



2012 PHS COI Regulations & Subrecipients

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Overview

- How the New Regulations Will Affect UCSD Investigators
 - Significant Financial Interests (SFIs)
 - Institutional Responsibilities
 - Training Requirement
 - Subrecipients
- How the New Regulations Will Affect UC San Diego
 - Investigator Responsibilities
- Next Steps
 - KC COI
 - Additional Resources

What has changed? – SFIs

1995

- De minimis threshold of \$10,000 for disclosure generally applies to payments or equity interests

2012

- Publicly Traded Entities:
 - combination of equity and/or compensation exceeding \$5,000
- Non-Publicly Traded Entities:
 - any equity interest, no matter the value
 - compensation exceeding \$5,000
- Intellectual Property
 - payments in excess of \$5,000 for any IP rights or interests
- Travel Reimbursement
 - any sponsored or reimbursed travel organization that has sponsored or reimbursed any travel

What has changed? – Institutional Responsibilities

- PHS-funded investigators (i.e., the Project Director/PI, any other person identified as Senior/Key personnel in a grant application, progress report, or other report submitted to PHS) must disclose at proposal submission and annually SFIs related to their **Institutional Responsibilities**
- Institutional Responsibilities include the teaching/education, research, outreach, clinical services, training and University and public service performed on behalf of the University and directly related to those credentials, expertise and achievements upon which your University appointment/employment is based.

What has changed? – Examples of SFIs Related to Inst. Responsibilities

- **Income or honoraria** received for outside activities arising from the professional credentials, expertise and achievements upon which an Investigator's University position is based, such as:
 - Providing expert testimony or consulting services
 - Serving on a board of directors, scientific advisory board, committee, panel or commission, including professional or scholarly societies
 - Acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals
- **Stock or stock options** in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities
- **Royalties** or income from an organization other than The Regents for use or sale of patented or copyrighted intellectual property (e.g. software, textbooks, or other scholarly works)
- **Travel** paid for or reimbursed by a professional society, foreign university, or company for which the Investigator is consulting

What has changed? - Types of Awards Subject to FCOI Disclosure

- The 2012 regulation defines “Research” as any such activity for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement
- These awards are now subject to FCOI disclosure:
 - Career Development Awards (K series)
 - Research Training and Fellowships (T & F series)
 - Minority Biomedical Research Support (S series)

What has changed? – Investigator Training

- Investigators must complete PHS-specific training before engaging in PHS-funded research and every four years thereafter
- Requirement also applies to new faculty and when faculty change institutions

What has changed? – Subrecipient Disclosure

- As of August 24, 2012, before the issuance of any Subaward funding, Subrecipients must certify:
 - The subrecipient organization has its own PHS-compliant financial conflict of interest policy or,
 - Will agree to adhere by the University of California's PHS FCOI policy

What has changed? – Subrecipient Disclosure

- Federal Demonstration Partnership (FDP) Clearinghouse of PHS FCOI Compliant Institutions
 - The FDP has created an online Clearinghouse of PHS FCOI Compliant Institutions
 - As of August 24, 2012, over 270 institutions and organizations are listed
- If a Subrecipient Organization is listed on the Clearinghouse or has its own PHS FCOI Compliant policy, no further action is required by the UC San Diego COI Office and the contract can be sent to the Subrecipient to be executed.

