

REGULATORY TIPS AND UPDATES— DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

How do I get my UCIRB
Number for my CTA?

UC IRB Number Requirement for Clinical Trial Contract Submissions:

Effective 5/9/2022, a UC IRB number will be required when submitting clinical trial contracts. There are several reasons this identifier is being required when a study is submitted to REDCap. The UC IRB number in REDCap will be used to further strengthen study identification across collaborative teams and will help support the UC IRB in some of their internal processes. The information required to generate a UC IRB number is minimal and the pre-submission information can be edited as more information becomes available.

This change may require minor adjustments to departmental start-up processes. If your team has not historically created UC IRB numbers this early in start-up, please make sure to account for how this will affect other regulatory processes within your department.

I'm not ready to submit for Regulatory Services yet. How do I get my UCIRB number to start my Clinical Trial Contract submission process?

In order to submit to ARS Regulatory Services for study startup, you need to know important study details such as:

- All facilities you will be using
- List of your complete study team
- Compensation language for your consent

If you are not yet ready to submit that level of detail to ARS IM Regulatory, but will be using our Regulatory services in the future on this study, you can still get your UCIRB number to start your CTA submission process by following these steps:

Send an email to Gina Shelton at sheltohn@ucmail.uc.edu with the following information:

- State that you are requesting a UCIRB number for an upcoming study
- Attach protocol and CTA template
- Provide the name of the PI
- Identify which IRB will serve as the IRB of record (external or UCIRB)

Gina will start the RAP submission and generate the UCIRB number. She will provide the UCIRB number to you to start your CTA submission process, as well as communicate the number to the Regulatory CRP once the intake for Regulatory Services is submitted for startup and the study is assigned.

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!