

The Final Rule: Implementing New Policies for Financial Conflict of Interest at the University of Central Florida

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ABSTRACT

Academic institutions modified their financial conflict of interest policies (FCOI) in response to the Public Health Service's (PHS) 2011 revised regulations (42 CFR 50 Subpart F) on *Responsibility of Applicants for Promoting Objectivity in Research* and *Responsible Prospective Contractors* (45 CFR 94), which were to go into effect on August 24, 2012. Using the National Institutes of Health checklist for the 2011 revised FCOI policy development as a guide, many institutions began to prepare for compliance in 2011 following passage of the final rule (National Institutes of Health, 2012). However, changes to conflict of interest policies and procedures began at the University of Central Florida (UCF) in 2009, providing a smoother implementation in 2012 of the revised federal regulations. UCF's Office of Research and Commercialization, University Compliance and Ethics Office, Office of Faculty Relations, and Office of General Counsel joined in the effort to update the university's policies and procedures concerning financial conflict of interest and conflict of commitment to ensure compliance with federal regulations, state statutes, and university regulations. This case study describes how UCF created a new conflict of interest policy, created new institutional procedures, and used its on-line systems to ease the implementation of the revised PHS regulations.

Keywords: financial conflict of interest, PHS final rule 2011, University of Central Florida, 1995 PHS regulations, conflict of commitment

INTRODUCTION

In 1995 the Public Health Service (PHS) and the Office of the Secretary of Human Health Services under the Department of Health and Human Services (DHHS) published regulations (42 CFR 50 Subpart F and 45 CFR 94) to promote objectivity and ensure integrity in research endeavors funded by PHS agencies, which includes the National Institutes of Health (NIH) (*The Federal Register*, 53256, 76:165 [25 August 2011]). NIH is the largest federal research granting agency with \$30.9 billion invested annually in medical research (NIH Budget, 2012).

Prior to the federal regulations, institutions and professional organizations implemented their own versions of the federal mandate. The 1995 regulations required institutions receiving federal research funding to create, maintain, and enforce written financial conflict of interest policies (FCOI) to ensure the FCOI is identified, mitigated, or eliminated in the conduct of research. The 1995 regulation also required principal investigators to disclose potential FCOI and to comply with their institution's FCOI policies. The purpose of the 1995 regulations was to ensure that the design, conduct, and publication of research was reasonably free from bias generated through financial gain by an individual or institution conducting

research (*The Federal Register*, 53256, 76:165 [25 August 2011]).

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The 1995 regulations began to prove inadequate as private biomedical research funding soared from \$37.1 billion in 1994 to \$94.3 billion in 2003, well exceeding federal funding. Despite the billions of dollars in biomedical research funding from the NIH, industry or private sources provided more than 55% of total biomedical research funding. The financial relationships between industry and biomedical researchers that followed created the potential for compromises in research integrity, jeopardizing the public trust and the public health. The DHHS Office of the Inspector General (OIG) reported in 2009 that "vulnerabilities exist at grantee institutions regarding conflicts" (*The Federal Register*, p. 53257, 76:165 [25 August 2011]). This report and increased public scrutiny ultimately led to the adoption of changes to the 1995 regulation in 2011

UCF's Preparedness

Background

In 2009 UCF's Office of Research & Commercialization, University Compliance and Ethics Office, Office of Faculty Relations, and Office of General Counsel joined in an effort to overhaul and formalize the university's procedures concerning financial conflict of interest (FCOI) and conflict of commitment (COC) to ensure compliance with federal regulations, state statutes, and university policies. At this time, a simplistic one-page document was replaced with a comprehensive electronic conflict of interest (COI) and conflict of commitment (COC) reporting, monitoring, and tracking system. Requirements for reporting, reviewing, approving, and storing disclosures drastically changed from disassociated papers in file cabinets to a unified, central electronic repository containing detailed disclosures as well as state exemptions and monitoring plans. This new repository is available to the UCF administration, departments, and research administrators.

