

Disclosure Requirements in Research

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ROADMAP TO TODAY'S DISCUSSION

LEGAL/REGULATORY/POLICY REQUIREMENTS (Ellen)

CONFLICT OF INTEREST – FINANCIAL INTEREST DISCLOSURES

700-U (CA FPPC) Federal PHS (NIH) NSF

Other Sponsors UC Policies Journals

CONFLICT OF COMMITMENT – OUTSIDE PROFESSIONAL ACTIVITIES

APM 025 APM 671

❖ OTHER GRANT-RELATED DISCLOSURES - NIH, NSF, OTHER SPONSORS

Other Support | Foreign Components | Bio Sketches

❖ OTHER DISCLOSURES (examples...There are more...)

InventionUse/Acquisition of Export-
controlled techInt'l travel,
shipments



ROADMAP TO TODAY'S DISCUSSION

LOCAL IMPLEMENTATION (Bruce)

- Similarities, Differences
- **Review Processes, Management Plans**
- **Additional Campus Requirements**
- Scenarios, Case Studies



INTRO/OVERVIEW: WHY ARE DISCLOSURES IMPORTANT IN CONNECTION WITH RESEARCH?

- Commitment to ensuring research is carried out under high standards of ethical conduct, integrity, adherence to applicable laws, regulations and policies
- **❖** Disclosure facilitates review to determine if personal interests present Conflicts of Interest that need to be managed, and to take action
- Disclosure, review, and management processes bolster credibility and enhance confidence in the integrity of research

Why require disclosure/review of researchers' personal financial interests?

> Concern about Potential Conflicts of Interest (COI):

- Having a financial interest related to your research is not wrong or even always completely avoidable. The concern is about the possibility that investigators' personal financial interests could directly and significantly affect or appear to affect their professional judgment.
- Disclosure allows review, to assure the UC community, sponsors, and the public that the principles central to the research process are followed.

Key Principles (from UC APM-028):

- Separate Personal Interests from UC Interests -avoid traditional COI situations where possible)
- Research Should be Appropriate to the University
- Teaching and Research Environment Should be Open
- Freedom to Publish and Disseminate Research Results Should Be Preserved
- University facilities and Resources Must Be Used Appropriately

Potential Consequences for Inadequate Disclosure

- ➤ Could result in the institution and/or sponsor having insufficient information to evaluate whether there are relevant conflicts of interest, commitment, or potential overlap in funding; could prevent full consideration of factors relevant to making/accepting/managing an award.
- > Could undermine credibility and trust in the investigator, the research, the institution.
- ➤ Discovery of potential omissions or inaccuracies may trigger investigation of the individual and/or the institution. Depending on facts/circumstances, could trigger notification requirement; disallowance of costs; withholding future awards; suspending award activities; suspension or debarment; termination of award, or if fraud is involved, more severe legal action.

California State Law: Political Reform Act/FPPC Regulations – 700-U Form (for Pl's)

lease type or print in ink.	PRINCIPAL INVESTION A Public Document			Campus:
NAME (LAST)	(FIRST)			(MIDDLE) TELEPHONE NUMBER
ACADEMIC UNIT OR DEPARTMENT		MAI	L CO	() DDE E-MAIL ADDRESS
TITLE OF RESEARCH PROJECT				
. Information Regarding	Funding Entity		3.	Filer Information - Cont.
(Use a separate Form 700-U for	each funding entity.)		D.	Have you received loans from the entity in Part 1 for which the balance exceeded \$500 during the reporting period?
Name of Entity:		.		No Yes — highest balance:
Address of Entity:				\$500 - \$1,000 \$1,001 - \$10,000 Exceeded \$100,000
Principal Business of Entity:				Secured Unsecured Interest rate:%
Amount of Funding: \$		-		Was the loan entirely repaid within the last 12 months? No Yes
Estimated Actual Actual			E.	Have you received gifts from the entity listed in Part 1 within the last 12 months valued at \$50 or more? No Yes — – describe below.
2. Type of Statement (Chec	ck at least one box)			Description:
☐ Initial (for new funding)				Description.
Date of initial funding:/_				
Interim (for renewed funding) Funding was renewed on:				Value: \$ Date Received:
		- 1	F.	Has the entity in Part 1 paid for your travel during the

CA 700-U Form – PI Statement of Economic Interests

Who Must Report??

