

# Data Steward Guidelines

## Meetings and Structure

1. The data steward(s) should meet with or otherwise communicate with study team members without the presence of the conflicted Principal Investigator (PI), no less than annually, to determine if there are any concerns that the PI's conflict of interest has led to bias or potential bias in the conduct of the trial or research results. The data steward(s) should meet with the study team members who acquire the data and also with the team members who analyze the data. The data steward(s) may meet with those team members individually or in a group, at the data steward(s)' discretion.
2. The data steward(s) must have access to all information deemed sufficient by the steward(s) and necessary to fulfill their responsibilities.
3. If oversight has been assigned to a data steward committee, then a majority of the members of the committee must participate in the oversight function and must sign off on any reports submitted.

## Data Analysis Considerations

Where appropriate, the data steward(s) should attempt to answer the following questions:

- Is inclusion or exclusion of data well justified based upon the study protocol?
- Do the statistical analyses correspond to those that were planned and described in the study protocol, including variables designated as primary and secondary outcomes or are sound justifications given for change?
- Are the results that are presented in the project report representative of the statistical analyses?
- If any data were excluded from the results, is there an explanation of the reason for the omission?
- Are the conclusions presented in the project report appropriate to the results in the opinion of the data steward(s)?
- Have the study team members been positively or negatively influenced regarding collection and interpretation of data?

## Reporting Requirements and Confidentiality

1. The data steward or committee will submit reports to the COI Committee (via the COI Office), at least annually, documenting the dates and times of oversight meetings and communications with the investigators and providing the opinion of the data steward(s) regarding the integrity and interpretation of the data.
2. Any concerns about the integrity of the project data and data analyses should be reported to the COI Office immediately.
3. The data steward or committee should not divulge the results of the research under oversight that has not yet been publicly disclosed to any individuals (including investors and investment analysts) outside of the University of Pittsburgh or to any individuals at the University of Pittsburgh who are not working on this study.
4. The data steward or committee should inform the COI Office of any additional concerns regarding the conduct of the project.

## Need Help?

Please feel free to [contact the COI Office](#) with any questions regarding these data steward guidelines.