


**Worksheet 304 – Primary Reviewer Supplemental Worksheet**  
**Waiver or Alteration of the Informed Consent Process**

**For a Waiver or alteration of Informed Consent process**

Is this a non-emergency study regulated by FDA?

- Yes.  FDA Regulations do not allow waiver or alteration of the consent process.
- No

Are **all** waiver or alteration criteria met (see below)?

- The research involves no more than minimal risk to participants
- The waiver or alteration will not adversely affect the rights and welfare of participants
- The research could not practicably be carried out without the waiver or alteration

- Yes  
 No

Comments:

**For a waiver of written documentation of the consent process being requested:**

Are the criteria for a waiver met? (see below)

- The research involves no more than minimal risk to participants.
- The waiver or alteration will not adversely affect the rights and welfare of participants.
- The research could not practicably be carried out without the alteration.
- The P.I. will provide to participants additional pertinent information following participation in the study (review the written description of information to be provided to participants, and describe any concerns in the comments section below.)

- Yes.  
 No.

Comments:

Should the investigator provide participants with a written statement regarding the study?

- Yes.  
 No.

Comments: