

Guidance on Exculpatory Language in Informed Consent

DRAFT GUIDANCE

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Rockville, MD 20852

Food and Drug Administration
Division of Dockets Management (HFA-305)
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U.S. Department of Health and Human Services

Office for Human Research Protections

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This draft guidance, when finalized, will represent the Office for Human Research Protections' (OHRP's) and the Food and Drug Administration's (FDA's) current thinking on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP, FDA or the public.

OHRP and FDA guidance should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP and FDA guidance means that something is required under the Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the Food and Drug Administration regulations at 21 CFR parts 50 and 56. The use of the word *should* in OHRP and FDA guidance means that something is recommended or suggested, but not required. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the OHRP or FDA staff responsible for implementing this guidance.¹

I. INTRODUCTION

This draft guidance has been prepared jointly by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). This document applies to non-exempt human subject research conducted or supported by the Department of Health and Human Services (HHS) and is intended for clinical investigators, institutional review boards, and funding agencies that may be responsible for review or oversight of human subject research conducted or supported by HHS. This document also applies to human subject research regulated by FDA and is intended for clinical investigators, sponsors, and institutional review boards conducting or reviewing such research.

This document provides guidance on the regulatory prohibition on the inclusion of exculpatory language in informed consent. The document includes examples of language that OHRP and FDA consider acceptable as well as examples of language that the agencies would consider exculpatory. When finalized, this document will supersede OHRP's November 15, 1996, guidance entitled, "'Exculpatory Language' in Informed Consent" and question number 52 in FDA's January 1998 guidance entitled, "Institutional Review Boards Frequently Asked Questions – Information Sheet Guidance for Institutional Review Boards and Clinical Investigators."

OHRP's and FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe OHRP's and FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

II. DISCUSSION

¹ Contact information for both OHRP and FDA can be found in Section III of this guidance.

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Section 46.116 of 45 CFR and section 50.20 of 21 CFR state: “No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.” Thus, for particular language in a consent document to be impermissible under this provision, not only must the language involve a waiver, release, or the appearance of a waiver or release, but it must also be “exculpatory.” 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 50.20.

On the other hand, a subject’s waiver of any rights he or she may have with respect to a biospecimen obtained by investigators for research purposes would not be exculpatory because it does not have the effect of freeing the investigator, sponsor, institution, or others involved in the research from malpractice, negligence, blame, fault, or guilt. Accordingly, including such waiver language in an informed consent document would be permissible under 45 CFR 46.116 and 21 CFR 50.20. OHRP and FDA understand it has long been common practice of investigators and sponsors not to compensate research subjects who agree to provide biospecimens for research purposes even if those biospecimens are later used for commercial purposes. Moreover, OHRP and FDA are not aware of any federal or state laws or policies that suggest that research subjects would have any legal right to such compensation if they voluntarily signed an informed consent form which clearly stated that they would not be paid or otherwise compensated for providing their biospecimens.

Given these circumstances, OHRP and FDA have concluded that language in an informed consent form is not exculpatory if it informs subjects that, by agreeing to allow the use of their biospecimens for research purposes, they are giving up any legal right to be compensated for the use of the biospecimens.² In other words, such releases or waivers of rights to biospecimens would be permissible when the waiver does not have the effect of freeing the investigator, sponsor, institution or others involved in the research from malpractice, negligence, blame, fault, or guilt. Such language may be considered an acceptable way to accurately inform subjects that they will not be receiving any financial compensation, now or in the future, for the use of those

² While this guidance focuses primarily on biomedical research conducted in a healthcare setting, its application is not limited solely to those circumstances.

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biospecimens. Such language may, therefore, be appropriately included in an informed consent form without violating 45 CFR 46.116 or 21 CFR 50.20.³

In an effort to help the research community understand what may or may not constitute exculpatory language in violation of 45 CFR 46.116 and 21 CFR 50.20, we provide the following examples below:

Examples of Acceptable Language

- Although future research that uses your samples may lead to the development of new products, you will not receive any payments for these new products.
- By agreeing to this use, you are giving up all claims to any money obtained by the researchers from commercial or other use of these specimens.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the [name of research institution] and hereby relinquish all property rights, title, and interest I may have in those samples.
- By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples collected during this research.
- Although the results of research, including your donated materials, may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research.
- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. No financial compensation will be provided to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- Because of hospital policy, the hospital is not able to offer financial compensation should you be injured as a result of participating in this research. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.
- Because of hospital policy, the hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.⁴

³ This guidance document is not intended to address the issue of subject withdrawal from research.

⁴ As discussed in the guidance entitled, “Guidance for Industry: Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects,” FDA expects that the hospital will

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- In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.⁵

The above examples are permissible under 45 CFR 46.116 and 21 CFR 50.20 because in each example, the waiver or release does not have the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

Examples of Exculpatory Language

The examples below would be in violation of 45 CFR 46.116 and 21 CFR 50.20 because in each example, the waiver or release has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

- I waive any possibility of compensation, including any right to sue, for injuries that I may receive as a result of participation in this research.
- If you suffer a research-related injury, neither the institution nor the investigator can assume financial responsibility or liability for the expenses of treatment for such injury.
- In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer.

III. CONTACTS FOR QUESTIONS

For questions regarding this draft document contact:

OHRP

By phone at:
(866) 447 – 4777 (toll-free within the U.S.) or
(240) 453-6900, or
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make efforts to ensure that the investigator provides reasonable medical care for any adverse events, including clinically significant laboratory values, related to the trial participation. If the investigator does not possess the expertise necessary to provide the type of medical care needed by a subject, the investigator should ensure that the subject is able to obtain the necessary care from a qualified practitioner. This guidance is available at:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

⁵ This sentence as used in this example, as well as in the previous two examples, is only one potential way of explaining in an informed consent document that a subject's legal right to seek to collect compensation for research-related injuries in certain situations is not being waived. Other language that similarly conveys this concept would also be acceptable.