Any UC employee with "principal responsibility" for a research project (i.e., the PI) supported by a non-governmental entity

What Triggers Disclosure?

Receipt of <u>any amount</u> of research support from a non-governmental entity (other than an entity on FPPC "exempt" list or a non-profit tax-exempt educational institution) via:

Research contracts/grants	Research contracts/grants Research gifts earmarked for a specific	
	individual, research project, or lab	

What Must Be Disclosed?

Financial interests of the PI* in the nongovernmental sponsor, including:		
income ≥ \$500 rec'd w/i 12 mo prior to award	Director, Officer, Partner, Employee, Trustee, Consultant or Management position	
investments ≥ \$2,000 held as of award date	Gifts valued at \geq \$50 (note: ban on gifts \geq \$500) rec'd w/i 12 mo prior to award	
Loan Balances ≥ \$500)	Travel payments rec'd w/i 12 mo prior to award	

^{*700-}U also requires PI to report specified financial interests of Spouse, Registered DP, dependent children

When Is Disclosure Required?

Before final acceptance of the contract, grant or gift	w/i 30 days of renewed/added funding
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CA 700-U Form – PI Statement of Economic Interests

Where does the 700-U form get filed?

Must be submitted by PI to designated campus office (e.g., Sponsored Projects; Gifts).

How is the 700-U reviewed?

- Negative Disclosures (no PI Financial Interest in sponsor): No further review required.
- Positive Disclosures: Campus must conduct "independent substantive review" by Designated
 Campus Reviewer and/or (if certain criteria are met) by an Independent Substantive Review
 Committee.
- Reviewer recommends to Chancellor/Designee whether disclosed Financial Interests present a
 COI and if so, how COI can be reduced, managed or eliminated (or, if it is not feasible to
 adequately manage COI, may recommend that the campus reject the award).

What is the timeline for review?

Must be completed and any COIs managed, reduced or eliminated prior to expending award funds

CA 700-U Form – PI Statement of Economic Interests

What factors guide the review of PI disclosures? (APM 028)

- Assuring adherence to relevant UC policies, guidelines, regulations
- Considering nature/extent of PI's interest, and potential effect of research on the sponsor/PI
- Special consideration when certain circumstances exist, such as:
 - Testing of sponsor's products/inventions
 - Research in sponsor's facilities, involving sponsor proprietary info, or conducted w/ sponsor
 - When PI has ownership interest in sponsor, opportunity to receive substantial \$ benefits from sponsor, or long-term/ongoing consulting relationship
- Applying UC principles

Relevant questions reviewer may consider include:

- Will PI's Financial Interest affect or impair conduct of research in accordance with applicable rules and highest professional standards?
- Will the research advance knowledge beyond routine testing that primarily benefits sponsor?
- Will the research contribute to UC mission of teaching/research/public service?
- Do public benefits outweigh any potential erosion of academic freedom, collegiality or public trust?

CA 700-U Form – PI Statement of Economic Interests

Possible outcomes of Substantive Review – Recommendation that the Campus:

ACCEPT the grant/gift

NOT ACCEPT the grant/gift

ACCEPT contingent on certain conditions

Examples of Conditions that may be required/recommended

- ➤ Reduce or eliminate PI's financial interest in the sponsor (e.g., through sale of an equity interest or through severance of relationships that create real or perceived financial conflicts);
- ➤ Require disclosure of PI's financial interest to public (e.g., in publications/presentations), lab members, research subjects
- > Appointing an independent non-conflicted monitor capable of taking measures to protect design, conduct, reporting or research against potential bias that might result from the financial interest;
- ➤ Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research

FINANCIAL INTEREST DISCLOSURE REQUIREMENTS PUBLIC HEALTH SERVICE POLICY

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F)

PHS Financial Conflict of Interest Policy – Disclosure Requirements

Who Must Disclose?

Investigators (anyone, regardless of title or position, responsible for design, conduct or reporting of research to be funded by PHS)

What Triggers Disclosure?

