

From: OC GCP Questions
To: [REDACTED]
Subject: Exculpatory language question
Date: Friday, February 27, 2015 11:25:46 AM

Good morning –

Please review the draft guidance on Exculpatory Language in Informed Consent. It states –

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM271036.pdf>

OHRP and FDA consider exculpatory language to be language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt. Therefore, a waiver in an informed consent document of any legal right a subject may have may be permissible so long as that waiver does not have the general effect of freeing or appearing to free an individual or an entity from responsibility for malpractice or negligence, or from blame, fault, or guilt (i.e., the waiver is not exculpatory).

For example, if an informed consent document contains language by which a subject waives his or her right to be compensated for injuries arising from participation in the research, such language would meet the definition of exculpatory language because it has the general effect of freeing or appearing to free the investigator, sponsor, and/or the research institution from malpractice, negligence, blame, fault, or guilt. For that reason, such language would violate 45 CFR 46.116 and 21 CFR 31.20.

Exculpatory language is also addressed in FDA's draft guidance on Informed Consent issued July 2014 –

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf>

Please see section # 4 starting at the bottom of page 5.

Based on the above mentioned guidances, I believe the information that you have provided meets the definition of exculpatory language.

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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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: [REDACTED]
Sent: Thursday, February 26, 2015 6:59 PM
To: OC GCP Questions
Subject: Exculpatory language question

Good Evening

I have a question regarding exculpatory language. For a study that involved minimal risk, would the following be acceptable ICF language, or is this an example of exculpatory language?

IN CASE OF STUDY RELATED INJURY

In case of study related injury, no form of compensation is offered.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

Thank you
[REDACTED]