**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Questions regarding biospecimens
**Date:** Friday, November 13, 2015 7:58:33 AM

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Good morning –

Please review the FDA guidance document below.
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf

The intent of this guidance is to address the use of specimens from specimen banks where the samples are not individually identifiable so informed consent cannot be obtained. In order to allow the use of these de-identified specimens, FDA issued this guidance, which indicates that FDA intends to exercise enforcement discretion, under these limited circumstances, with respect to obtaining informed consent for the use of these specimens in FDA regulated research. Clearly, FDA intends that research on specimens requires informed consent.

You may also want to look at question 8 in section V of the frequently asked questions guidance, cited above. This question asks about using a human specimen that was initially collected in a study with the informed consent of the subject and whether it may be used in a later study without a new consent process. The response to this question states "If ... the original informed consent document contains a statement that excess specimen(s) will be stored for future use in specified types of studies and the new study meets the criteria stated in that consent document, it is possible that no further consent is necessary. This assumes that the original informed consent document contains all of the other essential elements, including notice to the subject that FDA may review their files and an explanation of the purposes and benefits of the research. (See 21 CFR 50.25.) We recommend sponsors and investigators consult with the IRB regarding the need for a new informed consent process in such a case. The IRB decision should include consideration of any state and/or local requirements regarding informed consent and patient rights. If new testing could expose the subject to previously unanticipated risks (e.g., privacy concerns for the subject and/or his family related to testing for a genetic marker), a new consent may be needed. In addition, if the original informed consent did not address future research use at all, or did not cover the type of study now under consideration, it is likely a new consent will be needed." From this response, it is clear that FDA intends for the consent form to address all the required elements of informed consent as they relate to the specimens collected.

If this guidance does not specially answer your question, please contact FDA's In Vitro Diagnostics office at --

301-796-5450
CDRH-Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO66-5521
Silver Spring, MD 20993

I hope this information is helpful. Please contact us again at gcp.quesitons@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



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**From:** [redacted]

**Sent:** Thursday, November 12, 2015 3:54 PM
**To:** OC GCP Questions
**Subject:** Questions regarding biospecimens

Dear GCP,

I was referred to you by CDER and CBER. An FDA regulated research study (vaccine clinical trial) obtained consent from participants to store bio specimens for future research (not the research objectives of the original vaccine trial). These biospecimens are stored in a repository and distributed in a de-identified manner to a researcher doing bench research (the type of research activity is broadly covered under the original consent to store and use specimens in future research).

Our IRB is trying to clarify if these biospecimens when used in future research are still under FDA jurisdiction since they were originally collected in a FDA regulated clinical trial. I know the FDA and OHRP are not the same on whether a de-identified bio specimens involves a 'human subject'. Current OHRP guidance says if de-identified to researcher it does not involve a human subject and therefore does not require IRB review. What I understand from FDA guidance on *in vitro* diagnostics is that the FDA does not consider use of de-identified bio specimens as 'non-human subjects' research and would require IRB review.

Our IRB just concluded an FDA inspection and we are working to more precisely spell out when a study is FDA regulated. The FDA inspector gave me a name in CDER who is helping clarify some issues we have when PATH is involved in medical device research conducted internationally.

We are currently working on guidance for setting up repositories and reviewing our policy on use of stored biological specimens that are de-identified. We are not clear if specimens originally collected under an FDA regulated clinical trial of an IND vaccine or drug, if future use of the stored specimens is subject to FDA regulations.

Thank you for your assistance.
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