Online Systems

UCF's conflict of interest and commitment on-line system is implemented within the university's Academic Research and Grants Information System (ARGIS®), used exclusively by researchers, research administrators, staff, and university administrators for tracking all research

contract and grant activity from pre-award through commercialization. By incorporating the disclosure submission, review, approval, monitoring, and tracking process digitally within ARGIS®, UCF gained the advantage of correlating each investigator's submitted disclosure data with information on file for the investigator's proposals, awards, subcontracts, other agreements, inventions, and technology transfer licenses. This was an important feature for UCF's institutional reviewers who may not have always known the interrelated facets of an investigator's research endeavors.

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UCF's ARGIS® system clearly identifies the types of potential conflict of interest activities requiring disclosure, as well as the rationale for the questions asked. During the reporting of potential conflicts, UCF

investigators are provided with links to policies, regulations, and definitions of terms for each question asked through the use of underlined terms and an information icon next to each question. For those UCF investigators completing the disclosure but not involved with outside activities, the form is short with just 10 Yes/No style questions. When UCF investigators positively affirm that certain activities or situations apply, the on-line submission form expands to prompt for additional sub-questions. Multiple responses to each of the 10 questions can also be provided if the investigator works with more than one outside entity.

Once an investigator submits the report of potential conflict of interest, disclosures are directly routed for review and approval to the investigator's immediate supervisor,

the department chair, college dean, and, depending on the responses, the compliance officer in UCF's Office of Research & Commercialization for a regulatory review. Lastly, the disclosure or amendment is routed to UCF's Faculty Relations Office for a final administrative review. If during the review a disclosure indicates a potential conflict of interest, the disclosure is diverted to the UCF Conflict of Interest Committee for review and recommendations. The ARGIS® system requires comments from the reviewers, which are viewable by all reviewers, the investigator, and the COI committee members, thereby establishing context and an historical record. Figure 1 provides an example and overview of UCF's conflict of interest and commitment process and system.

