From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, December 01, 2004 10:45 AM
To: [Redacted]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Sir/Madam,

Your inquiry was referred to our office for a direct reply. Under 21 CFR 50.27(a), informed consent must 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. Section 50.27 goes on to note that the consent form may be either:

1) a written consent document that embodies the elements of informed consent required by 21 CFR 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator must give either the subject or the representative adequate opportunity to read it before it is signed [21 CFR 50.27(b)(1)]; or
2) a short form written consent document stating that the elements of informed consent required by 21 CFR 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there must be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the representative. However, the witness must sign both the short form and a copy of the summary, and the person actually obtaining the consent must sign a copy of the summary. A copy of the summary must be given to the subject or the representative in addition to a copy of the short form. [21 CFR 50.27(b)(2)]

As noted in the preamble to Part 50 (http://www.fda.gov/oc/gcp/preambles/46fr.html) under comment #51:

"The consent form itself is an aid to assure that a required minimum of information is provided to the subject and that the subject consents. The entire informed consent process involves giving the subject all of the information concerning the study that the subject would reasonably want to know; assuring that the subject has comprehended this information; and finally, obtaining the subject's consent to participate. The process, to be meaningful, should involve an opportunity for both parties, the investigator and the subject, to exchange information and ask questions. The consent form, thus, should not be viewed as an end point. Rather as a beginning."

As you can see, neither the regulations nor the preamble to Part 50 specifically require that each page of the informed consent document be signed by the subject or the subject's legally authorized representative. The regulation aims to ensure the subject has access to all of the information he/she may want to have before deciding whether to participate in a study. The informed consent document may be a simple, one page short summary or a multiple page (long) informed consent document.

Your question is a good one though. To ensure that a subject receives information that the subject would reasonably want/need to know (e.g.., the purpose of the study, the procedures the subject might expect to occur during the conduct of the study, and the risk/benefits associated with the subject's participation in the study), it is not uncommon for each of the pages of the (long) informed consent form/document to be numbered. And certainly, it is always permissible to include a signature block on each of pages of the informed consent document. Using either of these approaches (or other approaches, for

that matter) for ensuring the subject had the opportunity to read/hear all of the information contained on the informed consent document would be more a matter of institutional preference (verses an explicit regulatory requirement).

I hope this information is helpful.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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.

-----Original Message-----
From: CDER DRUGINFO
Sent: Friday, November 19, 2004 1:47 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Thursday, November 18, 2004 2:14 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

Comments: Is it necessary for subjects in a clinical trial to initial each page of an informed consent document?If so, please tell me which regulation covers this. Thank you very much.