UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

Why your intake form needs to be complete and accurate.

What is the purpose of the ARS IM Regulatory Intake Form?

- Submitting this intake form and the additional sponsor/protocol documents is required for ARS IM Regulatory to begin the study start-up process.
- This form tells us the information we need to:
  - start building your Investigator Site File (regulatory binder)
  - provide the sponsor with required start-up documents
  - complete the correct IRB submissions required to get our site approved and activated

Why is this information so important at start-up?

- Every Regulatory action required for a study is generated utilizing the information provided on this form:
  - 1572 completion
  - UC COIs
  - Financial Disclosure Forms
  - Training
  - Study Delegation Log
  - Staff credentialing check
  - Informed consent edits
  - Sponsor triggered access to study portals/trainings

If this information is incorrect or incomplete, it could substantially slow down site activation. It could also cause our site to be non-compliant if regulatory documents are not accurate.

Review of questions to ask prior to submitting the ARS IM Regulatory Intake Form:

- ✓ What type of study is this?
  - Industry sponsored
  - Federally Funded
  - Investigator Initiated
- ✓ Will UCIRB serve as the IRB of record, or will the sponsor be using a central IRB? If central, who?
- ✓ Who is funding this study?
- ✓ What type of study is this?
  - Drug
  - Chart Review
  - Device
  - Trainee
  - NHSR
  - HUD
- ✓ What facilities will be needed to complete this protocol correctly?
- ✓ Will a local lab be used for safety labs? Will I need to use the IM Division Processing Lab to process/ship my specimens?
- ✓ Will I be using IDS pharmacy?
- ✓ Is there ionizing radiation involved in this protocol? (RSC review is required even if SOC)
- ✓ Is IBC review required for this protocol?
- ✓ Who will be my study team? (Sub-Is, Coordinators, Research Assistants, etc.)
- ✓ Will patients be compensated? If so, based on the schedule of events, what do I want the consent to read in terms of compensation?

It is imperative that PIs review the protocol in detail, and all schedules of events to determine the "who, what, and where" required to complete this study, and have conversations with those to be involved prior to submitting for IRB approval.

If you have any questions, please do not hesitate to reach out to: IMRegulatory@uc.edu

For more information, please click: Tools and Templates

Thank you!