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

Policy owner: General Counsel and Interim Chief Compliance Officer · Effective date: October 10, 2026 · Approved by: Derek Kung, General Counsel and Interim Chief Compliance Officer

1. Purpose and scope

This policy promotes objectivity in research by 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 an Investigator's financial conflict of interest. It implements 42 CFR Part 50, Subpart F, and 45 CFR Part 94. It applies to every Investigator who plans to participate in, or participates in, PHS-funded research at BAMF Health or under a BAMF Health subaward.

2. Definitions

- **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. This may include collaborators and consultants.
- **Institutional responsibilities.** An Investigator's professional responsibilities on behalf of BAMF Health, including research, research consultation, clinical activities, administration, and service on boards or committees.
- **Significant financial interest (SFI).** A financial interest of the Investigator, or of the Investigator's spouse and dependent children, that reasonably appears related to the Investigator's institutional responsibilities and meets any of the thresholds in Section 3.
- **Financial conflict of interest (FCOI).** An SFI that the Institutional Official determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.
- **Institutional Official.** The person designated by BAMF Health leadership to receive disclosures, make FCOI determinations and report to NIH. This role is held by Derek Kung, General Counsel and Interim Chief Compliance Officer. The Institutional Official does not review his or her own disclosure or the disclosure of an Investigator on a project in which the Official is also an Investigator. In those cases, BAMF Health leadership designates an alternate reviewer.

3. What counts as a significant financial interest

An SFI may involve a U.S. or a foreign entity. Interests from foreign entities, including foreign universities, foreign hospitals and foreign governments, are disclosed under the same rules as U.S. interests.

Any of the following is an SFI:

- Publicly traded entity: remuneration received in the prior 12 months plus the value of any equity interest at the time of disclosure that together exceed $5,000.

- Non-publicly traded entity: remuneration received in the prior 12 months that exceeds $5,000, or any equity interest of any value.
- Intellectual property rights and interests, such as patents and copyrights, upon receipt of income related to them.
- Reimbursed or sponsored travel related to institutional responsibilities, of any amount. Disclosures are made within 30 days of each trip and include the purpose, sponsor, destination and duration. The Institutional Official may ask for more information, including the monetary value.

Not an SFI: salary, royalties or other remuneration paid by BAMF Health to the Investigator, including income under BAMF Health's intellectual property sharing arrangements. Income from investment vehicles such as mutual funds and retirement accounts that the Investigator does not directly control. Income for seminars, lectures, teaching or advisory or review panels for a U.S. federal, state or local government agency, a U.S. institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center or a research institute affiliated with a U.S. institution of higher education. Travel reimbursed or sponsored by any of these U.S. entities. These exclusions do not apply to foreign entities: income and travel from a foreign university, a foreign hospital or research institute, or a foreign government must be disclosed.

BAMF Health interests. Because BAMF Health develops technology that may be studied in its own PHS-funded research, any ownership, equity, option or profit interest that an Investigator holds in BAMF Health or its affiliates will be disclosed and reviewed under this policy.

4. Training

BAMF Health informs each Investigator of this policy, the Investigator's disclosure responsibilities and 42 CFR Part 50, Subpart F. Each Investigator completes FCOI training before engaging in PHS-funded research and at least every four years after. Training is also required right away when this policy changes in a way that affects Investigator requirements, when an Investigator is new to BAMF Health, or when an Investigator is found not to comply with this policy or a management plan. The NIH online FCOI training module satisfies this requirement. Investigators give a copy of their completion certificate to the Institutional Official.

5. Disclosure by Investigators

Each Investigator discloses SFIs to the Institutional Official at these times:

- No later than the time of application for PHS-funded research.
- When an Investigator joins an ongoing PHS-funded project, before beginning work on it.
- At least annually during the period of the award, on the schedule set by the Institutional Official, including updated information on any SFI disclosed earlier.
- Within 30 days of discovering or acquiring a new SFI.
- Within 30 days of each occurrence of reimbursed or sponsored travel.

Disclosures cover both U.S. and foreign interests and are made on the BAMF Health FCOI disclosure form and submitted to the Institutional Official.

