

Consent Process Examples
Consent Cover Letter Process for a Mailed or Online Research Questionnaire

1. **Provide the participant with all of the required information about the study.**
 - a. Use the consent cover letter template on the IRB website to ensure all required consent elements are included.
 - b. Include a statement in the cover letter saying that completion and return of the questionnaire acts as the individual's consent. If the individual does not want to participate, he/she does not have to complete and return the survey.
 - c. Make the consent cover letter available to the individual using one of the following methods:
 1. Include with the mailed questionnaire
 2. Include in an email to the participant
 3. Include as the first page of the online survey
2. **Give information in a language the participant understands.**
3. **Give the participant an opportunity to ask questions before providing consent.**
 - a. Have an appropriate avenue, usually telephone or email, for individuals to talk with a member of the study team about questions or concerns.
4. **Give the participant enough time to consider being in the study.**
5. **Do not use exculpatory language in the consent process.**
6. **Document that the participant's consent was obtained before beginning study procedures.**
 - a. A returned questionnaire 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.