Proposing or receiving research grant/cooperative agreement/contract funding from a PHS agency (e.g., NIH, CDC, FDA, HRSA).

What Must Be Disclosed?

<u>Significant Financial Interests</u> of the Investigator (including spouse and dependent children) related to Investigator's <u>institutional responsibilities</u> (professional responsibilities on behalf of UC, including teaching, research, outreach, clinical service, and other activities in course and scope of UC appointment/employment). SFI's include:

Publicly-traded entity: SFI exists if total value of non-UC remuneration (e.g., income, honoraria, consulting fees) rec'd w/i 12 mo prior to disclosure AND equity added together > \$5K

IP rights and interests (other than royalties from UC) > \$5K (income rec'd w/i 12 mo prior to disclosure)

Non-publicly traded entity: SFI exists if there is ANY equity interest OR if non-UC remuneration (e.g., income, honoraria, consulting fees) rec'd w/i 12 mo prior to disclosure > \$5K

Sponsored travel, travel reimbursements* made to or on behalf of Investigator (but not including reimbursements from U.S. gov't agencies, U.S. higher ed institutions or academic medical centers).

*Campuses may adopt policies excepting travel < \$5K from disclosure

When Is Disclosure Required?

Before proposal is submitted	w/i 30 days of acquiring new SFI	At least annually thru life of grant
When new Investigator joins project	Before submission of progress reports	14

PHS COI Policy – SFI Disclosures

Where do Disclosures of SFIs related to PHS-funded researchers' institutional responsibilities get filed?

Must be submitted by PI to designated campus office (e.g., Sponsored Projects).

How is the form reviewed?

Each campus has process for reviewing to determine:

- (1) if any of the Investigators' disclosed SFIs relate to proposed PHS-funded research and, if so,
- (2) whether a financial COI exists (could the interest directly and significantly affect the design, conduct or reporting of the research?); and if so,
- (3) a management plan for reducing, managing or eliminating the FCOI

What is the timeline for review?

Prior to expending award funds:

- (1) reviews must be completed;
- (2) any COIs managed, reduced or eliminated;
- (3) FCOI report (with info re management plan) must be submitted to PHS awarding component re any FCOI that has not been eliminated.

FCOI report also must be submitted to PHS awarding component when an Investigator does not timely disclose an SFI (in which case, a **retrospective review** must be conducted) or when an SFI is not timely reviewed and the institution then determines that and FCOI exists.

NATIONAL SCIENCE FOUNDATION Financial Interest Disclosure Requirements

NSF Proposal & Award Policies & Procedures Guide, Ch IX.A.

NSF Financial Conflict Of Interest Policy – Disclosure Requirements

Who Must Disclose?

Investigators (anyone, regardless of title or position, responsible for design, conduct or reporting of research to be funded by NSF)

What Triggers Disclosure?

Proposing or receiving grant/cooperative agreement/contract funding from NSF

What Must Be Disclosed?

Significant Financial Interests of Investigator (including spouse/RDP and dependent children) that would reasonably appear to be affected by the research or that are in entities whose financial interests would reasonably appear to be affected by the research

Income > \$10,000 (including non-UC salary, consulting fees, honoraria, travel reimbursements, royalties, etc.) rec'd w/i 12 mo prior to disclosure or anticipated in next 12 mos

(does not include income from seminars, lectures, teaching engagements sponsored by public/nonprofit entities or from serving on advisory committees/review panels of such entities)

Equity Interest > \$10,000 (e.g., stocks, options, real estate, ownership interests, etc.) or > 5% ownership interest in any one entity (does not include ownership interest in SBIR or STTR applicant)

Intellectual property interest (other than IP owned by UC)

When Is Disclosure Required?

Before proposal is submitted

When new investigator joins project

When new reportable SFI is acquired

NSF COI Policy – SFI Disclosures

Where do Disclosures of SFIs related to NSF-funded research get filed?

PI must submit to designated campus office (e.g., Sponsored Projects).

How is the form reviewed?

Each campus has process for reviewing to determine if a disclosed SFI constitutes a COI that should be reduced, managed or eliminated.

What is the timeline for review?

Reviews must be completed prior to expending award funds.

