Trustees of Dartmouth College • Dartmouth-Hitchcock Medical Center
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Office of Grants and Contracts • 11 Rope Ferry Road #6210 • Hanover, NH 03755-1404
Phone (603) 646-3053 / 646-1598 • fax 646-1941

TO: Principal Investigators and Research Coordinators
FROM: Liz Bankert, Director Dartmouth CPHS
RE: Informed Consent Evaluation Tool (ICE FT)
****

Federal regulations and ethical principles require every research participant be fully informed of the basic elements of the research study prior to enrollment. Obtaining informed consent is a difficult task. The CPHS approved Consent Form contain the elements needed to ensure informed consent. However obtaining informed consent consists of more than just the Form – it is a process and an ongoing dialog with the potential participant.

The CPHS is introducing a tool to assist in the consent process. The tool is an evaluation procedure designed to enhance the communication between researcher and potential participant. The tool is referred to as "Informed Consent Evaluation Feedback Tool" (ICE FT). The ICE FT is a simple list of questions which include the basic elements of informed consent. The ICE FT can be used *during* the consent process in order to evaluate the level of understanding of the potential research participant.

Using the ICE FT, the researcher can evaluate, in real time, the level of understanding of the potential participant. The participant should not enroll in the research study until both the researcher and the participant are confident of his/her understanding of the basic elements of the informed consent.

In addition, the ICE FT can be used as a recording mechanism that can document the discussions that took place. For example, the researcher can take notes on the ICE FT and the completed ICE FT can become part of the study record. It can also be used as a source of reference as the participant proceeds in the study.

With the increased scrutiny of researchers, research institutions and institutional review boards, we believe this the opportune time to introduce ICE FT and incorporate it into the consent process.

While using the ICE FT is not required, we do hope that you will give it a try. We think you will find it a helpful tool in your research, and ask that you please contact us with any questions or comments.

Enclosures
- ICE FT Instruction Sheet
- ICE FT

Informed Consent Evaluation Tool (ICE FT)
Instruction Sheet

There are at least two ways to use the ICE FT tool to evaluate the understanding of the potential research participant during the consent process. Please remember this is not a test for the researcher or the potential participant. The questions are designed to help initiate a meaningful dialogue in which the potential participant feels comfortable asking questions.

Example One: The ICE FT is given to the potential participant prior to discussing the details of the research study with a statement such as, "We are about to discuss a research project. It is important you understand the research study as you make your decision whether or not to participate. We will use this tool to assist us in making sure you understand the project. Take a look before we get started." The researcher then uses the ICE FT tool throughout the consent process as a prompter to encourage an interactive dialogue. The intent is to create an atmosphere of verbal interaction between researcher and potential participant. The researcher refers to the ICE FT and asks the participant to explain the purpose of the study. The researcher and the participant may complete the ICE FT together.

Example Two: After the research project has been described to the potential participant the researcher will hand him/her the ICE FT. Allow time for the potential participant to review and respond to the questions on the form. The researcher reviews the items on the form with the participant and answers any questions that the participant does not adequately address. The dialogue is initiated as the researcher more completely describes any aspect of the research project that the potential participant does not understand according to the ICE FT.

Informed Consent Evaluation Feedback Tool (ICE FT)

IRB #: _____

Title of the study:

1. **The purpose of the research is:** **or** I am not sure

2. **Possible benefits of the research include:** **or** I am not sure

3. **Possible risks of the research include:** **or** I am not sure

4. I have no treatment choices other than enrolling in this study.

True False Not Sure

5. The costs of this research will be paid by the sponsor of the study.

True False Not Sure

6. Participation in this research is voluntary.

True False Not Sure

7. My medical records related to this study may be reviewed by federal agencies and the sponsor of the study.

True False Not Sure

8. I must continue in the study until completion.

True False Not Sure

9. The researcher will choose my treatment.

True False Not Sure

10. I may not benefit by taking part in this research study.

True False Not Sure

I have some questions for the research team: