

The University of Toledo
Human Research Protection Program
Center for Creative Education Building, Suite 2102
3000 Arlington Ave., Toledo, Ohio 43623-1470

Guidance for Obtaining Informed Consent via Telephone

The University of Toledo IRB follows applicable research consent regulations and guidance

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 ~~is not~~ provided 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 another person besides 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 ~~amendments to the ICF are made~~ (e) - (n) - 7 - 7P11 (n) - t (b)