If reviewer determines that conflicts cannot be satisfactorily reduced, managed or eliminated and that potential negative impacts that may arise from an SFI are outweighed by interests of scientific progress, tech transfer, or public health/welfare, research may go forward without conditions, but NSF must be notified (and NSF OGC may conduct its own review).

Journals Financial Interest Disclosure Requirements



Journal Disclosure Requirements

- Journals have various requirements for disclosure by authors, peer reviewers; editors.
- ICMJE (International Committee of Medical Journal Editors) COI form is used by many journals
 - ICMJE requires authors to disclose financial relationships with any entity that could be considered broadly relevant to the work (not just sponsors), that could be perceived to influence the submitted work or that could be perceived to be affected financially by the submitted work; also asks about IP. Notes that in some cases they may require authors to provide journal with copies of agreements with study sponsors (in confidence).

CONFLICT OF COMMITMENT and OUTSIDE ACTIVITY DISCLOSURES

UC Academic Personnel Manual 025 UC Academic Personnel Manual 671

Why Disclose Outside Activities?

The general intent of APM - 025 and APM - 671 is to ensure that when a faculty member participates in activities outside of the University, those activities do not interfere with fulfilling the individual's responsibilities to the University.

Outside professional activities that interfere with a faculty member's professional obligations to the University constitute a "Conflict of Commitment."

UC APM 025 and APM 671

Who Must Disclose?

What Triggers Disclosure?

- Annual Report Requirement: All covered faculty must submit annual report disclosing
 Cat I and Cat II OPAs or lack thereof conducted during preceding 12 months.
- Prior Approval Requirement: Required before:
 - Undertaking any Category I OPA; and/or
 - > Involving Students (including trainees, postdocs, residents, fellows) in any OPA

What Must Be Disclosed?

- <u>Category I</u>: OPAs (activities related to training/expertise that qualifies the individual for UC, but performed for 3rd party; and/or that require significant professional commitment). E.g., teaching, research, administration of a grant at a non-UC entity; employment outside UC; assuming founding or co-founding role in company; assuming an executive or managerial role outside UC (other than at a professional society).
- <u>Category II: OPAs that are typically shorter-term and outside course/scope of UC employment.</u> E.g., Additional UC-compensated teaching (e.g., UNEX); consulting; testifying as expert witness; engaging in professional practice outside UC; serving on a Bd of Directors; presenting a workshop for industry

UC APM 025 and APM 671

What Information Must Be Disclosed? Each campus has own procedures

• <u>Type/nature</u> of activity; <u>description</u> of the outside entity and of individual's relationship to entity and of their activity; <u>estimated days spent</u> on the OPA (there is a limit on the # of days faculty can spend on OPAs). In addition, <u>APM 671 requires info about amount of compensation</u> for compensated OPAs.

Where do OPA Forms Get Filed?

- Usually filed with Department Chair
- 9 campuses are participating in UC Outside Activities Tracking System (OATS) web-based reporting platform.

How are OPA Reviewed?

Examples of review considerations:

- Does the activity cause real or apparent conflict or interference with fulfillment of faculty obligations?
- Does the activity fall within the time limits allowed for OPAs?
- How does this activity enhance the mission of the University?

OTHER GRANT-RELATED DISCLOSURES

NIH and NSF Policies

Other (Current/Pending) Support Foreign Components
Bio sketches

OTHER GRANT-RELATED DISCLOSURE REQUIREMENTS

OTHER SUPPORT (NIH), CURRENT and PENDING SUPPORT (NSF): In order to ensure no scientific, budgetary, or commitment overlap, sponsors like NIH and NSF require applicants to disclose information about other research support they currently have or that is pending review/award. Specific requirements vary by sponsor.

FOREIGN COMPONENTS: Recent heightened concerns about identifying the existence of any significant scientific element or segment of a project that is outside the U.S.

BIOGRAPHICAL SKETCHES: Sponsors like NIH and NSF require applicants to submit information about relevant positions, honors held by the PI/Sr/Key Personnel. Information provided should be current and thorough in compliance with sponsor policies (and should include information about membership in foreign "talent programs," if applicable).

