Understanding Waivers

45 CFR 46.116 outlines the general requirements for informed consent. Alternatively, some studies may qualify for a waiver of some or all elements of consent. These are considered on a case-by-case basis; the IRB must consider regulations and policies from several sources when determining whether or not a waiver is appropriate for a study. According to §46.116(c)(d), an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or the IRB may waive the requirement to obtain informed consent provided the IRB finds that the research meets certain guidelines. The guidelines for altering or waiving consent will be outlined in the Board Reviewer Checklist as you review the study.

Consent Verses Authorization

When considering waivers, it is important to understand the difference between *consent* and *authorization*. When a participant signs a consent document, they are affirming that they have read the information presented in the consent document, and they are voluntarily agreeing to take part in the research study.

Certain studies that include Protected Health Information (PHI) require additional agreement from the participant to "authorize" the researchers to use and disclose health information about the participant for the study (see "Health Insurance Portability and Accountability Act of 1996 (HIPAA)" in the Glossary for more information).

Most Main Campus studies do not require that the researchers obtain authorization for use of PHI, because they often do not use or record participant health information as a part of the research. Research that takes place within the Covered Entity (e.g. medical research) usually involves PHI, and so authorization is generally required. The "Authorization for Use of Protected Health Information" section of the consent document template (available on the IRB website) includes the language required to obtain authorization from patients.

Waivers Quick Reference

The following is a brief overview of the types of waivers that may be requested, where in the application they are requested, and common examples of situations where it may be appropriate to grant the waiver(s).

Waiver of Informed Consent:

Description: No contact with participants and no documentation of consent.
Example: Chart or archived record review.

New Study Application:

1. **Section 3.4, How will CONSENT be obtained?:** Select "Waiver or Alteration of Informed Consent".
2. **Request for Waiver or Alteration of Consent page**: Select "Waiver of Informed Consent" under "Type of Request" and complete the rest of the page.

Alteration of Informed Consent:

Description: Specific elements of informed consent are removed or altered. A consent document is still used.
Example: When a study uses deception, the researcher may need to remove or alter an element of consent (e.g. the actual purpose of the research).

New Study Application:

1. **Section 3.4, How will CONSENT be obtained?**: Select "Consent Document" and "Waiver or Alteration of Informed Consent".
2. **Request for Waiver or Alteration of Consent page**: Select "Alteration of Informed Consent" under "Type of Request" and complete the rest of the page.
3. **Consent Process Page**: Complete this page entirely.
4. **Documents and Attachments**: If applicable, attach a debriefing form in addition to the consent document.

Waiver of Documentation:

Description: Consent is obtained, but no documentation of consent (i.e. signature) is required.
Example: A questionnaire cover letter or web-based consent with no signature block where submitting the completed questionnaire constitutes consent to participate in the research.

New Study Application:

1. **Section 3.4, How will CONSENT be obtained?**: Select "Consent Document".
2. **Consent Process page, #8**: Select "Yes" and complete Sections 8a and 8b.
3. **Documents and Attachments**: Attach a consent document altered as requested in the waiver.

Waiver of Authorization:

Description: Waives the requirement for authorization for all uses of Protected Health Information (PHI) for a particular study, or a particular aspect of a study. This waiver is only applicable if the study involves PHI.
Example: Investigator uses medical records for screening or recruitment purposes, or to identify potential eligible participants to invite them to participate.

New Study Application:

1. **Section 4.1a, PHI**: Select "Waiver of Authorization".
2. **Request for Waiver of Authorization page**: Complete this page entirely.
3. **Documents and Attachments**: If participants will be contacted for participation in research, attach the appropriate consent document(s).

If you need assistance determining which consent process is appropriate for a study, please contact the IRB staff.