From: Woollen, Stan - OC
Sent: Monday, November 25, 2002 4:45 PM
To: [purged] Lepay, David; Woollen, Stan - OC; ohrp@osophs.dhhs.gov
Cc: Zollo, Mary Jo; Lee, Bonnie
Subject: RE: Clarification on Exculpatory Language

Dear Ms. [purged],
The statement you quote below in which the subject "waives all rights to the previously mentioned data, and other materials" seems to be rather broad and does appear to be prohibited exculpatory language within the meaning of 21 CFR 50.20. 21 CFR 50.20 states in part, "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..." The language you cite certainly "appears" to waive the subject's legal rights. If the subject is not being asked to waive any of their legal rights, then why is this language necessary.
I hope this is responsive to your request.
Stan W. Woollen
Associate Director for Bioresearch Monitoring
-----Original Message-----
From: [purged]
Sent: Monday, November 25, 2002 12:20 PM
To: dlepay@oc.fda.gov; swoollen@oc.fda.gov; ohrp@osophs.dhhs.gov
Subject: Clarification on Exculpatory Language
Importance: High

I have a problem with a clinical trial where the sponsor [purged]insists that the following language be included
"I agree that all data and materials derived from this study are the property of the drug sponsor, [purged]. I waive all rights to the previously mentioned data, and other materials."
I have emailed them directly and notified them that this language is not allowed by federal regulations. Their legal counsel insist that this language is acceptable and is not violating the "intent" of the 21 CFR 50.20 or 45 CFR 46.116. I have read all of the guidance documents issued by both OHRP and FDA and it appears clear to me that this does violate the intent of these regs and the guidance as issued.
Please confirm that I am not being too conservative and that the statement "I waive all rights to previously mentioned data and other materials" is not acceptable. I have proposed alternative language to them, but they are threatening to pull the study from our investigator is we do not allow that language in the consent.
Thanks for your help!
[purged]