Department: UAMS Human Research Advisory Committee
Policy Number: 7.8
Section: Procedures for Study Review
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SUBJECT: Data and Safety Monitoring Plan (DSMP)

The purpose of having Data and Safety Monitoring is to provide for oversight such that if the research protocol needs to be modified, or changes to the risk-benefit level occur, the information from this process will be brought to the attention of the HRAC for review and appropriate action. This oversight involves not only reviewing adverse events and effectiveness but also should contain adequate provision to protect privacy of subjects and confidentiality of data. Indeed, all aspects of the research protocol need to be monitored as they may affect the risk benefit ratio. Oversight, of varying degrees of scope and intensity, is thus required for both biomedical and psychosocial research and for protocols qualifying for expedited review as well as full board review.

For many low risk research studies, continuous and close monitoring by the study investigator may represent an adequate and appropriate plan, with prompt reporting of adverse events in accordance with the described mechanism(s). In some instances (e.g., randomized, blinded studies) an independent individual is more appropriate for study monitoring. In studies involving small numbers of subjects, unexpected risks or problems may more readily become apparent through close monitoring of individual subjects; while in larger studies, risks or problems may be better assessed through statistical comparisons of the treatment groups. For multisite research studies involving greater than low risk, it is anticipated that the data and safety monitoring plan will address a central reviewing and reporting entity (e.g., a data and safety monitoring board) that will be responsible for analyzing the accrued data and preparing timely summary reports of study risks for distribution to the multicenter sites and corresponding HRACs. A data and safety monitoring board should also be considered for limited site research studies (e.g., Phase I and II clinical trials) that employ particularly high-risk interventions or vulnerable populations. For certain studies, consideration should be given to a data and safety monitoring board that is independent of the research sponsor and study investigators.