



A Discussion of Conflict of Interest

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Chair of the UMCP Conflict of Interest Committee

and

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Member, Conflict of Interest Committee

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UMCP Senate
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Why Are We Here?

The point of COI training is to remind us that the university's objectivity and integrity in generating new knowledge is its most precious asset and must be protected at all costs.

Why Are We Here?

- State Ethics Law defines conflicts of interest
- State gives exceptions to Universities for Research & Development under following conditions:
 - University develops COI Policies and Guidelines
 - University requires disclosure of any interest to a designated official – **at UMD this is the COI Committee!!**
 - This designated official determines what information must be disclosed and what restrictions must be imposed to manage, reduce or eliminate the COI
 - Management plans are approved by the President of the University

Universities and federal funding agencies
have become entrepreneurial and
have established “relationships” with
commercial and non-profit entities

At UMCP, the stated goal is for the University
to spin out 100 new companies based on
UMCP intellectual property



PRECISION
POLYOLEFINS, LLC

Principles of the Land Grant University



- Educate Students
- Create and disseminate new knowledge

Research Integrity in a University

“... scientific integrity is a principle of scientific thought that corresponds to a kind of utter honesty - a kind of leaning over backwards.....you should report everything that you think might make it invalid.....details that could throw doubt on your interpretation must be given...you must present all of the facts that disagree with it, as well as all that agree with your hypothesis...”

Richard Feynman
(Physicist - Nobel Laureate)

What is a Conflict of Interest?

Conflict of Interest (generic definition)

A conflict of interest exists when an individual exploits, or appears to exploit, their position for personal gain or for the profit of a member of their immediate family or household.

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The generic definition of a COI is often too simplistic to deal with COI in more complex environments involving university research. And it sometimes leads to erroneous and unhelpful conclusions such as, “...If no money changes hands, it can’t be a conflict of interest...”

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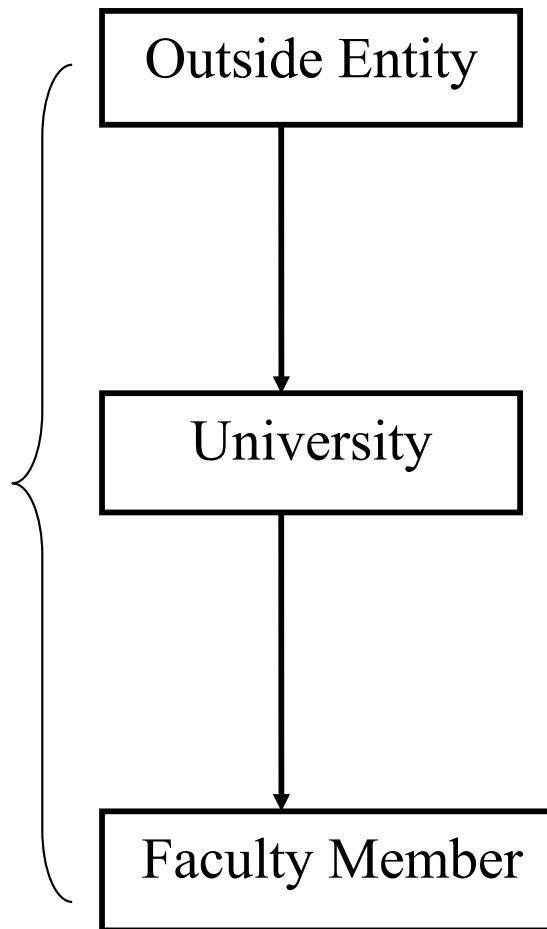
In University Research

A conflict exists when a secondary interest provides an incentive for a researcher to make a judgment or determination in research that differs from what would be made in the absence of the secondary interest – i.e. a biased judgment or decision.

