Navigating the IRB Submission Process

Megan Richmond, BS CIP
IRB Analyst II
Program for the Protection of Human Subjects

Icahn School of Medicine at Mount Sinai

Where do we come from?

- What is the Institutional Review Board?
  - IRBs are mandated by the government to review and approve research on human subjects.
  - All IRBs follow the same umbrella of regulations, but each institution also has its own policies in addition to those regulations, so the IRB process varies from institution to institution.

- Examples from history that emphasize the importance of IRBs:
  - Nazi Experiments WWII (1933-1945)
  - Tuskegee Syphilis Study (1932-1972)

What is Research?

- **Systematic** investigation
- Including, research development, testing and evaluation
- **Designed** to develop or contribute to **generalizable** knowledge

What is a Human Subject?

- Obtaining from a **living individual**:
  - Data through **intervention** or **interaction** with the individual;

  OR

  - **Identifiable** private information

QA/QI

- A working group from the Hastings Center define QI as "…**systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings.**"
- Improving the quality of care of patients is a fundamental obligation of healthcare providers.
- Not Research
- May involve "Human Subjects"
- Departmental QA/QI Committee

Case Reports

- A case report is a retrospective analysis of a single case.
- IRB review is not required in most cases.
- For a case report or a case series involving more than one case, the decision as to whether IRB review is required must be made by the PPHS/IRB office.
- PPHS Website > Guidance & Policies > Case reports and case series guidance
- Please email the PPHS/IRB office at irb@mssm.edu with “Case Report/Case Series Information” in the subject line of the email message. Provide the following in your email:
  1. Your name
  2. Your department
  3. Your contact information (email and phone)
  4. Indicate whether your case report activity is a systematic investigation?
  5. Indicate whether your case report activity is designed to contribute to generalizable knowledge?
  6. Are the patients within your case report your own patients? Please specify patient source.
  7. Number of records to be reviewed.

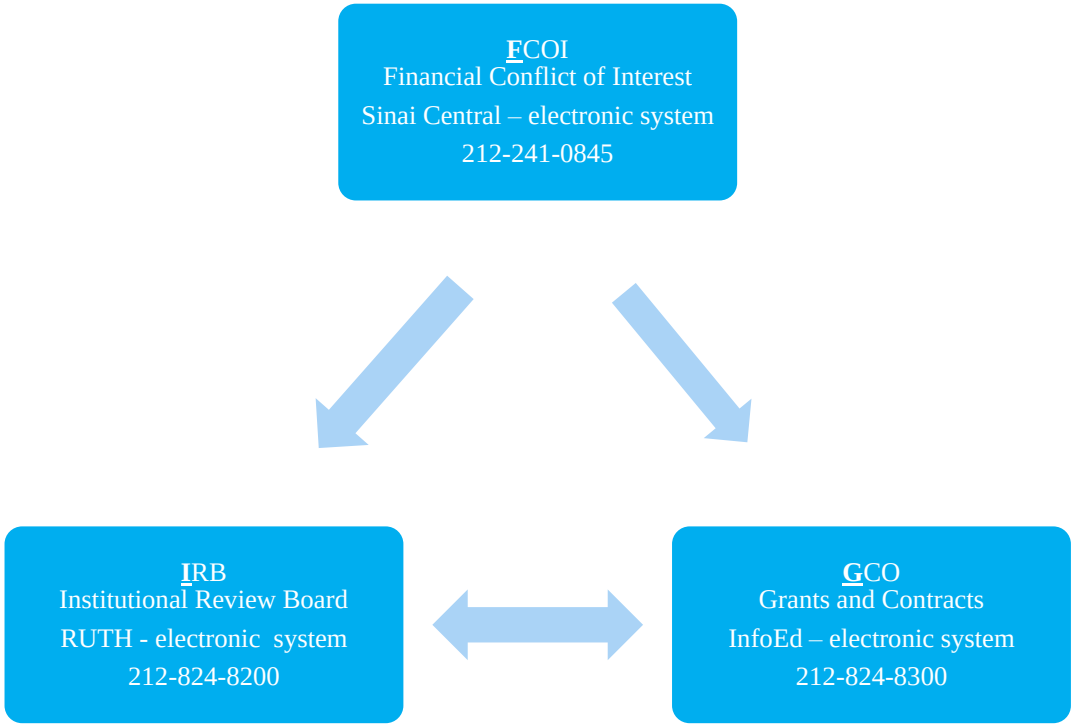
Levels of Review

- **Not Human Subjects Research**
  - minimal risk research determined to not involve human subjects
- **Exempt**
  - minimal risk projects that are exempt from the regulations and administratively reviewed
- **Expedited**
  - minimal risk projects that fall under expedited criteria for approval
- **Full Board**
  - greater than minimal risk projects that require review by the convened IRB