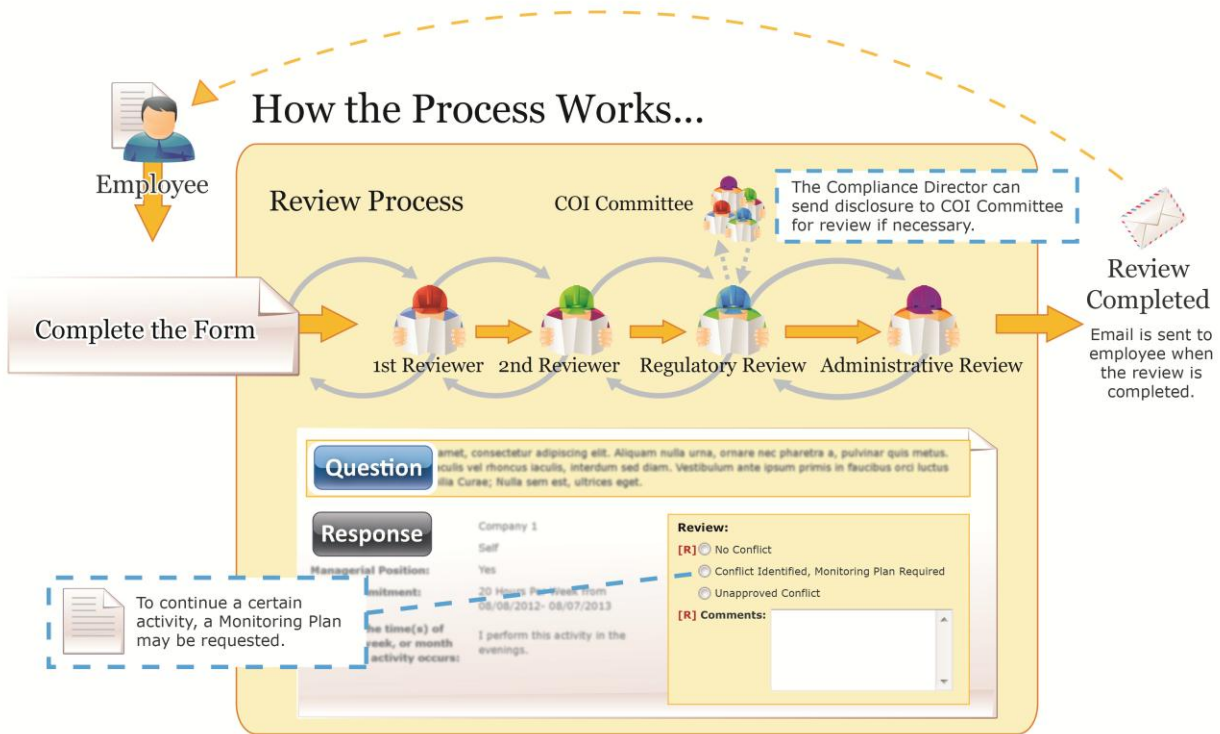


Figure 1. UCF Conflict of Interest & Commitment System—Overview

UCF’s 5 Steps to Implementation of the PHS 2011 Regulations

Upon issuance of the PHS 2011 regulations for each PHS-funded grant or cooperative agreement, UCF needed to make further changes to its existing policies and on-line system. With the university administration’s commitment and an institutional culture of disclosure already established three years prior through its on-line disclosure system, UCF was well equipped to revise its processes and implement the regulations on time. UCF revised and expanded not only the

questions asked of investigators but extended the requirement to disclose and comply to award subrecipients and other researchers who participate in the design, conduct, or reporting of research. UCF’s administration also decided to apply its revised 2012 COI and COC policy to all sponsored and non-sponsored research projects, not just PHS-funded grants and agreements. With anticipated adoption of the revised PHS regulations by other agencies over time, UCF wanted to be in compliance by consistently managing all research activities. UCF began its process to

ensure compliance with the final rule by taking the following steps.

Step 1—Created a Potential COI and COC Research Policy

To effectively address both financial conflict of interest and commitment as it applies to research, UCF established a new conflict of interest or conflict of commitment in research policy. This new policy expands on the existing university policy, addressing FCOI and COC by expanding who must disclose, when they must disclose, why they must disclose, what they must report, and in the new FCOI guidelines, the remedies UCF will enforce in the event of noncompliance. To ensure the policy conformed to the revised PHS regulations, the checklist published by the NIH was consulted. The checklist is available at:

http://grants.nih.gov/grants/policy/coi/checklist_policy_dev_20120412.pdf (NIH, 2012).

To effectively address both financial conflict of interest and commitment as it applies to research, UCF established a new conflict of interest or conflict of commitment in research policy.

Under the final rule UCF is required to monitor significant financial interest for all investigators (including their spouses and children) responsible for the design,

conduct, or reporting of research, not just the principal investigator. The financial threshold for disclosure dropped from \$10,000 to \$5,000 and requires disclosure of remuneration and/or equity interest and any income realized from non-university intellectual property rights that exceeds \$5,000 to be reported. Additionally, all extramural travel costs paid on behalf of an investigator and related to the investigator's institutional responsibilities must be disclosed. Implementing these procedures to comply with the final rule will result in additional federal reporting obligations for UCF, specifically for PHS sponsored awards. ARGIS® will be used to track, store and produce reports for submission to sponsoring agencies as required.

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To communicate the revised policy and guidelines document across the university, the following communication plan was executed:

1. New policy announcement sent by the President and Provost to the Dean's Council and Vice Presidents.
2. New policy announcement sent by the President and Provost to the Faculty Senate.
3. New policy announcement sent by the Vice President for Research Office to Deans, Associate Deans, and Chairs.
4. New policy announcement sent by the Vice President for Research to administrative unit directors affected by the policy change.