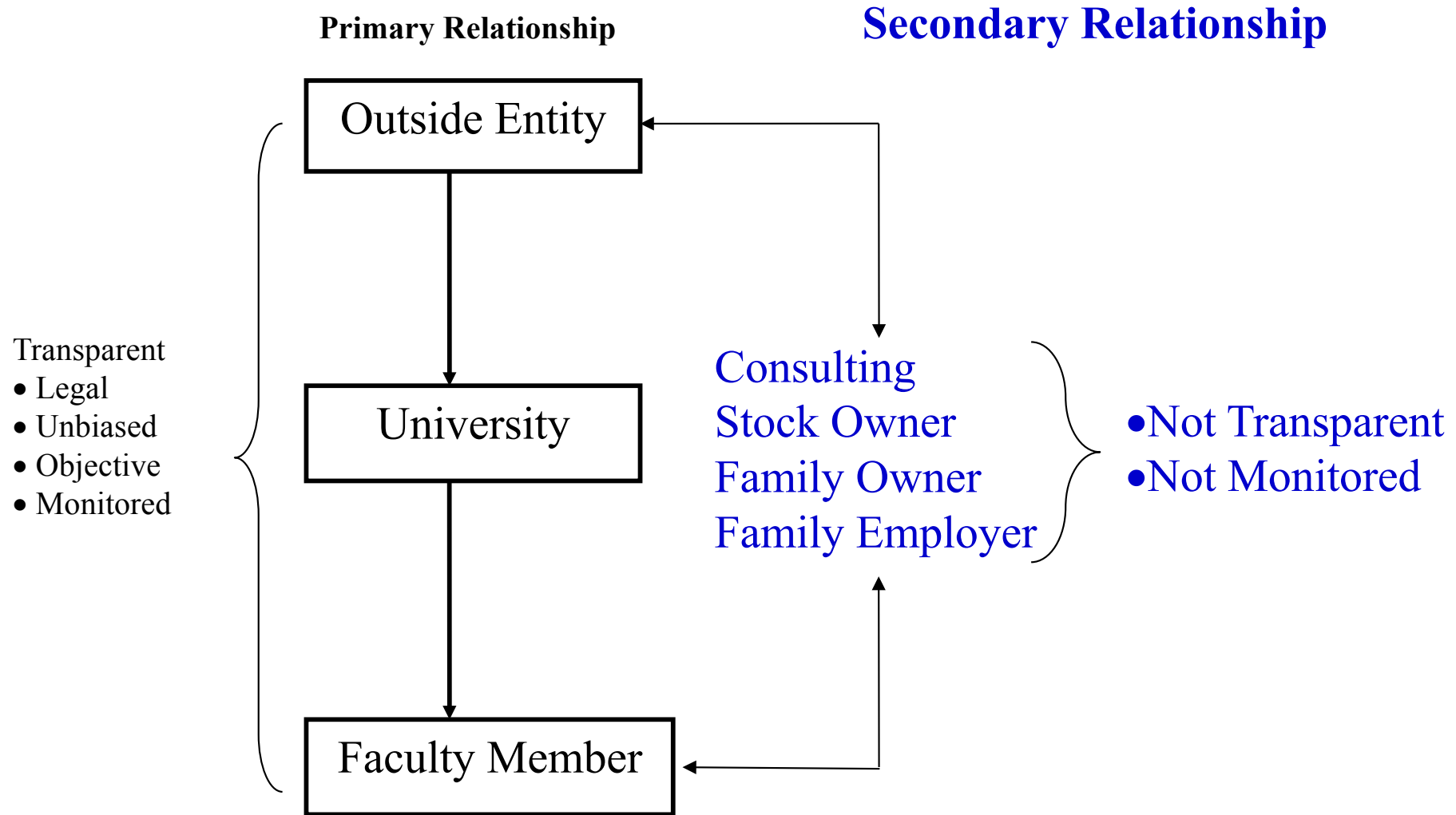
Outside Entity - University - Employee Relationships