NIH DISCLOSURE REQUIREMENTS

OTHER SUPPORT: Applicants must report ALL resources (regardless of whether they have monetary value), whether Federal, non-Federal, commercial, or institutional, available in support of ALL of an individual's research endeavors (regardless of where that research is conducted), including but not limited to research grants, cooperative agreements, contracts, institutional awards, support for lab personnel, provision of high-value materials not freely available (e.g., biologics, chemicals, model systems, technology).

Includes requirement to:

1. List ALL positions and scientific appointments (domestic and foreign) held by Sr/Key Personnel that are relevant to an application. Includes affiliations with foreign entities or governments; titled academic, professional or institutional appointments, whether paid or unpaid, full- or part-time, or voluntary (including adjunct, visiting and honorary).

NIH DISCLOSURE REQUIREMENTS

OTHER SUPPORT: Applicants for NIH support must (continued)

- 2. Report ALL resources and other support (domestic and foreign) for all individuals designated in an application as Sr./Key Personnel and for others who contribute to the scientific development or execution of a project in a substantive measureable way (regardless of whether they request salary support/compensation). Info must be provided re ALL current support for ongoing projects, regardless of whether such support is provided thru the applicant organization, thru another organization, or directly to an individual that support's the Sr/Key personnel's research efforts.
- 3. Report ALL current projects/activities involving Sr/Key Personnel, even if support is received only in-kind (e.g., office/lab space; equipment, supplies, employees). All research resources must be reported includes financial support, research/lab personnel, lab space, scientific materials, includes selection to a foreign "talent" program.
- 4. Provide total award amount for the entire award period covered (including F&A costs), as well as person-months (full or partial) per year to be devoted to the project by the Sr/Key personnel involved.

When To Report At time of application, report all current and pending support (Just In Time reporting procedures); and prompt notification to NIH re substantive changes after initial JIT info was provided; and (after award) detailed in annual research performance progress reports.

NIH DISCLOSURE REQUIREMENTS

<u>FOREIGN COMPONENTS:</u> Recipients must disclose/get prior NIH approval to include a "foreign component" in their NIH-supported activities.

Foreign component is defined as the existence of any significant scientific element or segment of a project outside the U.S., i.e., activities that are significant that involve:

- 1. Performance of work by a researcher/recipient in a foreign location (whether or not NIH grant funds are expended; and/or
- 2. Performance of work by a researcher in a foreign location employed or paid for by a foreign organization.

E.g., Would include having a collaborator outside the U.S. perform experiments in support of an NIH-supported project – regardless of whether that collaborator gets funding from the NIH-supported PI's grant.

Info about Foreign Components should be included, as applicable, in:

- the Application/Proposal (Biosketch; Current & Pending or Other Support, if applicable; Performance Site locations; Foreign Subawards; Budget and Budget Justification);
- Just-In-Time (Prior to Award): (Changes/Additions to Key Personnel or Other Support; Updates to Budget)
- Progress Reports and Final Reports (Post-Award) (Updates to Biosketches; Other Support; Changes/Additions of Foreign Components).

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NSF DISCLOSURE REQUIREMENTS

CURRENT AND PENDING SUPPORT:

- ➤ In order to ensure no scientific, budgetary, or commitment overlap, information must be provided about all current and pending support of all senior project personnel irrespective of whether such support is provided thru the proposing organization or directly to the individual.
- ➤ E.g., report all support received from Federal, state, local, foreign governments, entities or organizations, from public or private entities including foundations, nonprofits, industrial or commercial organizations, from consulting, or internal funds allocated toward specific research projects.
- All projects/activities that require a time commitment of the PI and any other senior personnel should be reported even if support is only in-kind and even if the personnel receive no salary support from the project. Reports are to include amount of support, the source, and the number of person-months devoted to the project.

