From: OC GCP Questions
To: [redacted]
Cc: OC GCP Questions; Nelson, Robert "Skip"
Subject: RE: Thanks and futher question on your recent post to IRB Forum
Date: Tuesday, May 12, 2015 10:50:11 AM

Dear [redacted],
Dr. Nelson asked the Office of Good Clinical Practice to respond to your inquiry. Responses are in orange, below each question.

1) Just to confirm the point, do you mean that the investigational use of a product or device that is exempt from the IND or IDE regulations would still require an IRB to review such use under 21 CFR 50, 56?

Investigational use of a product that is exempt from the IND or IDE regulations may need to comply with 21 CFR 50 and 56. FDA has guidance titled "*Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors – Frequently Asked Question About Medical Devices*", which can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf. Question #12 addresses what type of device studies the IDE regulations cover. Question #13 of this guidance addresses whether IDE exempt studies are subject to the requirements for informed consent and IRB review and approval under parts 50 and 56:

> ***13. Are IDE exempt studies subject to the requirements for informed consent and IRB review and approval under Parts 50 and 56?***
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> *If an exempt study is being conducted to collect data to support either a clinical investigation or a marketing application, then the study must comply with 21 CFR Part 50 and should comply with 21 CFR Part 56. 21 CFR 50.1(a), 21 CFR 50.20, 21 CFR 56.101(a), 21 CFR 56.103.*

IND exemption information can be found at 21 CFR 312.2(b)(iv)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2

2) Can the investigational use of a device that FDA has classified as needing only general controls (Class I) qualify for exemption under the provisions of 812.2(c)? The reason I ask is because I don't believe that Class I devices require FDA review of labeling.

A class I device may be exempt from the IDE regulations in 21 CFR 812 if the device is used according to its labeling, but the study may require informed consent and IRB approval if it meets the criteria identified in Q1.

3) A study randomizes subjects who are at risk for a disease to four interventions [redacted] or a control group that receives no [redacted] intervention. One of the four [redacted] interventions uses a FDA Class I device. The study is done to determine if the [redacted] intervention will prevent the disease for which they are at risk.

   Would that be an investigational use of a device that is regulated by FDA and require review under 21 CFR 50, 56? Since the study may not be able to tease out the effect of the device intervention from the other [redacted] interventions does it meet the criterion for a clinical investigation of a device to determine safety and effectiveness?

It is difficult to tell from this limited information if the study requires review under 21 CFR 50 and 56, or possibly under 812 as well. If you would like to have FDA review the protocol and make a formal determination, please ask the study sponsor to submit a study risk determination per the instructions on pp 20-21 in the guidance, *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff*, which can be found at

http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf . The submission should be sent to CDRH at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

For questions about device trials or for questions about the pre-submission process, you may also contact Soma Kalb, Ph.D., Director of the IDE Program, at soma.kalb@fda.hhs.gov .

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: Friday, May 08, 2015 06:50 AM
To: Nelson, Robert 'Skip'
Subject: Thanks and futher question on your recent post to IRB Forum

Dr. Nelson,

First of all thank you very much for clarifying on IRB Forum that the investigational use of a product or device that is exempt from the IND or IDE regulations is not exempt from regulation by FDA. I would be most grateful if I can impose upon you for a bit more clarification of an IRB's responsibility for FDA-regulated devices.

1) Just to confirm the point, do you mean that the investigational use of a product or device that is exempt from the IND or IDE regulations would still require an IRB to review such use under 21 CFR 50, 56?

2) Can the investigational use of a device that FDA has classified as needing only general controls (Class I) qualify for exemption under the provisions of 812.2(c)? The reason I ask is because I don't believe that Class I devices require FDA review of labeling.

3) A study randomizes subjects who are at risk for a disease to four interventions [redacted] or a control group that receives no [redacted]. One of the four [redacted] interventions uses a FDA Class I device. The study is done to determine if the [redacted] intervention will prevent the disease for which they are at risk.

   Would that be an investigational use of a device that is regulated by FDA and require review under 21 CFR 50, 56? Since the study may not be able to tease out the effect of the device intervention from the other [redacted] interventions does it meet the criterion for a clinical investigation

of a device to determine safety and effectiveness?

Thank you very much for considering my questions.

Sincerely,

[redacted]