2025

# Lessons Learned: Regulatory Processes & Compliance

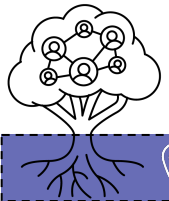
## Research Directors and Chairs

Family Medicine Research

*A National Strategic Plan*

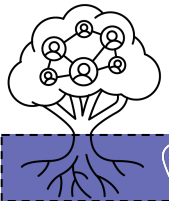
# Overview

- General requirements
- Institutional Review Board (IRB)
- Clinical Trials Office (CTO)
- Office of Sponsored Research (OSR)
- Institutional Requirements
- Grants Management



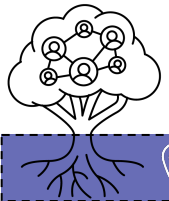
# General Requirements

- Complete required training
  - All personnel involved in project
  - Human Subjects Training – IRB
  - Animal Research Training
- Learn your other institutional requirements
- Ensure faculty, residents, students are familiar with regulatory process and compliance
- Communicate, communicate, communicate
- Monitor faculty compliance



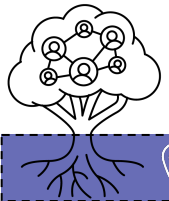
# IRB

- Get to know your IRB
- Find a liaison & build relationship
- Questions to ask 
  - Common pitfalls
  - What are common questions asked of the IRB?
  - Is there a pre-review process?
  - How often does the committee meet?
  - Turnaround time?
  - Are there pet peeves that we should avoid?
  - Can you share examples of successful IRB submissions?



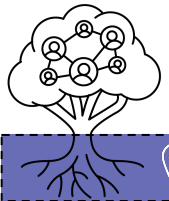
# IRB

- Get training on the IRB submission system
- What are rules around consent?
  - Is there an institutional required consent form / format?
  - Is there universal consent or does each participant need to be consented for each project?
- When is a Data Safety Monitoring Board required?



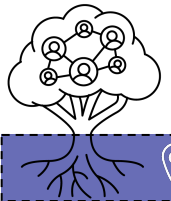
# IRB

- When are protocols considered exempt?
  - What forms have to be submitted for exempt protocols?
  - Publishers often request proof of IRB approval, even for exempt protocols
- Is QI exempt?



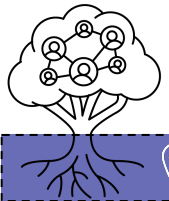
# IRB

- Consider ways to work with IRB to develop alternatives for QI
- Understand when IRB is needed
- Acquire system
  - Used for QI
  - 3-page description to allow IRB to determine not research
- Are there other systems within the IRB to streamline identification projects as QI?
  - Explore whether opt-out system could be used



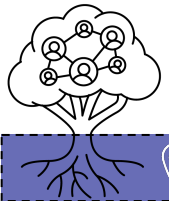
# IRB

- Best Practices:
  - Have research director or assigned staff pre-review IRB submissions before they are submitted
  - Train a research staff or coordinator to be primary resource for IRB application development and submission  (especially for learners)



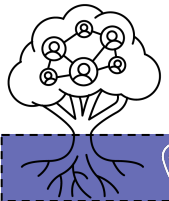
# Clinical Trials Office

- Get to know the Office of Clinical Trials
  - Find a liaison
  - Questions to ask:
    - What support is offered?
    - Who are the experienced clinical coordinators on campus?
    - Is there a pool from which coordinators can be assigned?
    - Do you have to hire your own coordinators?
    - What training is available for them?
    - Is there budget development support?
    - Who is the contracts liaison?



# Office of Sponsored Research

- Get to know the Office of Sponsored Research
- Find a liaison
- Questions to ask 
  - How is the office organized?
  - Where are the institutional policies for responsibilities?
  - Are there separate pre- and post- award staff?
  - How are staff assigned?
  - Is it separate by pre and post award?
  - By funding mechanism?
  - What level of support is offered?
  - What is the department responsible for?
  - Is foundation funding going through OSR or does it go through development?
    - What is the communication between the two?

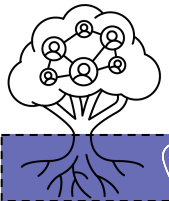


# Institutional Requirements

- Who invites patients to be participants
- Data security
- Determine who “owns” access to data from your clinics
- Supervision of trainees and research coordinators
- How to advocate when problems arise?

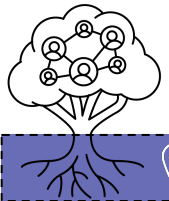
# Grants Management

- Every grant has administrative burden (large & small)
- Understand funder requirements and post award reporting obligations
  - Different funders have different requirements
- Think about how to support mission yet balance burden
- Be sure PIs are qualified & understand
  - PI responsibilities & obligations
  - Supervision of staff
  - Requirements for budget management & reporting
    - Make sure they have data needed



# Grants Management

- Understand funding management
- Understanding funding limitations
  - Know what NIH will and won't fund
  - Cap gap (PCORI is lower than NIH)
  - University requirements for funding (e.g., minimum requirements)
  - Understanding how different financial streams can cover gaps



# Summary

- Learn the universal and institution-specific regulatory and compliance policies
- Faculty and learners need to obtain required training
- Develop relationships with the IRB, CTO, and OSR offices
  - They will make the process smoother
- Learn institutional and funder requirements surrounding grants management