

CONFLICT OF INTEREST IN AN ENTREPRENEURIAL ENVIRONMENT

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- ① Quick overview of the NSF Financial Conflict of Interest requirements
- ① Case studies & options

COMPETING INTERESTS

- ⊙ Requirements that are attached to funding mechanisms
- ⊙ Emphasis on commercialization and entrepreneurial activity
- ⊙ Protect US taxpayer from inappropriate use of tax dollars
- ⊙ Instill confidence in the results of research
- ⊙ Serve the public interest
- ⊙ Stimulate the economy
- ⊙ Make good use of federal research dollars

WHAT IS CONFLICT OF INTEREST?

- ⊙ A conflict of interest exists when there is the possibility (or perception of a possibility) that an individual's private, financial interests or his /her family's interests may influence the individual's professional actions, decision or judgment.

CONFLICTS OF INTEREST IN RESEARCH

- ◉ In research, a conflict of interest may compromise the collection, analysis, and interpretation of data as well as the hiring of staff, procurement of materials, sharing of results, protocol design and use of human subjects
- ◉ Casts a cloud over the objectivity of the researcher
- ◉ COI may result in biased research

PURPOSE OF FCOI REGULATIONS

- ⊙ Prevent personal financial interests from causing bias in research
- ⊙ Promote objectivity in research
- ⊙ Public Trust

HEADLINES

- ◎ GREAT EASTERN UNIVERSITY FACULTY MEMBER DIVERTS FEDERAL FUNDS GIVEN TO THE UNIVERSITY
- ◎ “When most of us think of a professor we envision someone spending countless hours grading papers, meeting with students, writing papers and living somewhat modestly. Not so for Great Eastern University Professor Jane Doe. Neighbors have noticed her luxurious lifestyle – her beautiful home, fancy cars and extensive travel. For many years Doe’s company has been the recipient of contracts from GEU. As a Principal Investigator at the University she has diverted Federal research funding from the university to her privately owned company, Doe Inc. Both Doe and her husband receive salaries from the company. Doe is a tenured faculty member with a full time position at GEU.

NSF COI REQUIREMENTS

- ⊙ Each investigator must disclose to the institution all Significant Financial Interests (SFI) of the investigator (including those of the investigator's spouse and dependent children) in entities whose financial interests would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF by such activities

DISCLOSURE OF SFIs

- ⦿ Significant Financial Interest (SFI)
 - ⦿ An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, is greater than \$10,000 and represents more than a 5% ownership interest in any single entity
 - ⦿ Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are expected to exceed \$10,000 during the twelve-month period.

INSTITUTION REVIEW OF DISCLOSURES

- ⊙ A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities

CRITICAL QUESTIONS

- ⊙ Does the flow of funds create a situation where a research activity or result may create an undue financial benefit to an investigator?
- ⊙ What is the risk that the research will be biased?
- ⊙ Could the facts be construed to create a perception of conflict?
- ⊙ What is the risk to the investigator, the research and the institution?

NSF MITIGATION OPTIONS

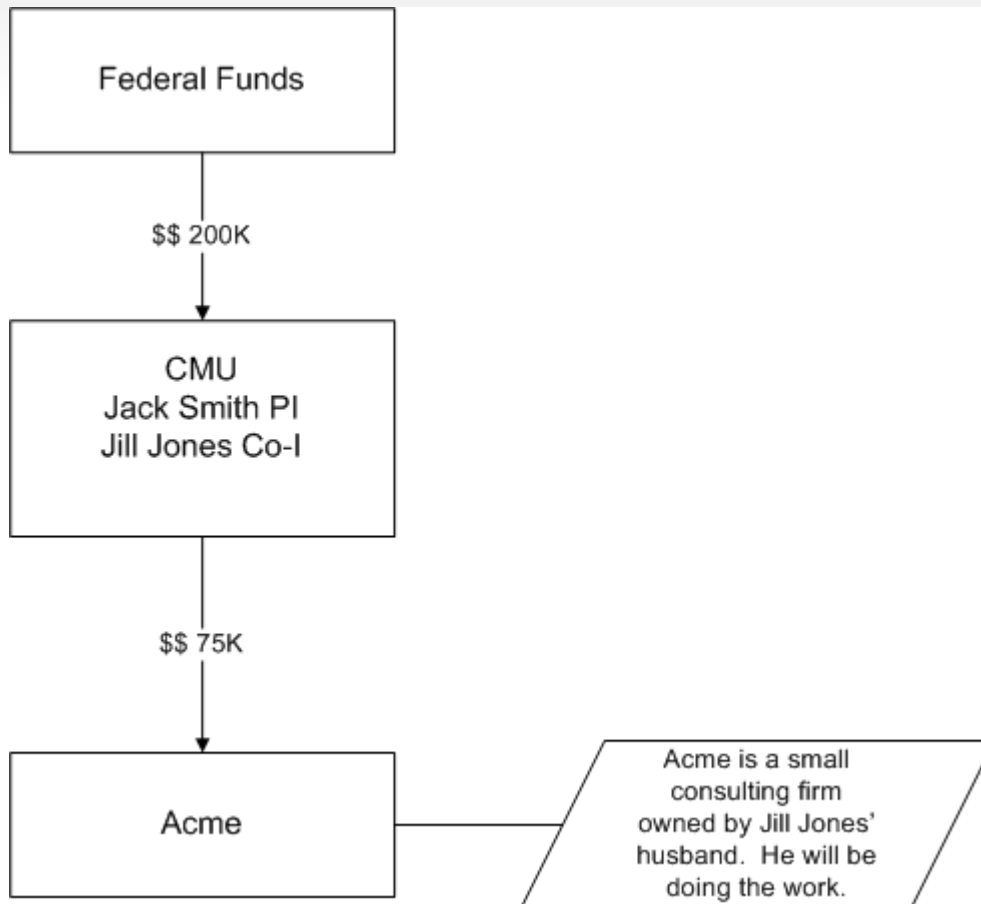
- ⦿ Manage, reduce or eliminate conflicts of interest by:
 - ⦿ public disclosure of significant financial interests;
 - ⦿ monitoring of research by independent reviewers;
 - ⦿ modification of the research plan;
 - ⦿ disqualification from participation in the portion of the NSF-funded research that would be affected by
 - ⦿ divestiture of significant financial interests; or
 - ⦿ severance of relationships that create conflicts.

