

# Monitoring Financial Conflict of Interest

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## ABSTRACT

Conflict of interest is heavily intertwined with research. The purpose of this study was to examine the literature and regulations in order to describe efforts required to properly monitor and disclose conflict of interest as researchers become steadily involved in innovation and discovery. The public assumes that when a conflict is disclosed, it means negative or unlawful behavior, but conflict of interest is not always bad. The primary effort should be expended on acknowledging conflicts and being transparent about whatever the conflict entails. To handle conflict of interest in an upfront manner, it is necessary for institutions to maintain strict policies, review conflicts on at least an annual basis, and have guidelines in place to manage the conflict and follow up with ongoing monitoring of the conflicts.

## INTRODUCTION

“Conflict of interest means that because of activities or relationships with other persons or organizations, a person is unable or potentially unable to render impartial assistance or advice to the Government, that the person’s objectivity in performing the contract is or might be otherwise impaired, or that the person has or might acquire an unfair competitive advantage” (U.S. Food

and Drug Administration, 2014, para. 1). This paper primarily focuses on financial conflict of interest, but the terms financial and conflict of interest are used interchangeably. The majority of conflicts of interest reported are associated with financial issues.

This article will discuss how Financial Conflict of Interest (FCOI) is viewed by academia and research institutions and their efforts to remain in compliance. In the 1980s

several prime examples of bad decisions within the research community helped raise the public's awareness of how conflict of interest may impact research integrity. Early in the 1990s guidelines were introduced to handle conflicts of interest although the academic medical institutions were reluctant to get on board (Korn, 2000). In 1995 federal regulations required *institutions* conducting research to develop conflict of interest policy (42 CFR Part 50); whereas FDA 21 CFR Part 54 required sponsors to *ensure compliance of investigators*. On August 24, 2011, 42 CFR Part 50 was revised and published with institutional implementation required by August 24, 2012.

## BACKGROUND

The updated regulation promotes objectivity in research by establishing principles that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflicts of interest (42 CFR Part 50, 2011). Two new stipulations came from this revised regulation—investigator training in COI was required and COI information had to be accessible to the public (42 CFR Part 50, 2011). With this in mind it was hoped that end results could improve research integrity, transparency, human subject protection, and the public's perception (U.S. Food and Drug Administration, 2015).

Editors of scientific journals have grave concern over conflict of interest. The World Association of Medical Editors (WAME) has called upon all journals to take this issue seriously and to manage conflict of interest to preserve the trust held by its readers (Ruff, 2015). In 2013 WAME, Committee on Publication Ethics (COPE), the Directory of Open Access Journals, and the Open Access Scholarly Publishers Association released a publication entitled *The principles of transparency and best practice in scholarly publishing* (Ruff, 2015). The general opinion is that some journals have policies in place to adhere to these principles, but it does not appear that many enforce them. Ruff provided several examples of conflict of interest that were brought to the attention of various publishers. Most of these publishers stated that they follow the COPE guidelines, yet no action was taken to update their policies with regard to conflict of interest.

It is clear that the scientific community remains unclear on how to control accountability and transparency within scientific writings. Ruff provided some call for action steps from the ethical scientific community to help eliminate corruption within research and to promote accountability and regain “public trust and scientific integrity” (Ruff, 2015, conclusion, para. 1). Examples include: having a proven ethical scientist to create a Center for Monitoring and Implementing Publication

Ethics to oversee reports of unethical behavior; having a Center that can enforce sanctions and report their findings; and having several oversight organizations provide a small percent of funds to the Center that could be charged to the organization's members which would also send a message that they are serious about transparency (Ruff, 2015).

There are many reasons financial conflict of interest occurs in the research world. It can be for job advancement, monetary rewards, genuine interest in taking a product to market, accepting gifts from sponsors, or publishing notoriety, among many others. Not all instances of financial conflict of interest are ill-intended, but all still need to be disclosed. Being transparent about financial conflicts of interest takes the assumptions out of the equation when the public or scientific community is making a decision about a discovery, drug, or device, or simply reading an article. The public needs to have complete trust and be able to make an informed opinion with all facts presented to them. Disclosing conflicts is mandated; however, it should not stop at that point. Once a conflict has been disclosed, it is imperative for the institution to create a management plan based on their current policies and to monitor this conflict throughout its lifespan.

