

INSTRUCTIONS FOR UNSIGNED (VS. SIGNED) CONSENT FORMS

If you wish to obtain **verbal** or **online** unsigned consent instead of signed (written/ documented) consent:

a. **For Verbal Consent.**

-In the protocol, you must apply for waiver of signed consent. Go to the **Informed Consent** section; under the **Informed Consent** tab, in the pop-up box for **Consent/ Waiver Description**, click on Consent Type field and select "*Unsigned Consent*" (or "Altered and Unsigned Consent" if appropriate, e.g., if the study involves deception). Select Criterion A, B, or C for waiver justification, and answer questions asked in the box.

Note: Most studies do not qualify under Criterion A, which requires that there are absolutely NO other data besides the signed consent form that could link the subject and the research. Criterion C is also relatively rare. Thus, it is usually preferable to select *Criterion B*, providing justification that the research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside of the research context (assuming the latter is accurate).

-In the consent form discussion of **confidentiality** measures, include mention that subjects will be asked for oral rather than signed consent.

-In the **Consent** section at the end of the form, remove signature and date lines and replace with appropriate wording, e.g.:

CONSENT:

If you agree to participate in this research study, please say so. We will give you a copy of this form to keep for future reference.

[Optional]

Signature of Investigator/Person Obtaining Consent

Date

b. **For Online Consent.**

-Apply for waiver of signed consent in the protocol as outlined above. Select Waiver Criterion B (if accurate that the study involves no more than minimal risk, etc.) and explain that waiver is requested because consent will be obtained online.

-In the Consent section at the end of the form, remove signature and date lines and replace with appropriate wording, e.g.:

CONSENT:

If you agree to participate in this research study, please *[give instructions, e.g., "print a copy of this page to keep for future reference, then click on the "Accept" button below."]*