From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, October 16, 2002 1:13 PM
To: [purged]
Subject: RE: General question about Informed Consent

Dear [purged], I apologize for the delay in getting back to you. FDA's informed consent regulations require subjects to be provided with, among other things, "A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental." See 21 CFR 50.25(a)(1). Thus, if the purpose of the study is to test urine or blood samples for analytes A, B and C (as in your first question), that ought to be stated in the consent form. If the investigator decided to test for other analytes, the consent form would need to be modified (or supplemented) to obtain your consent for the additional testing (of analytes D or E). It does not matter whether the samples are subsequently anonymized unless as part of the consent process, you are advised and agree to further unspecified testing (or specified testing of analytes D or E) of the samples collected. In that case, it is possible that the sponsor or investigator would provide some assurance of confidentiality--which could include anonymizing the sample. I hope this is helpful to you. And, again, I am truly sorry about the delay in getting back to you.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Wednesday, September 11, 2002 1:09 PM
To: gcpquestions@oc.fda.gov
Subject: General question about Informed Consent

Dear ogcp,

My question regards the extent to which an investigator may do additional unstated analyses during clinical trials.

1. For instance, if the Informed Consent states that urine or blood samples will be tested for analytes A, B and C, may the investigator or sponsor also test for analyte D or E, or perform additional testing? I was under the impression that this would not be permitted, since the additional testing is not described in the Informed Consent. However, I can not find any such regulation or statement in the guidances, and presumably the subject is not exposed to any additional risks. Can you please clarify for me whether testing of subject samples outside of what is described in the Informed Consent is allowable?

2. What if the samples above were anonymized subsequent to collection, and then the sponsor wanted to perform previously unanticipated analyses on these anonymized human samples? Would this testing be permitted?

Thank you very much.
[purged]