**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Consent Question - Appendices
**Date:** Friday, December 30, 2016 9:33:00 AM
**Attachments:** [redacted]

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Dear [redacted] -

Thank you for your question. As you know, the FDA regulations do not address your specific question. When the regulations are silent, IRBs, institutions, sponsors, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

Requirements, such as to follow the Ethical & Religious Directives, are local/institutional requirements that are usually implemented on a local/institutional level and should be discussed with the investigator, the IRB and the appropriate institutional officials.

It is somewhat difficult to envision what you mean by "*two appendices with birth control/regulation options*", but you should discuss with the IRB how such a form and process will be implemented, taking care to ensure that potential subjects are provided with complete and correct information to make an informed decision about whether to participate or not.

FDA has draft guidance titled, "*Informed Consent Information Sheet - Guidance for IRBs, Clinical Investigators, and Sponsors*" that can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf. Although draft at this time, I copied a few excerpts out of the draft guidance that may be helpful to you:

> **Page 2** - The informed consent requirements in 21 CFR part 50 are not intended to preempt any applicable Federal, State or local laws that require additional information to be disclosed for informed consent to be legally effective. (21 CFR 50.25(c).)
>
> **Page 21** - The IRB has the authority to require that information, in addition to that specifically mentioned in 21 CFR 50.25, be given to subjects when, in the judgment of the IRB, the information would meaningfully add to the protection of the rights and welfare of the subjects (21 CFR 56.109(b)). For example, local circumstances may necessitate the inclusion of additional information relevant to the informed consent process for potential subjects from that particular community.
>
> **Page 22** - IRBs should also address institutional requirements and applicable Federal, State, and local laws and regulations. (21 CFR 56.103(c) and 56.112.) Institutions may develop standard language or a standard format to use in portions of all consent forms (for example, for those elements that deal with confidentiality, compensation, answers to questions, and the voluntary nature of participation) to meet these requirements.
>
> **Page 26** - Sponsors often provide clinical investigators with a model consent form that may be adapted by the clinical investigator to meet local needs.
>
> **Page 27** - For multicenter clinical investigations, minor changes may need to be made to the consent form to address local and institutional requirements. When IRB review results in substantive modifications to the consent form, i.e. changes that affect the rights, safety, or welfare of the subjects, FDA recommends that the sponsor share the revisions with the investigators and their IRBs. If the clinical investigation has a central IRB working in cooperation with local IRBs, the revisions should be forwarded to the central IRB.[48] Alternatively, local issues may be addressed by the central IRB depending on the review agreement between the local IRB(s) and central IRB.

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**
*Policy Analyst*

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

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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.

**From:** [redacted]
**Sent:** Thursday, December 29, 2016 9:09 AM
**To:** OC GCP Questions
**Subject:** Consent Question - Appendices

Good morning,

A client is providing IRB review for two health systems in close proximity, one that applies the Ethical & Religious Directives and one that does not. It is possible that a single PI might oversee a clinical trial at both health systems. The client is proposing a consent that would include two appendices with birth control/regulation options. Potential subjects would be asked to review the information in the appendix that applies to the health system they are being recruited or referred from.

Is this approach acceptable or are two distinct consents required (or preferred)?

Thank you in advance for any clarification or guidance you can provide.

Sincerely,

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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