

Policy on Financial Relationships with Outside Entities (“Consulting Policy”)

An outside entity is defined in this section as any entity other than Icahn School of Medicine and its affiliated institutions.¹

A faculty member may enter into an agreement to act as a private individual in a consultative or other financial arrangement with an outside entity, or serve as a member of an advisory board of an outside entity or as an expert witness, and retain all income that derives from such arrangements providing that the following provisions are met ²:

1. Activities of any kind with an outside entity must be set forth in a written agreement and approved by the Department Chair. All agreements must be submitted to the *Office of Industry Engagement and Conflicts of Interest* (COI Office) for review and approval. The submitted agreements must be accompanied by a signed [Attestation of Compliance with Institutional Policies for Relationship with Outside Entities \(“Attestation Form”\)](#). By signing the Attestation Form the faculty member acknowledges that he/she has read the relevant institutional policies and will abide by them. The chair also signs the form acknowledging approval of the activity. Chairs are encouraged to seek guidance from the Office of Industry Engagement and Conflict of Interest (“COI Office”). Chairs, Deans, and Institute Director must obtain direct approval from the Dean of the Medical School or his/her designee before entering into arrangements with outside entities.
2. The [Mount Sinai Uniform Provisions for Consulting \(“Addendum”\)](#) must be included with all proposed consulting agreements and takes precedence over any conflicting provisions in the consulting agreement. The Addendum reinforces Mount Sinai institutional policies, including intellectual property provisions, by which both the faculty member and the company must abide.
3. The arrangement must be relevant to and enrich the employee's research, education, or other professional responsibilities.
4. The consulting agreement cannot encompass situations in which the faculty member is engaged directly or indirectly as a practitioner of medicine, including telemedicine, is engaged in product/IP development, or is engaged as the director of a research effort of the third party.
5. The consulting agreement cannot encompass situations in which the faculty member participates in corporate development meetings or fund-raising meetings. Consulting activities cannot include speaking to investors or potential investors on behalf of the company or as an agent of the company. In addition, the arrangement should not involve product or company endorsements or marketing activities. Please refer to the [COI Website](#) and the [Speaking Engagements Policy](#) for additional examples of permissible and non-permissible activities.
6. Any arrangement wherein a faculty member proposes to serve on the Board of Directors of and/or serve in a Senior Executive Leadership Role (CEO, COO, CFO, CMO, or CSO) of an external healthcare company is prohibited without prior written approval from the Dean or his/her delegate. Please refer to the [Guidelines and Process for Faculty Requesting Board of Directors for Outside Entities, Guidelines for Faculty Requesting Executive Leadership \(C-Suite\) Positions with Outside Commercial Entities](#), and the Dean’s Approval Policy.
7. Any arrangement that involves faculty requests for a personal consulting agreement with an early stage, company in which they have a personal financial interest (e.g. licensed intellectual property, founder/co-

founder, or equity ownership greater than *de minimis* (>1%)) requires Faculty Business Conflicts Committee (FBCC) approval.

8. All remuneration must be fair market value for the services actually performed and should be based on an hourly rate.
9. The faculty member must be in compliance with all institutional policies, including those on [Conflicts of Interest](#), [Use of Mount Sinai name](#), Mount Sinai Insider Non-Trading Policy (to review this policy, access [Policy Tech](#) via the Intranet), and [Intellectual Property/Patents](#), and [Speaking Engagements](#).
10. The arrangement may not take precedence over, interfere, or conflict with any responsibilities or requirements made on the faculty member by the medical school or health system, nor shall the arrangement adversely affect the integrity or reputation of Mount Sinai.
11. The agreement must be limited to a one-year, renewable term, which may be terminated by the company or Mount Sinai. The agreement may not automatically renew. The faculty member is responsible for submitting an updated/continuation consulting agreement annually to the COI Office.
12. Any changes to the statement of work or scope of services must be submitted to the COI Office for review and approval prior to engaging in the revised scope of activities. Faculty members are not permitted to sign a new statement of work from the company without review and approval from the COI Office.
13. For Master Service Agreements (umbrella agreements), faculty members must submit a written scope of work/services for each activity under the Master Service Agreement in addition to the Master Service Agreement for review and approval to the COI Office. The Master Service Agreement may not exceed a term of three years, and may not automatically renew. Each activity is limited to a one-year, renewable term, similar to a consulting agreement.
14. The aggregate number of days allocated to financial arrangements with outside entities, including expert witness or medico-legal consultant arrangements, shall not exceed fifty-two (52) calendar days per school year (July 1 - June 30). Personal consulting arrangements are not an absolute right, and department chairs retain discretion over the number of days any individual faculty can engage in outside consulting activities based on institutional and other departmental needs.
15. When a paid activity requires less than a full day of effort, time devoted to the activity will be calculated using a formula in which 10 hours equal one calendar day. For example, five hours of consulting are equivalent to 1/2 day and 100 total hours consulting to a company in a year are equivalent to 10 days. Travel hours must be included in the time away calculation if the activity takes place during hours in which the faculty member would otherwise be conducting School business. Travel on weekends and holidays can be excluded from the calculation.
16. With the exception of the use of the library facilities and the *de minimis* use of the individual's own office and personal computer, no Mount Sinai facilities, resources, students/trainees, or personnel may be used in the performance of an outside paid activity. After Mount Sinai approvals are in place, and agreements executed and signed, all paid personal consulting activities (including expert witness activities) should be conducted using a personal e-mail address.
17. Some affiliates of Icahn School of Medicine may have rules that restrict a faculty member's right to enter into arrangements with outside entities; faculty are required to check the policy at their particular institution. Faculty must comply with policies at Mount Sinai and the affiliate institution.
18. On occasion, faculty may seek to provide services through expert networks, which are organizations that connect subject matter experts to clients of the network seeking expert services. For a faculty member to

