

## Approval Criteria: Data and Safety Monitoring

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Approved by: Interim Vice Chancellor for Research  
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AAHRPP Elements: II.4.B.

### POLICY:

- I. The UIC IRB members determine that research plans include provisions for monitoring the data to provide adequate protections for the safety of subjects. The UIC IRB members articulate when provisions for data and safety monitoring are required.
- II. For Department of Defense sponsored research, the appointment of a research monitor is required for greater than minimal risk, although the IRB can require for a portion of the project of for studies involving no more than minimal risk studies, if appropriate. In addition, an independent monitor must be appointed by name. Further, the research monitor has the authority to: stop a research study in progress; remove individuals from the study; and take any steps to protect the safety and well being of subjects until the IRB can assess.

### PROCEDURE:

- I. The PI is responsible for accurately providing sufficient information in the appropriate application so that the IRB members have sufficient information to make a determination as to whether the protection provisions for monitoring data to ensure the subjects' safety is appropriate.
- II. The IRB members use the appropriate review guide as a reference to determine when data and safety monitoring is necessary. For additional information, refer to the UIC Tip Sheet - [Data and Safety Monitoring Plans \(DSMPs\), Data and Safety Monitoring Boards \(DSMBs\), and Data Monitoring Committees \(DMCs\)](#).

### REFERENCES:

NA

### REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 08/12/09	1.0, 1/22/09	Added relevant DOD sponsored research requirements (policy section II).