UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES–
ARE YOU REALLY READY FOR AN IRB SUBMISSION?

IM Regulatory Newsletter

In this issue:

- Am I really ready for Regulatory Services?
- Steps to check prior to submitting to IMReg.

Four simple steps to follow before submitting to IMReg for Study Start- up/IRB submission:

1. Review the protocol details.
2. Build your team! Talk to your Sub-I's, Coordinators and Research Assistants. Consider having a pre-start up meeting with key staff to go over the details.
3. Make note of what facilities will be involved. We need to know all locations that will be part of conducting your study.
4. Talk to ancillary services that are necessary in completing all protocol required tasks.
    - Will you be using the UCMC Clinical Lab for safety labs?
    - Will you be using IDS Pharmacy?
    - Will you be using ARS Division Lab Services for shipping/processing?
    - Will radiation services be involved?

Ancillary services need to know **prior** to submitting to us, and likely have their own intake processes that need completed in order to help with your study. Please remember to reach out to them prior to completing your regulatory intake form so that when we add them, they are aware.

Questions to ask before I request services from IM Regulatory:

⇒ Have I reviewed the details of the protocol?

⇒ Have I talked to key staff that I'm going to need to do this study correctly?

⇒ Have I started the internal processes for the required ancillary departments I'm going to need to utilize for this study?

⇒ Can I accurately and completely fill out the IMReg intake form, knowing my start-up documents will be correct and I've provided Regulatory with proper information?

Please Note: Once a study is submitted to IMRegulatory Services to begin work on the Reg. Packet and Sponsor Documents as well as IRB submission, the assumption is that everyone that is listed on the IM Regulatory intake form is on board, conversations have been had and they know to expect that they will be signing regulatory documents, completing trainings, and reviewing / signing the delegation log in Complion.

DID YOU KNOW? The details on our intake form directly affect every piece of Regulatory documentation and processing going forward. ***TIP:*** *It does not speed things up to send it with incorrect information, with intentions of fixing it later. It can significantly slow things down, and cause errors in having solid regulatory documentation.*

If you have any questions, please do not hesitate to reach out to:

IMRegulatory@uc.edu