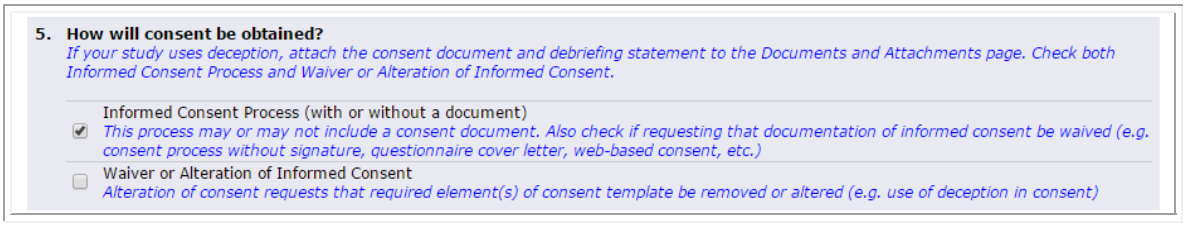
INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

CONSENT COVER LETTER
INSTRUCTIONS FOR USE

For studies involving questionnaires or surveys, the IRB may waive the requirement to document informed consent (i.e. waive the need for a signed consent document) if the IRB can make the appropriate findings. Follow the directions below to request a waiver of documentation of informed consent using a consent cover letter.

1. Use the Consent Cover Letter template provided on the IRB Forms webpage (http://www.research.utah.edu/irb/forms/index.html). Include all the information as directed in the template.

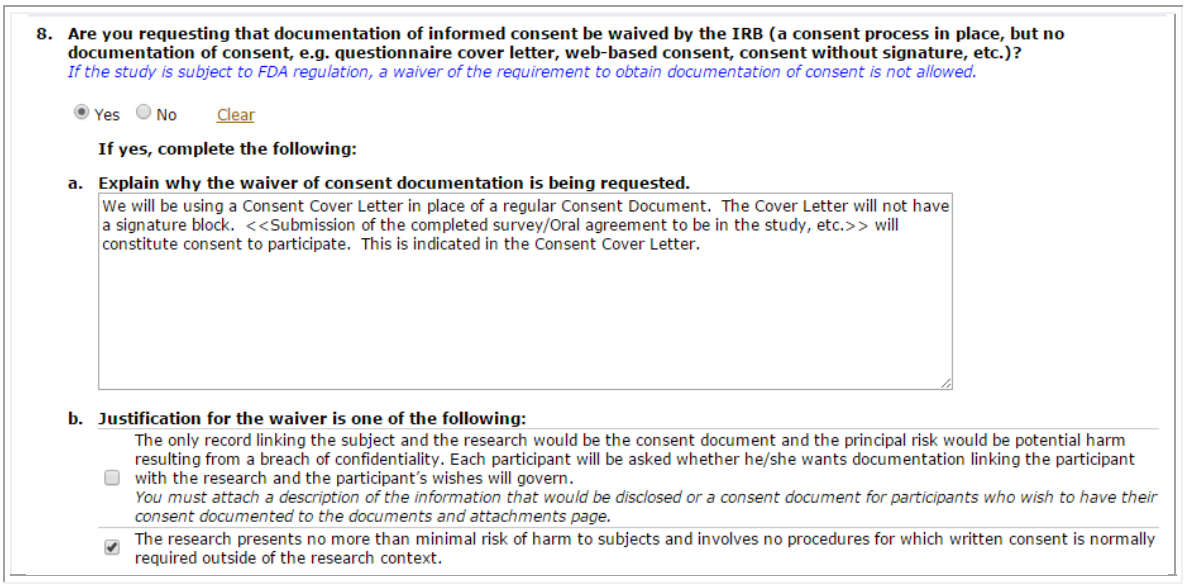
2. In the ERICA application, check "Informed Consent Process (with or without a document)" in question #5 on the **Study Information Page** (see below). The IRB considers a questionnaire cover letter a consent document. You will be prompted to complete the Consent Process page later in the application.



5. How will consent be obtained?
If your study uses deception, attach the consent document and debriefing statement to the Documents and Attachments page. Check both Informed Consent Process and Waiver or Alteration of Informed Consent.

- [x] Informed Consent Process (with or without a document)
  This process may or may not include a consent document. Also check if requesting that documentation of informed consent be waived (e.g. consent process without signature, questionnaire cover letter, web-based consent, etc.)
- [ ] Waiver or Alteration of Informed Consent
  Alteration of consent requests that required element(s) of consent template be removed or altered (e.g. use of deception in consent)

3. In the ERICA application, request that documentation of consent be waived by the IRB on the Consent Process Page, question #8 (see below).
   a. Explain why you are requesting that documentation of consent be waived.
   b. Check the box next to "The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context."



8. Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?
If the study is subject to FDA regulation, a waiver of the requirement to obtain documentation of consent is not allowed.

(•) Yes ( ) No Clear

If yes, complete the following:

a. Explain why the waiver of consent documentation is being requested.

We will be using a Consent Cover Letter in place of a regular Consent Document. The Cover Letter will not have a signature block. <<Submission of the completed survey/Oral agreement to be in the study, etc.>> will constitute consent to participate. This is indicated in the Consent Cover Letter.

b. Justification for the waiver is one of the following:

- [ ] The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participant's wishes will govern.
  You must attach a description of the information that would be disclosed or a consent document for participants who wish to have their consent documented to the documents and attachments page.
- [x] The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.