From: OC GCP Questions
To: [redacted]
Subject: [redacted] Question - FDA Rule on Ethics in Blood & Serum Collection?
Date: Thursday, June 07, 2018 9:38:00 AM
Attachments: image003.png

Hi [redacted] –

Thank you for speaking with us. I hope we were helpful. I am providing links to the three FDA guidances that we mentioned.

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf

FDA's In Vitro web page – phone number at the bottom of the page on the right side.

In Vitro Diagnostics

Center for Devices (CDRH) contact information –

Phone: 1-800-638-2041
Phone: 301-796-7100
Fax: 301-847-8149

Email: DICE@fda.hhs.gov

PRIM&R website –

PRIM&R | Public Responsibility in Medicine and Research

Take care,

Doreen

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Tuesday, June 05, 2018 3:39 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: [redacted] Question - FDA Rule on Ethics in Blood & Serum Collection?

[redacted]

[redacted]

[redacted]

[redacted]

From: OC GCP Questions [mailto:gcpquestions@fda.hhs.gov]
Sent: Wednesday, May 30, 2018 9:00 AM
To: [redacted]
Cc: [redacted]
Subject: [redacted] Question - FDA Rule on Ethics in Blood & Serum Collection?

Dear [redacted] –

It seems your email came full circle back to OGCP. We are happy to discuss your question with you. I know you are out this week. We can give you a call next week on Wed pm from 1-2pm or Thursday at time that is convenient for you. We can call your office number. Pat McNeilly, my OGCP colleague, will be joining us on the call. We anticipate the phone call to take less than ½ hour. Please let me know what time works for you. You can send your response back to our OGCP mailbox.

Kind regards,

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

From: [redacted]
Sent: Wednesday, May 23, 2018 6:51 AM
To: [redacted]
Subject: [redacted] Question - FDA Rule on Ethics in Blood & Serum Collection?

Good afternoon,

My name is [redacted] and I work in the [redacted] I serve as OPP's Human Research Ethics Review Officer, and my job is in part to ensure that research involving human subjects submitted to OPP meets the necessary ethical standards – we review research conducted by 3rd parties (not federally conducted or funded) under a separate rule modeled on the Common Rule – 40 CFR 26, Subparts K-Q.

[redacted] here at [redacted] suggested I contact you with my question – he's my go-to person for human studies issues.

I am hoping you can help me understand how FDA regulates the collection of blood products and tissues, especially for use in secondary research. Specifically, I'm interested what ethical standards apply to the collection of these specimens. One of my colleagues was a meeting of the [redacted] and the use of human-derived serum was discussed as part of the development of in vitro assays to replace animal-based testing (the discussion is around testing for skin sensitization, but will apply broadly). Many labs conducting this type of research use human products (e.g., blood serum, tissue) from FDA certified facilities. A question came up related to the ethical standards around FDA's collection of samples – the type of consent, what the consent covers, whether and how much compensation is offered, etc. Without an understanding of the protections for subjects and type of consent given, there is hesitance at the global level to use US-derived products.

I will be out of the office next week, but it would be good to set up a time to chat the first week of June if you can identify someone who is knowledgeable and available. Please let me know if you would like more information prior to our conversation.

Thanks in advance for any information you can provide.

[redacted]