**From:** OC GCP Questions
**To:** [redacted]
**Subject:** GCP question_informed consent
**Date:** Wednesday, January 08, 2014 7:48:31 AM
**Importance:** High

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Good morning –

We have not addressed this issue before and I conferred with my colleagues here in OGCP. There is nothing in the regulations that prevents the informed consent to be given to subjects (couples) simultaneously. However we suggest that you bring this issue to your reviewing IRB as it is a subject protection issue. Coercion might be an issue if one member of the couple agrees the other might may not want to argue, particularly not in front of the 3rd party, even if he or she has real reasons for no longer wanting to participated give the nature of the study.

Please consult with your reviewing IRB.

Additionally you may want to review the FDA guidances on informed consent and IRB FAQs.

Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet

Guidances > A Guide to Informed Consent - Information Sheet

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



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**From:** [Redacted]
**Sent:** Monday, January 06, 2014 9:04 PM
**To:** OC GCP Questions
**Subject:** GCP question_informed consent
**Importance:** High

Dear Sir/Madam,

I am the clinical project coordinator for a clinical trial where the intervention is a procedure conducted on consenting homosexual men.

Sometimes the enrolled men are couples. The usual procedure is that the couples are consented individually but some of the investigators wish to consent these couples together.

We are reconsenting our participants at the moment following the implementation of a protocol amendment and when the couple are offered the opportunity to consent in presence of the other, they agree to this.

Can you please advise if there is any problem with privacy and confidentiality issue in consenting the couple together in the same room?

I have believe that this process could be interpreted as a form of coercion and against the principles of privacy and confidentiality.

I would like confirmation on my understanding of ICH GCP guidelines and all other regulatory statements.

Many thanks for your advice.

Best regards,

[Redacted]