From: OC GCP Questions
To: [redacted]
Subject: Mandatory banking for future unspecified research
Date: Sunday, March 08, 2015 2:33:33 PM

Good afternoon –

Since you state that you are operating under the Federal Wide Assurance and are following 45 CFR 46, it is best to send your question to OHRP. Please see their contact information below.

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the United States: (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
E-mail: OHRP@hhs.gov

Kind regards,

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

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, March 06, 2015 4:59 PM
To: OC GCP Questions
Subject: FW: Mandatory banking for future unspecified research

Dear Sir or Madam,

I have a question about US regulations on mandatory banking for future unspecified research for a study that involves treatment. Our usual practice is that for studies involving treatment that banking of specimens for future research unrelated to the primary objective of the study must be optional. We have seen an number of US-based multi-center studies that involve a treatment tied to mandatory banking, which may include whole genome sequencing or unspecified future research. I was unclear what the US regulations are on mandatory banking of this nature. I found on the website of the [redacted] IRB the following comment:

"Due to changes in HIPAA regulation released in March 2013, investigators may not condition participation in a treatment/interventional trial upon participation in a tissue bank. Participation in the tissue bank must be an optional sub-component for treatment/intervention trials." (http://irb.utah.edu/about/news/2013/09-13-2013.php)

The related HIPPA language discussing “Compound authorizations” which they quote is below ([46 CFR] 164.508(b)(3)(i) and (iii)):

“An authorization under this section…may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment…on the provision of one of the authorizations.”

Although we are a Canadian IRB, we operate under US Federal Wide Assurance. We would view mandatory specimen banking (for future research unrelated to the primary objective) as being coercive/unduly influential in a study that involves a treatment or intervention, but would appreciate your agency’s comments. Is there someone at the FDA that could provide an opinion on this issue?

All the best,

[redacted]