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Assessing Relatedness Under the Revised PHS COI Regulations: The University of California Approach

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The University of California

- Large portfolio of PHS-supported research demands development of streamlined approach for handling workload
- All campuses will adopt web-based disclosure systems to facilitate disclosure and review
- Most campuses will adopt a Just-In-Time approach to reviews in order to manage workload without holding up awards



Assessing Relatedness: New Requirements

- “Prior to the Institution’s expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall: ... *determine whether any significant financial interests relate to PHS-funded research ...*”
- “An investigator’s significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), **reasonably** determines that the significant financial interest: *could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research.*”



What does Reasonably Mean?

- The term “reasonably” was used in the 1995 and 2011 PHS COI regulations without definition
- There does not appear to be a clearly articulated rule for defining “reasonably”
- Conclusion: “Reasonably” means that the determination is a “reasoned decision” made as the result of a regular process and not done in a capricious or arbitrary manner



Involving Investigators

- Per the regulations, “...the institution may involve the investigator in the designated official(s)’s determination of whether a SFI is related to the PHS-funded research”
- How to involve the Investigator?
 - At initial disclosure, Investigators will indicate which SFI’s are related to PHS-funded research



Involving Investigators

- Is the investigator's input sufficient?
 - UC considers it necessary but not sufficient
- To what extent does the institution need to collect additional information and how?
 - Post-disclosure follow-up consultation
 - Solicitation of additional information in writing



Possible Default Assumptions

- All disclosed SFIs are related to PHS-supported research unless proven otherwise
 - If so, what criteria will be used?
- Disclosed SFIs are not related to PHS-funded research unless there are reasons to believe they are
 - If so, what criteria will be used?
- All SFIs are related and should all be reviewed to determine if they are FCOIs (significantly and directly affect the PHS-research)



Criteria to Assess Relatedness

- UC campuses are working collaboratively to create a list of criteria to assess relatedness
- The list is a work in progress
- The list is not inclusive
- The list will be expanded with experience



Some Criteria for Assessing Relatedness

- IP developed by the investigator is being used, tested or further developed in the research
- IP owned by the institution and optioned/licensed to an entity in which the investigator has a SFI is being used, tested or further developed in the research
- Products/services are being provided by or purchased from a company in which the investigator has a SFI
- The investigator has a SFI in a company which manufactures or sells a concomitant or comparator drug or device, or procedure
- The investigator has a SFI in an entity to which research space will be leased or from which research space will be rented



Additional Criteria for Assessing Relatedness

- Entity in which the investigator has an SFI is a sub-recipient under the proposed research
- The investigator will be involved in research under a subaward from an entity in which he/she has a SFI
- The investigator has a SFI in an entity that is part of a consortium or will otherwise participate in the research
- The investigator is a founder, holds a management or executive position, serves on a Board, is a consultant (with or without compensation) and/or has received travel income/reimbursement from an entity whose products or services will be used in, are the subject of and/or are closely aligned with the research



How Assessments Will be Conducted

- All campuses anticipate most relatedness reviews will be handled administratively
 - Most campuses anticipate that many reviews will be done by administrative staff
 - Existing Conflict of Interest Committees or scientific experts may be consulted
 - Some campuses may ask Committees to review high \$ value SFIs (threshold to be determined) and all human subject research
 - Some campuses may hire graduate students/postdocs on an ad-hoc basis to help with reviews
 - All campuses will need to manage increased workload



Questions for COGR Colleagues

- How and to what extent will investigators be involved in assessing relatedness?
- Will relatedness be assumed from the outset?
- What criteria will be used to determine relatedness?
- How will assessments be conducted?
- How will assessments be documented?