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National Center of Neurology and Psychiatry

Guidelines for management of FCOI for research funded by NIH or other PHS funding agencies

This is an English translation of the original Japanese and is for informational purposes only.

Chapter 1: Outline

In National Center of Neurology and Psychiatry ("NCNP")'s promotion of industry-academia-government collaboration activities, the appropriate management of possible conflict of interest (COI) situations ("COI management") is carried out by the COI Committee (the "Committee") through investigations, hearings, examinations, etc. based on self-reports from NCNP officers and employees following the forms, methods, items, and timing prescribed by the Committee in accordance with the Regulations for the Management of Conflict of Interest (Reg. No.50, 2010）.

For purposes of these Guidelines, the COI Committee serves as NCNP's designated official(s) responsible for reviewing disclosures, determining relatedness, determining whether an FCOI exists, and overseeing management plans. The COI Committee may seek additional information from an Investigator and may consult subject matter experts, administrative officials, or legal counsel when necessary to evaluate a Significant Financial Interest.

On these industry-academia collaboration activities that are subject to COI management, research that is funded by the U.S. National Institutes of Health (NIH) or other U.S. Public Health Service (PHS) funding agencies, and prospective research activities that are scheduled to be funded by such agencies ("Applicable Research") are required to be managed for financial conflict of interest (FCOI) in compliance with the matters prescribed in US Department of Health and Human Services (HHS) regulations, 42 CFR Part 50 Subpar F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ("Federal FCOI Regulations"). In line with this, NCNP is responsible for management of FCOI in accordance with Federal FCOI Regulations.

The following "Guidelines for management of FCOI for PHS-funded research" ("the Guidelines") are guidelines established by NCNP to comply with the Federal FCOI Regulations. All investigators involved in Applicable Research at NCNP must comply with the Guidelines in addition to other items requiring compliance under the Regulations for the Management of Conflict of Interest.

Chapter 2: FCOI management guidelines for research funded by NIH or other PHS funding agencies

The Guidelines were established as NCNP's guidelines for compliance with Federal FCOI Regulations, and regardless of what is stated in the Guidelines, the most current version of the Federal FCOI Regulations will prevail. Moreover, the Guidelines prescribe matters that are required in addition to other matters stated in the Regulations for the Management of Conflict of Interest. Any matters not listed below that require compliance under the Regulations for the Management of Conflict of Interest must also be complied with. In making an FCOI report to the PHS Awarding Component, the policy of the PHS Awarding Component should also be confirmed, and compliance kept for any applicable provisions therein. For NIH conflict of interest policies (NIH Grants Policy Statement 4.1.10 Financial Conflict of Interest), as with Federal FCOI Regulation, it is necessary to always verify the most current policy.

1. **Purpose**

The purpose of these Guidelines is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

2. **Applicability**

The Guidelines are applied to Applicable Research. The responsibilities specified in the Guidelines are prescribed to NCNP as the recipient of the funds and to each Investigator who plans to participate in or who is participating in the Applicable Research.

3. **Definitions**

(1) "Disclosure of significant financial interests" means an Investigator's disclosure of significant financial interests to NCNP.

(2) Financial Conflict of Interest (FCOI) means a Significant Financial Interest that NCNP reasonably determines:

  (a) is related to PHS-funded research because the Significant Financial Interest could be affected by the research, or is in an entity whose financial interests could be affected by the research; and

  (b) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(3) "FCOI report" means NCNP's report of a financial conflict of interest to a PHS Awarding Component.

(4) "Financial interest" means anything of monetary value, whether or not the value is readily ascertainable.

(5) "Investigator" means 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 Applicable Research, which may include, for example, collaborators or consultants.

(6) Institutional Responsibilities means an Investigator's professional responsibilities on behalf of NCNP, including but not limited to research, research consultation, professional practice, institutional committee memberships, and service on panels such as institutional review boards, data and safety monitoring boards, and similar activities.

(7) "FCOI management" means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of Applicable Research will be free from bias.

(8) In the context of PHS-funding for disclosure, "Domestic" sources are based in the United States of America, "Foreign" sources are non-US entities.

(9) "Significant financial interests" means the following:

  (a) A financial interest consisting of one or more of the following interests 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 (see above) performed on behalf of NCNP:

    (i) With regard to any publicly traded company, a significant financial interest exists if the value of any remuneration received from the company in the twelve months preceding the disclosure and the value of any equity interest in the company as of the date of disclosure, when aggregated, exceeds US $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

(ii) With regard to any non-publicly traded company, a significant financial interest exists if the value of any remuneration received from the company in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when any equity interest (e.g., stock, stock option, or other ownership interest) is held.

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

a. NCNP will require disclosure of income related to intellectual property rights and interests when the aggregate value received during the preceding twelve months exceeds US$5,000.

(b) Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities, whose value exceeds US $5000 over the preceding twelve months, must be disclosed. The disclosure shall include, at a minimum:

- purpose of the trip,
- identity of the sponsor or organizer,
- destination,
- duration, and
- monetary value, if known.

Travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education is excluded from disclosure requirements.

Investigators must disclose newly occurring reimbursed or sponsored travel within 30 days of the travel occurrence.

(c) Significant Financial Interests do not include the following financial interests; therefore, Investigators are not required to disclose these financial interests:

a. salary, royalties, or other remuneration paid by NCNP to the Investigator if the Investigator is currently employed or otherwise appointed by NCNP; salary, royalties, or other remuneration paid by NCNP to the Investigator if the Investigator is currently employed or otherwise appointed by NCNP; Intellectual property rights assigned to the Institution (NCNP) and agreements to share in royalties related to such rights.

b. income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions;

c. income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education;

d. income from service on advisory committees or review panels for the same categories of organizations listed above.

e. For purposes of these Guidelines, the exclusion for income from seminars, lectures, advisory committees, and review panels applies only to the categories of organizations specifically listed above. Income received from “foreign” (including

Japanese) institutions or organizations that do not fall within the listed exclusion categories must be disclosed unless otherwise exempted under these Guidelines.

