From: OC GCP Questions
To: [redacted]
Subject: RE: FDA"s views on Protocol documents required IRB submission
Date: Thursday, May 01, 2014 10:27:00 AM

Dear Ms.[redacted]

FDA's regulations in 21 CFR part 56 (Institutional Review Boards) do not specify what documents related to a study an IRB must review during initial review. We also do not have specific FDA guidance but there is guidance in the ICH GCP guidance document (E6 at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf) which has been adopted as official FDA guidance.

In section 3, ICH E6 discusses IRBs/IECs. Under section 3.1.2 it states:

The IRB/IEC should obtain the following documents:

Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may require to fulfil its responsibilities.

We would interpret the highlighted wording to mean that it is up to the IRB to obtain whatever documents they believe are necessary to conduct a complete and adequate review of a clinical study. If the appendices you reference are an actual part of the study protocol, we would agree it is essential to collect the entire protocol. If, however, you mean by "appendices" any supplement information about a study, whether or not it is officially part of the protocol, then the decision as to what to request is up to your IRB. FDA's IRB regulations are purposely general in many aspects, to allow an IRB to conduct review and oversight in a manner that is best suited to the given institution. FDA expects to see specifics as to how your IRB conducts business in your standard operating procedures (SOPs), which would include your IRB's policies.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

From: [redacted]
Sent: Tuesday, April 29, 2014 8:45 PM
To: OC GCP Questions
Subject: FDA's views on Protocol documents required IRB submission

Please provide feedback on what is reasonable to require for initial review. We have always required a "full protocol" to be submitted. To us this means the protocol and any appendices (case report forms, patient diaries, advertisements, etc.) in the case of IDE this also includes instructions for use . I have a new clinical investigators office extremely upset that we are requiring case report forms, and other appendices. We were also told that [redacted] or the larger university IRB in our area do not require them to be submitted. Are we asking for too much?

Regardless, our policies state "full protocol" to include the protocol with appendices so we will require them to be submitted.

You feedback is appreciated.

Best regards,
[redacted]