From: OC GCP Questions
To: [redacted]
Cc:
Subject: RE: Exculpatory language
Date: Wednesday, August 12, 2015 1:34:00 PM

Dear [redacted]

Thank you for your question and your continued patience in our response. As I mentioned to you, I consulted with others within FDA, and also shared your question with OHRP.

As is evident in the question you asked, determining whether or not proposed wording in the informed consent form (ICF) is exculpatory in nature can be difficult and is typically a decision for legal professionals to make.

As we discussed your question we acknowledged many of the IRB's concerns about the use of the phrase "*…properly performed study procedure*", including that such wording is likely inaccurate and seems more appropriate for a contract *vs.* an ICF. In addition, such wording may be misleading to potential subjects who may not understand the distinction between a "*properly performed study procedure*" vs. "*an improperly performed study procedure*".

We also appreciate that your sponsors/clients are likely trying to factually state what they will and won't compensate for in the event of an injury. Although the proposed wording does not appear to explicitly state that the sponsor would not pay for other costs through any subsequent legal action, the proposed wording is not very clear and may not be understood by potential subjects.

While we are not able to give you a definitive "yes" or "no" answer to your question of whether the phrase "*properly performed study procedure*" is exculpatory in this case, we suggest that you may want to consult with your IRB's legal staff. Having said that, we note that 21 CFR 56.109(a) authorizes an IRB to decide what is acceptable wording to be included in the IRB-approved ICF. Perhaps there is alternative wording that can be agreed upon between your sponsors/clients and the IRB that would better facilitate the spirit of the basic element of informed consent found at 21 CFR 50.25(a)(6).

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us 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.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Thursday, July 16, 2015 12:29 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Exculpatory language
Importance: High

Good afternoon,

I spoke with Janet Donnelly, FDA Policy Analyst, this morning and she recommended that I send the following question to the FDA's GCP inbox.

[Redacted] IRB is seeking input/opinion from the FDA regarding use of the following language in the Compensation for Research

Related Injury section of the informed consent form (ICF). Specifically, [Redacted] IRB is asking the FDA's opinion on whether or not the phrase "**properly performed study procedure**" is potentially exculpatory in nature. The following is an example taken from the Compensation for Research Related Injury section from a sponsor-submitted ICF:

- ***The sponsor will pay for reasonable medical expenses related to such care, that are not covered by your insurance or third party coverage (excluding governmental health insurance programs, such as Medicare), under the following circumstances:***

    - ***It is the opinion of the study doctor and sponsor that the injury or illness is a direct result of the sponsor's proprietary drug or any properly performed study procedure;***

The board considers the "properly performed" description for the study procedure as exculpatory due to the following:

The statement (or similar wording with the same purpose, e.g. "done correctly") that a sponsor will only "pay for reasonable costs of medical care required as the result of an injury caused directly by a properly performed study procedure" does not belong in an informed consent document because:

- **The phrase "properly performed" is undefined and therefore uninformative.**
- **That phrase is potentially harmful to the relationship between the potential subject and the Principal Investigator**
- **That phrase is possible and even probably inaccurate, since a sponsor may have to pay some of the damages even if the cause of the injury to the subject is an improperly performed procedure.**
- **That phrase, which is appropriate for a contract, is irrelevant for the functions of an ICF, which is not a contract.**
- **That phrase is indefinable except by a court.**

We have received appeals from sponsors/clients disagreeing with the boards interpretation and would like FDA's opinion on whether or not [Redacted] IRB is being overly conservative, thus adding no value to human subject protections, in its thinking/rationale for "properly performed."

Regards,

[redacted]