Step 2—Created COI and COC Policy Guidelines

Perhaps of equal or greater importance is ensuring that when a new policy is established, a guideline is created to advise administrative staff and investigators on the implementation and procedures to ensure FCOI and COC policy compliance. UCF has done this in a comprehensive guideline document incorporated into the new policy.

If an investigator has a financial interest exceeding \$5,000, related to an investigator's institutional responsibilities, UCF requires disclosure prior to application

5. New policy announcement sent by the Director of Compliance, Office of Research & Commercialization, to academic and research unit faculty and administrators.
6. Policy information statement provided to new faculty upon appointment.
7. New web page was established and dedicated to the conflict of interest policy.
8. On-line COI system training updated to refer to new policy and to inform users of changes to the disclosure questions when completing their submission.

UCF's policy can be found at:

<http://www.policies.ucf.edu/documents/4-504.2ReportingaPotentialConflictofInteresttoConflictofCommitmentinResearchFinalLetterhead08-20-12.pdf>

to a sponsor and no later than time of award and prior to the expenditure of any funds. If new activity or discovery of a potential COI occurs after research has started, disclosure is required within 30 days.

UCF is requiring a disclosure from all of its investigators and also subrecipient's investigators on all proposals and awards, not just PHS awards and agreements. The subrecipient can choose to either adhere to UCF's policies or provide certification that its own conflict of interest policy complies with Title 42 CFR Parts 50 and 94. Should

the subrecipient be unable to provide this certification, UCF will require the subrecipient and its investigators to be subject to UCF policies, procedures, and guidelines. This includes participation by the subrecipient's investigators in UCF's mandatory training programs on FCOI such as those described herein. UCF is preparing additional written guidelines for its subrecipient's investigators to participate and comply with UCF's FCOI policies.

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Enforcement of policies requires careful consideration. In establishing its new policies and procedures, UCF formulated remedies within its guidelines that apply when an investigator fails to comply with the new policy. The institutional remedies require that a project account be suspended until the investigator complies; inactivation of projects and accounts; and delay, suspension, or termination of subrecipient agreements if their investigators have not completed training or not submitted the disclosures required. Lastly, personnel disciplinary action(s) may be implemented by UCF to ensure compliance with the university's conflict of interest policies and

procedures, should other measures prove to be ineffective.

Step 3—Implemented Financial Conflict of Interest Training

An important supplement to the FCOI guidelines is the inclusion of mandatory training for investigators prior to participation in any research, to occur no less than once every four years. UCF's Office of Research & Commercialization has the responsibility of providing and overseeing the FCOI training as well as tracking the investigator's completion. The training is designed to educate researchers, raising awareness of both the new policy and UCF's reporting requirements. UCF's training implementation plan requires on-line training through the Collaborative Institutional Training Initiative (CITI) for faculty, staff, and students responsible for the design, conduct, and reporting of research. At the time of proposal submission, any investigator expected to have these research responsibilities must be identified among the research team members, including students. Completion of two CITI modules is required prior to engaging in funded research activity, while Module 4 is optional.

- Module #1: *Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules*
- Module #2: *Institutional Responsibilities as They Affect Investigators*

- Module #4: *Conflicts of Commitment, Conscience, and Institutional Conflicts of Interest (optional)*

The minimum requirement for any student responsible for the design, conduct, and reporting of sponsored research is to complete CITI Module 1. Principal Investigators are also encouraged to provide conflict of interest and other ethical training to their graduate students during the sponsored research activity.

A Responsible Conduct in Research workshop series was also established by the UCF College of Graduate Studies and in concert with the Office of Research & Commercialization. This workshop series is required for each doctoral candidate and addresses conflict of interest scenarios as well as ethical decision making and personal integrity.