FACTORS TO CONSIDER IF SUB-CONTRACTING

- ⊙ Is the work being subbed appropriate for CMU?
- ⊙ Does CMU have the capability to do the work that is being subbed?
- ⊙ Is the subcontractor truly the best choice?
- ⊙ What about IP?
- ⊙ Are transactions being conducted at fair market value?
- ⊙ Can/should a management plan be put in place?

KEY MESSAGE TO INVESTIGATORS

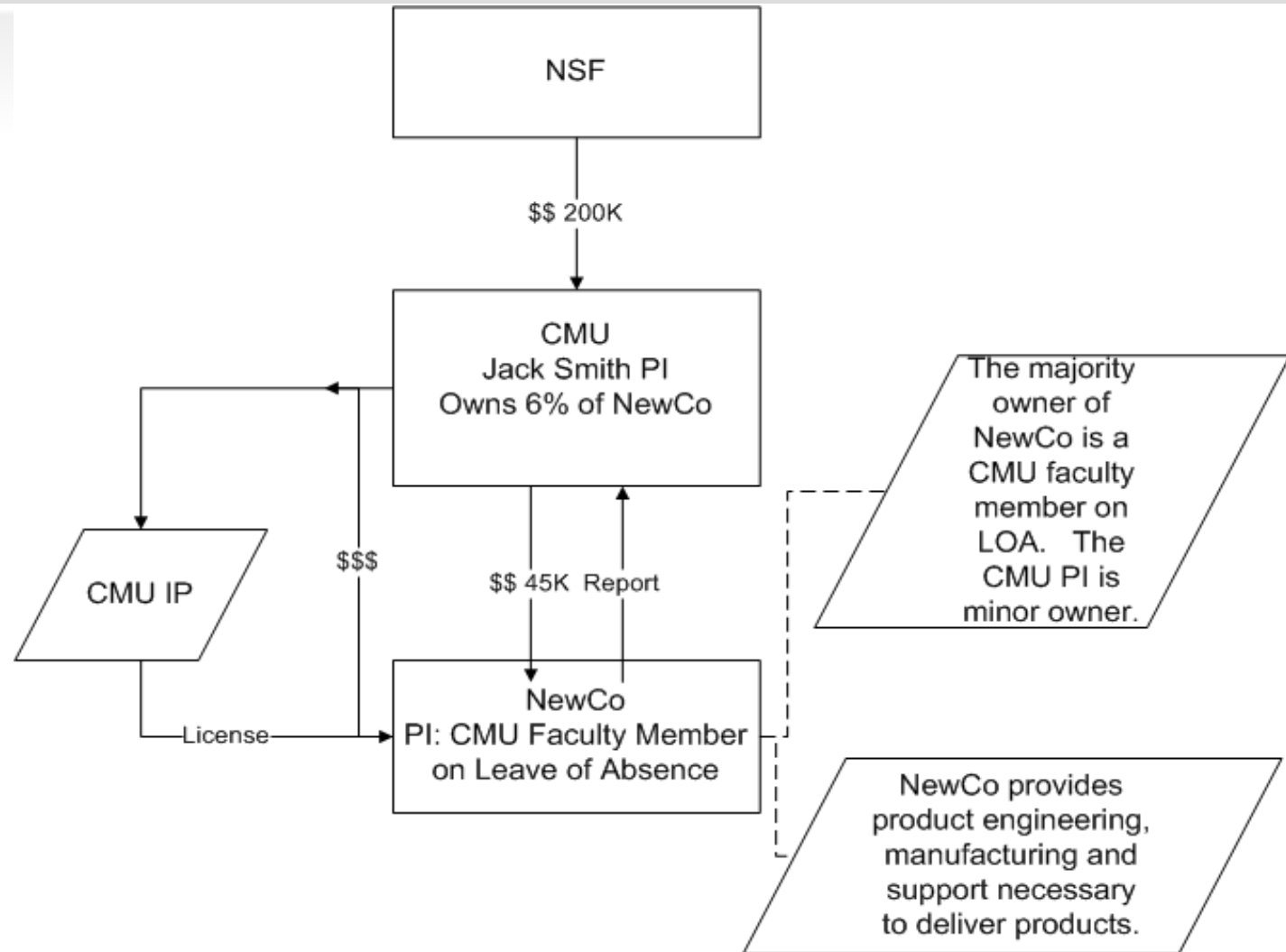
- ⊙ A conflict of interest is not inherently bad
- ⊙ Disclose, disclose, disclose



