

**IRB Observation: Informed Consent
Process/ Ombudsman**

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POLICY:

- I. In accordance with the federal regulations, UIC IRB has the discretion of requesting that a third party observe the informed consent process. The UIC IRB also has the discretion of appointing an ombudsman to oversee the research process in cases where the subject is particularly vulnerable or becomes incapacitated during the research study.

PROCEDURE:

- I. Third Party Observer to the Informed Consent Process.
 - A. The IRB Chair, Vice Chair, or convened IRB may appoint an unbiased individual as a third party to observe the informed consent process on behalf of the IRB. The individual may monitor the process of informed consent conducted by the PI (or a member of the IRB approved research staff delegated this role by the PI) with the prospective research participant or the participant's legally authorized representative.
 - B. The third party may collect data on the informed consent process by employing a variety of methods, including but not limited to, a physical presence (monitoring) during the consent process and/or employing written and verbal questionnaires to evaluate the effectiveness of the consent process. For additional information regarding the direct monitoring of the consent process refer to the Standard Operating Procedure - Procedure for Observation of the Consent Process
- II. Ombudsman.
 - A. The IRB Chair, Vice Chair, or convened IRB may appoint an unbiased individual to act as a subject advocate or a liaison between the PI and the research subject, the subject's family, or the subject's legally authorized representative. The UIC CRC has a Research Subject Advocate who functions as an ombudsman for all research studies conducted within the CRC;
 - B. The IRB Chair or Convened IRB may appoint an unbiased ombudsman specializing in a vulnerable population to oversee the research process, typically a scientist or an individual with expertise in the research area. This individual would observe the ongoing consent process and study conduct if

- the subject has become incapacitated during his or her research participation;
or
- C. The IRB Chair or Convened IRB may also appoint an unbiased ombudsman to oversee that a subject who is particularly vulnerable receives equitable and ethical treatment throughout the course of the research study. This type of ombudsman should have experience with the vulnerable population at issue or may also be a group of people with an interest in the safety of human research subjects, generally with a particular research focus. This type of ombudsman is permitted to be an IRB member, affiliated with UIC, or a JBVAMC representative.

REFERENCES:

[21 CFR 56.109 \(f\)](#)
[38 CFR 16.109 \(e\)](#)
[45 CFR 46.109 \(e\)](#)