UNIVERSITY OF
Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

IRB approval before my CTA is final? How can that happen? And what does it mean?

New Clinical Trial Agreements (CTAs) for Industry funded studies are no longer going through UC Health. They are now going through UC, which means that indemnification is no longer needed.

What does this mean?

➢ **Previously, CTAs were routed through OCR/UC Health. When this was the process, IRBs would hold approval documents until indemnification was confirmed. This step indicated that once we received IRB approval, and our study documents were released, we could assume that the CTA was also final.**

➢ **CTAs are no longer going through OCR/UC Health and indemnification is no longer needed. This means that the IRB is no longer required to hold approval letters and stamped consents until indemnification is received, so approvals could be released prior to CTAs being finalized.**

IRB approval does NOT mean that your CTA is finalized.

Due to this institutional change in processing, please make sure your division has a process in place to verify the following steps have been completed prior to enrolling patients:

❖ CTA and Budget are final and **FULLY EXECUTED**

❖ UC Health Approval has been received

❖ Sponsor has approved Site Activation

ARS IM Regulatory will notify the clinical team when IRB approval has been received and will provide you with the IRB approval letter and study approved documents. It is the clinical team's responsibility to confirm all other milestones have been met prior to starting the study.

In some instances, the CTA could be finalized prior to IRB approval, however, it's more likely that IRB approval will come before the fully executed CTA. Please have a check in place to verify your CTA is complete. *Study activities may not begin until the contract is fully executed.*

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!