Office of
QUALITY COMPLIANCE
THE UNIVERSITY OF UTAH

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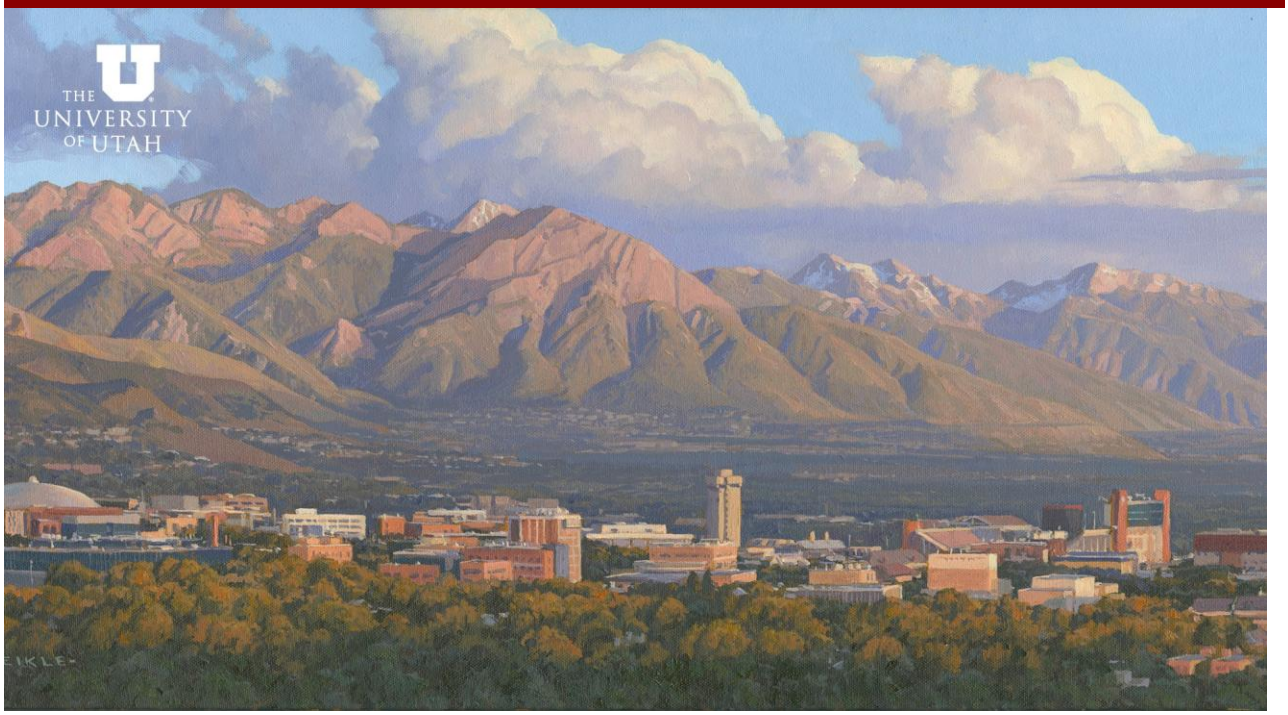
Tip of the Month



Investigational New Drug (IND)

Conducting a clinical trial with an investigational drug as a sponsor-investigator? You may need an IND application under FDA regulations (21 CFR 312.3).

Here's what you need to know:

IND Requirements:

- An IND must be in effect prior to the initiation of a clinical study of an investigational drug.
- Investigational use can mean a product not approved by the FDA for any use, or the use of an approved product in a way that is beyond its approved labeling (e.g., use, route, administration, etc.).
- If a clinical trial is using an investigational drug to gather information about the products safety or efficacy, an IND may be required.

IND Process:

- Once determined an IND is required, a pre-IND meeting can be requested with the FDA.
- Finalized versions of all IND documents MUST be sent to the CRSO IND specialist, **CRSO.FDAsupport@hsc.utah.edu**, for review and approval prior to FDA submission.
- Complete protocol, informed consent and information about the investigational product are required for submission of the IND.
- The FDA has 30 calendar days of receipt of IND submission to review. After 30 days, the sponsor- investigator may begin the study unless the FDA notifies the site otherwise.
- Emergency use and expanded access (compassionate use) IND options are available if urgent access is needed for a patient.

CRSO IND specialist, Jonna Davis can assist Investigators through the process of preparing and submitting IND's. Contact CRSO.FDAsupport@hsc.utah.edu for assistance.