



Guidance for Appropriate Involvement in Start-ups by Members of the WCM Community *Applicable only to Weill Cornell Medicine*

1.0 Overview

A central mission of Weill Cornell Medicine (WCM) is to provide benefit to society by bringing important scientific discoveries, technological innovations, and medical advances to the marketplace, training the next generation of researchers, and fostering the economic development of New York State and the nation. Consistent with the Bayh-Dole Act of 1980, the university encourages and supports the efforts of its faculty and other research personnel to participate in the development and dissemination of WCM intellectual property (IP) by entering into relationships with existing business entities and start-up companies. For purposes of this guideline, a start-up is any entity formed by a member of the WCM community whose goal is commercialization in the realm of healthcare, biomedical science or related fields. This document will only focus on start-ups that are related to an individual's role at WCM, as determined by the WCM Conflicts Advisory Panel (CAP), and does not supersede any institutional policies.

Such relationships can take various forms including, but not limited to:

- Creating or inventing University IP that is licensed to a WCM faculty member's start-up company;
- Founding and/or taking a financial interest in a start-up company;
- Consulting/serving on advisory boards of the licensee; or
- Receiving funding from a licensee to advance knowledge in areas related to that of the original IP or in new areas of research.

These relationships generally benefit WCM, its faculty, staff, and students, as well as the public, by enhancing awareness of innovative research and accelerating its economic and societal impact, by helping to attract and retain faculty, and by providing job opportunities for its graduates. Such relationships, however, also may create real or apparent conflicts of financial interest and/or commitment or may not be consistent with the terms of grants, contracts or gifts funding the underlying research. Conflicts of financial interest and commitment arising from faculty/staff involvement with a WCM-associated start-up can be successfully managed to ensure the integrity of the research process, protect students and trainees' ability to pursue their studies and research activities with appropriate independence and objectivity, support the appropriate entrepreneurial participation and external engagement of faculty and other research personnel, ensure compliance with applicable regulations and institutional policies, foster an open academic environment, ensure the primary professional commitment of full-time faculty and staff to the university, and certify the unbiased and effective development of University IP. Guidelines for doing this are presented below.

2.0 University/Center for Technology Licensing (CTL) Responsibilities

CTL is responsible for licensing WCM IP to achieve the optimal fulfillment of the university's missions of research, education, and societal benefit, including the promotion of local and regional economic development. CTL is required to manage the licensing in a businesslike manner so as to obtain a fair return to WCM for its investments in research and in technology transfers. The goal is to be able to provide shared benefit to the faculty/staff creators of the IP and the public. CTL licensing agreements may be exclusive or nonexclusive depending on what is most suitable for achieving technology transfer, promoting economic development, and providing societal benefit. Readers should also refer to the document "Guidelines for Addressing Potential

Conflicts of Interest and Commitment in Faculty/Staff Startups”
(<http://www.ctl.cornell.edu/inventors/forms/Guidelines-for-Managing-Faculty-Startups.pdf>).

3.0 When Should I Discuss My Start-Up Plans with the Conflicts Office?

The best time to address any potential conflict is in the planning/preliminary phase of the start-up. You are encouraged to reach out to the Conflicts Office during the earliest stages of the start-up to best manage any potential conflicts. The CAP must review any actions or proposed plans of action that present a potential financial conflict of interest, and if a CMP already exists, the faculty/staff member’s assigned Dean’s Designee must review any actions or proposed plans of action that present a potential conflict, as described below.

When planning a WCM-associated start-up or when CTL determines that a WCM-associated start-up is potentially an appropriate licensee, the following steps must be taken promptly:

