1.0 SCOPE

1.1. This SOP describes the process for obtaining and documenting informed consent, assent and parental permission from individuals involved in research involving human subjects as defined in CCHMC Research Policy R-03, when the individual are not physically present for the consenting process.

1.2. This SOP applies to the informed consent process of research only; it does not replace any informed consent requirements related to standard medical treatment.

2.0 PROCEDURES

2.1. **This SOP supplement SOP 41-1.4 – Informed Consent Process and Documentation and describes additional requirements to the standard informed consent process.**

2.2. **Obtaining informed consent/assent/parental permission from individuals who are not physically present for the consenting process**

2.2.1. Unless the IRB approved otherwise, the following process for obtaining consent in this circumstance should proceed as described in SOP 41-1.4 with the following exceptions.

2.2.1.1. Prior to obtaining informed consent, the researcher must ensure that the individual has received complete copies of all information related to the informed consent process (i.e. consent/assent/parental permission forms, information sheets, etc)

2.2.1.2. The consent discussion should take place directly with the individual via conference call, video conference, web conference, etc.

2.3. **Documentation of consent/assent/parental permission from individuals who are not physically present for the consenting process**

2.3.1. Unless the IRB has approved otherwise, the following process for documentation of consent should be completed at the time consent is obtained:

2.3.1.1. The participant/LAR signs ad dates the consent form on the appropriate line.

2.3.1.2. The participant/LAR electronically transfers a copy of the signed and dated document to the research team via fax or email.

2.3.1.3. The person authorized to obtain the consent signs ad dates the form on the appropriate line.

2.3.1.4. The method/process used to obtain the consent/assent/parental permission is documented on the signature page of the consent form as well as in the informed consent progress note.

2.3.2. The signed and dated consent form should be distributed per ORCRA SOP 41-1.4.

2.4. **Requirements for additional IRB review and approval**

2.4.1. A deviation from this process without specific IRB approval constitutes a protocol violation. The researcher should consider whether it is likely that compliance with the above process will be possible (i.e. the participant/LAS will not have access to fax or email) and that researcher should consult the IRB to establish an acceptable alternative process.

3.0 REFERENCES

3.1. CCHMC Research Policy R-03

3.2. ORCRA SOP 41-1.4

3.3. CCHMC ORCRA Guidance Informed Consent: Process, Elements, Documentation, & Waivers

3.4. 21 CFR 50 Protection of human subjects

3.5. 21 CFR 56 Institutional Review Boards

3.6. 21 CFR 312 Investigational new drug applications

4.0 APPROVAL

Approved electronically via Compliance360

REVISION HISTORY	
Original Date	**July 1, 2009**
Revision Date	June 1, 2013
No changes. Management review.	