

Data & Safety Monitoring Committee (DSMC)

Fact Sheet

Setting. The DSMC was formed by the MU Institute for Clinical and Translational Science. On December 15, 2008, it was activated as an advisory committee within the MU School of Medicine. Its structure and processes are consistent with National Institutes of Health, National Cancer Institute, and U.S. Food and Drug Administration guidelines.

Mission. The DSMC helps investigators, and MU research compliance oversight mechanisms protect human-research participants and ensure the integrity and scientific validity of research data.

Functions. The DSMC:

- Provides education for investigators, research teams, and faculty regarding data and safety monitoring.
- Reviews proposed Data & Safety Monitoring Plans.
- Establishes Data & Safety Monitoring Boards.
- Conducts independent, interim reviews of study safety and progress.
- Makes recommendations concerning the continuation of studies, including recommendations regarding the modification, suspension, or termination of a study.

Composition.

- 13 voting members representing: medicine, nursing, health professions, pharmacology, ethics, biostatistics, behavioral science, information technology, social science, and research participant advocacy.
- 7 non-voting members: compliance officers for the health science and campus institutional review boards, compliance officer for the campus conflict of interest committee, managers of the clinical trials offices at University Hospital and Ellis Fischel Cancer Center, director of compliance for the school of medicine, and the executive secretary of the DSMC.

Leadership

- Chair. Greg Flaker, MD, Brent Parker Professor of Medicine (Cardiology).
- Vice Chair. David Fleming, MD, Professor of Clinical Medicine and Director, MU Center for Health Ethics
- Executive Secretary. Don Reynolds, JD, Director, Office for Responsible Research.

Administrative Coordination

- School of Medicine Office of Compliance and Quality.

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Visit the DSMC website
som.missouri.edu/Research/Office/DSMC.aspx