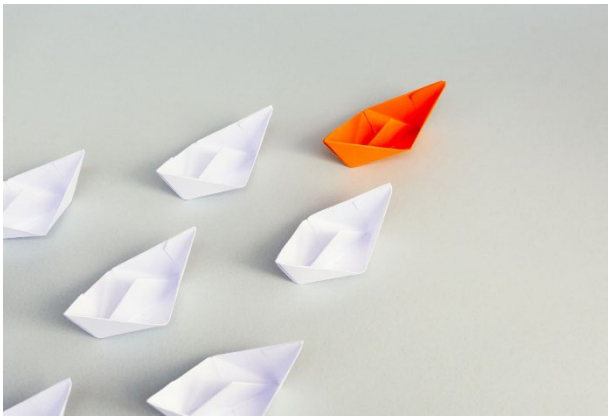
# CRSO Insightalyst

## FDA Informed Consent Guidance

September 1, 2023

### It is here!



The U.S. Food and Drug Administration (FDA) announced in August that it has finalized the guidance document titled "Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors" to promote clarity on procedures and expectations for stakeholders carrying out informed consent in clinical investigations of FDA-regulated products. This guidance takes the place of "A Guide to Informed Consent," issued in September 1998, and finalizes the 2014 draft guidance titled, "Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors." The informed consent guidance does not address future potential changes to FDA's informed consent regulations that may result from the FDA's harmonization efforts with the 2018 Common Rule.

### Structure

The updated 61-page informed consent guidance includes the following sections:

- A summary of the consent process
- Informed consent requirements and discussion
- Roles and responsibilities of IRBs, investigators, sponsors, and the FDA
- Frequently asked questions

## Highlighted Updates

- Reorganized to first present general guidance on FDA's regulatory requirements for informed consent and roles and responsibilities of stakeholders engaged in the informed consent, followed by a series of frequently asked questions, including newly documented information related to:
  - considerations for enrolling children, including children who are wards of the state;
  - considerations for enrolling participants with limited English proficiency; low literacy and numeracy, physical or sensory disabilities, and impaired consent capacity;
  - who can serve as a legally authorized representative (LAR);
  - obtaining informed consent through electronic means; and
  - whether subjects should be informed of aggregate study results at the conclusion of trials.
- New references and links, and editorial edits to improve clarity.
- Dedicated sections for investigators and sponsors (applicable to sponsor-investigators) about their roles and responsibilities in informed consent are included.
- Emphasis on the informed consent process; informed consent is more than obtaining the participant's or LAR's signatures. It involves facilitating the prospective participant's understanding of the relevant clinical investigation information, providing adequate opportunity for the prospective participant to ask questions and consider whether to participate, obtaining the prospective participant's voluntary agreement to participate, and continuing to provide information as the clinical investigation progresses or as needed.
- Detailed discussion of the concept of coercion and undue influence.
- Clarification regarding "understandable language." The information given to a prospective or consented participant or LAR must be presented in a language and at a level they can comprehend.

## More Information

If you have questions about the information presented in this issue of the *Insightalyst*, please contact the CRSO at crso@med.unc.edu.