CONSENT MONITORING

4/18/2021

The IRB has the authority under 45 CFR 46.109 and 21 CFR 56.109 to observe or have a third party observe the consent process and the research. In order to ensure that the consent process is appropriate and the approved process is being followed, the IRB may determine that special monitoring of the process must occur.

Such monitoring may be necessary in particular circumstances in order for the IRB to meet its responsibilities to ensure human subject protections for research that:

- Involves a vulnerable population
- Involves use of a highly risky and innovative procedure
- Is conducted by an inexperienced investigator and/or research team
- Is research about which the IRB has concerns that the consent process is not being conducted properly

In reviewing the adequacy of proposed informed consent procedures, the IRB will determine on a protocol-by-protocol basis as a part of the initial and/or continuing review process those protocols that require third party observation/monitoring of the consent procedures. The person(s) authorized to conduct the monitoring will be identified by the IRB Chair, and the meeting minutes will document these plans. The monitoring results will be reported to the specific board that requested the monitoring and reflected in the minutes, and the monitoring report will be included in the protocol file.

Previous Version Date(s): 11/12/2007, 3/1/2016