

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** RE: IRB involvement  
**Date:** Wednesday, December 03, 2014 10:24:00 AM  
**Attachments:** [REDACTED]

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Dear [Redacted]-

Thank you for your question. We are not able to answer your specific question because we are not familiar with your institutional set up, or other institutional agreements or arrangements you have. Whether or not your IRB needs to be involved may be dependent on such agreements and arrangements and is a decision you need to discuss internally to determine. I suggest you talk to the appropriate institutional officials at your institution to determine what, if any, involvement of your IRB may be necessary.

I'm sorry I couldn't be more helpful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, [gcp.questions@fda.hhs.gov](mailto: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.

Best Regards,

Janet

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [Redacted]  
**Sent:** Monday, December 01, 2014 2:43 PM  
**To:** OC GCP Questions  
**Subject:** IRB involvement  
**Importance:** High

Hello!

A study proposal came our way from a campus that has a full board IRB. The campus decided to keep their study internally, which means no other PI's involvement outside of their campus.

My IRB question: When the campus receives approval from their IRB, they would like to submit to the breast cancer support groups in ~~ONYUMXQ~~ a contact information for anyone who would be interested in participating in this study. The contact information will be from their Campus/PI/Student, NOT from our hospital. Do we (our IRB) need to be involved in this? I heard the contact information will be in an area for the individual to view, if interested.

I would greatly appreciate it if you will be able to reply to my question as soon as possible. If our IRB needs to be involved it will need to be submitted for IRB meeting in Dec. I would like to thank you in advance!!

Sincerely,

~~ONYUMXQ~~