UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

Regulatory Credentialing – what's needed and why?

There are several regulatory credentialing items that must be collected and maintained for all faculty/staff participating in research. Below outlines the most commonly required documents that ARS IM Regulatory collects from all research staff:

CITI TRAINING

***Good Clinical Practice (GCP)* –** This is required by all industry sponsors. All researchers listed on a delegation log must maintain their GCP training for the duration of the study. GCP is required to be completed every 3 years.

***Human Subject Research (HSR)* –** This is required by UCIRB, as well as most industry sponsors. All researchers listed on a delegation log must maintain their HSR training for the duration of the study. HSR is required to be completed every 3 years. ***The IRB will not renew studies if there are staff listed with expired HSR training.*

FDA Training

For studies that require FDA oversight, the UCIRB will require FDA training for PIs, Co-PIs, and Study Coordinators. This is a onetime request and does not need renewed.

Current CV – This is required to be on file for all research staff participating on any research study.

Guidelines for a proper regulatory CV:

1. No personal information should be on your business CV, such as sex, date of birth, place of birth, home address, ethnicity, etc.
2. All pages should be numbered.
3. Your name on your CV should match the name on your license if applicable.
4. Your business address and affiliated addresses need to be listed on your CV. Example, you have a business office located in the MSB, but you are affiliated with UCMC and Holmes Hospital – all three addresses should be listed on your CV.
5. Your current position within the institution should be listed on your CV.
6. The TOP page of your CV must be manually signed and manually dated – not typed.
7. CVs are good for two years from the signed date, at which time they will need updated and resigned/dated.

Writing Sample

A writing sample template will need to be completed and loaded into the eRegulatory system. This document is used for sponsors/auditors to verify handwriting on source documentation. This is a onetime request and does not need renewed.

UC M# - Your UC M# is needed (if applicable) to set up your account in our eRegulatory system to allow you to log in using your UC 6+2 credentials.

IMPORTANT: Check your CITI account and make sure your primary email is your work email address. This will ensure that you receive notifications of expiring trainings required for research.

www.citiprogram.org

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!