1. The faculty/staff member reports the existence or the promise of any interest (equity, options, consulting fees, etc.) in the start-up to their department chair and CTL, and provides an amendment to his/her annual financial disclosure report (Conflicts Survey) to the Conflicts Office describing relevant financial interests in and commitment to the start-up.
2. CTL documents and submits its rationale for the licensing decision and the proposed licensing agreement to the Conflicts Office and to the faculty/staff member’s unit head.
3. The faculty member meets with the Conflicts Leadership, Conflicts Advisory Panel (CAP) Chair and CTL to develop a structure and conflict management plan that would be consistent with all WCM policies and regulations.
4. Depending on the stage of the start-up, its level of capitalization, the attainment of significant milestones, and especially before any related human subjects research can commence, the CAP may be asked to determine whether the real or apparent conflict associated with the faculty/staff involvement with the start-up can be managed.
 - a) If the conflict is deemed manageable the CAP must assign a Dean’s Designee and develop a conflict management plan (CMP) within three months of receipt of the CTL documentation and faculty/staff report.
 - b) If the CAP determines that the conflict cannot be managed, it must so inform CTL and the faculty/staff member within three months of receipt of CTL documentation and faculty/staff report.
5. CTL may proceed with licensing the technology once the management plan is approved by Conflicts Leadership, the CAP Chair, CAP (if appropriate) and the Dean and signed by the faculty/staff member(s).

4.0 What Kinds of Issues May Present a Conflict of Interest or Conflict of Commitment?

The following financial relationships are common, but not all, issues that may arise:

4.1 Gifts and Sponsored Research Funds

Conflicts of interest are magnified when you receive funds (e.g., sponsored research grants or gifts) from a company with which you have a financial relationship. The university may accept sponsored research or gifts from a company in which you have an interest that are to be used at your direction or discretion, but under the following requirements:

- The use must be approved by the CAP and under a management plan to oversee the use of the funds and resources.
- There must be prior written agreement with the university regarding the ownership and disposition of any intellectual property that may arise from the use of such funding or gift.
- The solicitation and receipt of gifts from your company to your department should be reported to and coordinated with your department chairperson, the WCM Office of Development, and any additional appropriate university officials.

4.2 Stock or Stock Options

A conflict might arise out of an equity interest in a start-up that licenses technology from WCM or in the nature of royalties to be earned therein.

Equity can create or appear to create incentives that may compromise objectivity or could bias or appear to bias the design, conduct, reporting, or research, particularly where human subjects are involved. You must accurately report any equity interests in your Conflicts Survey.

5.0 What Role Can You or Will You Hold in the Company?

A conflict of commitment is caused when an individual undertakes external commitments that may burden or interfere with his/her primary obligations and commitments to the university, even if the outside activity is valuable to the university or contributes to professional development and competence. To avoid a conflict of commitment, the activity or service for the company is limited to no more than “equivalent of one day a week”. A conflict of commitment can occur even if overall consulting is less than one day per week if the outside activities detract from your job responsibilities. You must separate and clearly distinguish the focus of ongoing university research and educational responsibilities from your involvement in any effort being conducted for the start-up company. If you decide to move into a part-time WCM appointment, you must make arrangements that are satisfactory to your department chairperson. Such arrangements must cover all of your WCM responsibilities and cannot be detrimental to your department or WCM.

5.1 Founder

You may not serve in an executive or management capacity for any company while a WCM employee, unless the role is specifically allowed in a CMP. In the very early stages of the start-up, before significant capitalization is achieved, such a role may be permitted under appropriate circumstances.

5.2 Officer and Board of Directors

Service as a company’s officer or member of the Board of Directors creates a fiduciary duty to act in the company’s best interest and that poses a conflict with your duties to WCM. This is among the reasons you are prohibited from negotiating with WCM on behalf of your start-up (and vice-versa). Furthermore, service as any company’s officer or member of the Board of Directors can only be accepted with permission from the CAP and your department chair. You must recuse yourself from all board decisions involving WCM. You may not serve as chairman of the board unless specifically allowed in a CMP which will describe the circumstances under which the role must be ended.

Titles such as Chief Executive Officer, Chief Scientific Officer, Chief Technology Officer, and the like, imply management responsibilities and are perceived as such, irrespective of actual job description or payment for services under such a title. You are not allowed to serve in roles whose titles or duties suggest or entail management responsibility in a company, unless specifically allowed in a CMP. In very early stages, before there is significant capitalization of the start-up, such roles may be permitted, but in general, there must be at least one employee of the company that is independent of WCM and has the authority within the company to make decisions independently from you. The CMP will describe the circumstances under which such roles and/or titles are permitted or must be ended, and have the signed approval of the WCM member’s Department Chair or Dean. Members of the WCM Community must be prepared to justify the necessity of their managerial role at their respective annual review. Considerations by the CAP in their initial and annual reviews of when a managerial role is permitted or must end include, but are not limited to:

- Reviewing the company’s capitalization amounts;
- The company becomes engaged in the conduct of human subject research to validate and/or potentially commercialize products; and

- The company has several contracts for licensable products with individual or aggregate annual license fees of a substantial amount.

