

## **COI Management Plan Risk Level Resource**

This document provides sample Conflict of Interest disclosures that have been reviewed by the COI Committee. When a Conflict of Interest disclosure is approved, the COI Committee assigns **a risk level of 1-Low, 2-Moderate, or 3-High.** Examples of each level of risk are provided below.

**PLEASE NOTE:** The left column highlights the perceived/actual conflict and the right column highlights possible management plan elements put in place to manage the conflict.

## Management Plans - Risk Level 1:

These Management Plans present the lowest level of risk but may also be asked to complete a Quality Assurance Audit by the COI Office.

Consulting Agreement	
Conflict of Interest:	Possible Management Plan Elements:
<ul> <li>UMD Professor is the PI for a research project with <u>Company X</u>.</li> <li>UMD Professor has an existing consulting agreement with <u>Company X</u> to teach two short courses and a limited number of additional hours consulting.</li> <li>The proposed research does not relate to the educational content/consulting in any way.</li> </ul>	<ul> <li>As long as listed as a PI or Co-PI on a UMD contract from <u>Company X</u>, Professor will not perform any additional hours or personal consulting for <u>Company X</u>.</li> <li>Professor has informed the appropriate individuals at <u>Company X</u> about the potential conflict, so they are aware of the possible overlap of the research project award and existing consulting agreement.</li> </ul>

Consulting Agreement - Mentorship	
Conflict of Interest:	Possible Management Plan Elements:
<ul> <li>UMD Professor is the PI on a sub-award from <u>Company X</u> who received the award from ONR.</li> <li>UMD Professor began three separate consulting contracts with <u>Company X</u>.</li> <li>UMD Professor is mentoring a <u>Company X</u> employee as well.</li> <li>The employee is a former UMD graduate and attends meetings at UMD regarding the subaward work in order to gain experience. The employee is not paid off the subaward or the prime award. The employee is not UMD faculty or staff.</li> </ul>	<ul> <li>UMD Professor must cease and/or cancel any formal consulting agreements during the period of performance from any subaward originating from <u>Company X</u>.</li> <li>The intent of mentorship of the <u>Company X</u> employee is for the employee to learn about UMD's results from the award and better understand how to transition the research. The employee has no direct influence on UMD planning or decisionmaking. All interactions are academic in nature and focus on technical results and ideas.</li> </ul>

Spouses / Significant Others	
Conflict of Interest:	Possible Management Plan Elements:
<ul> <li>UMD Professor has been granted funding by <u>Federal</u> <u>Agency</u> for a project.</li> <li>UMD Professor is the PI on the prime award; UMB Professor is the Co-I on the prime award and the PI on the subaward at UMB.</li> <li>The UMD Professor and the UMB Professor are married.</li> </ul>	<ul> <li>The two professors are on different campuses and report to different supervisors.</li> <li>If there is a proposed change to the UMB Professor's salary on the subaward, it will be reviewed and approved by the Department Chair at UMB.</li> <li>The Department Chair will ensure that all lab personnel will be provided with a COI <u>Acknowledgement Memo</u> to review and sign. This document will be kept up to date and on file.</li> <li>All subaward request forms for the UMB subaward and UMB subaward invoices will be approved by the Chair of the Department at UMD (prime award).</li> </ul>

Ownership / Equity – Use of UMD Students	
Possible Management Plan Elements:	
<ul> <li>UMD professors cannot employ their current graduate students in their company.</li> <li>The students cannot be actively enrolled in any of the UMD Professor's courses.</li> <li>The UMD Professor cannot serve as either students' Dean's Representative on their dissertation committees while the students are employed at <u>Company X</u>.</li> <li>The UMD Professor will not serve as either students' direct supervisor at <u>Company X</u>.</li> <li>The students' work for <u>Company X</u> will not utilize UMD equipment and will not be performed at UMD facilities.</li> <li>The students will be made aware that any IP created at <u>Company X</u> will be owned by the company and</li> </ul>	

## Management Plans - Risk Level 2:

These Management Plans present a moderate level of risk and are typically overseen by an <u>Oversight Official</u>. Risk Level 2 management plans may also be asked to complete a Quality Assurance Audit by the COI Office.

Ownership / Financial Interest – MIPS –	Use of UMD Students & UMD Lab Space
Conflict of Interest:	Possible Management Plan Elements:
<ul> <li>Professor at UMD is the PI of a MIPS Phase 1 award.</li> <li>They also are the CEO and a majority stakeholder of <u>Company X</u> that is involved in the MIPS award.</li> <li><u>PI serves two roles</u> on the MIPS project: UMD PI and <u>Company X</u> Representative.</li> <li>One co-founder for Company X, holds equity interest.</li> <li>Company X has been incubated by UMD; UMD holds equity interest in Company X.</li> <li>As UMD PI for MIPS project, a portion of the research will take place in the PI's lab on campus.</li> <li>Company X will hire UMD undergrads as interns.</li> </ul>	<ul> <li>UMD Faculty cannot serve as both UMD PI and Company PI.</li> <li>Development of a Quality Assurance Project Plan (QAPP) for the project.</li> <li>The QAPP ensures there is an evaluation of the study design and research methodologies prior to data collection, allows for spot checking of the data collection, and validation of the analysis of data and results by an independent scientist prior to releasing to the PI.</li> <li>PI will not be the hiring official or direct supervisor of students hired as company interns. QA Director will be the hiring official. Co-founder will serve as a direct supervisor for UMD interns on the MIPS project. PI may hire and supervise non-UMD interns.</li> <li>Students taking PI's courses or being advised by the PI cannot serve as interns.</li> <li>Facilities Use Agreement must be established for <u>Company X</u> to use the PI's lab space. <u>Company X</u> will pay UMD for use of the facilities.</li> <li>All lab personnel will be provided with a <u>COI</u> <u>Acknowledgement Memo</u> to review and sign.</li> </ul>

