From: OC GCP Questions
To: [redacted]]
Subject: RE: IND and IDE validation question.
Date: Thursday, February 06, 2014 2:40:00 PM

FDA regulations do not have a requirement that the IRB verify the IND or IDE number associated with a protocol under review. Although not a regulatory requirement, FDA's guidance "IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed" (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm366335.htm) recommends the following:

> "When reviewing a proposed study, IRBs should ask the clinical investigator whether the sponsor determined that an IND is or is not required and the basis for the determination. If the sponsor has determined that an IND is not required, the IRB may request that the investigator provide a copy of any available supporting documentation (e.g., letter from the sponsor or FDA, other basis for that determination)."

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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Office of Good Clinical Practice
Food and Drug Administration

From: [REDACTED]
Sent: Thursday, February 06, 2014 1:57 PM
To: OC GCP Questions
Subject: IND and IDE validation question.

Good afternoon,

My question is in reference to the IRB responsibilities to review and approval protocols being conducted under an externally sponsored IND or IDE application.

I am reviewing our IRB policies. I need to determine if there is an actual reference (FDA regulation or correspondence) to the process ~ the IRB Research Review to determine whether the IND or IDE number provided by the investigator is valid.

Our policy and many other IRB organization's policy describe the following "validation of the IND or IDE" process as:

Validation can be done by determining that the IND or IDE number provided on the application submission to the IRB matches the IND or IDE number specified in: the corresponding sponsor's protocol; communication from the sponsor, or; communication from the FDA.

Is the above an acceptable process to validate the IND or IDE number?

If you can help with my question or suggest someone who can? Thank you in advance for your time and help.

[REDACTED]