UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

- New Research staff? Let's connect!

- What's needed for a new researcher to be added to my protocol?

What onboarding credentials are needed prior to adding any researcher to a research study?

- ✓ Signed and dated CV. *to be renewed every 2 years. Manual signature and manual date required.*
- ✓ CITI Training – GCP 2017 (required for Industry and NIH grant funded studies) and HSR CORE 2017 (IRB requires for HSR studies)
- ✓ FDA training (if applicable) *PIs and Study coordinators on any FDA regulated research*
- ✓ Medical/Nursing/Pharmaceutical etc. license if applicable
- ✓ UC M# - to initiate registration for a Complion account
- ✓ A one-time writing sample to be stored in Complion
  - After credentials have been collected, the new researcher will be added to the study team in the Complion system. The assigned Reg. CRP will then send out study trainings via Complion. Once training is complete, new researchers can be added to the Delegation Log.
  - Key personnel may also need to be added to RAP as to notify UCIRB of their involvement. COI's may need to be collected through Complion as well.

**Please Note: All staff adds MUST be communicated with your study's assigned Reg. CRP. It is imperative that all of the previous indicated steps are completed prior to the new researcher performing any study tasks.

New Research Staff? Connect them with us!

By connecting us to your new research staff we will be able to….

⇒ set up CITI/FDA trainings.

⇒ register them in Complion.

⇒ and collect credentials so they are ready to work on your protocol!

Our Goal: To maintain current credentials and regulatory documents on all studies, eliminating action items from Audit/Monitoring visits.

*…So! Let us help with onboarding of your new research staff! If you have new staff that will participate in research, there are specific things IMRegulatory needs to collect prior to adding them to a study. **Getting us involved during onboarding can significantly expedite the timeline of getting them active on your protocols!** We will start a credential file for them and to make sure they stay current on their credentialing, we will send reminders to ensure all credential files are*

> Tip: **Hiring new researchers?** Put them in contact with *IMRegulatory@uc.edu* right away, and we will work to get what's needed in terms of regulatory credentialing. This will help you keep your research teams current and compliant! Don't wait to connect with us. Make this part of your onboarding.

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

IMRegulatory@uc.edu