Ownership / Financial Interest – MIPS Award – Use of UMD Lab Space	
Conflict of Interest:	Possible Management Plan Elements:
UMD Professor, Co-founder, and Chief Scientific	• The Department Chair will serve as the UMD PI's
Officer at Company X.	Oversight Official.
• <u>UMD</u> received a MIPS award.	• MIPS award - <u>Company X</u> is required to submit twice
• Professor is the PI for UMD; Founder is PI for	yearly progress reports. The Chair will be given copies
Company X.	of these reports prior to submission to MIPS.
• The studies will be performed in <b>Company X's labs on</b>	The Oversight Official will meet with all UMD
campus. FUA has been approved. Company X	personnel at his discretion to discuss the project.
personnel will not have access to the PI's lab (except	The Oversight Official will also be provided with
where stated in the approved FUA).	copies of patent applications, conference
• <u>UMD personnel</u> will not have access to Company X's	presentations, and manuscripts to be submitted for
lab.	publication prior to their submission.
<u>No personnel employed by UMD will be employed</u>	All lab personnel will be provided with a <u>COI</u>
by Company X, including undergraduates, graduate	Acknowledgement Memo to review and sign.
students, post docs, and technicians.	

Ownership / Financial Interest -	- MII Grant – Family Relationship
Conflict of Interest:	Possible Management Plan Elements:
<ul> <li>UMD Professor has been awarded a Maryland Innovation Initiative (MII) grant. The grant will lead to starting a business based on an intervention licensed from UMD.</li> <li><u>Dr. X</u>, who has substantial expertise in starting up companies and acquisition of venture capital, will be the CEO of the company started as part of the MII grant.</li> <li><u>Dr. X's company has a subaward</u> on the MII grant for market research, as allowed and expected by the MII.</li> <li><u>Dr. X is the UMD Professor's sibling</u>.</li> </ul>	<ul> <li>UMD and subaward work must be kept separate. Any company created will also have its work separate from any UMD work.</li> <li>The subaward is separate from the research in the UMD Professor's lab and as such, none of the UMD students working in the Professor's lab will have contact with Dr. X.</li> <li>This conflict and the conflict associated with the project leading to the initiation of a company that is licensing technology from the university will be managed by having an <u>Oversight Official</u>. However, if a company is formed, the UMD Professor will be required to submit a new COI disclosure.</li> <li>The Department Chair will serve as the Oversight Official and will conduct twice-yearly reviews of project data, financial records, and other relevant supporting documents. All subaward request forms for the company subaward and company subaward invoices will be approved by the Oversight Official.</li> <li>All lab personnel will be provided with a <u>COI</u><u>Acknowledgement Memo</u> to review and sign.</li> </ul>

Ownership / Financia	al Interest - Subaward
Conflict of Interest:	Possible Management Plan Elements:
UMD Professor, Chief Technology Officer, and	• <u>Company X</u> will work on subaward work in the
founder of <u>Company X.</u>	Company X lab.
Federal Agency has selected UMD for an award.	• IP discussions must be held with UMVentures.
• Professor is PI on the Federal Agency grant at UMD.	The CEO of Company X will negotiate subaward
<ul> <li>Professor owns 25% of <u>Company X.</u></li> </ul>	contractual issues with UMD and sign on behalf of the
<u>Company X</u> will be a subawardee to UMD on the	company.
federal grant.	FUA will be routed if UMD facilities are needed and
• The CEO of Company X will be listed as the PI on the	will be provided to COI Committee. No UMD students
subaward.	in UMD Professor's lab or enrolled in their classes will
	be involved in Company X's subaward.
	All lab personnel will be provided with a COI
	Acknowledgement Memo to review and sign.
	UMD Professor's Chair will serve as the Oversight
	Official for the award from Federal Agency.
	The Oversight Official will provide oversight of COI
	issues by conducting twice yearly reviews of project
	data, financial records, and any other necessary
	supporting documents. Any concerns will be reported
	to the COI Committee.

## Management Plans - Risk Level 3:

These Management Plans present the highest level of risk and are typically overseen by an Oversight Committee.

Ownership / Financial Interest – Employment Inte	erest – Participation in Research – Married Couple
Conflict of Interest:	Possible Management Plan Elements:
UMD Professor, equity holder, and founder of	• Professor may not serve as an officer or employee of
Company X.	<u>Company X</u> .
Receives no compensation from <u>Company X.</u>	No UMD employee may receive compensation from
Professor is married to the Chief Science Officer at	<u>Company X</u> .
Company X.	All postdocs, graduate students, and lab members
Chief Science Officer is the PI of an award from a	involved in the research will be made aware of the
Federal Agency to <b>Company X</b> .	COI, notified in writing, and will sign a memo
UMD is a subawardee on the proposal.	indicating their acknowledgement.
• Professor will serve as Co-PI on the subaward.	• Since the UMD Professor and Chief Science Officer
	(PI of subaward) are married, a co-PI on the
	subaward or Department Chair will be responsible
	for signing Subaward Request Forms for Company X
	as well as approving <u>Company X</u> invoices.
	<ul> <li>Students employed at UMD will not conduct</li> </ul>
	research for Company X or be allowed in the
	company's research facilities.
	Any Intellectual Property (IP) will be handled
	through standard UMD licensing agreements.
	Non-UMD personnel must not have access to any
	UMD lab space unless an FUA is in place. FUA will be
	routed if UMD facilities are needed and will be
	provided to COI Committee.
	An Oversight Committee has been established to
	oversee the conflict. The committee will hold twice
	yearly meetings to monitor the project.