SELECTED RESOURCES

California Form 700-U Statement of Economic Interests for Principal Investigators and Instructions (Fair Political Practices Commission)

http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/LegalDiv/Regulations/ProposedRegs/IP%20Meetings/Form%20700-U%202019.pdf

Public Health Service Regulations – 42 CFR Part 50, Subpart F -- Promoting Objectivity In Research

https://www.ecfr.gov/cgi-bin/text-

idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f

NIH FAQs re: PHS COI Regulations:

https://grants.nih.gov/grants/policy/coi/coi faqs.htm

NIH Grants Policy Statement

https://grants.nih.gov/policy/nihgps/index.htm

NIH Notice NOT-OD-19-114 (Reminders of NIH Policies on Other Support and on Policies Related to Financial COI and Foreign Components (July 10, 2019); and related FAQs (Last Revised August 6, 2019):

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html https://grants.nih.gov/grants/faq-other-support-foreign-components.htm

NSF Proposal and Award Policies and Procedures Guide

http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/LegalDiv/Regulations/ProposedRegs/IP%20Meetings/Form%20700-U%202019.pdf

Select UC Policies/Guidance re Research-Related Financial Interest and Outside Activity Disclosures

- <u>Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research</u>
- APM 028: Guidelines for Disclosure and Review of Principal Investigator's Financial Interest in Private Sponsors of Research
- <u>Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service</u>
 <u>Research Awards</u>
- UCOP RPAC Operating Guidance Memo 13-03 re Travel Disclosure Options under PHS COI Policy
- <u>Disclosure of Financial Interests and Management of Conflicts of Interest, National Science</u>
 <u>Foundation Awards</u>
- UCOP RPAC Guidance Memo 17-03 Guidance for Review of 700-U Forms
- Statement of Principles and Policies on Institutional Conflict of Interest in Research
- UC Compendium of COI and Intregrity Policy (Guidance replacing BFB G-39)
- <u>UCOP RPAC Operating Guidance Memo 11-04 (Financial Interest Disclosure in the Research Consent Form)</u>
- APM 025 Conflict of Commitment and Outside Activity of Faculty Members
- APM 671 Conflict of Commitment and Outside Activities of Health Sci Comp Plan Participants

LOCAL IMPLEMENTATION of Research Conflict of Interest Disclosure Requirements

Local Implementation Framework

- Sponsor rules and regulations inform systemwide policies
- Systemwide policies inform UC location policies and procedures
- Local policies and procedures inform local implementations and practices
 - Consistent from location to location

,	V. RESEARCH	A FACULTY OR OTHER ACADEMIC APPOINTEES	B STAFF EMPLOYEES (RESEARCH)
1.	Policy on Disclosure of Financial Interest in Private Sponsors of Research and Guidelines (April 29, 2010), Academic Personnel Manual Section 028. Summary	✓	
2.	Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects (March 4, 2010) (As of August 24, 2012, no longer applies to research funded by Public Health Service Awards – see #5, listed below). Summary	✓	✓
3.	Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University (December 14, 1994) Summary	✓	✓
4.	University Policy on Integrity in Research (June 19, 1990). Summary	✓	✓
5.	Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards (August 23, 2012) Summary		✓
6.	<u>Disclosure of Financial Interests and Management of</u> <u>Conflicts of Interest, National Science Foundation Awards</u> (December 23, 2014) <u>Summary</u>	✓	✓
7.	Office of Research and Graduate Studies, Research Policy Analysis Coordination, Operating Guidance 11-05, Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research (June 1, 2011) Summary	✓	✓
lit	Office of Research and Graduate Studies, Research Policy Analysis Coordination Memo Operating Guidance 11-04, Financial Interest Disclosure in the Research Consent Form (June 1, 2011) Summary	✓	✓
9.	Research Grants Programs Office, Conflict of Interest and Professional Activities Policy (January 2013) Summary	✓	✓



The Same, but Different

- Common elements
 - A review committee
 - Faculty representation on the committee
 - Committee is advisory
 - Recommendations made to a high ranking location official (or designee) for final decision
 - Vice Chancellor for Research
- Local implementations may vary
 - Location specific policies and thresholds associated with COI in human research
 - Name of the committee
 - Committee ex-officio members
 - Services provided to researchers by committee support staff
 - Process for determining if a significant financial interest is related to the research
 - Approaches to managing Financial Conflicts of Interest



Disclosure Review

- Process flow and forms may vary by location and applicable policy
 - Electronic systems v. paper processes
- General process
 - Disclosure forms completed by disclosing individuals
 - Routed to staff supporting the committee
 - In some cases, disclosures may be received by Contract and Grant Officers and forwarded to committee staff
 - Review for errors, completeness and to determine review level/process
 - Additional or clarifying information solicited
 - Full committee, expedited/subcommittee/administrative review
 - Outcomes
 - Approved (existing safeguards are adequate)
 - Approved with management plan (additional safeguards required)
 - Not approved



Case Study 1

A PI has equity interests in Company A and also receives income from them. Company A is sponsoring her research, which is testing three compounds believed to block receptors linked to diabetes. Company A's primary product is one of the three compounds. The project team includes undergraduate and graduate students, as well as postdocs.

