



FINANCIAL CONFLICTS OF INTEREST POLICY FOR PHS-FUNDED RESEARCH

Effective Date: September 26, 2025

1. PURPOSE AND SCOPE

1.1 Purpose

This Financial Conflicts of Interest Policy ("Policy") promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed by Investigators and Senior/Key Personnel under Public Health Service (PHS), including Advanced Research Projects Agency for Health ("ARPA-H")-funded contracts, grants, cooperative agreements, and subcontracts, will be free from bias resulting from Investigator financial conflicts of interest.

1.2 Applicability

This Policy applies to Assistive Technology Development, Inc. ("ATDev") when ATDev is performing PHS-funded research, and all Investigators who are planning to participate in, or are participating in, PHS-funded research conducted by ATDev.

1.3 Regulatory Compliance

This Policy complies with 45 CFR Part 94 and applicable PHS requirements regarding financial conflicts of interest in research.

2. DEFINITIONS

Financial Conflict of Interest ("FCOI"): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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, including collaborators and consultants.

Significant Financial Interest: A financial interest of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities, consisting of:

- With regard to publicly traded entities: remuneration and equity interests exceeding \$5,000 in aggregate value in the twelve months preceding disclosure;
- With regard to non-publicly traded entities: remuneration exceeding \$5,000 in the twelve months preceding disclosure, or any equity interest;
- Intellectual property rights and interests upon receipt of related income;
- Reimbursed or sponsored travel related to institutional responsibilities (excluding travel reimbursed or sponsored by governmental agencies, institutions of higher education, academic teaching hospitals, medical centers, or affiliated research institutes).
- See Appendix for examples of financial interests that do not need to be disclosed.



Institutional Responsibilities: An Investigator's professional responsibilities on behalf of ATDev, including research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.

3. INVESTIGATOR RESPONSIBILITIES

3.1 Training Requirements

All Investigators must complete the National Institutes of Health Office of Extramural Research Course on FCOI prior to engaging in PHS-funded research, and again every four years. To the extent that this FCOI policy is revised, all investigators must retake this training, and any new Investigators must complete the FCOI training immediately upon joining ATDev. Lastly, ATDev will require Investigators to take this training immediately upon a finding of non-compliance with this Policy.

Training module link: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

3.2 Disclosure Requirements

Investigators must disclose significant financial interests to the designated ATDev official(s) as follows:

Disclosure Type:	Disclosure Requirement:
Initial Disclosure	No later than the date of submission of ATDev's proposal for PHS-funded research.
Annual Updates	At least annually during the award period, including any previously undisclosed interests and updates to previously disclosed interests.
Ongoing Disclosure	Within thirty days of discovering or acquiring any new Significant Financial Interest.

3.3 Compliance with Management Plans

Investigators must comply with all conditions and restrictions imposed in FCOI management plans and cooperate with ongoing monitoring.

4. ATDev RESPONSIBILITIES

4.1 Designated Officials

ATDev will designate the Research Integrity Officer as the official responsible for soliciting and reviewing Investigator disclosures of significant financial interests.

4.2 Review and Determination Process

The designated official(s) shall:

- Review all Investigator disclosures of significant financial interests;

- Determine whether any significant financial interest is related to PHS-funded research (i.e., could be affected by the research or is in an entity whose financial interest could be affected by the research);
- Determine whether a financial conflict of interest exists (i.e., whether the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research);
- Complete this review prior to ATDev's expenditure of any PHS funds; and
- For new or newly disclosed interests during ongoing research, complete the review within sixty days.

4.3 Management of Financial Conflicts of Interest

When a financial conflict of interest is identified, ATDev will develop and implement a management plan that may include, among other aspects: (1) public disclosure of financial conflicts of interest in presentations and publications; (2) appointment of an independent monitor to protect against bias; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification from participation; (4) reduction or elimination of the financial interest; and (5) severance of relationships that create financial conflicts. ATDev will monitor Investigator compliance with management plans on an ongoing basis until completion of the PHS-funded research project.

