

Academic Research Organization (ARO) Agreements Guidelines Relating to Conflicts of Interest

I. Introduction

The Icahn School of Medicine at Mount Sinai (ISMMS) is committed to maintaining the highest standards of integrity and transparency in scientific inquiry, advancement and discovery. Consistent with this commitment, these guidelines ensure that all Academic Research Organization (ARO) agreements are aligned with institutional policies and practices relating to conflicts of interest.

ARO agreements are formal, written contracts between the Icahn School of Medicine at Mount Sinai (ISMMS) and commercial or other biomedical entities. These agreements encourage scientific inquiry and collaboration, and enable faculty, as part of their employment by the School, to provide research-related expertise as defined below, and to assume leadership roles in industry-funded studies or research entities.

Mount Sinai's participation in an ARO agreement creates a financial relationship that requires appropriate oversight and management essential to protect the scientific integrity of research and the integrity of associated patient care.

These guidelines contribute to the management and mitigation of potential institutional conflicts and to transparency by articulating disclosure requirements, restrictions, limitations, accountability and oversight.

II. Types of ARO Agreements:

There are two types of ARO Agreements into which ISMMS might enter:

1. **Comprehensive ARO Agreement** -- The more common ARO agreement is a comprehensive agreement in which an ISMMS Designated Clinical Research Center (an institutionally recognized clinical research unit) provides a package of research-related support services to an outside commercial or research entity. This may include multiple line-item services such as faculty research roles (global PI, Data Safety Monitoring Board member, event adjudication committee member), data management, clinical trials management, statistical analyses, and medical monitoring.

For an ISMMS clinical research unit to qualify as a Designated Clinical Research Centers (DCRC) it must have recognized expertise as either a clinical coordinating center or a data coordinating center, as well as the necessary infrastructure to carry out its work. The infrastructure may in some cases be supported by a collaborative agreement with the ISMMS Institute for Transformative Clinical Trials. In all cases, creation of a DCRC requires presentation to the Faculty Business Conflicts Committee for review and approval by the Dean.

The School may not enter into an ARO agreement if either of the following conditions applies:

- The school has equity ownership in the proposed partnering entity;
- The School has financial incentives linked to the success of a clinical trial that would be conducted under the auspices of the ARO.

2. **Limited ARO Agreement** -- An ARO agreement may be more limited in scope, involving only the participation of a faculty-investigator as a global PI or in another specific research support role. In such cases, the faculty-investigator must be a member of an ISMMS Designated Clinical Research Center or obtain an approval in the process described below.

When an individual faculty member who is not part of an institutionally recognized research unit requests an ARO agreement, the approval process will include review by the *Office and Industry Engagement and Conflicts of Interest*, review by a faculty working group of the Financial Conflicts of Interest in Research Committee (FCOIRC) as needed, and approval by the faculty member's supervisor (Departmental Chair, Division Director, or Institute Director). The supervisor will approve and attest that the faculty member is contributing services as part of his/her role as an ISMMS faculty member and that there is no conflict of commitment.

III. Arrangements That Would Not Qualify for ARO Agreements

Some types of arrangements with industry or other biomedical entities would not meet the requirements for an ARO agreement. The most common are:

- Consulting and Other Individual Agreements -- Paid personal agreements between a faculty member and an outside entity, such as consulting or participation in scientific advisory board meetings or other investigator meetings, are independent of ISMMS and would not be covered by ARO agreements.
- Sponsored Research Agreement (SRA) -- These are contracts between the School and a sponsor for funding and conducting a specific research project at ISMMS. The sponsoring entity may be for profit, e.g., industry, or not-for-profit, e.g., foundation or government agency.

IV. ARO Agreement Requirements

Every ARO agreement, regardless of whether it is comprehensive or limited in scope, must be negotiated through the ISMMS Financial Administration of Clinical Trials Services (FACTS) Office.

Faculty cannot participate in an ARO agreement if they or any of their related parties (spouse/domestic partner and/or children) have personal financial interests with the proposed entity or any other related commercial entity which has a clear financial interest in the outcome of the research. Examples of personal financial interests include personal consulting agreements, licensed IP, equity interest, any board of director or senior executive leadership (C-suite) position, and/or any employment position in the company. Such interests would pose an unmanageable conflict of interest for the individual in relationship to the ARO.

In order to address, manage or otherwise mitigate institutional conflicts of interest that arise from ARO participation, all ARO agreements must include the following:

- Identification of a specific ISMMS Designated Clinical Research Centers for participation (if applicable);
- Description of the faculty member's study specific roles/scope of work and an acknowledgement that the faculty member will be providing these specified services in their capacity as a ISMMS faculty member
- Fee structure for ISMMS faculty that reflect fair market value for any and all services that they provide through the agreement;
- Promotion of responsibility and accountability through proper disclosures and reporting of ARO funding

For purposes of the COI review and management, faculty members serving as investigators or otherwise participating in ARO agreements must:

- Track their time and effort on ARO activities consistent with ISMMS requirements;
- Follow ISMMS document retention policies to preserve all relevant research-related documents, including email correspondences;
- Use only their ISMMS email system for study-related communications. No communication between faculty members and entities sponsoring ARO agreements can use personal email accounts;
- Disclose to research collaborators and on all publications/presentations that ISMMS has received financial compensation for the faculty member's study-specific roles; and,
- If Mount Sinai is participating as a clinical trials site, disclose to research subjects in informed consent documents that ISMMS has received financial compensation for the faculty member's study specific roles.

Adherence to the above guidelines and requirements for faculty members engaging in ARO agreements will be monitored by the Compliance Department and shall be reported to *Office of Industry Engagement and Conflicts of Interest*. Faculty who fail to adhere to time/effort documentation, disclosure requirements, limitations on outside financial interests, and/or other requirements may be subject to audits. Repeated failure may result in termination of participation in ARO agreements, and possible disciplinary action.

ISMMS will promote transparency through public disclosure on the School website of the institution's participation in ARO agreements.