

Conflict of Interest (COI) Management Plan Monitoring	Effective Date	08.01.2023
	Revisions Date	

- 1.0 Purpose:** East Carolina University (ECU) is committed to compliance with all federal, institutional, and sponsor requirements regarding disclosure and management of conflicts of interest (COI). In accordance with rules and regulations governing COI, ECU’s Conflict of Interest Officer (COIO) who is the Director of the Office of Research Integrity and Compliance, administers the University’s program to manage COI and conflicts of commitment (COC). This standard operating procedure (SOP) establishes guidelines for routine monitoring of COI management plans by REDE’s Office of Compliance Monitoring (OCM). The OCM functions independently of the Office of Research Integrity and Compliance (ORIC). The aim of routine compliance monitoring is to ensure compliance with the terms of the fully executed management plan and mitigate risks associated with non-compliance with the terms of the plan.
- 2.0 SOP:** On a regular basis, or at specified intervals if required by the management plan, OCM ensures that all parties included within the fully executed COI management plan understand the requirements of the plan that are applicable to them and are complying with the terms of the plan. OCM reports findings to the COIO in ORIC.
- 3.0 Definitions:**
- 3.1 Monitoring:** review and oversight of adherence to the fully executed COI management plan; ensuring all parties to the plan understand their responsibilities, ensuring all elements of the management plan are being followed and determining whether there are any revisions required for the management plan.
- 3.2 Supporting Documentation:** documents that can be used to document implementation/adherence to the management plan, including, but not limited to, the following:
- 3.2.1** Documentation of required disclosures
 - 3.2.2** IRB approved informed consent documents
 - 3.2.3** Related publications or citations
 - 3.2.4** Related presentation slides (should include title slide and financial interest disclosure slide)
 - 3.2.5** Memos, emails, meeting minutes, correspondence related to data oversight or independent data monitoring
 - 3.2.6** Memos, emails, documentation related to project financial transactions
 - 3.2.7** Communication or other correspondence regarding project oversight
- 4.0 Responsibilities:**
- 4.1 Conflicted Employee** is responsible for complying with all aspects of the COI management plan, updating annual COI disclosure(s) when any response would change, notifying the COIO of any changes that would impact the management strategies included in the plan, and complying with the request from the Office of Compliance Monitoring for meetings, information and supporting documentation for the purposes of monitoring the management plan.
- 4.2 University Conflict of Interest Officer,** in collaboration with the Department Chairs and the managed employees, is responsible for the following: initial plan requirements definition, composing the initial plan draft, ensuring mutual agreement of all individuals named and/or those defined by position titles, as applicable.
- 4.3 Department Chair** in collaboration with the COIO, has responsibility for overseeing the conflicted employee(s) and the implementation of the management plan.
- 4.4 Compliance Monitoring Officer** is responsible for monitoring the ORIC management plan list to ensure routine monitoring is scheduled on a regular basis (or specific intervals if required by the management plan) for all active management plans and reporting the findings of the monitoring efforts to the COIO.

5.0 Procedures:

- 5.1 The Compliance Monitoring Officer will review the ORIC management plan spreadsheet on a regular basis and select COI management plans for monitoring based on either the date of the last monitoring review or based on the requirements of the monitoring plan. Unless required by the management plan or allegations of non-compliance, monitoring will not occur more frequently than annually. Conflicted employees whose management plan has been selected for monitoring may request to postpone monitoring for a reasonable period, generally no more than sixty (60) days; however, they may not decline to have their management plan monitored; their full cooperation is expected.
- 5.2 In preparation for the monitoring review, the Compliance Monitoring Officer will review the current, fully executed management plan to become familiar with the nature of the conflict, the personnel named in the plan as well as the specific elements of the plan. Any questions about the fully executed document; the timeframe for the annual review and follow-up by ORIC or any information contained in the plan will be directed to ORIC prior to notifying the employee their management plan has been selected.
- 5.3 Employees will be notified by email that their management plan has been selected for monitoring. Included on the email will be the employee’s Department Chair and any other individual who may be named in the management plan as having responsibility for one or more elements of the management plan. The email will contain an explanation of the monitoring process, the rationale for monitoring and an outline of the supporting documentation being requested and the deadline by which it is requested. A copy of this SOP will be attached to the email.
- 5.4 Upon receipt of the source documentation the Compliance Monitoring Officer will review the source documents and compare them to the elements of the management plan. Any missing information or questions that arise during this review will be addressed directly with the appropriate party (i.e., employee, Dept Chair, COIO, etc.) via either email, telephone call or face-to-face meeting (in person or virtually).
- 5.5 After review of the source documentation and any required discussion with the parties to the management plan, a draft summary of findings will be created. The summary of findings will contain a general description of the monitoring, any observations made during the monitoring review and an outline of corrective actions (if required). In addition, the summary of findings may contain best practice recommendations related to observations that do not require specific corrective actions.
- 5.6 The draft summary of findings will be emailed to the employee, Department Chair, the COIO or their designee and any other individual who may be named in the management plan as having responsibility for one or more elements of the plan. A response to the draft summary of findings will be requested within two weeks of their receipt of the draft summary which is generally considered within one (1) day of emailing.
- 5.7 Upon receipt of the response to the summary of findings, if all corrective actions have been addressed and there are no outstanding issues, a final version of the summary of findings with the response will be emailed to everyone and the monitoring file will be closed. Should the response come, and outstanding issues exist, the file will be kept open until all issues have been addressed.

6.0 Exclusions:

This SOP does not include actions that may be part of ORIC’s processes to validate that the COI management plan continues to be necessary and/or that changes may be required.

Revision History:

Date	Change	Reference Section(s)
07.18.2023	New SOP	All Sections