I. PURPOSE/SCOPE

A. The purpose of this policy is to:

1. Ensure the Health District’s research is free from bias or the appearance of bias;

2. Provide direction for the disclosure of potential financial conflicts of interests; and

3. Comply with federal reporting requirements for Public Health Service funded research.

B. This policy applies to the project director or principal investigator and any other Workforce member, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the U.S. Department of Health and Human Services Public Health Service agencies, or by a subaward, or proposed for such funding, which may include, for example, collaborators or consultants.

II. POLICY

Prior to the submission of an application to the PHS Grantee for funding, the Workforce member must have disclosed to the Health District’s Conflict of Interest Committee (COIC)/or it’s designated official an up-to-date listing of the Significant Financial Interests (SFIs), and those of their spouse and dependent children.

Each Workforce member who is participating in research under a subaward where the prime award originates from PHS must submit an updated disclosure of SFI at least annually, during the period of the award, and upon replacing a prior Workforce member. Such disclosure must include any information that was not disclosed initially.
to Health District, pursuant to this Policy, or in a subsequent disclosure of SFI, and must include updated information regarding any previously disclosed SFI (e.g., updated value).

A Workforce member who is participating in research under a subaward where the prime award originates from PHS must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

III. PROCEDURE

A. Training
Workforce members will complete FCOI training:

1. Prior to engaging in Research related to any PHS-funded grant.
2. At least every four (4) years.
3. Immediately if the Health District’s FCOI policy changes.
4. Immediately if it is determined the Workforce member is not in compliance with this policy.

B. Reviewing FCOI Disclosures
The COIC/designated official will conduct reviews of disclosures. The COIC/designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research subaward funded under a PHS prime to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research subaward.

C. Management of FCOIs
If a conflict of interest exists, the COIC/designated official will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias.

IV. REFERENCES

42 CFR 50.603
42 CFR 50.604(b)
42 CFR 50.604(e)(1)-(3)

V. SEE FORMS

PHS Financial Conflict of Interest (FCOI) Declaration
PHS Supplemental Disclosure Statement
Sponsored and Reimbursed Travel Form