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FDA Patient Engagement Advisory Committee Meeting

October 30, 2024

"Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products"

FDA PEAC Meeting Context *[excerpts from PEAC Meeting Notice]*

…On October 30, 2024, the Committee will discuss and make recommendations on "Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products." The individuals who volunteer to participate in clinical research play an integral role in advancing scientific knowledge and supporting the development of potentially life-saving therapies for patients in need.

Informed consent is a key element in clinical studies and can be one of a patient's first interactions with the clinical community. Too often, however, informed consent forms are lengthy and difficult for potential research participants to understand. FDA has worked to improve informed consent over the years, including several recent activities such as developing a draft guidance in identifying key information in informed consent.

The Committee will provide recommendations on the informed consent process and the areas of focus of the informed consent. The Committee will also provide recommendations on factors to consider when communicating informed consent to clinical study participants to increase the likelihood of participants understanding the key elements of research….

Public Comment by David R Curry, President, GE2P2 Global Foundation

[as delivered during Public Comment period of FDA PEAC Meeting of 30 October 2024]

Good afternoon. I am David R Curry, President of the GE2P2 Global Foundation, a nonprofit founded in 2016 to advance scientific rigor, ethical resilience, and integrity in research.

Our public comment today proceeds from ongoing work in the Foundation's Center for Informed Consent Integrity [see the link at bottom of slide].

We will focus on three areas which we believe to be extremely important but which did not receive adequate focus in the Executive Summary document posted for this meeting, and were not focused on during the excellent presentations this morning and the rich virtual session reports we just heard.

These three areas are:

:: IC comprehension – measurement and mitigation
:: assent, and
:: secondary or downstream research utilizing stored patient data or biospecimens.

First: Comprehension

While the Executive Summary document uses the term "comprehension" some 14 times, it does not acknowledge or address some key, critical weaknesses in consent processes overall.

Unfortunately the academic literature confirms that we [the global community] do not have tested, effective strategies, tools or techniques to meaningfully or consistently measure comprehension of informed consent information.

Rather, we have a number of measurement models that are in various stages of evolution – such as the "teach back approach" referenced by Dr. Morales this morning – but none, in our view, are near "gold standard."

Equally, the global community has not yet articulated what *thresholds* of comprehension would confirm that truly informed consent has been meaningfully and effectively given – whether a consent form has been signed or not.

Finally, we do not have specific, validated strategies to *mitigate* deficits in IC comprehension. Such strategies would ideally enable a potential patient/participant to improve their comprehension to levels allowing their responsible enrollment in a clinical trial.

The Advisory Committee might consider recommending that FDA focus appropriate resources to study consent comprehension, its measurement and mitigation strategies – all to advance patient-centered consent overall.

Second, Assent

We believe that consideration of patient-centered consent must also address assent – empowering younger persons who do not have legal standing to fully consent, as well as persons who may have transitory challenges in cognitive function [such as from injury] or who may experience other cognitive challenges across the life course.

Meaningful assent involves all the issues around comprehension we noted a few moments ago, but also involves complexities around parental, guardian and caregiver roles, and the right to refuse participation even if consented to by others.

Assent is often overlooked or given inadequate focus in discussions around consent. Indeed, we note that this meeting's Executive Summary document does not use the term "assent" even once. **We also note that across the six presentations made this morning, assent was not mentioned at all.**

The Advisory Committee might consider recommending that FDA focus appropriate resources to fully articulate how assent can play its full role as a dimension of patient-centered consent.

Third, Secondary or Downstream Research

There is a rapidly growing body of clinical research which utilizes patient data and/or biospecimens originally captured during an earlier clinical trial. Such research can occur well after the original trial and focus on questions which may or may not be directly related to the questions in the original trial.

Also, such research is able to consider new kinds of scientific questions, enabled by growing biobanks and data repositories of patient information, and driven by new tools such as generative AI.

The consent/assent issues here involve ensuring that sufficiently precise information about known or potential future use of a patient's data or biospecimens is clearly addressed in the original consent interaction, or by additional consenting at future points.

Such information should address what rights a patient can exercise – if any – to selectively modify or withdraw consent depending on the "new" research – its focus, the research organizations involved, the sponsor, or other parameters.

Finally, we note an important emerging theme in global clinical research ethics guidance involving non-clinical forms of "benefit" – such as intellectual property or non-trial-related compensation -- which might depend on outcomes of such future/secondary research utilizing a patient's data/biospecimen.

This complex issue receives only a single sentence in the Executive Summary, and was not addressed this morning.

The Advisory Committee might consider recommending that FDA focus appropriate resources to develop a robust and nuanced draft guidance on consent and assent around data and biospecimens use in secondary/future research.

These three areas -- comprehension, assent, and consent for using data or biospecimens in future research – deserve much additional focus.

I appreciate your attention…Thank you.

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"Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products"

Public Comment Summary

Three areas needing focus and investment:

- **IC comprehension measurement/mitigation**
- **Assent**
- **Secondary/future research involving stored patient data and/or biospecimens**

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