From: OC GCP Questions
To: [redacted]
Subject: RE: Question on GCP 4.8.10, 21 CFR 50.25 and FDA access to medical records for inspection/monitoring (UNCLASSIFIED)
Date: Thursday, June 05, 2014 2:40:00 PM

Dear Ms. [redacted],

Brazil's central Ethics Committee's stance is rather confusing. They are willing to let the CI speak to potential subjects about FDA's ability to inspect the records but not willing to have this information in the official informed consent document that will be signed. It would seem they would want the reverse since they have control as to what is stated in the informed consent document and can therefore be ensured that all individuals who agree to become study subjects have received the same complete information in this regard.

I also do not understand how approving a statement in the informed consent document is giving Ethics Committee (EC) "approval" for FDA to see the records. It is only when an individual would sign that document to agree to be a study subject that any "approval" is granted for study conditions explained therein. If the EC approves the statement in the document they are just agreeing that, if that is the fact, then everyone should know this up-front before agreeing to participate since it is a deviation from the strict privacy laws effective in Brazil.

If the study is officially under an IND, all parts of 21 CFR part 312 must be adhered to. That includes appropriate informed consent and the statement about FDA's ability to inspect is one of the essential elements of an informed consent document in 21 CFR 50.25. If the study is an FDA-regulated study conducted outside of an official IND (e.g., if Brazil will not allow its CIs to sign a Form FDA 1572) then the conditions in 21 CFR 312.120 must be met as to compliance with GCPs if the results would be submitted to support an application to FDA. It would seem to me if the latter is the case, the EC could make alternative but equal requirements to ensue study subjects are aware of FDA's ability to inspect their personal records. This method would need to be explained when discussing ethics oversight of the study in any submission to FDA including this study's data. Before the revisions to 312.120, to allow a non-US site to conduct a study under an IND, CDER and CBER often waived the requirement that ethics review had to be conducted by an EC/IRB that was compliant with part 56 because most non-US ethics committees do not meet all the requirements in part 56. Therefore, we are aware that there are differences but still expect EC review to meet international GCP standards. (However, the ICH E6 GCP document – which is just one version of GCPs – does include a statement in the informed consent that regulatory officials and study sponsors could see the records.)

If, as the funder of the study, your agency chooses to allow the Brazilian sites to go this route, a "form" can be supplied to all CIs to document that potential subjects are informed of FDA's ability to inspect the records. The EC might not allow subjects to actually date and sign that document but if the CI, or whoever on the study site staff conducts the informed consent process, does sign and date it, that can serve the desired purpose.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov. 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 Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

-----Original Message-----
From: [redacted]
Sent: Thursday, June 05, 2014 8:25 AM
To: OC GCP Questions
Subject: Question on GCP 4.8.10, 21 CFR 50.25 and FDA access to medical records for inspection/monitoring (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

Good Morning,

This GCP question is related to feedback we have received as a funder of an FDA regulated clinical trial in [redacted]. We were informed by the CRO that the central Ethics Committee (EC) in Brazil would not approve language in the subject's ICF regarding the FDA access to medical/research records for the purpose of inspection as due to their interpretation of Brazilian privacy laws, the data/medical information is solely the subject's property and the EC has no purview to approve whether the FDA/monitors/funder can inspect the records. The EC asserts the acceptable plan is the PI's responsibility during the informed consent process discussion to talk with the potential subject and seek verbal authorization to allow this access, which then is documented in the study records prior to any study procedures.

Please confirm this plan is unacceptable per GCP 4.8.10 (and 21 CFR 50) as the written authorization for FDA access to medical records requirement and please inform if there has been other possibilities for documentation of this subject authorization, such as a separate written subject authorization equivalent to our US HIPAA authorization standards.

Thank you for your consideration,

[redacted]