Primary Relationship

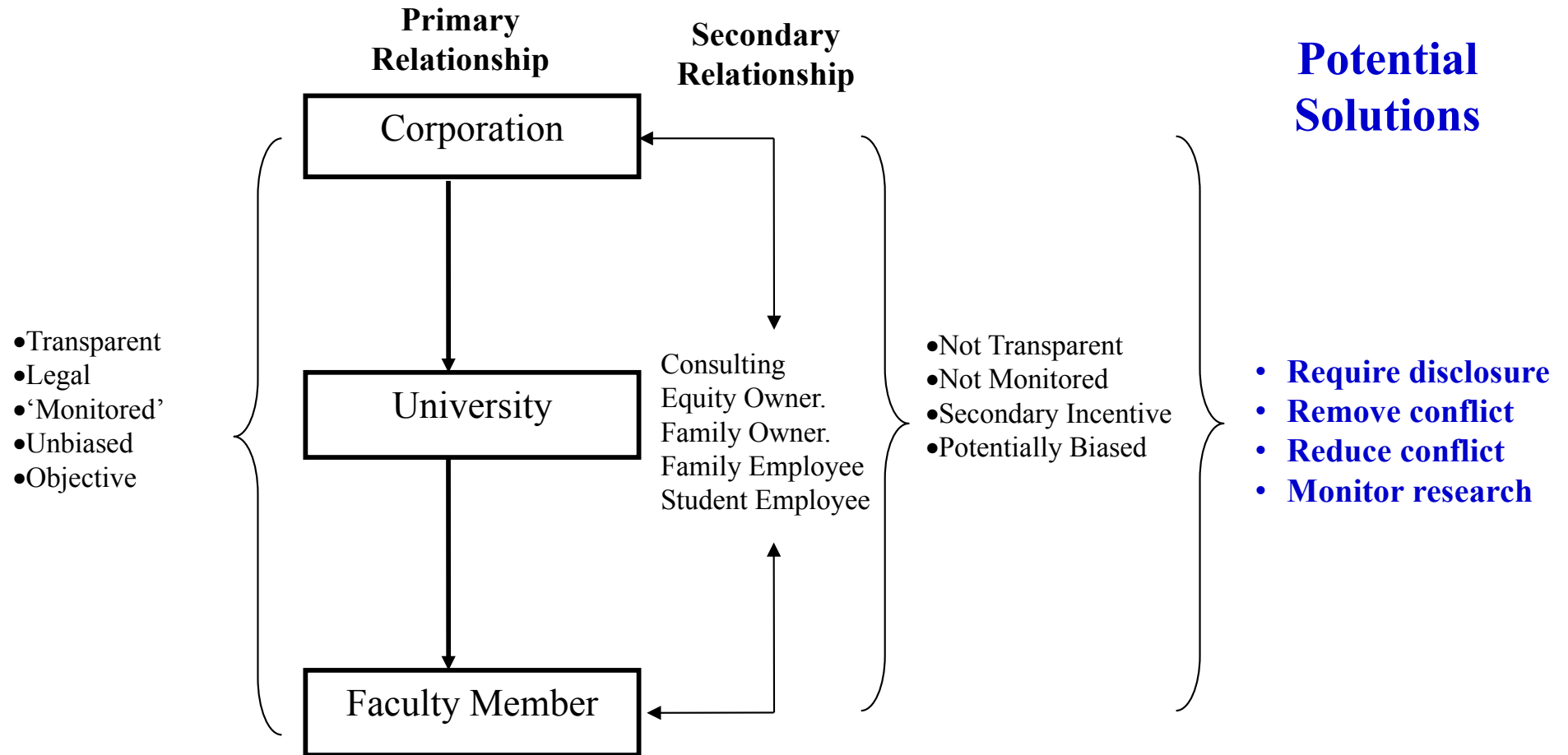
- Transparent
- Legal
- Unbiased
- Objective
- Monitored



Outside Entity - University - Employee Relationships



Outside Entity - University - Employee Relationships



Conflict of Interest in University Research - Principles

- A conflict exists when a secondary interest provides an incentive for a researcher to make a judgment or determination in research that differs from what would be made in the absence of the secondary interest – i.e. a biased judgment or decision.
- A COI is most likely to occur when the university is involved with commercial entities.
- Minimizing a Research COI involves management strategies that either:
 - **Eliminate the incentive bias (e.g. give up equity)**
 - **Reduce incentive bias to an acceptably low level (e.g. restrict equity)**
 - **Reduce the consequences of the incentive bias (e.g. independent monitoring).**

General Principles Regarding “Relationships”

These “secondary relationships” with outside entities may not:

- Lead to misuse of students, faculty, or employees
- Have the potential to skew or bias research findings
- Interfere with employee’s responsibilities
- Provide inappropriate resource allocations

Analyzing for Research/Academic COI

- Identify the primary interest
 - Unbiased generation/dissemination of new knowledge
- Identify any secondary interest
 - e.g. Company ownership/equity, consulting
 - e.g. authorship of required textbook
- Manage the conflict
 - Eliminate the incentive bias (e.g. give up equity in entity)
 - Reduce incentive bias to an acceptably low level (e.g. restrict equity)
 - Reduce the consequences of the incentive bias (e.g. monitoring committee).

Principles for Managing Conflicts

- Not possible to avoid all competing interests
- Potential conflicts are not necessarily ‘bad’
- Disclosure is always ‘good’

Managing Conflicting Interests

- Requiring full disclosure of all interests so others are aware of potential conflicts and can act accordingly
- Monitoring the research or checking research results of someone having potential COI for accuracy and objectivity
- Removing the person with the conflict from crucial steps in the research process. These steps might include collecting data, interpretation of data, or participating in particular review decisions, etc.

Case Studies

Example and Management Plan

Professor Smith consults for a company that develops and sells products related to her research at the university. Because of the Professor Smith's expertise on this topic, the company decides to give her a grant through ORA to conduct research of interest to the company.

Is this a conflict of interest?

Example and Management Plan

Professor Smith consults for a company that develops and sells products related to the her research at the university. Because of the Professor Smith's expertise on this topic, the company decides to give the her a grant to conduct research of interest to the company.

