

SmartDaaS, LLC

Policy on Financial Conflicts of Interest in Public Health Service–Funded Research

Effective date: September 24, 2026

1. Purpose and scope

SmartDaaS, LLC (“SmartDaaS”) is committed to ensuring that the design, conduct, and reporting of research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH), are free from bias resulting from Investigator financial conflicts of interest. This policy implements the PHS regulations at 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research.” It applies to every Investigator who is planning to participate in, or is participating in, PHS-funded research at or through SmartDaaS, including employees, consultants, and collaborators, and to any subrecipients.

2. Definitions

Terms in this policy have the meanings given in 42 CFR 50.603. In summary:

- Investigator: the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or proposals for such funding, which may include consultants and collaborators.
- Institutional responsibilities: an Investigator's professional responsibilities on behalf of SmartDaaS, including research, consultation, and professional service.
- Significant Financial Interest (SFI): a financial interest of the Investigator (and of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities and meets the thresholds in 42 CFR 50.603, including: remuneration from, and equity interests in, a publicly traded entity that together exceed \$5,000 in the preceding twelve months; remuneration exceeding \$5,000 from, or any equity interest in, a non-publicly traded entity; intellectual property rights and interests upon receipt of income related to them; and reimbursed or sponsored travel related to institutional responsibilities, subject to the regulatory exclusions.
- Financial Conflict of Interest (FCOI): an SFI that SmartDaaS reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

3. Responsible official

The Founder and Chief Executive Officer serves as the designated official responsible for administering this policy, soliciting and reviewing disclosures, and reporting to the PHS Awarding Component. Where the designated official is also an Investigator on the research in question, SmartDaaS will engage a qualified reviewer who is independent of the research, such as outside counsel or an external compliance professional, to review that Investigator's disclosures and to make the FCOI determination and any management plan.

4. Training

Each Investigator must complete training on this policy, the Investigator's disclosure responsibilities, and 42 CFR Part 50, Subpart F, before engaging in PHS-funded research, and at least every four years thereafter. Training must also be completed promptly if this policy is revised in a way that affects Investigator requirements, if an Investigator is new to SmartDaaS,

or if SmartDaaS finds that an Investigator is not in compliance with this policy or a management plan. The NIH FCOI online training module satisfies this requirement.

5. Disclosure of Significant Financial Interests

Each Investigator must disclose to the designated official all SFIs, including reimbursed or sponsored travel related to institutional responsibilities:

- no later than the time of application for PHS-funded research;
- at least annually during the period of the award; and
- within thirty days of discovering or acquiring a new SFI.

Consultants and collaborators who meet the definition of Investigator must make the same disclosures, either to SmartDaaS or, where they work through another institution with a compliant FCOI policy, under that institution's policy as set out in a written agreement with SmartDaaS.

6. Review and management

The designated official (or independent reviewer under Section 3) will review each disclosure before any PHS funds are expended and will determine whether the SFI is related to the PHS-funded research and, if so, whether it constitutes an FCOI. For each FCOI, SmartDaaS will develop and implement a written management plan, which may include public disclosure of the FCOI, disclosure to research participants where applicable, appointment of an independent monitor, modification of the research plan, change of personnel or responsibilities, reduction or elimination of the financial interest, or severance of relationships that create the conflict. SmartDaaS will monitor Investigator compliance with each management plan until the completion of the project.

7. Reporting to the PHS Awarding Component

SmartDaaS will report each identified FCOI to the PHS Awarding Component, through the NIH eRA Commons FCOI module, before any funds are expended under the award, within sixty days of identifying a new FCOI during the award, and annually for the duration of the award, with the content required by 42 CFR 50.605(b).

8. Public accessibility

This policy is posted on the SmartDaaS public website. Before expending funds under a PHS-funded award, SmartDaaS will make information concerning any SFI disclosed by senior/key personnel that SmartDaaS determines is related to the research and constitutes an FCOI available to any requestor within five business days of a written request, as required by 42 CFR 50.605(a)(5). Requests may be sent to lkchinthala@smartdaas.org.

9. Noncompliance and retrospective review

If an SFI is not disclosed or reviewed in a timely manner, or an Investigator fails to comply with a management plan, SmartDaaS will, within sixty days, determine whether an FCOI exists and implement interim measures. Where an FCOI was not identified or managed in a timely manner, SmartDaaS will complete a retrospective review within 120 days to determine whether any research conducted during the period of noncompliance was biased, and will submit a mitigation report to the PHS Awarding Component where required. Failure to comply with this policy may result in corrective action, up to and including removal from the research or termination of an employment or consulting relationship.

10. Subrecipients

Where PHS-funded research is conducted through a subrecipient, SmartDaaS will establish in the written subaward agreement whether the subrecipient's FCOI policy or this policy applies, and will require timely reporting of identified FCOIs so that SmartDaaS can meet its reporting obligations.

11. Records

SmartDaaS will keep records of all Investigator disclosures, reviews, determinations, and actions taken under this policy for at least three years from the date the final expenditure report is submitted to the PHS, or longer where required by 45 CFR 75.361.

12. Contact

Questions about this policy may be directed to the designated official at lkchinthala@smartdaas.org.