U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Center for Devices and Radiological Health

Patient Engagement Advisory Committee (PEAC) Meeting
Brief Summary on the topic Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products
October 30, 2024

Introduction

On October 30, 2024, the FDA's Patient Engagement Advisory Committee, or PEAC, met virtually to discuss and provide advice on the topic of patient-centered informed consent in clinical study of FDA-regulated medical products. According to Dr. Rita Roy, Temporary Voting Chairperson for this meeting, informed consent is a key element in clinical studies, and it can be one of a patient's first interactions with the clinical context.

Dr. Roy proceeded to call the agenda, and each of the Committee members and FDA experts identified in the meeting roster introduced themselves.

After the introductions, Dr. Robert M. Califf, FDA's Commissioner, provided a video with his welcoming remarks. He emphasized the importance of voluntary clinical study participants in advancing scientific knowledge and developing beneficial medical products, as these individuals provide the most relevant high-quality evidence. He highlighted three main points: the need for research on effective consent methods, better use of ClinicalTrials.gov, and more discussion on the risks in routine care when the best intervention is unknown. Dr. Califf concluded by stressing the importance of involving participants, patients, and caregivers in refining informed consent processes, aligning with the PEAC meeting's goal.

The Designated Federal Officer, Letise Williams, then read the Conflict of Interest Statement, and stated that all members and consultants of the Committee are subject to federal conflict of interest laws and regulations, and that the FDA has determined that all of them are in compliance with such laws. No conflict-of-interest waivers have been issued.

Once the Conflict of Interest Statement ended, Dr. Roy gave a brief overview of the meeting, and introduced Dr. Michelle Tarver, Director of the Center for Devices and Radiological Health, who made the welcoming remarks. She provided some background information regarding accomplishments previous PEAC meetings had and introduced the topic of today's meeting.

Informed Consent (IC) & Key Information: An Overview

Dr. Jose Pablo Morales, Senior Medical Advisor in the FDA Office of Clinical Policy, outlined four main objectives regarding informed consent: defining it, describing FDA regulations, presenting FDA guidance on informed and electronic consent (eConsent), and explaining key information guidance. He discussed FDA regulations divided into three sections—general provisions, requirements, and safeguards for children—plus the investigator's responsibility to obtain consent and IRB's role in approving consent materials. Dr. Morales highlighted eConsent's benefits over paper consent, and he also referenced guidance developed with the U.S. Department of Health & Human Services (HHS) Office for Human Research Protection (OHRP) to assist study participants. Despite FDA recommendations, he noted that consent documents are often complex and legalistic, and the FDA is exploring ways to improve and innovate the consent process in partnership with research participants, researchers and other clinical trials and clinical practice communities.

Industry Perspective

Ms. Allison Anderson, Associate Director of Clinical Trials at Boston Scientific, shared the industry's perspective on improving informed consent. She outlined key elements for consent documents—study purpose, trial specifics, testing needs, risks, and alternatives—while addressing the challenges of creating clear, concise consent documents, especially for global trials with diverse regulatory requirements. Ms. Anderson emphasized the importance of making documents patient-centric through simplified language, images, and tables, as well as involving patient advisors and adding IRB-approved resources like brochures and videos. She highlighted the need for transparency in communicating any additional study requirements that may go beyond standard care in order to minimize the burden on participants. She also mentioned the shift toward eConsent, accelerated by the COVID-19 pandemic, to improve accessibility and convenience, fostering a more patient-centered consent experience.

Academia Perspective

Dr. Nancy Kass, Phoebe R. Berman Professor of Bioethics and Public Health at Johns Hopkins University, presented the academic perspective on informed consent, noting that while FDA and federal regulations require IRB approval and voluntary consent, current practices often fail to align with evidence on effective consent methods. She pointed out that consent forms have become overly lengthy and complex, making them difficult for participants to understand. Research supports simpler, interactive formats, yet these are rarely implemented. Dr. Kass recommended using concise language, visuals, bullet points, interactive formats, and question-based sections, along with "corrected feedback" to enhance clarity. She mentioned that federal policies have made steps toward improvement. However, further action is needed to promote the

implementation of these practices. She concluded by posing three questions: Should guidance on simpler approaches be more widely disseminated? Should simpler approaches be mandated rather than suggested? Should there be stronger advocacy from patients or other groups to promote these improvements?