Case Study 1: Safeguards/Management Plans

- Project design
 - Utilizing blinding procedures to help ensure objectivity where the blind code is secured by a non-conflicted researcher
 - Ensuring that non-conflicted researchers code the compounds
 - Assigning non-conflicted researchers to key project activities
 - Ensuring that the PI is not involved in all aspects of the research (data collection v. analysis)
 - Results/data remain blinded throughout collection and analysis
 - Blind broken after analysis is complete
- Additional safeguards
 - Disclose to study staff
 - Requiring that the PI does not participate in decision making related to Company A
 - Assigning a non-conflicted researcher as the point of contact to which to students and postdocs can direct questions and concerns regarding the conflict of interest
 - Disclosing in research publications that the PI has financial interests in Company A



Case Study 2

Professor Con Flict is a Co-PI on a research project funded by the National Institutes of Health (NIH) with Professor Free N. Clear who is the PI. Professor Flict is co-founder of FlictRes, a company with business interests that overlap NIH grant's scope of work. As a co-founder, he has a reportable equity stake in the company and also receives reportable income as a consultant in the role of scientific advisor. The research team does not include students or post-docs, but does include staff researchers.

Case Study 2: Safeguards/Management Plans

- Dr. Clear designs the research and structures it such that:
 - Non-conflicted staff researchers collect data
 - Data is stored in a shared folder with Dr. Flict having view only rights, and discussed at team meetings involving both Drs. Clear and Flict
 - Dr. Flict is involved in data analysis along with Dr. Clear
 - Drs. Clear and Flict meet with each project staff member to discuss Dr. Flicts financial interests, as well as the safeguards built into the project design
 - Dr. Clear acts as the project conflict of interest advisor, providing a single point of contact for project staff to direct questions and concerns
- Additional safeguards
 - Disclosing in research publications that the PI has financial interests in Company A, and describing the methods used to safeguard objectivity



Case Study 3

Professor Con Flict is PI on a research project funded by the NIH with same interests and overlap as Scenario 2. The project will be carried out by Dr. Flict, a postdoc, three graduate students and several undergraduate students rotating through the lab. Dr. Flict did not consider his financial interests when designing the study.

Case Study 3: Management Plan

- Because the project design lacks safeguards, the following would likely be required as part of a management plan:
 - Add a non-conflicted faculty researcher of equal rank to Dr. Flict (or greater) and require that this person substantively participate in the research
 - Assign the non-conflicted faculty researcher the role of conflict of interest advisor
 - Ensure that all graduate students who have advanced to candidacy have a conflict of interest member added to their dissertation committee
 - Require that research data be accessible by all project personnel
 - Require that Dr. Flict disclose his financial interest to all project personnel
 - Require that Dr. Flict and the conflict of interest advisor implement a plan to disclose his financial interests to undergraduates rotating through the lab who will work on this project
 - Requiring that Dr. Flict disclose that he has financial interests in Company A in all research publications



Other Safeguards/Management Elements to Consider

- Making raw/curated data publicly available
- Adding independent, non-conflicted statisticians to the team for data analysis
- For clinical trials/human research, establish an independent data/safety monitoring board
- Location specific policy prohibiting conflict of interests for certain high risk research projects such as clinical trials

"Faculty who have, or participate in, a privately sponsored clinical study shall not concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study. In addition, they shall not have any investment in, or serve in a decision-making capacity (such as service on the Board of Directors or management committee), or be an officer or employee of the company sponsoring the clinical study." - UCSF COI Rule 11

QUESTIONS/DISCUSSION

