UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

FDA-Regulated Research

October 2020

Research studies that are considered FDA-regulated are required to comply with specific FDA rules and regulations. It is imperative that the PI and study team understand what applies and how to maintain compliance. Is your research FDA-regulated? …Are you sure?

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The US Food and Drug Administration (FDA) regulates clinical studies conducted on drugs, biologics, devices, diagnostics, and in some cases dietary supplements and food additives. All such research studies must be conducted in accordance with FDA requirements governing human subject protection and the conduct of clinical trials, regardless of source of funding.

A common source of confusion related to the FDA regulations is when and how to apply 21 CFR Part 11, which requires that electronic records and signatures must have specific assurances to verify authenticity. With use of electronic systems expanding and increasing needs to collect information and signatures electronically, study teams must understand the applicable regulations and how to maintain compliance with the regulations.

If the answer is yes to any of the below questions, your study is considered FDA-regulated and must be conducted in accordance with the FDA regulations, including 21 CFR Part 11:

- Is your study being conducted under an Investigational New Drug (IND)?
- Does your study fall into an IND-Exempt category?
- Is your study being conducted under an Investigational Device Exemption (IDE)?
- Is your study being conducted under an abbreviated IDE (also known as a non-significant risk (NSR) device)?
- Does your study fall into an IDE-Exempt category?

Additional Considerations:

- Is your study evaluating the safety or effectiveness of a drug or device (e.g. a post-market-approval study investigating a marketed drug or device being used in accordance with approved labeling)?
  Although the drug or device has already been approved and you are using it in accordance with the approvals, this type of study is still considered IND/IDE-exempt and is FDA-regulated.
- Will the study data (even preclinical data) be used to support a future FDA submission (i.e. IND or IDE) or marketing application (NDA, BLA, 510(k), or PMA)?
  If yes, then all data collected in the study must be Part 11 compliant, not just electronic consent and electronic signatures.

Systems that do not comply with Part 11 requirements include Qualtrics and UNC's REDCap. If a vendor or sponsor offers use of a system that is deemed to be Part 11 compliant, additional evaluation and documentation may need to be conducted locally in order to validate the Part 11

compliance before it may be used for FDA-regulated studies. As always, reach out to SOM ITS to review any plans related to electronic systems to ensure compliance.

Seeking new solutions

The CRSO is currently working with SOM ITS and the Office of the Vice Chancellor for Research to obtain and validate DocuSign for use by all study teams at UNC. Once available, this will include a Part 11 compliant module that may be used to obtain signatures for FDA-regulated studies. Updates will be shared as soon as available.

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