

From: Toth-Allen, Jean
Sent: Monday, March 17, 2014 3:29 PM
To: [REDACTED]
Subject: RE: follow-up question from SoCRA workshop in Newport Beach
[REDACTED]

Glad you found the workshop useful. It has been my privilege to be a part of it over the years, starting with the first workshop SoCRA put together when I was in CDRH's BIMO.

The requirement for a local IRB for device studies is in the Federal Food, Drug and Cosmetic Act (the Act) in section 360j at (g)(3)(A)(i). If you google the Act and go to the pdf version (360j is at <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec360j.pdf>), it is found on page 265. It is not clear why this did not get transferred into the regulations (part 812) but it may just be that almost all IRBs were local at the time of the finalization of 812 so no one thought about it. Not sure why the Act specifies "local" either!

Hope this is useful. While you are welcome to send questions to FDA staff with whom you are familiar, consider sending questions regarding human subject protection (HSP) and good clinical practice (GCP) to our official GCP mailbox, gcp.questions@fda.hhs.gov. This box is sorted each day and a response therefore does not depend on the availability of one individual. 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.

Sincerely yours,

Jean

Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

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.

From: OYXUM/XQ
Sent: Monday, March 17, 2014 3:12 PM
To: Toth-Allen, Jean
Subject: follow-up question from SoCRA workshop in Newport Beach

Hello Jean,

Thank you for the very educational and helpful workshop in Newport Beach, CA last week. I feel like I learned a lot and I'm better-equipped now to run clinical trials and to prepare for FDA in the future. I want to follow up on the discussion about central IRBs not being permitted to oversee medical device trials. I believe you mentioned that FDA doesn't enforce this guidance, but it's written somewhere, and so FDA let it slide. Can you remind me the rationale for this and let me know where this is written (website)? It peaked my interest as well as my colleague who was also at the workshop. I appreciate your help and the opportunity to learn and meet with FDA representatives.

Kind regards,