Donnelly, Janet

From: OC GCP Questions
Sent: Tuesday, January 28, 2020 9:18 AM
To: [redacted]
Subject: RE: Informed consent question

Dear [redacted]-

Thank you for your question. I am not familiar with your reference to the M035 informed consent template. I consulted a few of my colleagues who also are not familiar with what the M035 informed consent template is.

I can speak to what the FDA regulations require for an informed consent form. As you know, the FDA informed consent regulations found in 21 CFR part 50 (see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50) discuss the information that is required to be included in an ICF. The FDA regulations address the "content" of the ICF but do not address the "format" of the ICF.

When the regulations are silent, investigators, sites, institutions, IRBs, and sponsors are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

FDA also has various guidance documents that discuss the ICF, but, like the regulations, the guidance is not prescriptive as to the format of the ICF, but rather addresses content in accordance with the regulations.

You should consult the appropriate institutional officials at your site, as well as your IRB with your question about the use of the header in the M035 ICF template. There may be some institutional/IRB requirements for the ICF template that you may need to follow.

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 https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Friday, January 24, 2020 10:57 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Informed consent question

Hello,
I am a clinical trials nurse at [redacted] and we were having an in-house discussion about the header information on each page of our consent.
We currently use the M035 template where in the upper right hand corner of the consent we print labels with the subject's Name, Medical Record Number.

During our discussion someone thought that this information only needs to be on the first page of the consent. I was taught that it needed to be on every page.

Please respond and also provide source documentation if possible.

Thanks so much.

[redacted]