The University of Toledo
Human Research Protection Program
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Guidance for Obtaining Informed Consent via Telephone

The University of Toledo IRBs follows applicable research consent regulations and guidance which would allow obtaining informed consent via telephone and mail. Specifically, nothing in the federal regulations or Good Clinical Practice (GCP) guidance prohibits consent without a face to face interaction. However, for studies where signed, written consent is required, you may not obtain consent via telephone *only*. The subject must have a copy of the informed consent form (ICF) in front of them *before* the study is explained and consent is obtained. ,

Consent is always a three-part process – 1) providing information, 2) the ability to discussing/answer questions and 3) obtaining an agreement to participate/signing the ICF. Your application in IRB Manager should explain how you will execute all three parts.

In addition to IRB requirements, research taking place at UTMC must also comply with Policy # 3364-100-10-01, "Consent to Treat and Informed Consent." Under this policy, telephone consent will only be approved under extenuating circumstances, therefore, your IRB application should justify why you are requesting to obtain consent via telephone. After obtaining IRB approval for obtaining informed consent by telephone, you may send the ICF to the subject via mail or fax.

The telephone call to the subject may not take place until the subject has received the consent document. It is essential that the consent process include (but is not limited to) the following steps:

1. TWO copies of the ICF should be mailed to the subject (one to keep; one to send back) along with any other written material to be provided to subjects during the consent process;

2. an actual conversation regarding the study consent information and all required elements such as voluntariness, right to withdraw, and authorization for use and disclosure of protected health information (e.g. PHI info sent to sponsors; PHI may be reviewed by UT IRB, etc.) occurs prior to signing the consent;

3. the subject is given an opportunity to inquire about the study after receiving the ICF/after discussing the study with the person obtaining consent;

4. the subject is given ample opportunity to decide whether or not to participate prior to signing the consent;

5. a consent form signed and dated by the subject (or LAR) is obtained via mail (fax is okay);

6. the consent process is adequately documented in the study record by the person obtaining consent {e.g. date, time of conversation(s)}; (note: for research taking place at UTMC, consent by telephone must be witnessed by one other person besides than the physician, and this must also be documented.)

7. the person obtaining consent signs the ICF upon receipt of the form AND notes why there is a difference in the date the subject signed and the date the person obtaining consent signed.

8. a copy of the fully signed document (with signatures of subject & person obtaining consent) is provided to the subject PRIOR to participation.

Amendments: The same process should be used when an amendment to a protocol alters (increases) the risk to subjects or otherwise introduces new information that may impact the subject's willingness to continue in the study. In order to assure a subject's understanding of the changes, the same steps should be followed, and consent must be obtained prior to their continued participation in the trial.

Please remember - the method(s) of obtaining consent must be approved by the IRB, and you must be detailed and specific about this process in the New IRB Research xForm in IRB Manager.

If your research study is approved for a waiver of *written* consent and you will be obtaining informed consent via telephone, you must still follow steps 1,2 3, 4 and 6 above with the exception that you would only need to provide one copy of the ICF. It may be acceptable to provide the consent form to the subject via email when a waiver of written consent is approved, if the IRB determines this is appropriate for the study.

The IRB may require additional steps or safeguards depending on the research study, which will be stated in your IRB approval letter.