ACME (CONTINUED)

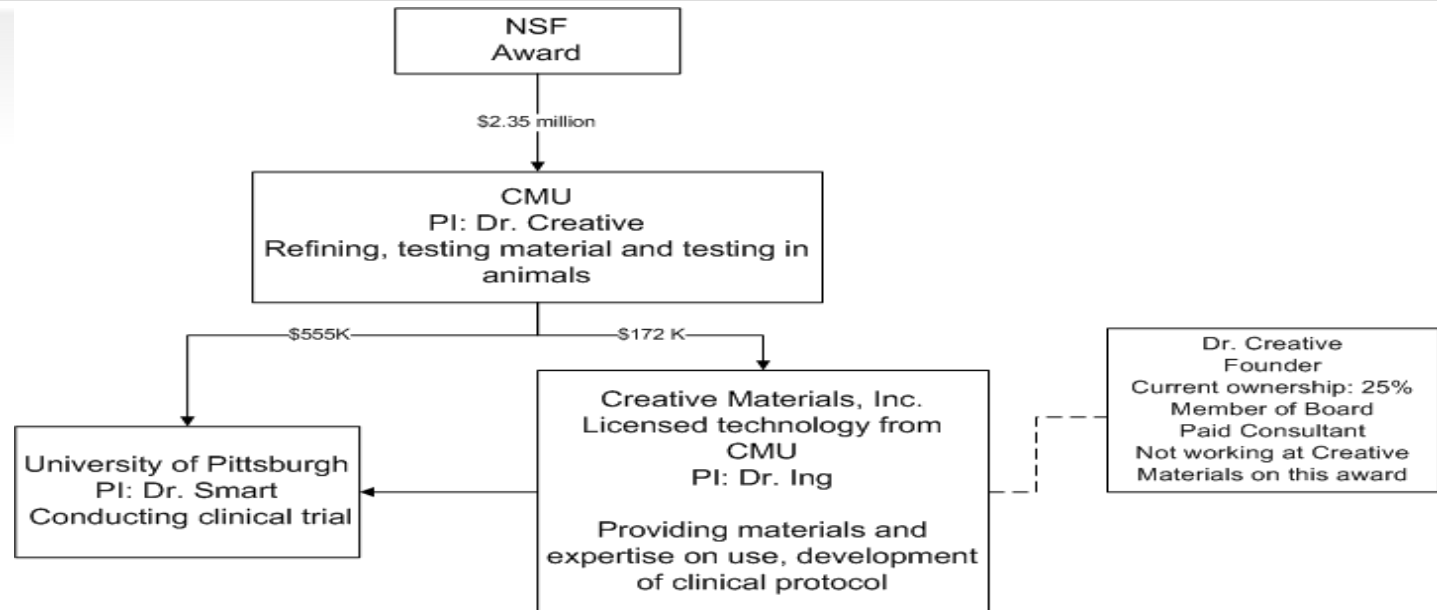
- ⊙ Is the work being sub-contracted, work that CMU can do?
- ⊙ Are other companies able to provide the service needed by CMU?
- ⊙ Should CMU engage Mr. Jones as an independent contractor?
- ⊙ Co-I / Spouse can not approve work from or payments to company
- ⊙ Third party must oversee – maybe PI in conjunction with department head

NewCo



- ⊙ Is the work being sub-contracted, work that CMU can do?
- ⊙ Are other companies able to provide the service needed by CMU?
- ⊙ Is a 6% interest in NewCo likely to influence the PI's work?
- ⊙ Third party oversight

CREATIVE MATERIALS INC.



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QUESTIONS?