From: OC GCP Questions
To: [redacted]
Subject: Group counselling for the Informed Consent Process
Date: Tuesday, August 18, 2020 10:54:00 AM
Attachments: [redacted]

Good morning –

Thank you for your inquiry. FDA regulations do not prohibit group counselling meetings. Even if potential subjects attend such a meeting, we would nevertheless expect the informed consent process to remain intact--that is, each subject should have an opportunity for one on one discussions so that subjects could ask their own questions and obtain answers, and all elements of informed consent could be addressed. If such meetings are planned and held, FDA would expect the meeting host to take appropriate steps to minimize the potential for group coercion or pressure.

As for IRB involvement in the process, as we have said in our Information Sheet Guidance on "Recruiting Study Subjects" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects)

FDA requires that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent document and, for studies conducted under the Investigational New Drug (IND) regulations, the investigator's brochure are examples of documents that the IRB should review. The IRB should also review the methods and material that investigators propose to use to recruit subjects.

Thus, because this may be considered a recruitment activity, we would expect the IRB to review the methods and materials that will be used at the group counselling meetings. The IRB might even want to observe "...the consent process and the research..." per 21 CFR 56.109(f), to ensure that subjects' rights and welfare are protected.

FDA does not have guidance that specifically addresses group counselling of study subjects. However, please see FDA's guidance on IRB Written Procedures - https://www.fda.gov/media/99271/download

Kind regards,

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From: [redacted]
Sent: Tuesday, August 18, 2020 7:14 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Group counselling for the Informed Consent Process

Hello FDA GCP,

Regarding Clinical trials, I will like to know if group counselling during the informed consent process is possible. Which are the requirements to do it? Is there an available Guideline for this specific kind of consent? Is there a maximum number of participants? This part of the informed consent should be documented by each patient or the process can be described through an SOP?

I appreciate your help.

Have a nice day.

[redacted]