From: OC GCP Questions
To: [redacted]
Subject: RE: IRB review of IND exempt studies
Date: Wednesday, May 27, 2015 1:43:00 PM

Good afternoon,

This topic is discussed in FDA's guidance document entitled "IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed." As noted in the guidance, 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. If during its initial review of a study, the IRB questions whether an IND is required, but is unable to resolve this issue, the IRB should follow its procedures for resolving controverted issues.

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Saturday, May 23, 2015 8:14 AM
To: OC GCP Questions
Subject: IRB review of IND exempt studies

Dear Office of GCP:

FDA's 2004 guidance "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer" discusses when IND submissions to the FDA are unnecessary, and notes that the individual investigator should usually be able to determine the applicability of the exemption.

As such, when IRB receives the study submission for initial review, is it necessary for the IRB to require investigators to include a point-by-point justification addressing how each criterion in § 312.2(b)(1)(i-v) is met? Or, is it appropriate for an investigator to simply indicate that they have determined that the study is IND exempt in accordance with §

312.2(b)(1) and then the IRB can examine the parts of the protocol and application materials that concern dose, schedule, route of administration, and patient population and determine whether the study is exempt? If enough information is provided within the investigator's protocol, it is not clear whether the IRB should require a point-by-point justification of the applicability of exemption as well.

Sincerely,

[redacted]