Step 4—Establish Conflict of Interest Committee

As UCF's activities in research grow, so does the complexity of and opportunity for potential conflicts. For example, six years ago UCF expanded its program offerings with a new College of Medicine, concentrating on biomedical research which can be prone to FCOI issues. UCF will establish a new Conflict of Interest Committee to review significant financial interests reported by investigators. Appropriately applying the bias principle to determine true conflicts will require people

who are trained and responsible, and who have a high level of appropriate expertise to understand the nuances of various research situations. In addition to establishing a Conflict of Interest Committee, UCF's Office of Research and Commercialization intends to recruit a full-time, dedicated compliance officer to manage the FCOI program. The new compliance officer and committee will review and monitor reported significant financial conflicts of interest at UCF.

When a potential significant financial interest is reported, UCF's compliance officer will refer the disclosure to UCF's Conflict of Interest Committee which will determine whether a conflict may exist and the appropriate mitigation measures to manage or eliminate the conflict by requiring state exemption requests, monitoring plans, or other management plans to ensure the research is free from bias or financial conflicts. ARGIS® will track a disclosure throughout the review process, to include recommended actions, and will produce reports as required to be sent to the research sponsor. Some general information about an investigator's significant financial interests will also be made publicly available on a UCF-dedicated web page.

When a potential significant financial interest is reported, UCF's compliance officer will refer the disclosure to UCF's Conflict of Interest Committee, which will determine whether a conflict may exist and the appropriate mitigation measures to manage or eliminate the conflict by requiring state exemption requests, monitoring plans, or other management plans to ensure the research is free from bias or financial conflicts.

Step 5—Modified Proposal Form and Potential Conflict Disclosure Questions

UCF is implementing its new policy on reporting of conflicts of interest through procedural updates to two key forms completed by investigators: 1) the proposal transmittal form used internally to initiate and receive approval for a research proposal, and 2) the annual employee disclosure of conflicts of interest and commitment.

The on-line UCF proposal transmittal and review form in ARGIS® was modified

so that during the electronic routing of the proposal, the principal investigator is asked to indicate who among the project team will be responsible for the design, conduct, or reporting of research. Each person so identified is then notified via email of their need to respond to UCF's FCOI disclosure questions. The ARGIS® system then tracks for compliance the date of disclosure and appropriately manages for multi-year awards and changes in project staffing.

Although questions regarding financial conflict of interest were included in UCF's existing COI disclosure, the final rule's change of the significant financial threshold required UCF to modify the questions asked of investigators. The new questions have also been rephrased to refer to an investigator's "institutional responsibilities" versus simply research. The type of remuneration an investigator receives, including the form of equity interests held, reimbursed or extramural travel, and non-university royalty income, including its sources, were added to the list of questions. Figure 2 highlights the new, revised questions asked by UCF of investigators to assess whether a significant financial conflict of interest exists or not.

UNIVERSITY OF CENTRAL FLORIDA

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UNIVERSITY OF CENTRAL FLORIDA
POTENTIAL OUTSIDE ACTIVITY, EMPLOYMENT, AND CONFLICT OF INTEREST AND COMMITMENT DISCLOSURE (AA-21)

Reporting Period: 08/08/2011 - 08/07/2012

NOTE: For each question answered "Yes", all sub-questions that appear are required and must be answered. Upon answering all sub-questions, use the "Add/Save Response" button to submit your answers to the question. Multiple responses may be submitted to each question.

Research

The university promotes objectivity in research by establishing policies and procedures that provide reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from an investigator financial conflict of interest. Questions 1, 2 & 3 apply to an investigator planning to participate (proposal application) in or that receives sponsored funding who is responsible for the design, conduct and/or reporting of the research.

