UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

What forms do I need to submit my investigator-initiated protocol to the IRB for approval?

SO MANY FORMS! WHAT DO I REALLY NEED?

Most commonly, Investigator-Initiated studies require the following forms when being submitted to UCIRB for review and approval:

HRP-503: Template Protocol

- *This form is required when submitting a protocol to the IRB. NOTE: N/A should be marked for sections that do not apply – **do not delete any sections**.*

HRP-502M (most studies) or HRP-502S (students): Consent Templates

- *Will you be consenting participants? The IRB requires that you write your consent utilizing their consent templates.*

Scientific Pre-Review form

- *This form must be completed and signed off by the Division Head or Designee for all studies that are non-exempt medical human research protocols, except those solely involving pre-existing records and/or specimens. **(Not required for chart review studies)***

HRP-209: HIPAA Waiver Request Form

- *Select **Full Waiver** if you will not be consenting patients but need to review patient charts.*
- *Select **Partial Waiver** if you will be consenting patients, but need to review charts for pre-screening.*

What if I think my study may qualify as Non-Human Subject Research (NHSR)…How do I know for sure?

*Your study still needs to be submitted to the IRB to make that determination, however, there is a different form to complete: **HRP-503N***

Two questions to ask: Does the research involve Human Subjects? Is the study considered research?

If both answers are yes, then your study does not qualify as NHSR. You should submit the HRP-503 and subsequent documents.

Human Subject is defined as: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction, or identifiable private information.

Research is defined as: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

Once I get IRB approval, am I finished in terms of Regulatory?

Nope! This is just a start!

At minimum, the following documents need to be maintained for your Investigator-Initiated study:

- Delegation of Authority Log – This is a 'living-document' and must be current at all times
- Training documentation – all protocol versions
- COIs - if the study has any funding
- Informed Consents and protocol - all versions
- Credentials- CV/Medical License/CITI trainings for the lifetime of the study

IM Regulatory and your Regulatory CRPs are here to help! It's what we do!

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

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