5.3 Advisory Board

- You may serve as a consultant and/or an advisory board member for the company, subject to standard WCM requirements regarding consulting.
- Consulting must not interfere with your duties and cannot provide services that are otherwise provided by WCM or you in the course of your usual duties.
- You are not permitted to serve as chairman of the company's advisory board or serve as the sole advisory board member.

5.4 Consulting

While consulting activities often enhance a faculty member's value to WCM, they can result in conflicts of interest and conflicts of commitment that compromise the faculty member and the institution. You should keep the following in mind:

- Consulting agreements must be between the faculty member and the entity employing them. WCM cannot act as a legal advisor to such external agreements.
- Remuneration is paid by the entity to the faculty member and not to WCM.
- Your total external commitments are limited to no more than the "equivalent of one day per week".
- You are required to include the "Model Addendum for Consulting Agreement" document, available through the institution website, as part of all private consulting agreements.

Please note, the institution's guidelines for advisory board and consulting roles in start-ups are the same as that for those with pre-existing companies.

6.0 Supervisory Conflicts

Students actively enrolled in an institution of higher education's degree program are not allowed to receive direct compensation or participate in research funded by the start-up company. If any students or trainees are participating in research projects related, but not necessarily funded by the start-up company, they must receive full disclosure of the relationship between the supervising faculty/staff member and the start-up company. Unless contractual arrangements (e.g. research support, grants, contracts, unrestricted gifts, materials or other financial instruments) are made between WCM and the start-up company that specifically provide for such supervised staff's duties, you may not:

- Involve¹ university research staff or other university staff over whom you have oversight or supervisory responsibility in professional activities at or for the company.
- Involve students over whom you currently have direct or indirect academic oversight responsibility in company activities. If a student asks to take a leave of absence or work In Absentia to participate in the company, the student must be referred to their department head or Dean for independent advice and review of the request. Student internships and coop assignments at the company may be appropriate with a CAP approved CMP.

¹ "Involve" for purposes of these guidelines is defined as any activity associated with the company, including, but not limited to providing funds or resources to, planning, performing duties, assessing or testing ideas/materials/other business-related items, providing representation or support of/for the company, discussing any aspect of company business, and performing any research directly or indirectly for the company, regardless of time, compensation, or location. "Involve" for the purpose of these guidelines does not include, for example, WCM research activities not sponsored by the company but under the direction of the faculty member that are in the same general areas as those of interest to the company, nor public discussions of the results of such research in the presence of company staff.

- Assign students or WCM staff to sponsored projects funded by or related the technology/IP licensed by the company without the explicit approval of the CAP and a management plan to oversee the activities of the students/staff involved.
- Involve in company activities junior faculty for whom you have a supervisory responsibility, or have the authority to vote on tenure or otherwise provide assessment of performance. Even if there is no supervisory role, faculty members must avoid situations in which junior faculty might feel obliged to participate.

7.0 Special Concerns for Students and Trainees

Involvement in faculty start-up companies by students and trainees, including summer students and post-doctoral trainees, presents a challenge to WCM supporting entrepreneurship while protecting its students and educational mission. Particular challenges arise when a faculty member serves as a mentor to a graduate student, the faculty member's company employs his/her postdoc (students are excluded from employment) or the faculty member directs a student into a project that appears to benefit the mentor's company. To manage such conflicts:

- No student or trainee, including summer students and post-doctoral trainees, shall participate in the conduct of the research related to a start-up company formed by a WCM community member without prior approval from the faculty member's conflicts Dean's Designee.
- If a student or trainee forms a start-up company and/or is an inventor of intellectual property, the relationship will be reviewed by the Conflicts Office and if necessary, the CAP at the request of the student or trainee.
- Students and trainees may not participate in research sponsored by the start-up if the terms and conditions of participation would prevent or inhibit them from meeting applicable WCM degree requirements, such as completion and public defense of a thesis or dissertation, publication of work, sharing of work at a meeting (or even in annual committee meetings with special committee) in a timely manner.
- If students or trainees are participating in research projects related to, but not funded by the faculty member's start-up, the faculty member must provide full disclosure of the implications of this, and limitations or restrictions, if any, on publication in a timely manner.
- The Dean's Designee or their agent will serve as an ombudsperson to mitigate concerns about the effect of the faculty member's conflict on their work. All communication related to those concerns will be held confidentially.
- Students under a faculty member's direction, paid for by a faculty member's grant, or in a faculty member's research group, may not be employed part- or full-time by the faculty member's start-up. If a student asks to take a leave of absence or work In Absentia to participate in the company, the student must be referred to their department head or Dean for independent advice and review of the request. Student internships, coop assignments and summer employment to work in a field unrelated to his/her academic program at the company may be appropriate with a CAP management plan.
- All students will be governed by the policy of their respective school in addition to WCM and Cornell's Conflict Policies.²

² Please see University Policy 1.7 addressing financial conflicts of interest related to research (https://www.dfa.cornell.edu/sites/default/files/policy/vol1_7.pdf), and the Weill Cornell Graduate School of Medical Sciences Policy and Procedures Governing Research Integrity (http://researchintegrity.weill.cornell.edu/pdf/RIP_062707_FinalJuly20200_1.pdf). WCM Medical College Students should contact the Office of Medical Education with questions related to their specific program.

8.0 Concerns Involving Human Subject Research

WCM has instituted a rebuttable presumption that research personnel who are involved in the design, participant selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. Similarly, there is a rebuttable presumption that human subject research related to WCM-licensed technology cannot take place at WCM. In other words, the default position is that participation in human participant research by conflicted research personnel and WCM is not allowed. This may mean that unless the presumption for this prohibition is overcome and the CMP specifically addresses the conduct of such human participant research, you may not:

- Serve as PI/protocol director for human participant research that is related to the company's business activities or objectives; or
- Supervise faculty, staff, or students who are PI/protocol directors for human participant research related to the company's business activities or objectives.

However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. Such circumstances, may include, but are not limited to:

- The investigators with real or apparent conflicts is nevertheless uniquely qualified, by virtue of attributes (e.g., experience, expertise, special facilities or equipment) to conduct the research and safeguard the welfare of human subjects involved; and
- The likelihood that a societally important development project will be substantially impeded if the research were not performed by the investigator with the conflict.

In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk. All financial interests and external relationships related to human-participant research that are not eliminated must be disclosed to all participants in the related research.

The management plan must be implemented before research personnel can participate in the design or conduct of the research, enrollment of participants, or analysis of the results.

The Ithaca Campus, Weill Cornell New York campus, and Weill Cornell Medicine Qatar campus each operate Institutional Review Boards (IRB) for human participants, which are charged with reviewing and monitoring human participant research conducted at the University. The IRBs have established rigorous policies and procedures for the review and approval of human participant research protocols. Those policies and procedures are followed in tandem with this policy.

9.0 Use of Resources

Other than library materials and assigned office space, faculty and staff are not permitted to use WCM resources (including WCM stationery or letterhead) for extramural activities without first obtaining written approval of the Dean or Dean's Designee and arranging for the payment for such use. WCM resources, including facilities, equipment (computers, telephones, research equipment, etc.), materials (such as office and laboratory supplies), data (including de-identified data), personnel, and services (including the Institutional Review Board, the Institutional Animal Care and Use Committee, etc.) exist for use by WCM and not for company business or personal gain. Exceptions to this prohibition include activities related to a scholarly publication, professional organization or professional review body.

- The company may utilize university facilities that are available for commercial or industrial users, e.g., shared research facilities, on the same basis and with the same fee structure that is offered to any other commercial entity. The company can use said property only for the purposes allowed and specified under the approved lease.

All company purchases of WCM furniture or apparatus must be approved by the cognizant WCM official with the appropriate transaction authority. Additionally, all purchasing or procurement decisions on behalf of the start-up, either directly or indirectly, must be adjudicated by a non-conflicted third-party.

For further information and specific guidance, review conflicts policies 4.14 and 1.7 or visit <https://research.weill.cornell.edu/research-administration>.