Health Care Provider Perspective

Dr. Neal Dickert, Cardiologist and Associate Professor at Emory University presented the healthcare provider perspective on improving informed consent, particularly in acute care settings, where patients often face stress, pain, and time constraints. Despite these challenges, most patients still wanted to be involved in research decisions. Dr. Dickert's team collaborated with patients and surrogates to develop a more patient-centered consent approach. Feedback emphasized that consent forms should be realistic, context-specific, and free from excessive generic information. Patients preferred documents that began with relevant study information, used plain language, and clearly addressed potential benefits, risks, and uncertainties. This revised approach was successfully applied in studies on bleeding and ischemic stroke, with patients feeling more respected and comfortable with the information provided. Dr. Dickert's team faced challenges working across multiple IRBs, but achieved meaningful, patient-driven changes when collaborating with a single IRB. Dr. Dickert highlighted that patient-centered consent processes can enhance trust, respect, and understanding, even in urgent care situations, and that these insights are broadly applicable across healthcare settings.

Patient Perspective

Dr. Greg Merritt, Founder of Patient is Partner, LLC, shared the patient's perspective on improving informed consent for low-income and rural communities, drawing from his own experiences and the barriers these populations face. He observed major gaps in care access and clinical trial participation for rural and underserved individuals. He noted that people with annual incomes under $50,000 are 32% less likely to join clinical trials, worsening healthcare inequalities. Dr. Merritt suggested that AI and digital tools—such as personalized prompts, videos, podcasts, and visual aids—could make informed consent more accessible, especially for those with limited healthcare literacy. He emphasized creating materials that resonate on a personal level, as traditional medical language often alienates those unfamiliar with it. He also proposed involving trusted community members to improve understanding and trust and recommended engaging low-income patients as co-designers to make consent truly inclusive. He concluded by posing questions on bridging the gap in clinical trial access for rural and low-income individuals, effectively involving community members in the consent process, and using technology to support a more inclusive approach.

Open Committee Discussion

After the presentations, Dr. Roy opened the Open Committee Discussion and allowed time for participants in the meeting to ask clarifying questions.

Mr. David White asked Dr. Morales about "exculpatory language," which Dr. Morales explained as language in informed consent that suggests patients give up their rights, privileges, and autonomy.

Dr. Elizabeth Joniak-Grant asked Dr. Kass about best practices for addressing data storage risks with patients. Dr. Kass explained that while data storage concerns may not be top of mind for patients, transparency is key, emphasizing broader themes like controlled data access and comparing data sharing in research to clinical care.

Ms. Necie Edwards asked Dr. Merritt about ensuring AI in informed consent is inclusive and properly trained. She also asked Dr. Kass about the demographics of her research participants, particularly in relation to African Americans. Dr. Merritt acknowledged his lack of expertise in AI but highlighted its potential to personalize and clarify consent, stressing the importance of addressing biases early in the process. Dr. Kass replied that this particular study included a significant number of African Americans and noted that issues in understanding often relate to how information is communicated, underscoring the need for clarity in the consent process.

Dr. Camille Nebeker asked Drs. Kass and Dickert how to improve consent practices despite the lack of incentives. Dr. Dickert noted that while there are often disincentives, sponsors can help by encouraging patient input in recruitment and consent materials, budgeting for feedback, and addressing concerns like privacy protections. He emphasized that with ongoing effort, consent processes can improve over time.

Dr. Adam Berger asked for thoughts on including post-trial information in informed consents, especially for implantable devices, to help participants understand long-term implications. Dr. Kass responded that post-trial details, particularly for devices left in the body, could be considered key information by patients, guiding what should be in consent forms. Dr. Dickert agreed, adding that some information is crucial at the outset, while other details are more relevant over time. Dr. Merritt highlighted the potential to build post-trial communities among participants, rather than ending all connections once the trial concludes. Dr. Roy concluded with a reminder on the importance of UX design and budgeting for multimedia consent materials to make information clearer and more accessible for patients.

Virtual Breakout Summations

The PEAC reconvened to present summaries from Breakout Rooms, where each group addressed scenario questions related to informed consent in clinical studies. FDA moderators facilitated discussions, and each room focused on a specific question, providing insights into preferences and concerns related to patient-centered consent practices.

The Breakout Rooms provided feedback on specific aspects of informed consent as follows:

1. Main Point of Contact

   Moderators Dr. Anita Bajaj (Room 1) and Dr. Caroline Moazzam (Room 6) shared that participants emphasized the importance of a designated, accessible contact within the study team who could provide information in plain language, considering both literacy and language needs. Groups suggested contact details be included in the consent document, proposing a helpline and interpreter options if needed. While some participants preferred consulting their physicians, like cardiologists, many noted the practicality of an informed study team representative as a knowledgeable alternative. Participants valued in-person discussions with trained representatives skilled at conveying complex information in accessible language.

   Other rooms added that a research coordinator or peer navigator might better address patient needs, while some recommended a trusted source like a patient advocacy group for more technical studies. Some preferred to consult with their primary care physician, leveraging their established relationship and knowledge of their medical history.