Why is this a conflict of interest? Accepting sponsored funding from a company for which one also consults, whether paid or unpaid, is considered a conflict of interest because the secondary interest in *maintaining the consulting relationship may influence objectivity in conducting the university's research.*

Example and Management Plan

Why is this a conflict of interest? Accepting sponsored funding from a company for which one also consults, whether paid or unpaid, is considered a conflict of interest *because a secondary interest of maintaining the consulting relationship may prejudice the outcome of the research.*

What should the employee do? To protect research integrity, University policy prohibits investigators from receiving grants from entities for which they consult. Therefore, *the employee should disclose the conflict.*

In this instance, the COI Committee would require that the PI choose to either forgo the grant or terminate the consulting arrangement.

Additional Case Studies

Situation: Professor Adams has a federally funded research program in sensing devices. As part of this program he develops a device that can measure glucose in blood.

- Acme Sensing Co. provides an unrestricted grant to pursue his studies.
- Acme Sensing Co. awards a contract to Dr. Adams lab to support his studies.
- After the contract from Acme has been running for one year, Acme asks Prof. Adams to become a member of the company's Scientific Advisory Committee.

Additional Case Studies

- Professor Adams establishes a company, GlucoSensing, LLC., and licenses his lab's technology from the university.
- Professor Adams's sister establishes a company, GlucoSensing, Inc., and licenses the technology from the university.
- Professor Adams is the Director of the UMCP Center for Biomedical Studies. The Center is funded by a mixture of federal and state funding, and private endowment. While serving as Center Director, he establishes a company, GlucoSensing, Inc., and licenses his lab's technology from the university.

Managing Conflicts

The COI Committee processed **468**
COI disclosures during the 2014-2015
academic year.

Thank You

Joe Smith
COI Compliance Officer
5-0678

Philip DeShong
Chair, COI Committee
5-1892

Full Disclosure

30. a. ☒ yes ☐ no **Conflict of Interest:** Is there a real or potential conflict of interest in connection with this work involving a University of Maryland employee, as defined by the University of Maryland Policies and Procedures II-3.10(A) or II-3.10(B) (www.umresearch.umd.edu/RCO/COI/index.html).
If yes, a disclosure form must be completed and submitted in accordance with these procedures.
30. b. ☐ yes ☒ no **FCOI Mandatory Disclosure:** Is this a proposal to a PHS sponsor, PHS prime sponsor, or a sponsor/prime sponsor which follows PHS's Financial Conflict of Interest (FCOI) regulations??
☐ yes ☐ no If yes to 30b, have all individuals responsible for the design, conduct, or reporting of the research completed the IRBNet Financial Conflict of Interest in accordance with the University of Maryland Policies and Procedures on Financial Conflicts of Interest in Public Health Service Funded Research II-3.10(C)?
For more information on FCOI, refer to: www.umresearch.umd.edu/RCO/FCOI/index.html

31. If proposal contains draft technical or other provisional materials and the PI will be responsible for submitting the proposal, PI is responsible for ensuring a copy of the final proposal as submitted to sponsor is provided simultaneously to ORA. All budget and cost sharing commitments must be finalized before the proposal is routed.

32. PI's signature below affirms that no changes in scope, budget, or institutional commitments will be made in the final proposal without first contacting ORA.

33. PI's & Co-PI's signatures below affirm:

- a) that the information submitted within the proposal is true, complete, and accurate to the best of the PI's & Co-PI's knowledge;
- b) that any false, fictitious, or fraudulent statements or claims may subject him/her to criminal, civil, or administrative penalties;
- c) that PIs and Co-PIs agree to accept responsibility for the conduct of the project and to follow any terms and conditions of any resulting agreement, including, but not limited to, providing required progress reports and adhering to any requirements regarding the handling of confidential information.

Note: Proposal cover page must have space for signature of the University's authorized signature authority (Office