become a member of an expert network's roster of subject matter experts, the faculty member and the expert network organization must sign an agreement governing their relationship, and the expert network organization must also sign the Mount Sinai Uniform Provisions for Consulting ("Addendum"). In addition, each engagement whereby the faculty member provides services to a client of the expert network organization will require advance approval by the faculty member's Chair (Attestation Form) and a signed agreement between the faculty member and the client containing a clear scope of work for the engagement and attaching a copy of the Addendum signed by the client.

19. Faculty may engage in medico-legal consultant or expert witness arrangements with department chair approval. Medico-legal consulting does not require COI Office review. However, in the case of third party subpoenas associated with the faculty member acting as a third party consultant or an expert witness, and Mount Sinai is brought in as a third party to a discovery request, the cost of these activities will be the responsibility of the faculty member.
20. Faculty must update their COI Disclosure Profile and Entity Disclosure Table (electronically via [eDMS](#)) whenever a payment is received from a new entity; payment amounts must be included in the disclosure.
21. All income or compensation will be independent of any compensation arrangements that the faculty member has with Icahn School of Medicine. Insofar as a faculty member will act as a private individual in an agreement with an extramural entity, all income that derives from the arrangement must be paid directly to the faculty member.
22. Insofar as a faculty member will act as a private individual in an arrangement with an extramural entity, such agreement is outside the scope of employment as a faculty member of Icahn School of Medicine, and therefore the faculty member will be solely responsible for his/her actions and any litigation that may arise. Icahn School of Medicine will not be liable for any actions of the individual or any litigation that may arise as a result of the consultative arrangement with the extramural agency. The faculty member will so inform the extramural entity.
23. Any Academic Research Organization (ARO) Agreements wherein the faculty member acts in their Mount Sinai capacity and the compensation goes to the institution (rather than to the faculty member as personal compensation) must be negotiated through the Icahn School of Medicine's Financial Administration of Clinical Trials Services (FACTS) Office and submitted to the COI Office. The [ARO Guidance Document](#) provides detailed information about both comprehensive and limited ARO agreements.

Footnotes

1. Commercial entities include but are not limited to: pharmaceutical, biotechnology, office supply, and medical device/supply companies; research supply and equipment companies; medical service providers; billing and collection companies. Non-commercial entities include but are not limited to: academic institutions, professional organizations, non-profit organizations, philanthropic organizations and non-commercial data safety monitoring boards.
2. The provisions of this policy do not pertain to:
 - Participation as a reviewer of scientific proposals or membership on study sections for not-for-profit or governmental extramural entities that sponsor non-profit scientific research. Faculty may retain any fees earned by such activities, and the time devoted to such activities will not reduce the number of days that may be allocated to outside arrangements. Chairs should be informed of participation in these activities, and Chair approval of planned travel relating to these activities is required.

- Occasional lectures given at other academic institutions, provided that the honorarium and travel costs are paid directly by that institution, there is no conflict of interest and there are no intellectual property issues. Such engagements must be approved in advance by the Chair, although financial disclosure is not required. In addition, Chair approval of planned travel relating to these activities is required.
3. Commercially-sponsored lectures that present no actual or perceived conflict of interest do not require MSIP review.