2. Critical Content in Informed Consent Documents

   Moderators Dr. Jacqueline Burgette (Room 2) and Dr. Zach McKinney (Room 7) reported that participants identified risk-benefit details and participation obligations as crucial. They wanted reassurance that devices met safety standards, detailing benefits and potential risks, and clarity on commitments like study duration, follow-ups, financial responsibilities, and support options. They also valued transparency on the study's purpose, sponsorship, data use, and any post-study responsibilities, especially if the device remains unapproved. Participants stressed concise, easy-to-understand information to overcome comprehension barriers posed by lengthy documents.

   Additional comments from other moderators indicated a preference for a detailed, step-by-step consent review, especially for risk and benefit comparisons. Participants also sought clarity on long-term obligations like device maintenance and potential adverse effects.

3. Preferred Consent Formats

Dr. David Gebben (Room 3) and Ms. Ann Meeker-O'Connell (Room 8) noted that participants preferred simplified consent formats, favoring concise, bulleted formats over lengthy text, with video supplements for flexibility. Visual aids such as illustrations, animations, and hyperlinks were seen as useful, especially for those with visual impairments, and interactive sessions like Zoom were suggested for real-time discussions. Accessible language, particularly for non-native English speakers, was also emphasized.

Other moderators suggested standardized formats for consistency across studies, recommending prompts to guide questions and minimize reliance on paper formats.

4. Post-Study Personal Responsibilities

Ms. Tracy Gray (Room 4) and Ms. Lexie Perreras (Room 9) emphasized participant concerns about long-term responsibilities post-study, such as financial burdens, device support, and follow-up needs. Participants wanted clear information on out-of-pocket costs, insurance coverage, and who to contact for device issues, especially if the company was unavailable. Long-term data handling, such as privacy and insurance implications, was also a concern.

Additional input from other rooms included requests for insurance pre-certification, clarity on medical responsibility for device removal, and acknowledgment of mental health impacts of study participation.

5. Long-Term Responsibilities and Their Impact on Participation

Drs. Cynthia Grossman (Room 5) and Caiyan Zhang (Room 10) highlighted that the main concerns about long-term responsibilities after a clinical study include device maintenance, potential surgeries, insurance coverage, and follow-up care. They emphasized the need for clear information in the informed consent about financial obligations, adverse events, and ongoing data collection. Participants also wanted to know if they would be informed about new findings or data breaches, and whether devices might need to be replaced if interoperability becomes possible.

Other rooms underscored the importance of long-term data on device safety, effectiveness, and data privacy. Providing clear information on potential medical scenarios, including device maintenance and long-term monitoring, was deemed critical for participants' decision-making.

During the clarifying questions segment, moderators highlighted several key points: concerns about insurance coverage and specific expenses that might be partially covered; a lack of consensus on who should be the primary point of contact, with preferences for either study

coordinators or participants' physicians; and the need for concise yet comprehensive consent documents. Moderators also discussed data protection, noting that while some groups mentioned data security and patient data rights, only a few explicitly raised data breach protocols. Finally, they acknowledged a preference for various consent formats, including shorter documents supplemented by visual aids.

Open Public Hearing

In the Open Public Hearing, patient advocates and specialists shared pre-recorded and live perspectives on improving informed consent in clinical trials to make the process more patient-centered and accessible.

- Mary McGowan, CEO of the Foundation for Sarcoidosis Research, highlighted the need for transparency and patient understanding in informed consent. She emphasized that patients, especially Black patients, need early discussions, community support, and visuals or hands-on device demonstrations to feel confident in clinical trial participation. Additionally, she advocated for patient access to trial data for personal healthcare.

- Richie Kahn, Co-Founder of Canary Advisors, and a rare disease patient, noted that consent documents are often too lengthy and filled with jargon, making them hard to understand. He recommended customizable electronic consent forms, with options like screen-reader compatibility and sign language interpreters, to support diverse patient needs. He argued that accessible, well-designed consent forms help participants make informed decisions.

- Jackie Miller, a rare disease patient, shared her personal journey and challenges with managing an undiagnosed condition. She highlighted the high cost and time burden of navigating healthcare and the need for rare disease patients to have flexibility in treatment approaches. She advocated for legislative support to ease medication access and remove barriers in managed care, which would reduce stress and improve patient outcomes.

- Dr. Jennifer Collinger shared insights from her work on a brain-computer interface (BCI) study, where informed consent is crucial due to the complexity and risk of device implantation. Her team uses a step-by-step process involving pre-consent visits, device demos, and caregiver involvement to ensure patients fully understand the commitment. This approach allows participants to experience the study setup and clarify expectations before formally consenting.

