**GUIDANCE 7**

**DATA SAFFETY MONITORING GUIDANCE**

**Data and Safety Monitoring**

1. Federal regulations require the IRB to determine that, “when applicable, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.” (45 CFR 46.111(a) (6))
2. The purpose of Data Safety Monitoring Plan (DSM) is to protect the safety of participants and ensure the integrity of the data. All studies involving human subjects require some level of data and safety monitoring.
3. Having a good DSMP helps insure the safety of study participants, the validity of data, and the appropriate termination of studies for which significant benefits or risks have been uncovered or when it appears that the investigation cannot be concluded successfully.
4. For multi-center trials, the drug or device manufacturer or other sponsor will typically name this committee. For the Institution’s internally-initiated research projects involving terminally-ill participants, sponsored trials and NIH-sponsored clinical trials conducted at the Institution's or affiliated facilities, the investigator must propose in the protocol how this committee is to be constituted and its functions are. Information on how to set up a data safety monitoring committee is posted on the IRB website at <https://sites.rowan.edu/officeofresearch/compliance/irb/index.html>.
5. The IRB office will assist the investigator(s) in meeting this requirement, but it is up to the investigator to appoint members to DSMB. Reports of DSMB must be submitted electronically through Cayuse IRB by creating a Reportable Event, select “DSMB Report”. The Report must be made by the Chair or his/her designee of the DSMB.
6. NIH Policy on for Data and Safety Monitoring is posted on the following link: <https://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DSMBGuidelines.htm>. The guidance for data safety monitoring for clinical trials is available on the following link: <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf>.