



Title: Obtaining Verbal Consent – The Basics

Date of Last Revision: 2013

Audience: Researchers Obtaining Verbal Informed Consent

Here are some **basic points for researchers to remember when obtaining verbal consent:**

- ✓ [Download](#) the current IRB approval letter.
 - Confirm that the IRB has approved a waiver of documented (signed) informed consent.
 - Determine if the IRB is requiring the use of a Study Information Sheet to facilitate the informed consent process.
- ✓ Download the IRB approved (containing the IRB approval stamp) Study Information Sheet, if applicable.

Steps to Obtaining Verbal Informed Consent:

- ✓ Only researchers approved by the IRB to obtain verbal informed consent can do so.
- ✓ If unsure who is approved to obtain consent, review Section 2 of the Protocol Narrative.
- ✓ The researcher should:
 - Explain the study to the prospective subject including a discussion of the study purpose, procedures, risks, benefits, compensation, and alternatives to participation, but above all, that participation is completely voluntary.
 - Provide the prospective subject the Study Information Sheet for review, when applicable.
 - Allow the potential subject sufficient time to ask questions. *NOTE: "Sufficient time" can range from minutes to hours, dependent upon how long it reasonably takes to evaluate the procedures, risks, potential benefits, and potential alternatives.*
 - Assure that the prospective subject understands the research procedures.
 - The researcher may ask open-ended questions to ensure comprehension.
 - Answer the prospective subject questions.
 - Obtain the subject's verbal agreement to participate in the research.
- ✓ Although not required, researchers may find it helpful to document the informed consent process in the research record. For example, how much time the subject was given to read the Study Information Sheet and consider participation, when and where the subject provided informed consent, along with any substantive discussions relating to the subject's participation.

Note re: Web-Based Studies: When posting the Study Information Sheet on the internet to obtain informed consent for a web-based research activity (e.g., survey, cognitive testing), informed consent is implied when the subject completes the activity.