- Madris Kinard, MBA and CEO of Device Events discussed medical devices in relation to the importance of including them in informed consent, and the potential risks after the trial is over. She touched upon the concept of "going concern."
- Laura Lytle, from the National Center for Health Research, shared insights into the importance of strengthening patient informed consent by using short checklists, visual and oral components and the order of relevance of key information about benefits and risks.
- Tess Robertson-Neel, from the National Center for Health Research and the Patient Consumer and Public Health Coalition, spoke on the necessity of improvement of true informed consent and of simple and to-the-point information for the patients to avoid long technical documents.
- David R. Curry, President & CEO of GE2P2 Global Foundation, expressed his thoughts on the weaknesses in the consent process and the measurements, the role of assent in young people without legal standing or cognitive functions and the consent of patient stored data in future research.

Open Committee Discussion/ Clarifying Questions Session

Committee members asked questions to the Open Public Hearing speakers. Questions included the following topics:

- The complete understanding of participants of the benefits and procedures

  Dr. Collinger explained how they carry out the process of explaining the benefits and procedures to patients. By repeated discussions with multiple members of the team, they invite family members or care partners to participate, and the patient, once enrolled, meets the clinicians and psychologists to discuss the changes and expectations.

- The most challenging aspect of implementing informed consent with patients

  According to Mr. Kahn, the most challenging aspect is changing how informed consent is thought in general, as it is considered a tick box instead of an opportunity. He explained that it is actually a process of building a meaningful relation and rapport between the coordinator and the potential participant.

  Ms. McGowan agreed with Mr. Kahn about building trust early in the process and she also added that it is a great opportunity to give clarity and support to patients as for them it could be a complex and new process.

- Data management processes and technologies

Ms. McGowan explained that at the Cleveland Clinic patients were able to have the opportunity to hold in their hands defibrillators that had been implanted in them and how that occasion was an emotional experience for them. She concluded by talking about the importance of explaining the medical device to patients in the process.

Dr. Berger reflected on what is the key information that will be shown in the consent form to facilitate data access, how the information will be conveyed, and what is the minimum amount of information people want to see regarding the concept of data access.

- Measuring comprehension in informed consent

  Mr. Curry highlighted the need for better tools to measure comprehension in the informed consent process. He pointed out that, although there are many strategies to help people understand consent information, there's still no reliable way to measure how well they actually understand it. He emphasized the importance of more precise measurement methods to ensure participants are fully informed, as required by regulations. This, he noted, would help make sure people are responsibly and accurately consenting to participate in clinical trials.

- Assent vs. consent for younger patients

  Mr. Curry explained that the legal standing of a young person to consent is triggered by age, and the age at which a person can consent varies from state to state and globally. He emphasized the need to involve younger patients who may understand enough to assent, even if they cannot legally consent. He suggested using accessible materials, like graphics or videos, to help them grasp complex information. Ignoring their ability to assent or refuse, he noted, is particularly concerning in critical areas like gene therapy.

- Final comments

  Ms. Miller expressed gratitude for the committee's openness and willingness to listen, sharing how meaningful it was for her as a patient with a rare disease to feel heard and valued. She emphasized the importance of being seen as a human and highlighted how the discussions provided her with new insights and hope for managing her own care.

Committee Discussion of FDA's Questions

Members of the Committee are asked to respond to three FDA's questions related to informed consent practices. Question 1 concerns how to improve informed consent practices by

analyzing the key elements that should be included in an informed consent form. Question 2 focuses on the order in which key information should be presented, as well as how to ensure the accessibility of the informed consent form. Finally, Question 3 addresses how to make the informed consent process accessible and effective for all potential participants to meet the needs of all diverse populations.

The Committee's answers to these questions include, but are not limited to the following points:

- Marrying the comprehensive nature of the information to the need for clarity and simplicity.
- Acknowledging legal requirements and standardization issues while addressing the individualized needs of patients.
- Explaining post-trial obligations and requirements and providing clear information about the long-term management of any devices or treatments.
- Recognizing the importance of ongoing dialogue and discussion in the informed consent process.
- Building an interactive or dynamic informed consent that allows customization based on individual needs.
- Considering timing and location and allowing for flexibility depending on when and where informed consent can occur.
- Using simple and clear language, as well as various formats, to explain the research, its voluntary nature, and the risks and benefits, which is also crucial for ensuring health and patient equity.
- Ensuring accessibility for all populations, including people with disabilities, rural populations and people from diverse cultural and age backgrounds.
- Making sure data management practices are clear and well communicated.

Closing Remarks and Adjournment

The importance of participation and discussion among participants is highlighted and mutual gratitude is expressed for everybody's contributions as part of the Patient Engagement Advisory Committee. The meeting is then officially adjourned.

FDA U.S. FOOD & DRUG ADMINISTRATION

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I approve the minutes of the meeting as recorded in this summary.

Rita T. Roy, MD
Temporary Voting Chair

I certify that I attended this meeting on October 30, 2024
and that these minutes accurately
reflect what transpired.

Letise W. Williams -S Digitally signed by Letise W. Williams -S
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