From: Michael Keherly
To: Williams, Letise
Subject: [EXTERNAL] Written comments PEAC 2024
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Dear Letise,

I would like to ask the FDA a very specific question regarding informed consent, or actually non-consent, and wanted to know if it is something that might be discussed during the PEAC 2024 meeting or not.

Question:

Would the FDA consider the scenarios listed below to be compliant to 21 CFR Part 50, if a clinical trial subject checked "No" to the use of their samples for research purposes in the informed consent form?

1. Use of the sample for internal proficiency testing to monitor the performance of the assay per CAP/CLIA?
2. Use of the sample for incurred sample reanalysis per ICH M10?
3. Use of the sample for additional method validation purposes, e.g., incurred sample stability, method transfer, etc.?
4. Use of the sample for validation purposes to obtain FDA approval of an LDT as an in vitro diagnostic?
5. Use of the sample to develop additional biomarker or bioanalytical methods as a positive or negative control?

If the answer to any of the scenarios listed above is noncompliance to 21 CFR Part 50, would the FDA consider these activities to be compliant if the samples were first deidentified and/or pooled to protect subject privacy?

Thank you,

Michael

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