From:	Brown, Sheila (OGCP)
To:	[redacted]
Cc:	Kalb, Soma
Subject:	FDA requirements for retrospective-prospective research studies
Date:	Wednesday, October 21, 2015 11:35:00 AM

Dear [redacted],
It is difficult to determine whether or not your study falls under FDA's regulations (21 CFR Parts 812, 50 and 56) the HHS regulations (45 CFR 46), or both sets of regulations, from the information provided.

I recommend that you submit a pre-submission to FDA for 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

If you have general questions about clinical trials, feel free to contact me or the Good Clinical Practice mailbox at gcp.questions@fda.hhs.gov .

For questions about device trials or for any 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 . She is copied on this email.

I hope this information is helpful to you.

Best regards,

Sheila

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From [redacted]
Sent: Wednesday, October 21, 2015 10:28 AM
To: OC GCP Questions
Subject: FDA requirements for retrospective-prospective research studies

Good afternoon,
I am in the early process of planning an observational study evaluating treatment for ώϲŜŘI·ÕǘŜŘϐ.
Preliminary study design includes retrospective data collection before training and potentially prospective data collection 3-6 months after training completion. Planned sites are in the US.
There is no randomization and treatment selection will be at the discretion of ώϲŜŘI·ǑǘŜŘϐ.
As there is a prospective component to the data collection does this study require FDA 45 CFR Part 46 or other FDA approval/compliance and are we required to obtain Informed Consent from the patients?
Thank you in advance for your assistance.
Warm regards,

[redacted]