

Clinical Trial Monitoring

Data Safety Monitoring

All human subject research should have an appropriate data safety monitoring plan to ensure subject safety regarding the risks, complexity, and nature of the research. Appropriate monitoring may include a data safety monitoring plan, as well as a Data Safety Monitoring Board (DSMB).

What is the researcher's responsibility for data safety monitoring?

The PI is responsible for assuring that the study has appropriate outcome monitoring.

Who at UNMC can provide support for data safety monitoring?

The Center for Collaboration on Research Design and Analysis (CCORDA) will coordinate data acquisition and management for research studies, including data safety monitoring. For more information, [see the CCORDA scope of services](#).

The Data and Safety Monitoring Committee (DSMC) of the Fred & Pamela Buffett Cancer Center monitors cancer trials. Forms for data and safety monitoring are available on the Fred & Pamela Buffett Cancer Center [Protocol Review and Monitoring System website](#).

Site Visits

All external vendors visiting the UNMC/NEMed campus, including clinical trial-related monitoring, are required to register with IntelliCentrics, prior to EACH visit, and check in once arriving on campus. It is recommended that monitors register online (Intellicentrics.com) in advance, to avoid delays once arriving on campus. Following check-in, monitors will be provided with a "Visitor" badge, which must be worn at all times while on campus. Specific registration instructions can be found in the [Clinical Research Center Standard Operating Procedures](#).

Revision #4

Created 16 September 2019 20:00:27 by James Geiger

Updated 8 November 2019 20:15:23 by James Geiger