From: [redacted]
To: [redacted]
Subject: Quick Question Regarding FDA Guidance
Date: Thursday, October 18, 2018 11:33:07 AM

From: [redacted]
Sent: Thursday, October 18, 2018 10:06 AM
To: [redacted]
Subject: RE: Quick Question Regarding FDA Guidance

Dear Ms. [redacted],

Joanne asked me to respond to your question below. The "Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable" guidance is still in use. IRBs can use this when determining whether to waive informed consent for investigations that use de-identified leftover specimens, as described in the guidance.

Best regards,
Janet Norden
Office of Good Clinical Practice, FDA
301-796-1127
janet.norden@fda.hhs.gov

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: Wednesday, October 17, 2018 10:15 AM
To: [redacted]
Subject: Quick Question Regarding FDA Guidance

Dear Joanne,

I hope this email finds you well and that things aren't too crazy with all the regulatory changes going on right now at HHS!

I had a quick question regarding FDA guidance. Is the *FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable* still relevant with the publication of the broader *FDA Guidance on IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects?* Is the

former guidance now obsolete?

Please advise.

Thanks. I had hoped to make it to the SACHRP meeting but other priorities got in the way. Hope to see you at PRIM&R.

Best regards,

[redacted]