

**Investigator Responsibilities for  
Prospectively Obtaining Legally  
Effective Informed Consent**

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**POLICY:**

- I. The PI and their research staff must develop an informed consent process and method of documentation appropriate to the research type and the study population, with an emphasis as to the importance of participant comprehension and voluntary participation.

**PROCEDURE:**

- I. The PI is responsible for obtaining legally effective informed consent from the participant or the participant's legally authorized representative except in cases wherein the IRB has granted an alteration or waiver of informed consent.
- II. In cases of waiver of documentation of informed consent, the PI must follow the requirements in the applicable UIC HSPP policies and procedures.
- III. The PI must follow the applicable UIC HSPP policies and procedures in obtaining informed consent.

**REFERENCES:**

[21 CFR 50.20](#), [21 CFR 50.25\(a\)\(7\)](#), [21 CFR 50.27\(a\)](#), [21 CFR 50.27\(b\)\(2\)](#)  
[45 CFR 46.116](#), [45 CFR 46.116\(a\)\(7\)](#), [45 CFR 46.117\(a\)](#)