Types of IRB Submissions

- New Study
  - A new proposal that the IRB has not yet reviewed.
- Continuing Review/progress report
  - A request to renew a currently-approved study for another year.
- Modification
  - A request to modify a currently-approved study
- Reportable New Information
  - A report of protocol violations, adverse events, unexpected harms, protocol deviations, or other actions by research team

Submission Process: FIG Triangle



IRB Submission Checklist: New Study

- ❑ All personnel uploaded CV/resume/biosketch to their profile
- ❑ IF# from SinaiCentral
- ❑ All personnel completed FCOI disclosures in IF
- ❑ All personnel completed CITI education requirements
  - ❑ Basic course for Investigators/Research staff (refresher needed every 3 years)
  - ❑ Data Security and HIPAA Training
  - ❑ HIPAA for Research Update
  - ❑ Rigor, Reproducibility and Ethical Behavior in Biomedical Research
- ❑ GCO submission started in InfoEd (except for internally funded studies i.e. funding source = ISMMS)
- ❑ HRP-503 Application Form
- ❑ Protocol
- ❑ Consent forms, if applicable
- ❑ Recruitment materials, if applicable
- ❑ PRMC approval letter for all cancer-related studies
- ❑ Other supporting documents, if applicable
- ❑ Ancillary Review Form in RedCap
- ❑ RUTH smart form

Ancillary Review Form

- Ancillary reviews are done by ancillary offices
- Ancillary offices are other research administration offices that are required to review and approve parts or all of a proposed study.
    - Biosafety
    - Blood Bank
    - Cellular Therapy Services
    - Clinical Research Unit (CRU)
    - Financial Administration of Clinical Trial Services (FACTS)
    - Information Security (InfoSec)
    - Imaging & Radiation Safety
    - Investigational Drug Services
    - Financial Conflict of Interest (FCOI) – must be assigned for ALL submissions
- You are responsible for assigning ancillary reviews in RUTH
- You will complete the ancillary review form in RedCap and attach it to your RUTH submission
- Link to the RedCap form is in RUTH

IRB Submission Checklist: Continuing Review and Modification

Continuing Review

- ❑ IF# from SinaiCentral
- ❑ All personnel completed FCOI disclosures in IF
- ❑ All personnel completed CITI education requirements
- ❑ GCO submission started in InfoEd
- ❑ Assign FCOI ancillary review
- ❑ RUTH smart form for Continuing Review

Modification

- ❑ All personnel uploaded CV/resume/biosketch to their profile, if study team member modification
- ❑ All added personnel completed FCOI disclosures in IF, if study team member modification
- ❑ All add personnel completed CITI education requirements, if study team member modification
- ❑ GCO submission started in InfoEd, if funding modification
- ❑ IF# from SinalCentral, if funding modification
- ❑ Updated documents per modification
- ❑ Assign FCOI ancillary review
- ❑ Updated RUTH smart form

HRP-503 Application and Protocol: What's the Difference?

- You will need to submit both a protocol AND HRP-503 Application

- Protocol: "a carefully designed plan to safeguard the participants' health and answer specific research questions"
  - Mostly scientific, some regulatory context

- HRP-503 Application: How the research will be operationalized/implemented
  - Tell us what will happen, who will do it, to whom, when, how often, how much, where

- Most submissions will require BOTH – exceptions:
  - If your sponsor has provided a protocol, a new one does not need to be created. HRP-503 application supplement still required.
  - HRP-503r: Chart/Specimen reviews
  - HRP-503e: Studies that qualify for exemption

- NIH Protocol Wizard (guide): https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

Informed Consent

- Elements of Informed Consent
  - Statement that study involves research
  - Purpose of the research
  - Duration of subject's participation
  - Description of risks and benefits
  - Disclosure of alternative procedures
  - Provisions to maintain confidentiality
  - Explanation of whom to contact for questions or in the event c
  - Statement that participation is voluntary

- Waiver of Informed Consent must be requested if applicable

- Exempt Research Information Sheet

Workflow: Submission to Approval

- Pre-Submission: Submission created by study team
- Pre-Review: Reviewed by an IRB analyst
- IRB Review: Reviewed by a designated Non-Committee Reviewer or by the full convened IRB
- Post Review: Review completed by the designated Non-Committee Reviewer or full IRB
- Review Complete: Approved/Exempt determination made/NHSR determination made

Electronic Submission System: RUTH

- Ruth.mssm.edu
- What to do:
  - Log in to RUTH (use your Mount Sinai SSO)
  - Upload your CV and check in with your team to make sure everyone has done this
  - Sooner the better to avoid delays!
- RUTH is accessible anywhere with an internet connection
- IT support? Open ticket via help portal
- IRB questions? Contact PPHS office

Questions?

- Ways to contact us:
  - Contact our team @ 212-824-8200 or email irb@mssm.edu
  - Open office hours via Zoom on **Wednesdays, 2-3pm**
  - Clinical Research Forum: every 1st Wednesday of the month
- RUTH-specific help:
  - http://researchroadmap.mssm.edu/reference/systems/ruth/
  - RUTH training sessions
  - RUTH Drop-In sessions