Management Plan: COI Disclosure Form

UNIVERSITY OF MARYLAND CONFLICT OF INTEREST DISCLOSURE FORM	
NOT FOR FCOI DISCLOSURE	
<p>This form is submitted for the purpose of obtaining an exemption from certain conflict of interest provisions of the Maryland Public Ethics Law, section 15-523 of the State Government Article of the Annotated Code of Maryland. I acknowledge that this form may be maintained as a public record at the University and, if approved, will be filed with the State Ethics Commission. I hereby state that the contents of this disclosure statement are true and correct to the best of my knowledge, information, and belief.</p>	
Philip DeShong	Chemistry & Biochemistry
Discloser Name	Department
<u>Philip R. DeShong</u>	17 June 2014
Signature	Date
5-1892	deshong@umd.edu
Telephone	Email
ADMINISTRATIVE REVIEW	
<p>Review by the Department Chair or Director and the Dean are required before this form is submitted to the COI Office for processing. The Department Chair is responsible for conducting the initial review of this disclosure and making the assessment below.</p>	
<p>Based on the activity reported, to the best of my knowledge and in my judgment:</p>	
<p><input type="checkbox"/> 1. No real or potential conflict of interest exists.</p>	
<p><input checked="" type="checkbox"/> 2. A real or potential conflict of interest exists, as described in the "Summary of Real or Potential Conflict", page 2.</p>	
<p><input checked="" type="checkbox"/> 3. The management plan described on page 2 will permit the conflict to be managed in accordance with University policies and procedures.</p>	
<u>[Signature]</u>	Date <u>6-30-2014</u>
Department Chair's Signature	
<u>Tajana R. B.</u>	Date <u>7/02/14</u>
Dean's Signature	
<p>I concur with the above _____ I do not concur _____</p>	

Management Plan: COI Disclosure Form

COI Disclosure form contains

- Summary of Real or Potential Conflict
- Mitigating Factors and Management Plan
- Ownership/Financial Interest
- Employment Interest
- Participation in the Research
- Selection of Subawardee

Management Plan: Research Oversight Official

Research Conducted Under COI or the Appearance of COI Conditions

This project entitled "Surfactant nanoparticles: a novel vaccine delivery system with unque stability and immunostimulatory potential" funded by Maryland Innovation Initiative has been identified as research involving a conflict of interest or the appearance of a conflict of interest. The University takes very seriously its role in ensuring that its research and scholarship is conducted with the highest integrity and is protected from influences which could lead to bias, or the appearance of bias, in the collection or interpretation of data, or publication of research results. The conflict of interest in this case cannot be eliminated with the usual procedures. Therefore, the following management plan will be implemented: Professor Daniel Falvey (Department of Chemistry & Biochemistry) will provide oversight of all the research involved with regard to the conflict of interest issues listed above for the period of time July 1, 2014 to April 30, 2017.

It should be understood that the management plan implemented for this case is unique to this case and does not imply that a similar plan will apply in future conflict of interest cases. The COI Committee decides each case on its own merits which include, among other things, considerations of the nature of the research, the potential risk to the University, and the benefits to public welfare.

Oversight Official: Name: Daniel Falvey Date: July 1, 2014

Signature: _____

Individuals with COI: Name: Philip R. DeShong Date: _____

Signature: _____

Management Plan: Cohort Disclosure Form

Grant #:

Grant Title: "Functionalized Cationic Surfactant Vesicles (FCSVs): A Platform for Vaccine Development."

This document is to inform you of a potential conflict of interest regarding the Principal Investigator, Dr. Philip DeShong. Dr. DeShong is the Principal Investigator on the award and has a conflict of interest due to his ownership of SD Nanosciences. Dr. DeShong co-founded SD Nanosciences and currently serves as its President. SD Nanosciences has licensed the technology from the University of Maryland, College Park.

To further mitigate any potential conflict of interest, Professor Daniel Falvey of the Department of Chemistry & Biochemistry has been appointed as the COI Supervising Official for this project. Professor Falvey will oversee both administrative and research aspects of this project. If you have any concerns or issues relating to the conflict of interest, please contact either Professor Falvey or Professor Janice Reutt-Robey, Chair, Department of Chemistry & Biochemistry.

If you have any questions or concerns regarding the potential conflict of interest, please contact Conflict of Interest Administrator, Joseph Smith at 301-405-0678.

Please print and sign your name below to acknowledge that you, as an employee on this grant, have been informed of the potential conflict of interest and the mitigation plan in place.

PRINT NAME

DATE

SIGN NAME

DATE

Research Conducted Under COI

or the Appearance of COI Conditions

This project entitled _____ funded by _____ has been identified as research involving a conflict of interest or the appearance of a conflict of interest. The University takes very seriously its role in ensuring that its research and scholarship is conducted with the highest integrity and is protected from influences which could lead to bias, or the appearance of bias, in the collection or interpretation of data, or publication of research results. The conflict of interest in this case cannot be eliminated with the usual procedures. Therefore, the following management plan will be implemented: Professor _____ will provide oversight of all the research involved with regard to the conflict of interest issues listed above for the period of time ____ to ____.

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Oversight Official: Name: _____ Date: _____

Signature: _____

Individuals with COI: Name: _____ Date: _____

Signature: _____

Others on Project: Name: _____ Date: _____

Signature: _____