From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Clarification on clinical research
Date: Wednesday, September 05, 2018 1:20:00 PM
Attachments: [redacted]

Good afternoon –

I have spoken to a few of my colleagues here in OGCP and we feel we don't have enough information to adequately answer your question. We think your question is best answered by CDRH at DICE@fda.hhs.gov.
CDRH's Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable may be helpful for the sponsor and IRB to review. It can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm071265.pdf There is a phone number and name identified on the front of this guidance. Additionally, please see FDA's In Vitro Diagnostics webpage link. In Vitro Diagnostics

You can also ask CDRH questions about your study and validation process design via their "pre-submission program". There is no charge for these submissions. The information for submitting a "pre-sub" can be found in the guidance, Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff, which can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information 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, August 31, 2018 10:29 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Clarification on clinical research

Dear [redacted],

I will appreciate clarification on following matter:

Patients routinely undergo bone marrow biopsy for a disease. As a sponsor of a study I would like to obtain portion of those samples through the hospitals to validate my diagnostic test. The

hospitals will obtain IRB approval or waiver depending upon their policies and send the samples for R&D validation. From GCP and regulatory perspective obtaining such samples with no stipulation for samples or intervention should it be considered clinical study and follow 21 CFR , or could it be a Material Transfer without the need for ICF?

Regards

[redacted]