From: OC GCP Questions
To: [redacted]
Subject: RE: Retention of Subject Specimens enrolled in Clinical Trial Testing
Date: Wednesday, September 27, 2017 1:40:02 PM

[redacted],

FDA's IND and IDE regulations do not contain specific requirements related to retention of subjects' tissues or other samples that are collected during the course of a clinical trial. Generally, after the trial is over, unless the subject has agreed to allow the residual samples to be used for other research purposes, the samples would be destroyed or discarded, in compliance with state or local biological waste disposal requirements.

You are asking a very general question, so I'll try to provide some general guidance.

If this is a question for a study that has not yet begun, and blood samples are to be collected for investigational testing related to the study, then the protocol and consent form should include information about what will be done with residual samples--that is, whether they will be used for other, future research. Either the investigational study's consent form, or a separate form presented to the subject at the time the blood samples are being collected, should request the subject's consent for this future use (i.e., use of the residual samples for other research purposes). The consent form should indicate whether subject identifiers will be removed, or that identifiers would remain and why the identifiers will not be removed. (Generally, removing the identifiers is preferred unless there is a valid scientific reason to maintain identifying information). These forms would need to be reviewed and approved by the Institutional Review Board responsible for the initial study.

If this is a question about samples that have already been collected in a study, then I will refer you back to the original study protocol (and/or the informed consent document) for the sponsor's instructions about the samples, how and why they are to be maintained (including provisions for maintaining privacy/confidentiality), the period of time for which they are to be maintained, and the potential for additional uses. If the informed consent document did not address this, then the subjects would need to be contacted again to obtain their consent to use the samples in any other research studies.

We recommend that you also consult with your legal counsel, the sponsor and the institution to be sure you are aware of all applicable policies and procedures.

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

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From: [redacted]
Sent: Friday, September 22, 2017 7:44 PM
To: OC GCP Questions
Subject: Retention of Subject Specimens enrolled in Clinical Trial Testing

Hi.
will you please provide guidelines on retention of samples collected/used in clinical trial testing, e.g. blood, paraffin blocks, slides, frozen tissue?
Thank you,
Regards
[redacted]