From: OC GCP Questions
To: [redacted]
Subject: Question for IND exempt trial PI
Date: Tuesday, June 05, 2018 7:50:00 AM
Attachments: [redacted]

Good morning –

It appears your interpretation is accurate. If the study is IND exempt from the 312 regulations, you still have to follow parts 50 and 56 and 312.7. Therefore, the 1572 form is not required.

The regulations in Title 21 Code of Federal Regulations (21 CFR), § 312.2(b)(1) provide for the exemption of some studies for some drugs from IND regulations if the studies meet the following five criteria:

1. The study is not intended to support FDA approval of a new indication or a significant change in the product labeling.

2. The study is not intended to support a significant change in the advertising for the product.

3. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product. 4. The study is conducted in compliance with institutional review board (IRB) and informed consent regulations set forth in parts 56 and 50 (21 CFR parts 56 and 50).

5. The study is conducted in compliance with § 312.7 (promotion and charging for investigational drugs).

See, for example, "Guidance for Industry: IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer" (January 2004), page 2, at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071717.pdf

The sponsor (or sponsor-investigator of an individual investigator-initiated study) should be able to determine whether the IND regulations apply to a planned clinical investigation as required under 21 CFR 312.2(a). If a sponsor is uncertain, FDA recommends that the sponsor contact the appropriate review division (i.e., for the therapeutic area being studied) in the appropriate center for advice about whether the IND regulations apply (21 CFR 312.2(e)). For products regulated by CDER, an inquiry concerning the application of the IND regulations should be directed to the Chief, Project Management Staff, in the appropriate CDER review division. (See "Guidance for Industry: Investigational New Drug Applications (INDs)-Determining Whether Human Research Studies Can Be Conducted Without an IND", October 2010, at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind

or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, June 04, 2018 3:09 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; [redacted]
Subject: Question for IND exempt trial PI

To whom it may concern,

I am writing as the Director of a small IST cancer group. My office is listed as the CRO and sponsor representative for the PI on our trials. We manage phase I and II IST cancer trials and are a central coordinating office, overseeing the trials at our local member hospitals who implement the trials and treat the patients. My office's responsibilities are inclusive of the following: initial protocol concept writing, creation of CRFs and databases, data querying, review of data for deviations, reporting of SAEs, amendment creation, data repository, overall study maintenance and publication (this is a short list of all responsibilities).

I have what I think is a quick question about IND exempt investigator initiated trials: If the PI of an IND exempt trial is transitioned (there is a new PI), please could you confirm that formal notification does not need to be sent to the FDA given the study is exempt and the change in PI does not effect the risk/benefit ratio, the content of the trial, the outcomes etc. Internally at my office, we handle the change of a PI (sponsor-investigator), by way of generating a protocol amendment, updating the 1572 and obtaining all internal approvals as necessary. I just wanted to confirm, with IND exempt trials, that notification does not also need to go to the FDA, as this has not been something I understood was a requirement.

Thank you
[redacted]

[redacted]

[redacted]

[redacted]