review/approval
5. Start study!
6. Follow-on actions

if necessary, return to 3

Regulatory/Investigator Binder Basics

- Purpose-
  - A regulatory binder or regulatory file contains all study-specific information and regulatory documentation in a centralized location. It organizes essential documents, provides easy access to essential documents for review/audit purposes, and allows study team members to reference information.
- Responsibility-
  - PI but may delegate management of files to staff
- Where to Store It-
  - digitally vs. hard copy(needs to be in at least one central location)
- How long to retain it-
  - minimum three years after study completion or longer if required by the funder
- Who should have access to it-
  - PI and key personnel
  - Auditors/ Monitors
- Why-
  - Best Practice
  - Required for Audit/ Monitoring Visits
  - ALCOA-C

https://files.nccih.nih.gov/s3fs-public/CR-Toolbox/Regulatory_Binder_Guidance_and_Tabs_ver2_07-17-2015.pdf

Regulatory/Investigator Binder Contents (abbreviated)

Protocol (all approved versions)	Recruitment Materials
Amendments/Modifications	All Correspondences
Informed Consents	Lab Certifications
Approvals	Lab Ranges
Continuing Reviews	Subject Logs
1572s	Enrollments
Curricula Vitae	Screening
SAE Reports	Blank CRF
IND Reports	Notes to File
IRB Membership Lists	Training Records
Subject ID Code Lists	DOA
Investigator Brochures	Pharmaceutical Logs

Post Approval NOW WHAT?!?!?

Post Approval

Modifications:

- Make a change to or revise your study: log into **RAMP IRB** and under the IRB and Help Center tabs refer to the IRB Researcher's Guide on p. 11, then follow the instructions on submitting a Modification.
  - Note the modification scope “Other parts of the study” will allow you to edit any of the original SmartForm sections except for study team member information; if you need to make changes to both study team member information and another section of the SmartForm, then both scopes should be selected. Was your study determined to be exempt from IRB review? If so, then in the official exemption determination letter that you received for this study you will find a list of planned study changes that do not and do require submission for review. Look over these examples to see if your proposed changes will require review. If so or if you are not sure, follow the instructions on p. 11 of the IRB Researcher's Guide to create and submit a modification for this study.
- **Changes to protocol cannot be implemented until they have been reviewed and approved**
- **Immediate hazard to Subject**

Reportable New Information (RNI)

Many incidents (e.g., adverse events, breach of confidentiality, awareness of **abuse/neglect/misconduct**, protocol deviations) require reporting to the IRB within business 5 days from when researchers become aware of the incident. Refer to page 3 on our **HRP-214 - Reportable New Information** form to see what incidents require reporting; refer also to the section, "What are my obligations after IRB approval?" in the **Investigator Manual.**

To submit a Report of New Information: log into **RAMP IRB** and under the IRB and Help Center tabs refer to the **IRB Researcher's Guide** on p. 13, then follow the instructions on creating and submitting a Reportable New Information.

Continuing Review (CR) if required

Some studies (generally those studies that, under the revised federal regulations an IRB has determined fit under one or more categories of expedited studies) no longer require continuing (or annual) IRB review. Those studies are still subject to IRB oversight (for modifications or other reportable incidents), but the previously annual (or more frequent) IRB review is no longer required. When applicable, IRB approval letters no longer indicate a continuing review date, so therefore such studies have no expiration date for IRB approval. When studies do actually end, faculty or other Principal Investigators are required to inform the IRB so that the study may be closed to further IRB oversight and our records updated accordingly.

ClinicalTrials.Gov

- OCRA is FSU's central administrator for **ClinicalTrials.gov** (CT.gov) a web-based resource that provides researchers, healthcare professionals, patients, their family members and the public with easy access to information on federally and non-federally supported clinical studies on a wide range of diseases and conditions in the United States and globally.
- We can advise you on whether your clinical study needs to be registered on the CT.gov website, provide initial account setup and assist with updating and managing your account throughout the life cycle of your study. Clinical trials that involve FDA-regulated medical devices, drugs or biological product for a disease or condition must be registered on CT.gov. In addition, all NIH-funded interventional clinical trials must be registered. Finally, for any clinical trial funded by a federal department or agency, a copy of an IRB-approved consent form must be posted on a publicly available federal website, such as CT.gov or Regulations.gov.
- Why is OCRA's assistance important? The penalty for noncompliance is $13,237 ***with an additional $13,237-per-day fine*** if your study does not come into compliance within 30 days of notification by CT.gov. Also, non-compliance with the consent posting requirement may result in suspension of a study. Moreover, investigators and their universities can face termination of NIH grants as well as jeopardize future grant applications for noncompliance.

Questions

Contact Us

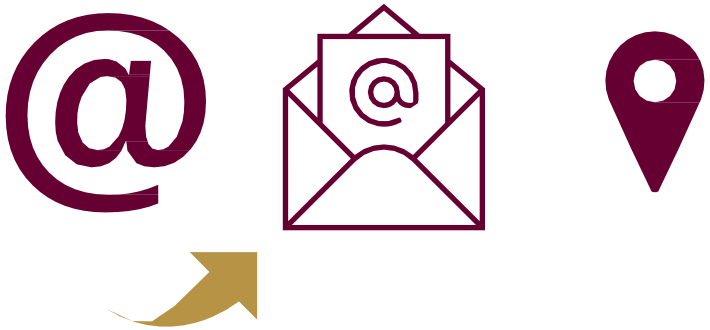
OHSP

Click an icon above to contact or find OHSP.

Or

Virtual IRB office hours, every Wednesday between 10-11 AM ET

OCRA



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For questions about this slide deck:

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