**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Screening for two protocols at the same time -Query
**Date:** Wednesday, December 02, 2015 8:08:19 AM

---

Good morning –

While the regulations do not prohibit the use of multiple consent documents, FDA suggests that they be used with caution. Multiple consent documents may be confusing to a research subject and if, inadvertently, one document is not presented, and critical information may not be relayed to the research subject. It depends on the complexity of the study and the subject's level of understanding to make an informed decision. See excerpt below from the Information Sheet on Screening Tests Prior to Study Enrollment:
Search for FDA Guidance Documents > Screening Tests Prior to Study Enrollment - Information Sheet

For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research.

The content (and format) of any form(s) that are used need to be worked out with the clinical investigator and with the IRB that will be reviewing the study. We would expect any informed consent form for a study (including a "screening form" for that study) to include all of the required elements. The consent form for the screening procedures (if a separate form is used) would need to include descriptions of procedures covered--in this case the screening procedures. In each case, the form(s) need to be signed before the activities covered by the form (screening or the research activities) can begin.

You might want to review FDA draft guidance on informed consent.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf Please see section 4 starting on page 9 through page 10.

That said it might be helpful to ask the reviewing IRB if they approve of presenting the potential subjects with multiple study ICDs for different protocols at the same time.

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

**From:** [redacted]
**Sent:** Monday, November 30, 2015 6:42 PM
**To:** OC GCP Questions
**Subject:** Screening for two protocols at the same time -Query

Good afternoon,

During quality control review I have encountered the following:

1- A patient signed on the same day the tissue consent for two different protocols. The tissue inform consent form (screening consent) for each protocol is to determine a marker that is require for each specific protocol, and depending on the result the patient can be part of either protocol and then sign the main informed consent form.

I consider this practice to be overwhelming for the subject and questions the ability of subject to choose which study he/she wants to be part of.

To the best of your knowledge, can you provide advice and determine if this practice is acceptable or not?

Thank you for your input.

Sincerely,

[redacted]