From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: IRB review of studies requiring an IND
Date: Monday, June 15, 2015 11:12:00 AM

Dear [redacted],

The IRB review and IND submission can be done in any order or even simultaneously. The critical thing is that the sponsor-investigator may not begin the study (e.g., screen or recruit subjects, secure informed consent) until the IND is in effect. See 312.20(b) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.20 and 312.40 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.40 .

It is recommended that the IRB approval letter indicate that the study requires submission of an IND to FDA prior to initiation of the study, per 21 CFR 312.40. The IRB may also choose to approve the study "with conditions", with the condition being that the IND is submitted to FDA and active before beginning the study.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Thursday, June 11, 2015 11:37 PM
To: OC GCP Questions
Subject: IRB review of studies requiring an IND

Dear Office of GCP:
For studies that are not IND exempt, is it appropriate for an IRB to review and approve a new study without conditions if the IND application has not yet been submitted to the FDA by the sponsor-investigator (and there is no IND number yet) provided that the research meets the criteria for approval?
Thank you,
[redacted]