UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

How do I get IM Regulatory Services involved in my IRB submission and regulatory process? What exactly do they do?

Who can utilize ARS IM Regulatory services?

- ARS IM Regulatory Services is a core regulatory unit for the Department of Internal Medicine. Our services are available to all DOIM faculty/staff to help with the IRB process, creation, and maintenance of Investigator Site Files for research studies.

Are there fees involved for ARS IM Regulatory Services?

- Yes. There are fees associated with our services. FY22 Fee Schedule
- These fees are separate from the IRB fees and Complion binder fees.

What's included in ARS IM Regulatory Services?

- Completion and maintenance of regulatory documentation
- Building and maintaining the Investigator Site File (Complion), including credentialing, delegation logs and training logs.
- Facilitating proper IRB submissions

What is not considered Regulatory?

- Budgeting/Contracting
- Ancillary Service intake processes
- UC Health Approval (EPIC)
- Maintaining patient documentation or any documents containing PHI

What's the process to get IM Regulatory services involved for your new study?

1. Review the protocol and determine:
   - ✓ What facilities will be utilized and who will be part of your study team.
   - ✓ Have conversations with the study team and ancillary areas to make sure they are aware and agree to be a part.
   - ✓ Will a local lab be utilized?
   - ✓ Are there any supplemental reviews required? (IBC/RSC)
   - ✓ Will participants be compensated for their participation? If so when and how much?
2. Once you have all this information, complete the regulatory intake form. Reg Intake Form
3. Attach intake form and all study documents (or reg packet if Industry sponsored) in **one email** and submit to IMRegulatory@uc.edu
4. We will review your request and a regulatory CRP will be assigned.
5. We will work with you each step of the way on getting IRB approval and site initiation from the sponsor (if applicable).

If you need to submit an Investigator Initiated study and are unsure which forms should come to us with your intake form, please refer to Issue 5 of our Newsletter or contact us.

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!