Mass General Brigham

Policy on Facilities and Administrative (F&A) Rate for Industry-Sponsored Clinical Trials

A. Policy Statement

Mass General Brigham ("MGB") is a world-renowned integrated health care system and research institution with expertise in clinical research for the purpose of discovering and making available to the public new and improved medical drugs, devices, procedures, and information. As a national leader in innovation, MGB's patient-centered mentality and systemwide collaborative approach are the keys to research breakthroughs that drive medical innovation, gain new knowledge, and improve patient outcomes.

It is critical that MGB maintain appropriate resources and staffing to support and advance MGB's research and innovation. In order to maintain such resources and staffing, MGB charges a Facilities and Administrative (F&A) rate on funding provided by external parties for clinical trials conducted at MGB entities. Facilities and administrative costs, also known as indirect costs, are costs incurred by a MGB entity in support of sponsored projects that cannot be charged directly to a specific grant, contract or other sponsored agreement. They represent expenses that are incurred for common or joint objectives, and are necessary for the general operation of an organization and the activities it performs.

F&A rates are applicable to all clinical trials funded by industry sponsors. The application of these rates allows MGB to recover facilities costs and administrative costs associated with research activity. Facility costs include, but are not limited to, building depreciation, lease expense, maintenance, utilities, housekeeping, security, net costs of parking, transportation, real estate and space management. Administrative costs include, but are not limited to, the research management activities performed by MGB's Clinical Trials Office, Research Compliance, Research Pharmacy, Institutional Review Board, Office of the General Counsel, Supply Chain, and Information Systems. Without application of the F&A rates, MGB is subsidizing the cost of the trial for the industry sponsor. This policy enables MGB to fulfill its financial obligations and comply with the terms and conditions of its research agreements.

B. F&A Rate for Industry-Sponsored Clinical Trials

It is the policy of MGB that all budgets included in agreements for industry-sponsored clinical trials that are accepted by a MGB entity will be charged a F&A rate of thirty-five percent (35%). This charge applies to direct funding to a MGB entity from an industry sponsor, as well as industry sponsor funding passed through a MGB entity to other institutions or organizations under a subcontract or other contractual arrangement. The F&A rate is applied to all direct costs (i.e., the rate applies to total direct costs without any exclusions).

For an industry-sponsored, multi-center clinical trial where a MGB entity is serving in a role as an academic research organization (ARO) or coordinating center and (1) the MGB entity is the primary recipient of funding from the sponsor, (2) the funding amount is equal to or greater than one million five hundred thousand dollars ($1,500,000.00), and (3) MGB will be entering into four (4) or more subcontracts with sites or academic service providers participating in the trial, then the

F&A rate of thirty-five percent (35%) will apply only to the first twenty-five thousand dollars ($25,000.00) of the budget included in each subcontract.

This policy brings MGB's F&A rate in line with rates charged by other large, academic medical centers and research institutions in the United States as of the Effective Date (defined below). Moreover, this rate is justified as a result of increased volume and complexity of contractual arrangements, financial assessments, and institutional reviews (e.g., IRB, information security, etc.) in connection with industry-sponsored clinical trials, which require adequate staffing to improve service, and increasing costs of services and personnel due to inflation.

This policy applies to all MGB entities, employees, and agents who are involved with the performance, oversight, and/or administration of industry-sponsored clinical trials.

C. Exceptions to Policy

Any exceptions to this policy (e.g., requests for a reduction or waiver of the F&A rate) must be approved in writing by the Senior Vice President of Research (or similar senior level position) of the applicable MGB entity.

D. Effective Date

This policy is effective as of July 1, 2023 ("Effective Date") and shall apply to all new agreements for clinical trials sponsored or funded by industry that are accepted by MGB's Clinical Trials Office on or after the Effective Date.

E. Review and Approval

Reviewed By: Mass General Brigham Clinical Trials Office, Mass General Brigham Interim Chief Academic Officer
Approved By: Mass General Brigham Clinical Trials Office, Mass General Brigham Interim Chief Academic Officer
Effective Date: July 1, 2023