

Consent Process Examples

Consent Cover Letter Process for a Questionnaire or Survey

Description: When research using a questionnaire or survey is minimal risk, a waiver of documentation of consent may be utilized. When a consent cover letter accompanies the questionnaire or survey, consent to participate is given by completing and returning the questionnaire. This example illustrates the steps a study team might take to obtain consent for a questionnaire or survey using a consent cover letter. ***The IRB must first approve a research proposal and waive documentation of consent. The Waiver of Documentation of Consent can be requested in the New Study Application, Consent Process page, question 8.***

1. **Provide the participant with all the required information about the study in a language the participant understands.**
 - a. Use the [consent document checklist](#) on the IRB website to ensure all required consent elements are included. Typically, the consent document for a questionnaire or survey only requires the basic elements of informed consent.
 - b. Include a statement in the cover letter saying that completion and return of the questionnaire or survey acts as the individual's agreement to be in the study. If the individual does not want to participate, he/she does not have to complete and return the questionnaire or survey.
 - c. Ensure a copy of the consent cover letter is made available to the individual using one of the following methods:
 1. Include a copy with the mailed questionnaire or survey.
 2. Include the text in an email to the participant.
 3. Include as the first page of the online survey.
2. **Give the participant an opportunity to ask questions before providing consent.** In some cases, a discussion will not take place with the individual if the questionnaire or survey is mailed or sent electronically. However, there should still be an appropriate avenue, usually telephone or email, for individuals to talk with a member of the study team about questions or concerns.
3. **Give the participant enough time to consider being in the study.**
4. **Document that the participant's consent was obtained before beginning study procedures.** A returned questionnaire or survey acts as documentation of consent instead of a signed consent document. In some circumstances, the study team will not be able to associate the questionnaire with an individual because the questionnaire is anonymous. In this case, it is not expected that the study team will have identifiable documentation of consent.