From: [redacted]
To: Goldkind, Sara
Subject: RE: Re-consent
Date: Tuesday, March 18, 2014 2:47:36 P

From: Goldkind, Sara
Sent: Tuesday, March 18, 2014 2:15 PM
To: [redacted]
Subject: RE: Re-consent

[redacted]

There is a consensus that the term informed consent should not be viewed as synonymous with obtaining a subject's signature on the consent form. Rather, obtaining a subject's signature on the consent form should be only a part of an informed consent process. Generally, the informed consent process begins with subject recruitment and continues after the consent form is signed. Depending on the clinical trial, additional information may need to be given to the subject, and the subject may need additional opportunities to ask questions and receive answers throughout the clinical investigation.

That said, there isn't any consensus on how often clinical trial subjects should be "re-consented," if at all, in the absence of any important change in the science.

For studies enrolling children, there may be an ethical imperative to consent the individuals once they've reached the age of majority (This, of course, would not be considered "re-consenting" them.)

Hope this helps. If not, please feel free to call me to discuss further.

Sara

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Email: Sara.Goldkind@fda hhs.gov

From: [redacted]
Sent: Monday, March 17, 2014 2:53 PM
To: Goldkind, Sara
Subject: Re-consent

Sara,

Is there a consensus, or anything near a consensus, among ethicists regarding how often clinical trial subjects should be re-consented, in the absence of any important change in the science?

Thanks,
[redacted]