University of Pittsburgh | Conflict of Interest
Office of Research Protections

Data Steward Guidelines

When an investigator has significant financial interests in an outside entity that create a conflict of interest (COI) in their University research, a conflict management plan (CMP) may be required. In some instances, this requires oversight of the research by a data steward. The document provides guidelines for conflicted investigators and data steward.

1. **Purpose**
   The purpose of a data steward is to assist the University in ensuring the design, conduct, and reporting of research is free from bias when a conflicted investigator has a COI. The data steward must be an individual who does not have a COI in the relevant research and who does not report to the conflicted investigator.

2. **Meetings**
   The data steward will organize and hold meetings with the study team at least annually. For purposes of these meetings, the study team includes individuals who collect or analyze the research data.

   The first data steward meeting should occur within 45 business days of the execution of the CMP. During these meetings, the data steward and study team members will discuss whether the conflicted investigator's financial interests may have led to bias in the design, conduct, or reporting of the research. The conflicted investigator will **not** be present during these discussions.

3. **Submitted and Published Papers**
   Prior to each data steward meeting, the conflicted investigator will email all submitted or published papers resulting from the research to the data steward. This includes papers the data steward has not yet reviewed and papers that were previously reviewed by the data steward that were subsequently edited.

4. **Requests for Additional Information**
   The data steward may determine additional information is necessary to determine whether bias exists. The conflicted investigator will respond to requests for additional information within 30 business days.

5. **Concerns**
   The data steward will immediately report any concerns regarding the research to the COI Division at coi@pitt.edu.

6. **Annual Reports**
   On at least an annual basis, the data steward will complete a report using the COI Division Data Steward Report template. The data steward will submit the report to the COI Division at coi@pitt.edu. The COI Division will share the reports with the COI Committee or Institutional Conflict of Interest (ICOI) Committee for review as required.

7. **Confidential Information**
   The data steward will not divulge results of research that have not yet been publicly disclosed.

8. **Questions**
   The conflicted investigator or data steward will contact the COI Division at coi@pitt.edu with questions.