4.4 Retrospective Review

When a financial conflict of interest is not identified or managed in a timely manner, ATDev will, within 120 days, complete a retrospective review of the Investigator's activities and the research project to determine whether any research conducted during the period of noncompliance was biased. If bias is found, ATDev will promptly notify the PHS Awarding Component and submit a mitigation report describing the impact of the bias and the plan of action to eliminate or mitigate its effect.

5. REPORTING TO PHS

5.1 Initial FCOI Reports

Prior to expenditure of PHS funds, ATDev shall provide an FCOI report to the PHS Awarding Component regarding any Investigator's significant financial interest found to be conflicting, unless the conflict is eliminated prior to expenditure of funds.

5.2 Ongoing FCOI Reports

For any financial conflict identified subsequent to the initial report, ATDev shall provide an FCOI report to the PHS Awarding Component within sixty days.

5.3 Annual FCOI Reports

For any previously reported financial conflict of interest, ATDev shall provide annual FCOI reports addressing the status of the conflict and any changes to the management plan for the duration of the project.

6. PUBLIC ACCESSIBILITY

6.1 Public Disclosure Requirements

Prior to expenditure of PHS funds, ATDev will ensure public accessibility of information concerning any significant financial interest that:

- Was disclosed by key personnel and is still held;
- Is determined to be related to PHS-funded research; and
- Is determined to be a financial conflict of interest.

6.3 Method of Disclosure

Information shall be made available via ATDev's publicly accessible website or by written response within five business days of a request. Website information shall be updated at least annually and within sixty days of identifying new financial conflicts of interest. Information shall remain available for at least three years from the date last updated.

7. SUBRECIPIENT MANAGEMENT

When ATDev carries out PHS-funded research through subrecipients, ATDev will:

- Incorporate written agreement terms establishing which FCOI policy applies (ATDev's or subrecipient's);
- If the subrecipient's policy applies, obtain certification that it complies with 45 CFR Part 94;
- Establish time periods for subrecipients to report identified FCOIs or submit Investigator disclosures;
- Provide FCOI reports to PHS regarding all subrecipient Investigator financial conflicts consistent with this Policy.

8. RECORD RETENTION

ATDev will maintain records relating to all Investigator disclosures, ATDev reviews and responses, and all actions under this Policy for at least three years from the date of final payment or as otherwise specified in applicable federal acquisition regulations.

9. ENFORCEMENT

9.1 ATDev Sanctions

ATDev shall impose appropriate sanctions or administrative actions for Investigator noncompliance with this Policy, which may include additional training, increased monitoring, removal from the project, and/or disciplinary action.

9.2 PHS Remedies

The PHS Awarding Component may take enforcement action, including issuance of a Stop Work Order, if it determines that a FCOI will bias research objectivity or that ATDev has not managed the conflict in accordance with 45 CFR Part 94.

9.3 Public Disclosure Requirements for Clinical Research

For PHS-funded clinical research evaluating the safety or effectiveness of a drug, medical device, or treatment, if an Investigator with an unmanaged or unreported FCOI designed, conducted, or reported the research, the Investigator must disclose the FCOI in each public presentation of results and request an addendum to previously published presentations.

10. POLICY ADMINISTRATION

10.1 Policy Availability

This Policy is publicly accessible via ATDev's website and is available upon request within five business days.

10.2 Policy Review

This Policy shall be reviewed and updated as necessary to maintain compliance with applicable regulations.

10.3 Certification

ATDev certifies in each contract proposal that it has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI, and that it shall fully comply with Part 94 requirements.

APPENDIX

The table below illustrates examples of financial interests that do not need to be disclosed.

Do I Need to Disclose?	
If...	You do not need to disclose:
you are currently employed or otherwise appointed by the institution	salary, royalties, or other remuneration paid to you by the institution.
the institution is a commercial or for-profit organization	any ownership interests in the institution that you hold
you do not directly control the investment decisions made in investment vehicles	income from investment vehicles, such as mutual funds and retirement accounts
your seminars, lectures, or teaching engagements are sponsored by certain institutions in the United States	income from seminars, lectures, or teaching engagements