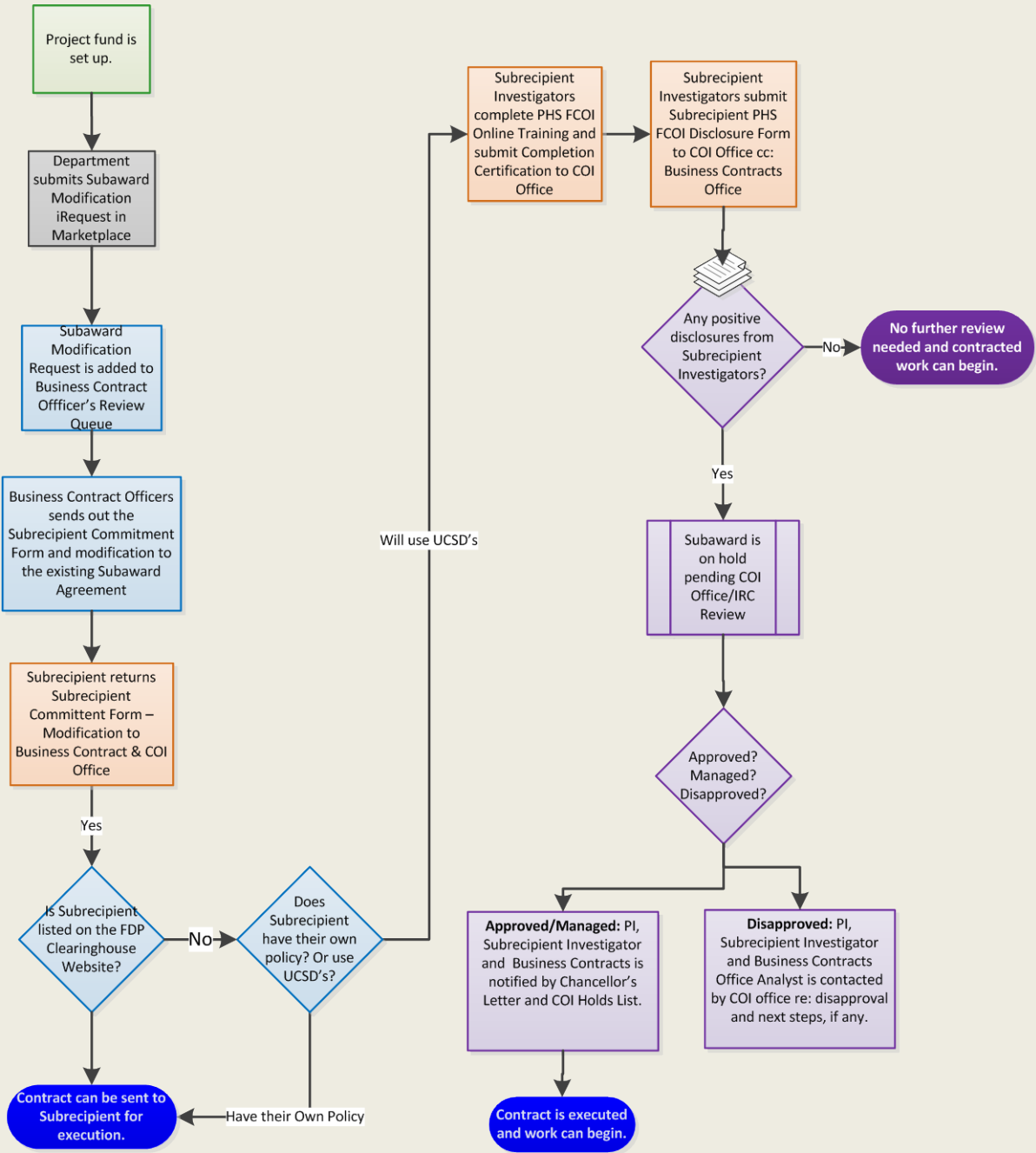
What has changed? – Subrecipient Disclosure

- If the Subrecipient is choosing to comply with the UC PHS FCOI Policy
 - The Subrecipient Organization must certify in writing its compliance with the UC PHS FCOI Policy
 - All Subrecipient Investigators must disclose using the UC San Diego PHS Financial Disclosure for Subrecipients
 - If any of the Subrecipient Investigators disclose a Significant Financial Interest then the COI Office will begin its review and if necessary, create a conflict of management plan
 - All Subrecipient Investigators must complete the UC PHS FCOI Training for Investigators
- ***The above steps must be completed BEFORE the issuance of the subaward contract***

What has changed? – Subrecipient Process for Existing Subawards that Involve Human Subjects

- Subrecipient Certification Form **MUST** be completed.
 - If the non-renewal of funding will result in the *loss of critical treatment* for research subjects **AND** the Subrecipient Investigators are unable to submit the Financial Disclosure for PHS-Funded Research for Subrecipients before the issuance of the Subaward, then the following must be included as terms in the Subaward agreement:
- Investigators have **14 calendar days** to complete the UCOP PHS COI Training and submit certification of completed training to the UCSD COI Office,
- Investigators have **14 calendar days** to complete and submit the Subrecipient PHS FCOI disclosure forms to the COI Office.
 - If any of the Investigators discloses a SFI, then the Informed Consent must be revised immediately to disclose this SFI to the research subjects.
 - Investigator must agree, in advance, to comply with any and all UCSD IRC imposed management strategies up to and including, the severance of any recompensed activities, dilution of equity and/or limited participation on the study.
 - After the IRC reviews the disclosed SFI(s), and the IRC approves of the Investigator's continued participation on the study, then the UCSD COI Office will contact the UCSD Business Contracts Office and the Subrecipient Investigator in writing.

Award Stage



How will this affect UC San Diego?

- Investigators:
 - Disclose SFIs related to Institutional Responsibilities
 - Complete PHS-specific training prior to engaging in PHS-sponsored research and at least every four years
 - Provide annual disclosures of SFIs
 - Subrecipient disclosure & proposal preparation
- Institution:
 - Develop new processes and procedures for PHS proposals and awards (including JIT review) and subrecipient monitoring
 - Relatedness assessments
 - Management plans
 - Reporting
 - Public Disclosure

Resources

- UC San Diego Conflict of Interest Office
 - Conducting departmental training sessions
 - Developing additional materials and handouts to provide additional guidance and to answer FAQs
 - <http://coi.ucsd.edu> or info@coi.ucsd.edu
 - (858) 534-6465
- UC San Diego Guidance for Subawards
 - <http://blink.ucsd.edu/buy-pay/contract-svcs/subcontract-subaward/index.html>
- UC PHS Conflict of Interest Training
 - <http://coi.ucsd.edu/Training/Overview.htm>
- FDP Sample PHS Compliant Conflict of Interest Policy
 - http://sites.nationalacademies.org/PGA/fdp/PGA_061001
- NIH Resources
 - http://grants.nih.gov/grants/policy/coi/coi_fags.htm
- UC Policy on Disclosure of Financial Interests Management of Conflict of Interest Related to Public Health Services Sponsored Awards for Research
 - <http://www.ucop.edu/research/policies/documents/12-0133-phs-researcher-financial-disclosure.pdf>

Questions?