6. Review and determination

The Institutional Official reviews each disclosure, determines whether the SFI relates to PHS-funded research and, if so, whether it is an FCOI. An SFI relates to the research when the Official reasonably determines that it could be affected by the research or is in an entity whose financial interest could be affected by the research. Reviews are completed before BAMF Health spends funds on a new award, and within 60 days of any new disclosure during an award, including a disclosure by an Investigator who is new to the project. If the Official finds an FCOI during an award, the Official puts in place at least an interim management plan within that 60-day period. The Official may involve the Investigator in the review.

7. Management of conflicts

Each FCOI is managed under a written plan that the Investigator agrees to before work continues. Each plan states the Investigator's role and principal duties in the research, the conditions of the plan, how the plan safeguards objectivity, the Investigator's agreement to the plan, and how compliance will be monitored. Plans may include any of the following measures.

- Public disclosure of the FCOI, for example in presentations and publications.
- Disclosure to research participants, for research involving human subjects.
- An independent monitor able to take measures to protect the design, conduct and reporting of the research.
- Modification of the research plan, or a change in personnel or personnel responsibilities.
- Reduction or elimination of the financial interest, or severance of relationships that create the conflict.

The Institutional Official monitors compliance with each plan until the award is completed.

8. Subrecipients

Each subaward agreement states whether the subrecipient follows its own FCOI policy or this policy. A subrecipient that follows its own policy certifies that the policy complies with 42 CFR Part 50, Subpart F. It reports identified FCOIs to BAMF Health within 30 days of identifying them, or within the period stated in the subaward, so that BAMF Health can report them to NIH on time.

9. Reporting to NIH

BAMF Health reports FCOIs to NIH as follows:

- Before BAMF Health spends funds under a new award, it reports any FCOI to NIH through the eRA Commons FCOI module.
- An FCOI identified during an award is reported within 60 days.
- An annual FCOI report is filed with the annual progress report and at any extension, describing the status of each FCOI and any changes to its management plan.

Each report includes the project number, the PD/PI, the Investigator's name, the entity, the nature of the interest, its value range, how the interest relates to the research and why it is an FCOI, and the key elements of the management plan.

10. Public accessibility

Before spending funds, BAMF Health makes the following information available for each FCOI held by senior/key personnel: the person's name, title and role in the research, the entity, the nature of the interest and its approximate value range. BAMF Health posts this information on its public website or provides it within five business days of a written request. Information is updated at least annually and within 60 days of a new FCOI, and remains available for three years from the most recent update.

11. Noncompliance and retrospective review

If an SFI was not disclosed or reviewed on time, or an Investigator did not follow a management plan, the Institutional Official reviews the SFI within 60 days and puts in place an interim plan if needed. Within 120 days of finding noncompliance, BAMF Health completes and documents a retrospective review of the Investigator's research to determine whether it was biased. The documentation includes the project number, project title, PD/PI, the name of the Investigator with the FCOI, the name of the entity, the reason for the review, a detailed methodology (the review process, who conducted it and the documents reviewed), the findings and the conclusions. BAMF Health updates any FCOI report already submitted to NIH as needed. If bias is found, BAMF Health promptly notifies NIH and submits a mitigation report.

If an Investigator's failure to comply with this policy or a management plan appears to have biased the design, conduct or reporting of PHS-funded research, BAMF Health promptly notifies NIH of the corrective action taken or to be taken.

If HHS determines that clinical research evaluating the safety or effectiveness of a drug, medical device or treatment was designed, conducted or reported by an Investigator with an FCOI that was not managed or reported as required, the Investigator discloses the FCOI in each public presentation of the results and requests an addendum to previously published presentations.

12. Enforcement

Failure to comply with this policy may result in corrective action, including additional training, restrictions on research activities, suspension from PHS-funded research and other actions under BAMF Health employment and contracting policies.

13. Records

BAMF Health keeps all disclosures, reviews, determinations, management plans and actions under this policy for at least three years from the date the final expenditure report is submitted to NIH, or longer where federal rules require.

14. Posting and updates

This policy is posted on the BAMF Health public website. It is reviewed when federal requirements change and at least every three years.

Approval

Approved by	Title	Signature	Date
Derek Kung	General Counsel and Interim Chief Compliance Officer (Institutional Official)		October 10, 2026