From: OC GCP Questions
To: [redacted]
Subject: NCT locations
Date: Wednesday, October 28, 2015 7:57:05 AM

Good morning

FDA regulations governing the conduct of investigational studies (21 CFR part 312 for pharmaceuticals and part 812 for devices) do not address the publication of study results. The ICH GCP document, which is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf and which FDA has adopted as official guidance, only states that the publication policy can be included in the study protocol (6.15) if not addressed in a separate agreement. The implication here is that publication policy is something agreed upon between the study sponsor and the participating investigators before initiation of the study. Such a legal agreement would not be under FDA's purview. As you note, many peer-review publications also have specific rules with regard to publishing study data, which would also be outside of FDA's purview. FDA regulations do, however, require that an investigational site maintain copies of all study documents for the prescribed retention period (312.62 and 812.140(a) and (d)).

FDA's Information Sheets give the following advice regarding billing:

"The FDA informed consent regulations require the consent document to include a description of any additional costs to the subject that may result from participation in the research [21 CFR 50.25(b)(3)]. IRBs should ensure that the informed consent documents outline any additional costs that will be billed to study subjects or their insurance company as a result of participation in the study. IRBs should also ensure that any such charges are appropriate and equitable." [Here is a link to the Information Sheets: www.fda.gov/oc/ohrt/irbs/toc4.html.]

The IRB is responsible for review and approval of the informed consent form, so if the site is planning to bill subjects for study related procedures,; the IRB SHOULD review the revised consent form to make sure that any potential costs and charges are clearly spelled out. After all, some insurance companies do not reimburse the costs of procedures related to clinical trials, so it would be important for the subjects to know that they may end up responsible for these additional charges.

Because the IRB "...shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations (see 21 CFR 50.109(a))," the IRB does not need the sponsor's "approval" to review the consent form. If the IRB requires changes in the consent form, then the sponsor needs to comply with the IRB's requirements.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, October 27, 2015 5:46 PM
To: OC GCP Questions
Subject: NCT locations

If there is already an NCT number and our facility location is not noted in Clinicaltrials.gov can we still bill for services and or publish data?

Thank you,
[redacted]