



Data Steward Guidelines

When an investigator has significant financial interests that create a conflict of interest (COI) in their University research, a conflict management plan (CMP) may be required. An intent of the CMP is to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

In some instances, the CMP includes oversight of the University research by a data steward. This document summarizes the responsibilities of the conflicted investigator and data steward.

1. Meetings

The conflicted investigator will organize data steward meetings with the study team on at least an annual basis. For purposes of these meetings, the study team includes, but is not limited to, individuals who collect or analyze the research data.

The conflicted investigator will schedule the first data steward meeting to occur within 45 business days of the execution of their CMP. The conflicted investigator will **not** be present at the data steward meetings. During these meetings, the data steward and study team members will discuss whether the participation of the conflicted investigator may have led to bias in the design, conduct, or reporting of the research.

2. Submitted or Published Papers

Prior to each data steward meeting, the conflicted investigator will email to the data steward copies of all submitted or published papers that resulted from the research. This includes newly submitted or published papers the data stewards have not yet reviewed and submitted papers the data stewards previously reviewed that were edited prior to publication. The data steward will review these papers to confirm the conflicted investigator's financial interest has been disclosed as required by their CMP.

3. Requests for Additional Information

If necessary, the data steward will request additional information from the conflicted investigator or study team members. If they are not able to obtain any requested information within 30 business days of the request, they will contact the Conflict of Interest Division at coi@pitt.edu for assistance.

4. Concerns

The data steward will immediately report any concerns regarding the research to the Conflict of Interest Division at coi@pitt.edu. This includes, but is not limited to, concerns that the participation of the conflicted investigator possibly led to bias in the design, conduct, or reporting of the research.

5. Annual Reports

The data steward will submit a report to the Conflict of Interest Division at coi@pitt.edu on at least an annual basis following the data steward meetings. The reports will document the dates the data steward meetings occurred and the study team members who participated and will indicate if the data steward identified evidence of bias in the design, conduct, or reporting of the research. If the data steward identified evidence of bias, the reports should provide further details.

The Conflict of Interest Division has a report template that may be used but is not required. When the data steward does **not** identify evidence of bias in the design, conduct, or reporting of the research listed in Attachment A of the CMP that might have resulted from the conflicted investigator's financial interests, the annual report may

consist of only a brief statement to that effect. The reports will be reviewed by the Conflict of Interest Committee and, when relevant, may be reviewed by the Institutional Conflict of Interest Committee.

6. Confidential Information

The data steward will not divulge results of the research that have not yet been publicly disclosed.

7. Questions and Assistance

The data steward should contact the Conflict of Interest Division at coi@pitt.edu at any time with questions or to request assistance with their responsibilities as outlined herein.