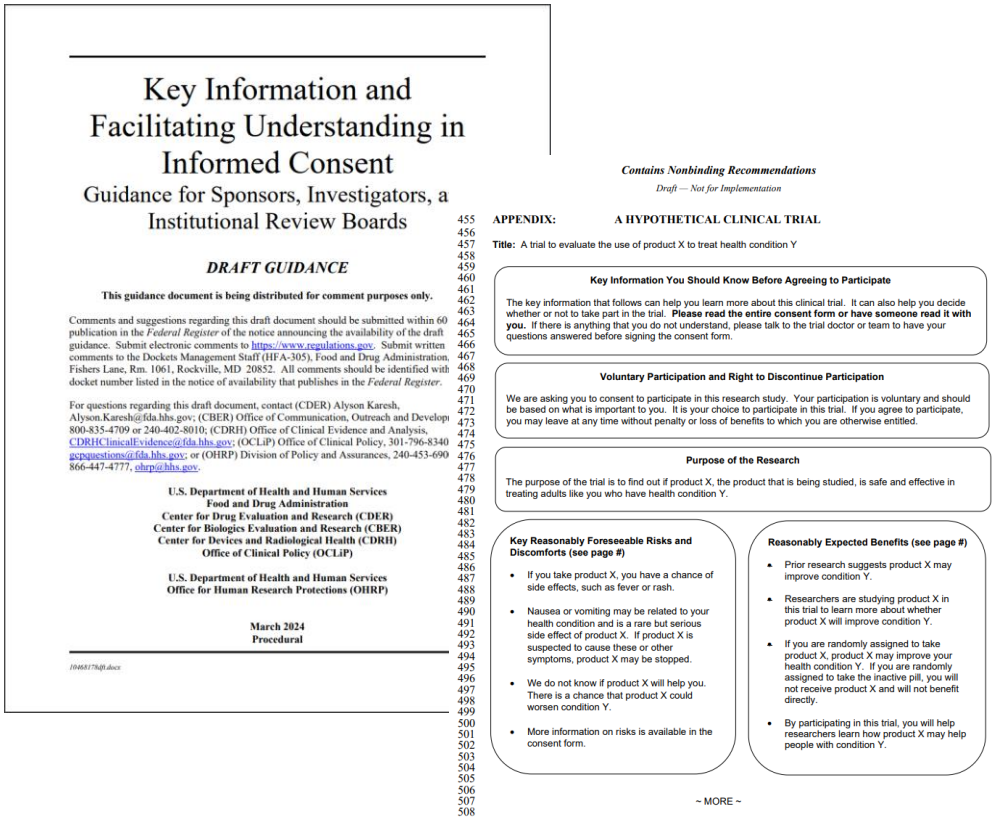
Ongoing / New Business and Announcements

NIH NATIONAL CANCER INSTITUTE

CTAC March 13, 2024

Recent FDA and OHRP Draft Guidance on Informed Consent



Key Information and Facilitating Understanding in Informed Consent

Guidance for Sponsors, Investigators, a Institutional Review Boards

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Alyson Karesh, Alyson.Karesh@fda.hhs.gov; (CBER) Office of Communication, Outreach and Develop 800-835-4709 or 240-402-8010; (CDRH) Office of Clinical Evidence and Analysis, CDRHClinicalEvidence@fda.hhs.gov; (OCLiP) Office of Clinical Policy, 301-796-8340 gcpquestions@fda.hhs.gov; or (OHRP) Division of Policy and Assurances, 240-453-690 866-447-4777, ohrp@hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Clinical Policy (OCLiP)

U.S. Department of Health and Human Services
Office for Human Research Protections (OHRP)

March 2024
Procedural

104681178dft.docx

Contains Nonbinding Recommendations

Draft — Not for Implementation

APPENDIX: A HYPOTHETICAL CLINICAL TRIAL

Title: A trial to evaluate the use of product X to treat health condition Y

Key Information You Should Know Before Agreeing to Participate

The key information that follows can help you learn more about this clinical trial. It can also help you decide whether or not to take part in the trial. **Please read the entire consent form or have someone read it with you.** If there is anything that you do not understand, please talk to the trial doctor or team to have your questions answered before signing the consent form.

Voluntary Participation and Right to Discontinue Participation

We are asking you to consent to participate in this research study. Your participation is voluntary and should be based on what is important to you. It is your choice to participate in this trial. If you agree to participate, you may leave at any time without penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

The purpose of the trial is to find out if product X, the product that is being studied, is safe and effective in treating adults like you who have health condition Y.

Key Reasonably Foreseeable Risks and Discomforts (see page #)

- If you take product X, you have a chance of side effects, such as fever or rash.
- Nausea or vomiting may be related to your health condition and is a rare but serious side effect of product X. If product X is suspected to cause these or other symptoms, product X may be stopped.
- We do not know if product X will help you. There is a chance that product X could worsen condition Y.
- More information on risks is available in the consent form.

Reasonably Expected Benefits (see page #)

- Prior research suggests product X may improve condition Y.
- Researchers are studying product X in this trial to learn more about whether product X will improve condition Y.
- If you are randomly assigned to take product X, product X may improve your health condition Y. If you are randomly assigned to take the inactive pill, you will not receive product X and will not benefit directly.
- By participating in this trial, you will help researchers learn how product X may help people with condition Y.

~ MORE ~

- Addresses the provisions of the revised Common Rule that require informed consent **begin with key information** that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research

- Submit comments by **April 30, 2024**

https://www.fda.gov/media/176663/download

NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE)

- Increase Veteran participation in NCI's National Clinical Trials Network (NCTN) and NCI's Community Oncology Research Program (NCORP) studies;
- Enable a sustained, long-term capability for participating in NCI clinical trials after the initial NAVIGATE support; and
- Establish the operation and organization of a national consortium of VA sites focused on improving VA participation in NCTN and NCORP studies.

To provide lasting efficiencies and effectively overcome barriers in conducting of cancer clinical trials within the VA healthcare system through a national coordinated effort supported by VA and NCI leadership.

NAVIGATE Sites (16) and Coordinating Center

Future CTAC Meeting Dates

- Wednesday, July 17, 2024
- Wednesday, November 6, 2024
- Wednesday, March 12, 2025
- Wednesday, July 16, 2025
- Wednesday, November 19, 2025

Thank You

cancer.gov

cancer.gov/espanol