UNC Consent Process for Isolation Areas

This checklist and form are meant to serve as an aide when alternate consent documentation processes are required for studies when a signed informed consent document cannot be collected from the subject's location and included in the study records (e.g., a COVID patient's isolation room). This consent process is permissible for all studies including FDA regulated (FDA March 2020 Guidance) for the duration of the public health emergency in relation to COVID-19. A modification to utilize this process does not need to be submitted to the IRB. However, the OHRE does recommend utilization of the checklist and that the documentation steps below are followed.

Please note, utilizing this process is never to be considered the standard consent process and an adequate reason for utilization (e.g. spread of COVID in COVID patient's room) must be documented in the utilization checklist below.

Individuals Involved:

- Subject/Legal Authorized Representative- If the subject is unable to appropriately participate or is incapable of providing consent and a LAR is not available please refer to alternate emergency consent procedures (Consent Process Algorithm for In-Patient Subjects and FDA Regulated Research).
- Study Staff-Individual obtaining consent- **does not need to be physically located with the subject.**
- Observer/witness (e.g. ideally an independent individual not associated with the study, but if not feasible a study staff member different than the individual conducting ICF process)-**does need to be physically present with the subject.**

Documentation Needed

- Signed Consent Form and HIPAA authorization forms that stay with the subject and documented in Attestation/Research Record.
- Attestation filled out below completely and placed in research record.
- Consent signed by study staff that obtained consent and witness for research record

The following attestation checklist will be completed by the study staff member conducting the ICF process.

Attestation Checklist IRB #: Study title: Subject ID: Witness/Observer Name: Study Staff/Consenter Name:		
Reason for Utilizing Process _____		
Y	**N**	**Consenting Process**
☐	☐	1. Observer/witness brought paper ICF, HIPAA Authorization & ink pen into subject's room.
☐	☐	2. Observer/witness provided their full name, and confirmation to the study staff member that they understand their role as a witness/observer of the ICF process .
☐	☐	3. Observer/witness confirmed to study staff member via phone, Zoom, FaceTime, WebEx or other IT approved mechanism (circle utilized mechanism) the version of ICF being used, version noted by study staff and the HIPAA Authorization form is present. • **ICF Version/date: _____ HIPAA Auth. Form: _____**
☐	☐	4. Investigator discussed consent forms with the subject and answered all of the subject's questions. • **Noted by study staff: _____**
☐	☐	5. Investigator discussed consent forms with the subject and answered all of the subject's questions. • **Noted by observer/witness: _____**
☐	☐	6. Subject signed the informed consent form, confirm same ICF Version as #3 and HIPAA Authorization Form. • **ICF Version/date: _____ HIPAA Auth. Form: _____**
		• **Time consent obtained: __ __ : __ __ (*24-hour*)**
☐	☐	7. Investigator obtained written informed consent before any study procedures took place.
☐	☐	8. Subject retained copy of signed informed consent form and HIPAA Authorization form.

Checklist complete. Informed consent for participation in research obtained. Signatures to be added below. Completed checklist and ICF and HIPAA Authorization signed by witness as well as study staff who obtained consent to be filed in subject's research record.

Signature of **study staff who obtained consent** Date

Signature of **observer/witness** Date

*The checklist is adapted from multiple sources including NIAD and Advarra.