## MONITORING

Financial conflict of interest can be difficult to track and monitor as it is dependent on the honor system, which trusts investigators and academia to report their financial holdings honestly. Some instances of financial conflict of interest are not disclosed because the investigator did not consider it to be a financial conflict of interest or overlooked the potential conflict altogether. Financial conflict of interest is not necessarily unlawful, but can be unlawful if it is used as an unethical means to someone's financial advantage (Hutchens, 2012). In fact, it is acceptable to have a conflict as long as the COI is disclosed, managed, and subsequently monitored. Hutchens (2012) stated that regardless of how robust your training program is, it will not be successful unless you have a strong way to "identify, manage, audit and document the COI compliance workflow" (p. 48).

Technology has increased the ability to monitor but there must be ample training to correspond with this technology to aid in identifying and creating a system-wide process (Hutchens, 2012). All staff should be informed of the management plan in place and know what types of monitoring will take place once a COI has been identified. Technology also allows for easier tracking mechanisms to provide oversight when suspicion arises. When institutions transfer the financial conflict of interest from paper

to technology, there needs to be a gatekeeper which monitors the information regularly, and standard operating procedures (SOPs) in place for this monitoring process. The SOPs should also clearly delineate what actions are to be taken should non-compliance occur.

Monitoring financial conflict of interest takes planning and resources to provide consistent oversight and compliance. Institutions should have sound policies in place in accordance with regulations for all researchers and research staff so that financial conflicts of interest “do not adversely affect the protection of participants, the integrity of the research, or the credibility of the Human Research Protection Program” (Association for the Accreditation of Human Research Protection Programs [AAHRPP], 2014 para. 1). Researchers and research staff are defined by AAHRPP as “anyone responsible for the design, conduct, or reporting of research” (2014, para. 1). AAHRPP provides tips for establishing effective policies that will ensure all areas of financial conflict of interest are covered effectively and to which regulation is being referenced. The U.S. Food and Drug Administration, U.S. Department of Health and Human Services, and National Science Foundation have regulations for financial conflict of interest, but it is important to reference which set of regulations have been

identified by the institution as applicable to its staff.

The following is a summary of the tips provided (AAHRPP, 2014, recommended comment section):

1. Cite or identify the laws or regulations related to financial conflict of interest that your organization must follow.
2. Define the individuals who are covered by the financial conflict of interest policy.
3. Define the financial interests that must be disclosed.
4. Provide education to staff and investigators.
5. Describe the process for disclosing financial interests.
6. Describe the time frame for reporting changes in financial interests related to approved research.
7. Describe the process used to evaluate and, when necessary, to manage financial conflicts of interest.
8. Describe the process used to monitor and enforce management plans and provide employee sanctions or other administrative actions to ensure research compliance.
9. Describe the role of the IRB.
10. Describe how reporting requirements are completed.
11. Maintain good record keeping.

## **DISCLOSURES**

There are advantages and disadvantages to disclosing conflicts of

interest. By disclosing conflicts, it is often assumed that the intended audience will understand that the transparency provided is enough for them to know the conflict at hand has not affected the outcome. However, it can have the opposite effect. Loewenstein, Cain, and Sah (2011) stated that “two major psychological mechanisms” can influence the recipients of the disclosure. These two psychological mechanisms are strategic exaggeration and moral licensing.

Strategic exaggeration is when the disclosure is artificially inflated for fear the normal disclosure would be taken too lightly (Loewenstein et al., 2011). Strategic exaggeration is indicated when a physician has made a conflict of interest disclosure, but is compelled to overstate the benefits of the research results, such as a new drug. How a disclosure is presented can influence the interpretation by the public. If the conflict of interest is presented with facts and comes across as an honest testimonial, it is perceived as trust in the person or institution disclosing (Loewenstein et al., 2011).

Moral licensing refers to a lack of professional behavior as a result of making a disclosure (Loewenstein et al., 2011). Moral licensing can be described as allowing yourself to act dishonest or immoral when you have previously been known as honest and moral. A researcher may perceive that disclosing a conflict

provides the rationale for or justifies biased outcomes or results.

These two psychological mechanisms can potentially cause confusion when a conflict of interest is disclosed due to exaggeration or minimization of the conflict or lack of moral behavior during the implementation of the research. The intended audience may not receive a perfectly clear picture of the extent of the reported conflict or measures taken to monitor the conflict of interest.

