U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Virtual

FDA DISCUSSION QUESTIONS

October 30, 2024

Improving informed consent practices may increase the likelihood that patients clearly understand informed consent materials, including the key information and all other aspects of the informed consent for clinical studies, before they or their family members decide to participate.

1) Informed consent forms and the discussions that occur with the health care provider prior to signing the form contain various key elements, including the purpose of the study, risks and benefits of participation, and the steps that will occur at the end of the study.

    a. What do you believe are important elements (sections) to include in the key information of the informed consent form?

2) How could the contents of the key information be presented to help you decide whether to participate in a clinical study? Please consider the following in your response and how they factor into your decision about whether to participate in a clinical study:

        i. Order in which information of the clinical study is presented

        ii. Accessibility of the informed consent form (i.e., language, literacy, considerations for physical or cognitive differences, etc.)

        iii. Other health equity and cultural considerations

3) Considering informed consent should be accessible and effective for all potential participants, what do you believe are the most effective approaches to providing information in the informed consent form and through the overall informed consent process?

    a. How can informed consents be tailored to meet the needs of all populations, including:

        i. Diverse racial, ethnic, socioeconomic, gender and sexual orientation populations

        ii. Underserved populations

        iii. The full spectrum of age groups (i.e., children and elderly)

        iv. Individuals with physical or cognitive differences

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b. How can technology (i.e., video, multi-media, computer-based techniques) be leveraged in the development of informed consent materials and process for a clinical study? What are important areas to consider in implementing electronic/digital consent in clinical studies?

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