FEE STRUCTURE FOR UTILIZATION OF THE WFSM INSTITUTIONAL DATA AND SAFETY MONITORING BOARD

INTRODUCTION

The WFSM Institutional Data and 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 WFSM-affiliated, IRB-approved clinical research studies. There is no charge for use of the I-DSMB for investigator-initiated, *pilot* research studies receiving NIH, departmental, or other non-industry support. Use of the I-DSMB for full-scale clinical research studies will involve charges as described below.

I-DSMB CHARGES FOR FULL-SCALE CLINICAL RESEARCH STUDIES

The fee for utilization of the I-DSMB for purposes of monitoring a full-scale (as opposed to a pilot) study will range from $5,000-$10,000 for the duration of a study. This fee range applies to WFSM investigator-initiated studies receiving government, departmental, industry or other types of funding. Charges will be based on factors such as study length, complexity, number of clinical sites, sample size and intensity of safety monitoring (frequency/rate of adverse event monitoring).

Study investigators should also take into consideration additional safety monitoring-related fees that may be charged from other 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).

CONTACT INFORMATION: For information concerning I-DSMB utilization fees, investigators should contact Dr. Abbie Eaton, I-DSMB Managing Director, abeaton@wakehealth.edu or 336-716-9134.