**From:** Brown, Sheila (OGCP)
**To:** [redacted]
**Cc:** [redacted]
**Subject:** RE: Questions re CIRBs
**Date:** Thursday, July 02, 2015 10:00:00 AM

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Hi [redacted],

Question (1) should we "Approve" or "Acknowledge" CIRB documents (i.e. global protocols, ICFs, etc.) ?
Assuming [redacted] IRB has ceded responsibility for oversight of the entire study to a central IRB (e.g., NCI's central IRB) in writing, you may acknowledge any documents forwarded to you that have been approved by the CIRB. Please note that there is no regulatory requirement for you to either approve or acknowledge these documents when authority for review has been ceded.

If only partial oversight is ceded, the agreement should clearly specify which IRB is responsible for which aspects of the review, e.g., the independent central IRB (CIRB) will be responsible for initial and continuing review, while [redacted] IRB is responsible for review of the informed consent document and process. In this example, [redacted] IRB would be responsible for reviewing and approving the ICF/process, while the CIRB would be responsible for reviewing and approving the initial study and CR documents. Both IRBs should have copies of all documents involved with the study.

If there are any local issues (e.g., economic, religious) that may be a factor in a decision to approve or disapprove the study, [redacted] IRB should notify the CIRB of the issue(s).

Question (2) should we Stamp said documents ?
There is no regulatory requirement for [redacted] IRB to provide a date or approval stamp for any documents that have been approved by the CIRB.
FDA has a guidance document titled, "Guidance for Industry - Using a Centralized IRB Review Process in Multicenter Clinical Trials" that may be helpful. It can be found at www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf.

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



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**From:** [redacted]
**Sent:** Wednesday, July 01, 2015 11:35 AM
**To:** OC GCP Questions
**Cc:** [redacted]
**Subject:** Questions re CIRBs

Hi there,

Please allow me to introduce myself. My name is [redacted] and I am currently working with the [redacted] IRB.
Question (1) should we "Approve" or "Acknowledge" CIRB documents (i.e. global protocols, ICFs, etc.) ?
Question (2) should we Stamp said documents ?

Any feedback you can provide would be greatly appreciated. Thank you.
Warmest regards,
[redacted]