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Rights to Compensation for use of Biospecimens: OHRP and FDA Clarify that Waivers of Rights in Informed Consents are not "Exculpatory"

September 12, 2011 by Peter S. Reichertz

In a Federal Register notice of September 7, 2011,[1] the Office of Human Research Protection ("OHRP") and the Food and Drug Administration have clarified that a waiver by an individual in an informed consent to compensation for use of his/her biospecimens is not "exculpatory", and permissible, if worded properly. This Guidance – entitled "Guidance on Exculpatory Language in Informed Consent" – applies to research conducted for purposes of FDA approval, as well as research sponsored by the Department of Health and Human Services ("DHHS").

Under current OHRP and FDA regulations, found at 45 C.F.R. § 46.116 and 21 C.F.R. § 50.21, a waiver by a subject in an informed consent is not permissible if it is exculpatory. In the Guidance referred to in the Federal Register notice, OHRP and FDA have clarified that a waiver is only exculpatory – and, hence, impermissible – if it has the "general effect of freeing or appearing to free an individual or entity from responsibility for malpractice or negligence, or from blame, fault or guilt. …" As stated in the Guidance:

> 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.

They provide the following examples of ACCEPTABLE waiver 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.
- 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.

Companies conducting clinical research for purposes of obtaining FDA approval should review their informed consents and make sure they are consistent with the FDA/OHRP Guidance.

Comments on the Guidance may be submitted to FDA or OHRP by November 7, 2011.

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