From: OC GCP Questions
To: [redacted]
Cc: OC GCP Questions; Industry.Biologics
Subject: RE: [redacted] Question regarding exculpatory language in Draft Guidance on Exculpatory Language in Informed Consent August 19,2011 vs FDA Frequently Asked Questions IRB
Date: Thursday, May 28, 2015 8:41:29 AM

Dear [redacted],

Your question was forwarded to my office for a response. FDA's current position on the issue of exculpatory language is that the terms "donate" and "donations" do not necessarily mean that an individual has "waived or appear to waive any of the subject's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence." [21 CFR 50.20] FDA does not consider donation/donate to be exculpatory because these terms would not have the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox (gcp.questions@fda.hhs.gov)

Thank you

Kevin Prohaska

Kevin A. Prohaska, D.O., M.P.H., Captain (USPHS)
Senior Medical Policy Analyst
Office of the Commissioner
Office of Good Clinical Practice

From: Industry.Biologics
Sent: Thursday, May 21, 2015 9:49 AM
To: OC GCP Questions
Cc: [redacted]
Subject: RE: [redacted] Question regarding exculpatory language in Draft Guidance on Exculpatory Language in Informed Consent August 19,2011 vs FDA Frequently Asked Questions IRB

Forwarding inquiry to the Office of Good Clinical Practice for response.

Cynthia
Manufacturers Assistance and Technical Training Branch
Division of Manufacturers Assistance and Training
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research/FDA
240-402-8020
800-835-4709
Industry.Biologics@fda.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, 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: Industry.Biologics
Sent: Wednesday, May 20, 2015 4:08 PM
To: [redacted]
Cc: 'gcp.questions@fda.gov'
Subject: RE: [redacted] Question regarding exculpatory language in Draft Guidance on Exculpatory Language in Informed Consent August 19,2011 vs FDA Frequently Asked Questions IRB

Dear [redacted]

Thank you for your telephone inquiry and follow up email. The Center for Biologics Evaluation and Research (CBER) is one of seven centers within the Food and Drug Administration (FDA). CBER is responsible for the regulation of biologically-derived products, including blood intended for transfusion, blood components and derivatives, vaccines and allergenic extracts, human cells, tissues, and cellular and tissue-based products (HCT/Ps), gene therapy and xenotransplantation products.

Contacts for questions about the August 2011 **draft** *Guidance on Exculpatory Language in Informed Consent* were provided under Section III including the Office of Human Research Protections (OHRP) and FDA. From our telephone conversation, I understand that you already contacted the OHRP, and I found that the FDA contact is no longer available. Therefore, by way of copy, I forwarded your inquiry to the FDA Office of Good Clinical Practice (OCGP) for response. Please follow up with the FDA OCGP regarding your inquiry questions at gcp.questions@fda.hhs.gov.

From our telephone conversation on Friday, it is my understanding that your inquiry questions are about information provided within the following two links on our FDA website:

1. Institutional Review Boards Frequently Asked Questions – Information Sheet, Guidance for IRBs and Clinical Investigators: http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm#InformedConsentProcess .

   You specifically asked about item 52 on this webpage under Section VI, informed consent document content. The questions asked under 52:

   "Is it acceptable for the consent document to say specimens are "donated"? What about a separate donation statement"

   While the response to item 52 includes the following statement:

   "It would be acceptable for the consent to say that specimens are to be used for research purposes. However, the word "donation" implies abandonment of rights to the "property". 21 CFR 50.20 prohibits requiring subjects to waive or appear to waive any rights as a condition for participation in the study. Whether or not the wording is contained in "the actual consent form" is immaterial. All study-related documents must be submitted to the IRB for review. Any separate "donation" agreement is regarded to be part of the informed consent documentation, and must be in compliance with 21 CFR 50."

2. **Draft** *Guidance on Exculpatory Language in Informed Consent*, August 19, 2011: http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm271036.pdf.
   Under examples of acceptable language within the **draft** guidance you inquired about the following **drafted** statements:

"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"; and

"The above examples are permissible under 45 CFR46 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."

Please be advised that FDA guidance, **when final**, represents the agency's current thinking on a topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An establishment can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If an establishment opts not to follow the recommendations in **final** guidance, that facility is required to demonstrate how the regulations are otherwise being met.

While you are waiting for a response from the OCGP, it may be helpful to utilize our Code of Federal regulations search function, located on FDA's main webpage under Regulatory Information, Code of Federal Regulations, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm . The Title 21 search can be performed with Part numbers, e.g. 50 or by using key words in the full text search function to locate regulations that may be applicable.

You may find information on Clinical Trials and Human Subject Protections at the following link: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

A Guide to Informed Consent – Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators: http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm.

I hope this is helpful.

Sincerely,

Cynthia
Manufacturers Assistance and Technical Training Branch
Division of Manufacturers Assistance and Training
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research/FDA
240-402-8020
800-835-4709
Industry.Biologics@fda.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, 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: Friday, May 15, 2015 11:07 AM
To: Industry.Biologics
Subject: [redacted] Question regarding exculpatory language in Draft Guidance on Exculpatory Language in Informed Consent August 19,2011 vs FDA Frequently Asked Questions IRB

Dear Cynthia:

Thank you very much for your prompt response to my phone call regarding the concern I have over the apparent divergent positions in the two above referenced documents on the issue of the use of the word

“donate.” As we have discussed in our phone conversation, at issue is Whether the use of the word ‘donate” in an informed consent, in reference to the transference in a clinical trial of blood, urine, and/or tissue samples constitutes a waiver of subject rights and is therefore exculpatory language?

You may response at either this e mail address or [redacted]

Kind regards,

[redacted]