

FEE STRUCTURE FOR UTILIZATION OF THE WFUHS INSTITUTIONAL DATA & SAFETY MONITORING BOARD

INTRODUCTION: The WFUHS Institutional Data & Safety Monitoring Board (I-DSMB) is a multidisciplinary group of researchers and clinicians with expertise in monitoring the safety, integrity and conduct of human research studies, especially randomized, controlled clinical trials. The I-DSMB is available to monitor WFUHS/WFUHS-affiliated, IRB-approved clinical research studies. There is no charge for use of the I-DSMB for investigator-initiated trials receiving NIH, departmental, or other non-industry support. Use of the I-DSMB for clinical trials initiated and sponsored by industry (i.e., pharmaceutical or device manufacturers) will involve charges as described below. I-DSMB fee considerations will be evaluated on a case-by-case basis.

I-DSMB CHARGES FOR INDUSTRY-INITIATED, INDUSTRY SPONSORED CLINICAL RESEARCH STUDIES ¹:

- The WFUHS Office of Research will charge a preliminary fee ranging from \$5,000-\$10,000 that will cover the following services:
 - Initial I-DSMB protocol review
 - Regular six-month review of study by I-DSMB (face-to-face meetings)
 - Communications between study sponsor and I-DSMB Director
 - Generation of I-DSMB recommendation reports

- The actual preliminary fee will be based on the following factors, all of which would influence I-DSMB members' workload:
 - Study phase
 - Complexity of study design
 - Sample size
 - Number of study sites
 - Duration of study
 - Nature of study population (e.g., frail and/or elderly subjects would likely involve more intensive review of adverse events)
 - Intensity of safety monitoring (frequency/rate of adverse event monitoring)

- Additional WFUHS fees will be charged for the following services (dollar amount to be determined on a case-by-case basis):
 - Need for DSMB to meet more frequently than every 6 months (e.g., quarterly)
 - Need for additional, unexpected DSMB meetings
 - Meetings with study sponsors or study investigators (off-site, on-site)
 - Verification activities (e.g., audit)
 - Extent of advice provided.

- The sponsor should also take into consideration additional safety monitoring-related fees that will/may be charged by non-WFUHS sources. This would always include a statistician to prepare the blinded/unblinded interim I-DSMB reports and may include honoraria for independent, expert adjudicators to evaluate pre-specified study outcomes (should the I-DSMB make this recommendation).

¹ I-DSMB fees for industry-sponsored studies will be evaluated on a case-by-case basis.

CONTACT INFORMATION: For information concerning I-DSMB utilization fees, investigators should contact Susan Margitić, I-DSMB Director (smargiti@wfubmc.edu, 336-716-5647) or Janice Grace, Director of Industry Relations (jgrace@wfubmc.edu, 336- 716-9941).