#### **REVISIONS TO UCF’S CONFLICT OF INTEREST DISCLOSURE SYSTEM**

The University of Central Florida (UCF) took a proactive approach to conflict of interest (COI) and Conflict of Commitment (COC) prior to the final regulations by implementing an electronic system capturing all disclosures by their researchers. That system is the Academic Research and Grants Information System (ARGIS®) (Adkins, McClellan, & Miner, 2013). Once the PHS 2011 regulations were finalized, UCF realized the need to make further commitments to enhancing its conflict of interest disclosure system.

Revised steps were implemented by UCF to ensure conflicts were captured and monitored. First, UCF created a Potential Conflict of Interest & Conflict of Commitment Research Policy. This policy was revised to include whom and when someone must disclose. UCF also used a checklist provided by the National

Institutes of Health to ensure the revised Public Health Service regulations would be followed. In addition to the standard proposed financial earnings to be reported, UCF added another layer by expanding its policy requiring researchers to report all extramural travel costs paid on their behalf. UCF took dramatic steps to ensure all staff were aware of this policy, such as distributing an announcement from the Vice President for Research Office to all Deans and creating a new web page, among other avenues of communication (Adkins et al., 2013).

Second, UCF created a conflict of interest and conflict of commitment policy guideline. This guideline is an all-inclusive guideline to aid investigators in identifying what is to be reported. Per this policy, COI is to be reported prior to any awards, or within 30 days of newly discovered COI. This guideline includes sub-recipients to either produce certification that a COI is in place or adhere to UCF's policies. Should an investigator be found non-compliant, all activities will be considered suspended until a proper COI is in place. If necessary, disciplinary actions can be taken (Adkins et al., 2013).

Third, UCF implemented financial conflict of interest training. This training is required prior to conducting any research and must be repeated every four years. UCF has mandated that all researchers, including students, utilize the CITI training prior to

any funded research. The two modules required through CITI are *Financial Conflict of Interest: Overview, Investigator Responsibilities* and *COI Rules and Institutional Responsibilities as They Affect Investigators*. A UCF workshop that addresses COI, integrity, and ethical decisions was also created for graduate students and required for doctoral candidates involved with funded research (Adkins et al., 2013).

Fourth, UCF established a conflict of interest committee. This committee and a Compliance Officer review significant financial interest as reported to determine whether a monitoring plan is needed (Adkins et al., 2013).

Fifth and finally, UCF created a modified electronic proposal submission form that includes potential conflict disclosure questions (Adkins et al., 2013). When using these electronic forms, the investigator will trigger a task to name the project team. The project team will in turn receive notice to complete a FCOI form in ARGIS®. UCF felt that being prepared and disclosing all conflicts was better than taking the risk of losing reputation or federal grant funding (Adkins et al., 2013).

UCF remains proactive in the collection of disclosures from all staff and students affiliated with research projects. The website provides all regulations and forms required along with ample guidance of what is needed. When a conflict is

disclosed, a monitoring plan is put into place and approved by authorized reviewers and the Chair of the UCF Board of Trustees (University of Central Florida, 2015).

The UCF IRB does not allow research to continue if a significant financial conflict exists unless the conflict of interest committee “(a) determines that an individual’s participation is essential for the conduct of the research and (b) establishes an effective mechanism for managing the conflict and protecting the integrity of the research” (University of Central Florida, 2016).

## CONCLUSION

Conflict of interest is a serious matter that needs to be handled proactively. Each university and institution needs to have sound policies with adequate training on a continual basis. These policies should be reviewed and updated regularly. When a conflict of interest happens, this should influence the leaders to enhance the policies so the same occurrence does not repeat itself. The only way to discern whether

disclosing practices have improved and the effects on the products will be based on “what information is delivered, how it is delivered, and how it is utilized by receivers” (Loewenstein et al., 2011, p. 427). Ruff (2015) pointed out many suggested actions that would help with monitoring publications for conflict of interest. At this stage some journals require authors to disclose their conflicts, but there doesn’t seem to be follow up or noted attention from the publishers. Loewenstein et al. believed that the scientific community needs to formulate a better mechanism to immediately ensure transparency and to eliminate undisclosed conflicts. By establishing clear institutional policies and processes for COI monitoring in addition to taking more proactive actions to identify COI by editors of science journals; the scientific community can maintain integrity and public trust with their published findings.

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## ABOUT THE AUTHOR

**Lorraine Hickson**, MRA, CCRP, is a graduate of the University of Central Florida Master's of Research Administration program. She currently holds the position of Research Operations Manager at Celebration Health Research Institute (CHRI), Florida Hospital. Lorraine's



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