Using the Multiple Language Verbal Translation Preparative Forms and Process

PURPOSE

The purpose of this document is to provide guidance to investigators about how to consent non-English-speaking participants using a Verbal Translation Preparative Sheet (VTPS).

PROCEDURE

The basic and additional elements of informed consent (including required disclosures when the research involves private identifiable information or identifiable biospecimens) must be made available to a research subject at the University of Texas MD Anderson Cancer Center. Informed consent is not a document, but a process. In order to assist investigators who are consenting individuals whose primary language is not English, summaries are now available that explain the basic elements of consent. This summary has been made available in the most commonly spoken foreign languages of patients at MD Anderson.

When consenting a non-English speaking patient to a research study, the patient should first be given a copy of the Verbal Translation Preparative Sheet (VTPS) in their primary language to read. The VTPS informs the potential participant of the types of information they should receive during the verbal translation of the Informed Consent Document.

The translator will verbally translate the information given in the English version of the informed consent. If the patient agrees to participate in the research, signatures can be obtained. The IRB Policy for Consenting Non-English Speaking Participants will be followed.

The VTPS forms can be found in several different languages (see VTPS Form - Spanish or Request the VTPS in Other Languages).

Below you can see the text of the consent summary as it is in English.

If you have any questions or concerns call the Office of Human Subjects Protection at 713-792-6477 or review the FAQ: How to Consent Non-English Speaking Patients.

If you need the VTPS translated into a different language, please contact IRB Help.
You are being asked to take part in a research study. The informed consent document will be read to you in the language you are most comfortable using. This is done to help you fully understand why the research is being performed and what your part in that research may be.

The topics that will be covered in this informed consent document include:

- The main goal/purpose of this study
- A description of what will take place if you take part in this study
- The risks, if any, that you may be exposed to while you are on this study
- The possible benefits to you and/or others that may come from taking part in this study
- Other options you may choose, instead of taking part in this study
- The person obtaining consent has discussed the basic and appropriate additional elements of disclosure to the participant or their legally authorized representative (LAR), including required disclosures when the research involves identifiable biological samples and/or private information

This study may have optional procedures. Optional procedures are “extra” research tests, such as extra blood tests, biopsies, x-rays, scans, and/or questionnaires. Optional procedures do not benefit you personally, but future patients may benefit from what is learned. If this study does have optional procedures, you do not have to agree to take part in them in order to take part in this study.

You will be told if there are any company(s) or institution(s) sponsoring this study. You may be told if any study drugs are provided at no cost to you. You will also be told how many people will be enrolled in this study at M.D. Anderson and at other institutions (if any).

At any time during this study, you will be able to contact someone to answer any questions you may have. If you have questions or concerns that you feel have not been addressed, you can leave the study. You are free to leave this study for any reason at anytime.

You may ask your doctor or the study chair any questions you have about this study, including financial considerations. You may also contact the Chair of the Institutional Review Board (IRB) at (713) 792-6477 with any questions that have to do with your rights as a research participant. The IRB is a committee made up of doctors, researchers, and members of the community that is responsible for protecting the participants involved in research studies and making sure all research is done in an ethical manner.
After reviewing the informed consent document and having all of your questions answered, you should know enough about this study to be able to make an informed decision about whether you want to take part.

SIGNATURE OF POTENTIAL PARTICIPANT ___________________________ DATE __________

SIGNATURE OF PARENT OR GUARDIAN, IF APPLICABLE ___________________________ DATE __________

SIGNATURE OF OTHER PARENT OR GUARDIAN, IF REQUIRED BY THE IRB ___________________________ DATE __________

SIGNATURE OF MINOR (AGE 13-17) ___________________________ DATE __________

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN A MEMBER OF THE RESEARCH STUDY TEAM) ___________________________ DATE __________