From: [redacted]
To: [redacted]
Subject: RE: Good Morning!
Date: Friday, January 09, 2015 3:42:57 PM

Hi [redacted]

The FDA regulations do not require a picture ID prior to pre-screening or screening an individual for participation in a clinical investigation. When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

I hope this information is helpful to you. If further assistance is needed please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.gov

Kevin

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From: [redacted]
Sent: Friday, January 09, 2015 9:26 AM
To: OC GCP Questions
Subject: Good Morning!

My inquiry is the following: Is there any FDA GCP requirement for each potential subject providing a PICTURE ID prior to pre screening or screening for participation in a clinical trial. Our PI has one particular subject who he has treated for approximately 15 years. She resides in a group home suffers from diagnosed mental illness and has NO picture ID as she does not drive there fore no drivers license.. She gets her mail and financial compensation at the group home so the US Post Office recognizes her address. Our PI can identify her and believes she will be a great candidate for the Investigational product under proposal. We understand this may be a best and preferred practice for most clinical sites, CRO's and Sponsors but believe this individual solution may legally fall under PI discretions. Please provide your best guidance as soon as possible since this particular subject is awaiting our decision.