From: OC GCP Questions
To: [redacted]
Subject: IRB Waiver or Alteration of Consent for Clinical Investigations Involving No More the Minimal Risk
Date: Wednesday, June 27, 2018 12:45:00 PM
Attachments: [redacted]

Good afternoon –

Your email was forwarded to my office for a response.

FDA would not grant a partial waiver of informed consent as you outlined below. The waiver applies to the criteria in section IV. on page 4 of the guidance.

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]
Date: June 22, 2018 at 7:18:24 PM EDT
To: [redacted]
Subject: IRB Waiver or Alteration of Consent for Clinical Investigations Involving No More the Minimal Risk

Dear [redacted],

I am hoping that you can help me with a question regarding the above referenced guidance document.

Under this guidance, would a partial waiver of informed consent be permissible (e.g., for a minimal risk activity such as a single blood draw prior to obtaining informed consent) or is this guidance intended to only permit waivers of informed consent when the entirety of the clinical investigation is minimal risk?

Many thanks for any guidance you can offer.

Best regards,

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]