1. During the reporting period do you, your spouse and/or dependent children have a **financial interest** related to your **institutional responsibilities**, in a publically traded entity in the form of remuneration and/or equity interest that when aggregated equals or exceeds \$5,000? (If you are a new employee please report remuneration and/or equity interests received in the last 12 months and during the current reporting period.) [\[Reporting exclusions\]](#)

Response: Yes No

2. During the reporting period have you been reimbursed, either directly or on your behalf for any extramural travel that is related to your **institutional responsibilities**? (If you are a new employee please report the value of extramural travel (paid directly to you or on your behalf) in the last 12 months and during the current reporting period.) [\[Reporting exclusions\]](#)

Response: Yes No

3. During the reporting period will the value of **intellectual property rights** (patents, copyrights, trademarks) upon receipt of income to you, your spouse, and/or dependent children, equal or exceed \$5,000? (If you are a new employee please report intellectual property rights received in the last 12 months and during the current reporting period.) [\[Reporting exclusions\]](#)

Response: Yes No

Figure 2. UCF Revised Disclosure Form (showing questions 1–3 re: FCOI)

CONCLUSION

When asked whether or not the 2011 revised PHS regulations fixed something that was broken, Doug Backman, UCF’s Director of Compliance and Contracts and

Grants, replied, “No. The final rule just demands a more complete disclosure in order to remain in compliance. And, this change puts more of the burden on the institution versus the investigator. Also, the new reporting requirements to the

government are more stringent." When faced with the choice of having federal funding suspended or remain in compliance, UCF acted swiftly to stay compliant. While this new rule still does not address institutional conflicts of interest, it places the burden on institutions receiving PHS funding to be the monitoring and enforcement arm for research integrity. UCF employees responsible for making policy and procedural changes, along with its web-based research administration system ARGIS®, made the plan for implementation of the new procedures within one year feasible and without unnecessary complications. The effectiveness of UCF's newly revised conflict of interest policies and procedures to address the final rule will

be judged over time and following the next A-133 or OIG audits.

AUTHOR'S NOTE

The authors wish to thank Mr. Doug Backman, Director of Compliance and Director of Contracts and Grants in the Office of Research and Commercialization, University of Central Florida, for providing institutional information on conflict of interest policies and procedures. The opinions expressed herein are those of the authors only and are not those of the University of Central Florida.

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ABOUT THE AUTHORS

Andrea Adkins is an Assistant Director in the Technology Transfer Office at the University of Central Florida. Ms. Adkins works with faculty, students, and staff on intellectual property matters originating from research and educational activities at UCF and licensing technologies to industry and new business start-ups. Prior to joining UCF in 1999, Ms. Adkins worked in the architecture, engineering and construction industry. Ms. Adkins also co-founded a small business that specialized in manufacturers' representative services. Ms. Adkins expects to receive a Master of Science degree in Research Administration from UCF in August 2013.

Tammie McClellan is the Director of the University of Central Florida's Center for Research Administration Technologies and Applications (CRATA) and Program Director of the Department of Information Systems Technology at UCF's Institute for Simulation and Training (IST). She has managed over \$16 million in external and internal awards, providing information technology consulting, application development and systems services utilizing the latest technologies in information systems and the public Internet. She develops advanced World Wide Web SQL applications to support data management, workflow, and decision-making. Her range of clientele spans every branch of the U.S. Armed Forces, universities, numerous commercial and non-profit agencies, as well as university departments where consulting and development support is offered to guide information system requirements. She is an author/co-author and holder of multiple software copyrights, to include the Academic Research & Grants Information System (ARGIS®), which have been successfully licensed by UCF. Ms. McClellan will receive a Master of Science degree in Research Administration in August 2013 from UCF.

John Miner has worked at the Office of Technology Transfer at UCF since 1999 and is an Assistant Director of Physical Sciences. He graduated with his undergrad degree from UCF in 2001 and is scheduled to graduate in August 2013 with his Master of Research Administration degree. He is active in the Association of University Technology Managers (AUTM), serving as an Assistant Vice President for Metrics and Surveys. He chairs the annual Salary Survey, a publication examining the salaries in the Technology Transfer field for academic and non-profit organizations across North America, Europe and Asia.
