- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, subjects will be provided with additional pertinent information after participation.

Requirements for waiving documentation of informed consent:

Federal regulations allow for waiving documentation of consent (i.e., a signed consent form) if an IRB determines that either:

1. 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 subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern;

OR

2. 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. Investigators may specifically request a waiver of documentation of informed consent by providing information that supports one of the two conditions above.

Even if a waiver of documentation of consent is approved, research subjects must be provided enough information to make a fully informed decision. Sometimes that information will be delivered verbally, such as over the phone. In other situations, research subjects may be given a written document containing information, that they do not sign. If research subjects are completing an online survey, the webpage should display the relevant consent information and end with a statement like the following: