From: OC GCP Questions
To: [redacted]
Subject: RE: Recruitment Website for Multi-Center Clinical Trial
Date: Wednesday, September 16, 2015 10:43:00 AM

Dear [redacted],
This response pertains to both your questions:

Per 21 CFR 56.109(a), "[a]n IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations". This authority applies to methods and materials used to recruit subjects; for example, the IRB could require that individuals who contact the site about the study be told if the information they provide will be stored, for how long, where, how confidentiality of the information will be maintained, expectations as to how the information may be used in the future (if at all), etc.

Since your study uses multiple IRBs, the changes should not be made until all of the IRBs have approved them. One, or more, IRB(s) may want to modify the proposed changes; if this situation occurs, all of the IRBs should approve the modifications prior to implementing the approved changes. If the changes were made after the approval of only one IRB, it would, in effect, allow the changes to be made without obtaining approval from the remaining IRBs.

You may also want to review FDA's Information Sheet Guidance on "Recruiting Study Subjects," which is available at the following link:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm .
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: Monday, September 14, 2015 12:00 PM
To: OC GCP Questions
Subject: Recruitment Website for Multi-Center Clinical Trial

I was hoping to get some guidance on the use of recruitment websites in multi-center clinical trials.

When a trial has a website that is used for recruitment and at some point during the study, the content is amended requiring additional IRB approval, when can the changes be made to website?

Would the approval by one IRB be sufficient to make the change to the website or would we have to wait until all of the study sites had IRB approval of the change before the changes could be made to the live website?

Thanks for any guidance on this.

[redacted]