From: OC GCP Questions
To: [redacted]
Subject: Data for Statistical analysis_ before Informed Consent
Date: Friday, February 21, 2020 10:24:54 AM
Attachments: [redacted]

Good morning–

Thank you for your email. Please see FDA's guidance on informed consent. https://www.fda.gov/media/88915/download Generally data collected prior to the subject signing the informed consent should not be used. However, "statistical analysis" is a broad phase. We recommend that you consult the FDA review division for advice related to your question and your Phase 1-IV studies.

See below for additional information.

Signing the ICF is not considered part of screening procedures. Obtaining informed consent that is documented by the subject's signature is a stand-alone process that generally occurs prior to initiation of any study-related interventions, with a few exceptions. You may find FDA's information sheet guidance, "Screening Tests Prior to Study Enrollment" useful. It can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/screening-tests-prior-study-enrollment .

As noted in the above guidance, "…informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out)."

Whether a new consent is required for a "roll-over study" should be outlined in the protocol and decided by the reviewing IRB. Every study is different so we can only comment in broad terms. Please consult the protocol and your reviewing IRB.

Kind regards,

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Office of Clinical Policy and Programs
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U.S. Food and Drug Administration

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]

Sent: Friday, February 21, 2020 7:54 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Data for Statistical analysis_ before Informed Consent

Dear all,

1. Is there a formal guideline indicating data prior to informed consent date should be excluded from statistical analysis of Phase I -IV studies?
2. What does the regulation/guidelines say for a roll over study, since patients already provided informed consent in the parent study.
   They should provide informed consent again for the roll-over study, but what if this is only done 2 weeks after roll-over date?

Kind regards,

[redacted]