



Date: 8/31/2020

Subject: Proposal for research evaluation project related to research objectivity

Background

If the Research Conflict of Interest (RCOI) Program determines that a financial conflict of interest (FCOI) exists in the context of sponsored research, they will develop a management plan based on state and federal requirements and a risk assessment of the FCOI scenario. The management plan is designed to mitigate the FCOI and promote research objectivity. Disclosure of the financial relationship in publications and presentations of the study results is a consistent mitigation of the management plan.

The federal regulations for research require ongoing monitoring of management plan adherence until the completion of the sponsored research project. However, publication of study results often occurs after the project has ended. Some academic research institutions have extended monitoring of this mitigation past the completion of the project (e.g., one year following the project's termination date). Virginia Tech applies the same disclosure and management principles to all sponsored research, regardless of sponsor, so the monitoring approach has significant implications for the RCOI Program since they handle management monitoring procedures. It is unclear if extended monitoring contributes to the promotion of research objectivity by ensuring accountability or if it is simply an extraregulatory burden on the RCOI Program.

Proposal

We propose the following research evaluation project to inform Virginia Tech's approach to monitoring management plan compliance:

An analyst will review the papers published by the Investigator with an FCOI in the 3-5 years following the project's termination date. The analyst will determine if the publications are related to the sponsored research project under the provisions of the management plan and, if so, confirm the presence or absence of the agreed upon disclosure. If, for example, the analyst determines that the vast majority of Investigators with an FCOI do not disclose in the publications related to the sponsored research involving a managed FCOI, it would be recommended to consider extending management plan monitoring past the project end date.

The analyst will perform a review of the research integrity and compliance literature in order to identify other longstanding or emerging areas of concern for the field of research conflicts of interest. The analyst will develop their own project in order to answer the research question they develop, taking into account the types of management plan data the Research Conflict of Interest Program has cultivated.

The final products of this research evaluation project will be publications in journals relevant to these lines of inquiry.