REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

I need to close a study. What's the process?

Closing an Industry Sponsored Study

- When our site has completed a study, a Close Out Visit (COV) must occur with the Industry Sponsor before submitting to close at the IRB.
- At the COV, the sponsor will review and verify that all site clinical and regulatory records are in order.
- Sponsor should issue (in writing) notification that our site has the green light to submit to close.
- A submission to the IRB of record for site closure is made. If using a central IRB, once the closure letter is received for our site from the central IRB, a submission is made to UCIRB to also close the study in RAP.
- Complion Investigator Site File (ISF) is archived.
- The PI or delegate must notify UC Health of the study closure so that the study is removed from all active study portals. (EPIC, etc.)

Closing an Investigator Initiated Study (IIS)

NOTE: It is the responsibility of the PI to confirm that all study related activities are complete prior to submitting to close an IIS. **A study must remain open at the IRB if identifiable data is being analyzed.**

The instructions below pertain to all IIS studies being managed by ARS IM Regulatory Services:

- The PI or delegate (with PI in copy) should send an email to the assigned Regulatory CRP (RCRP) stating that their IIS can now be closed.
- The RCRP will then reach out for the information required to submit the closure to the IRB.
- The RCRP will submit the closure to the IRB and provide the PI with the closure notice once received.
- The Complion ISF will be archived.
- The PI or delegate must notify UC Health of the study closure so that they study is removed from all active study portals. (EPIC, etc.)

Once a study is submitted to close, nothing more can be submitted to the IRB, which is why a written approval to close is required.

Studies deemed exempt by the IRB must still be closed out at the IRB.

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!