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

Guiding Principles for Virtual Breakout Sessions to Discuss Hypothetical Scenario

October 30, 2024

1. Participation in the breakout session is completely voluntary.

2. Participants in the breakout session cannot ask questions of one another but can comment on the questions or prompts included in the scenario and on the comments provided by other participants. FDA moderators and notetakers will interrupt you if you question one another. This restriction is a requirement of the Federal Advisory Committee Act.

3. FDA moderators will guide the discussion but will not be providing comments or feedback. They will also not be acting in their role as FDA staff members but solely as moderators to ensure that your voice is captured.

4. Participants in the breakout session should mute their phone if they are not speaking.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
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PEAC Informed Consent SCENARIO

Please note that this is a hypothetical scenario and is not describing a real medical product or patient situation. We are asking that you imagine yourself in the scenarios below as you answer the questions.

You have been recently diagnosed with a chronic heart condition and while on the internet, you come across an advertisement looking for participants to test a new implantable device in a clinical study. You decide to speak with your cardiologist about this clinical study and the possibility of you being a part of it.

Your cardiologist is familiar with the study and encourages you to learn more about it from the clinical study team. You reach out to the study team to let them know you are interested. The study team gives you an appointment time to come to the clinic. They mail you a 50-page informed consent document for you to review, sign and bring with you to the first visit to the study site. Overwhelmed and nervous with the length of the informed consent document, you want to reach out to someone that can help you with understanding this document.

1) **Who do you think should be the main point of contact to educate you on the informed consent of a clinical study?**

2) **What information would be most important for you to see in the informed consent document?**

3) **What specific format(s) would you prefer informed consent information be provided to you for better understanding?**

While going through the informed consent form with the clinical study investigators, you are told that many aspects of long-term medical care and device maintenance following your completion of the clinical study would be your responsibility to obtain or pay for, with limited support from the study investigators. You are concerned about the personal long-term obligations with limited support that may come after the completion of the study despite the benefits that might come from participating in this clinical study.

4) **What type of information about the long-term (i.e., post-study) personal responsibilities of a clinical study do you think should be included in an informed consent document, to inform your decision of whether to participate in a clinical study?**

5) **What concerns do you have about the personal responsibilities you will incur following the completion of this study?**
    a. **Do these concerns influence your decision on whether to participate in a clinical study? Please explain.**

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