SOP: Remote Informed Consent Process				
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HRP-092	03/19/2018	J.Morelli, C.Choy, and N. Mitra	J. Morelli, Health Sciences IRB	1 of 2

1 PURPOSE

1.1 This procedure establishes the informed consent process in situations where it is not possible for the subject or legally authorized representative (LAR) to physically come to Tufts Medical Center or Tufts University for an in-person informed consent discussion (for example, lives outside of Boston area, inclement weather, schedule constraint, study consent time frame, etc.).

1.2 The process begins when the PI or IRB determines that a situation has occurred where it is not possible for the subject or LAR to physically come to Tufts Medical Center or Tufts University for an in-person informed consent discussion.

1.3 The process ends when the subject is no longer a research subject or potential research subject.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 When there is a situation where it is not possible for the subject or LAR to physically come to Tufts Medical Center or Tufts University for an in-person informed consent discussion, the informed consent process may be performed remotely as described below.

3.2 Note that federal regulatory agencies do not regard verbal telephone consent as constituting the documentation of signed informed consent that is required by federal regulations. The process described below should not be confused with the IRB finding that a protocol meets the criteria for a waiver or alteration of the consent document /process.

4 RESPONSIBILITIES

4. 1 When the discussion or consent process takes place by a means other than face-to-face communication (for example over phone/Skype), but still requires written documentation of consent, follow the procedures below to ensure adequate documentation of prospective informed consent for research.

4. 2 The person conducting the informed consent process must carefully review each section of the informed consent form (ICF) and address the subject or LAR's questions and concerns.

5 PROCEDURE

5.1 E-mail, fax, (or mail) the ICF to the subject or LAR. (If mailed, two copies will be mailed, so the subject or LAR can keep a copy.) For studies that include sensitive information, take special precautions, as needed, to protect confidentiality (e.g. verify with the subject that the mailing address, fax, or e-mail is correct and it is acceptable to send the consent in this way).

5.2 The subject or LAR will be instructed to contact the investigator after reviewing the ICF.

5.3 The person consenting the subject or LAR will have the same consent discussion via telephone that they would have had in-person (including asking questions to gauge comprehension and answering the subject's or LAR's questions).

5.4 Consider including a method to ensure the person being consented is the subject or LAR, e.g., verification of state identification or other identifying documents or use of personal questions, biometric methods, or visual methods. For FDA regulated studies, FDA Guidance on Use of Electronic Informed Consent requires verification of identity if any or all of the consent process takes place remotely.

5.5 A witness will be present during telephone consent at Tufts Medical Center or Tufts University with the Investigator conducting the consent process. The witness will be able to hear both sides of the conversation (e.g. speaker phone, dual phones, conference line).

5.6 If the subject or LAR consents, the subject or LAR will complete and sign the ICF (in all appropriate sections) and either e-mail a scanned PDF, fax, (or mail) the signed and dated ICF to the research team. A pre-paid, self-addressed envelope should be provided to the subject or LAR to mail back one of the original ICFs.

5.7 The subject or LAR will be instructed to keep one signed copy of the ICF for his/her own records.

5.8 Once the ICF (signed & dated by the subject or LAR) is received by the research team, the Investigator who explained the study should sign the appropriate signature line with the current date (the date they receive the ICF and sign, not the date they consented the subject or LAR). Research cannot proceed until the ICF signed & dated by the subject or LAR) is received by the research team and has been signed and dated by the Investigator.

5.9 Ensure all signatures and dates are accurately documented. Any errors should be noted in a note or memo to file.

5.10 Document (in a separate note to file/progress note, or with a note under the Principal Investigator's signature line on the ICF) that consent was obtained over the telephone with the actual date and mailed/e-mailed/faxed back. For example "*Discussed with [subject or LAR name] via telephone on [insert date], and received signed consent form on [insert date].*" Specify in the note, the reason for performing the informed consent discussion over the telephone and the participation of the witness to the informed consent discussion.

5.11 No research-related activities will occur before the receipt of the signed ICF.

6 MATERIALS

6.1 SOP: Legally Authorized Representatives, Children, and Guardians

7 REFERENCES

7.1 21 CFR §50.20, 50.25

7.2 45 CFR §46.116

7.3 21 CFR §50.27

7.4 45 CFR §46.117