Consent Process Algorithm for In-Patient Subjects and FDA Regulated Research

1. Potential subject for greater than minimal risk FDA regulated research study
2. Is subject or LAR able to provide consent?
3. Does this subject and study meet the criteria for an emergency process (see below)?
4. Is the ICF able to leave the room?
5. Can a member of the study team go into room?
6. Obtain an individual who can serve as a witness and follow UNC Consent Process for Isolation Areas

**Criteria:**
- The patient is confronted by a life-threatening or severely debilitating situation, necessitating the use of the test article.
- Informed consent cannot be obtained from the patient (because the patient cannot communicate or is incompetent to give consent).
- Time is not sufficient to obtain consent from the patient’s legally authorized representative or not available, and
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient’s life.

**Attestation/Documentation**
The study physician and an independent physician need to attest to the above in the research record, a copy of the consent signed by both the study and independent physician should also be included with the attestation in the research record and submit to the IRB within 5 working days by submitting a modification with attestation attached.

* This algorithm was adapted from multiple sources including NIAD and Advarra.

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