From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: RE: question re: consent form
Date: Wednesday, December 03, 2014 3:35:00 PM

Dear [Redacted]-

Thank you for your question, which was forwarded to my office for a response. If I understand your question correctly, you are asking whether there are any specific regulations about the informed consent process that address how many "original" signed informed consent forms (ICFs) you have to collect from subjects. My response below is based on an assumption that you are referring to multiple "original" signed copies of the same ICF (e.g., the ICF for the main study only), and not multiple differing ICFs (e.g., one consent for the main study, another consent for the optional sub-study, etc.).

The FDA regulations for informed consent can be found at 21 CFR 50 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50).
The regulations at 21 CFR 50.27 address documentation of informed consent (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27). Specifically, 50.27(a) says:

> *Sec. 50.27 Documentation of informed consent.*
>
> *(a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.*

While the informed consent regulations describe "what" is required for informed consent, they are not specific about "how" you must fulfill these responsibilities. When the regulations are silent, investigators, sites, sponsors, IRBs, institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met. The regulations do not mention any requirement to have multiple "original" signed copies of the same ICF. The regulations do require that a copy of the ICF be given to the person signing the form. Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.

Keep in mind that while the regulations do not require multiple "original" signed copies of the same ICF, your site/institution may have policies and procedures on this topic that you must follow. You may want to consult the appropriate institutional officials at your site/institution about your specific question.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Monday, December 01, 2014 1:34 PM
To: CDER DRUG INFO
Subject: question re: consent form

Hello,

I am not certain if I have the correct contact information, but I need some clarifications regarding the consent form process which I was not able to locate any where in your website. Could you please let me know how many original signed copies should we collect from subjects? Are there any regulations regarding that?
We currently are disagreeing on that, so some folks are having the subjects to sign 2-3 copies, and some just one and then make copies of that to dissminate. Please clarify.

Thank you!

[Redacted]