All other financial interests, whether foreign or domestic, must be disclosed unless specifically exempted by these Guidelines.

4. **Responsibilities of NCNP and Investigators**

(1) Notification and training

NCNP will inform each Investigator of the Guidelines, the Investigator's responsibilities regarding disclosure of significant financial interests per the policy, and the regulations related thereto, and require each Investigator to complete training regarding the same.

Training may include completion of NIH's Financial Conflict of Interest training module or equivalent NCNP-approved training.

Training must be completed prior to engaging in Applicable Research, and at least every four years, and immediately when any of the following circumstances apply:

(a) When NCNP revises the Guidelines or procedures in any manner that affects the requirements of Investigators;
(b) When an Investigator is new to NCNP; or
(c) When NCNP finds that an Investigator is not in compliance with the Guidelines or management plan.

(2) FCOI Disclosures

(a) NCNP will require each Investigator who is planning to participate in Applicable Research to disclose to the Committee any of the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for the Applicable Research.
(b) NCNP will require each Investigator who is participating in the Applicable Research to submit an updated disclosure of significant financial interests at least annually, during the period of the research.
(c) All Investigators participating in Applicable Research shall submit an annual Significant Financial Interest disclosure within twelve months of their previous annual disclosure.
(d) NCNP will require each Investigator who is participating in the Applicable Research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
(e) NCNP will require each Investigator to disclose reimbursed or sponsored travel within 30 days of the travel occurrence.
(f) NCNP may require an Investigator to provide additional information, clarification, or supporting documentation relating to a disclosed Significant Financial Interest to enable an appropriate determination under these Guidelines.

(3) FCOI Management

(a) Prior to provision of any funds under an Applicable Research project, the Committee will review all Investigator disclosures of significant financial interests as in paragraph (a) of the preceding section; determine whether any significant financial interests relate to the Applicable Research; and if a financial conflict of interest exists, develop and implement a management plan that specifies the actions to manage such financial conflict of interests.
(b) Management plans may include, as appropriate:

- public disclosure of financial conflicts of interest (e.g., in publications and presentations, to research personnel working on the study, to the Institutional Review Board, any animal review committee, etc.);

- appointment of independent reviewers or monitors;
- modification of the research plan;
- changes in personnel responsibilities;
- reduction or elimination of the financial interest; or
- severance of relationships that create the conflict.

(c) An Investigator's Significant Financial Interest is related to PHS-funded research when NCNP reasonably determines that the Significant Financial Interest:

- could be affected by the research; or
- is in an entity whose financial interests could be affected by the research.

A Financial Conflict of Interest exists when NCNP reasonably determines that the Significant Financial Interest could directly and significantly* affect the design, conduct, or reporting of the PHS-funded research. *Significantly means that the financial interest would have a material effect on the research.

(d) NCNP may involve the Investigator in determining whether a Significant Financial Interest is related to PHS-funded research.

(e) The Designated Official shall develop and communicate its determination and management plan in writing to the Investigator and secure the Investigator’s agreement to the plan.

(f) NCNP shall monitor Investigator compliance with each management plan on an ongoing basis until completion of the project.

(g) Within 60 days of a new significant financial interest to the Committee in the course of ongoing Applicable Research, the Committee will review and determine the significant financial interest and develop and implement a management plan to address any financial conflicts of interest that may exist.

Retrospective Review:

(h) Whenever the Institution identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) will **within 60 days**: review the SFI; determine whether the SFI is related to the NIH-funded research; determine whether an FCOI exist; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward. The institution will also submit an FCOI report to the NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI,
- failure by the Institution to review or manage such an FCOI; or
- failure by the Investigator to comply with a management plan;

The NCNP will within 120 days of determining noncompliance:

1) Complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of the research;
2) Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ currently numbered I.2. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52895.

(i) Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, NCNP shall complete, within 120 days of the determination of noncompliance, a retrospective review to determine whether any PHS-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting.
The retrospective review shall include, at minimum:
   - project number;
   - project title;
   - Principal Investigator;
   - name of Investigator with the FCOI;
   - reason for retrospective review;
   - methodology used;
   - findings; and

conclusions.

If bias is found, NCNP shall promptly notify the PHS Awarding Component and submit a mitigation report describing the impact of the bias and actions taken or planned to eliminate or mitigate the effect of the bias.

If bias is not found following completion of the retrospective review, no further action will be taken unless new information is discovered that needs to be reported to the NIH. If applicable, the Institution will update an existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update the previously submitted report information (e.g., increase in value of the SFI or add any newly identified SFIs) following the completion of the retrospective review.

If the failure of an Investigator to comply with an Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, the Institution shall promptly notify the PHS/NIH Awarding Component of the corrective action taken or to be taken. The PHS/NIH Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS/NIH-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS/NIH award or when the transfer of a PHS/NIH grant(s) involves such an Investigator.

(4) FCOI Report

(a) Prior to the provision of any funds under an applicable research project, NCNP will provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by NCNP to be an FCOI and ensure that NCNP has implemented a management plan in accordance with the Guidelines. In case in which NCNP identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, NCNP will not submit an FCOI report to the PHS Awarding Component.

(b) For any significant financial interest that NCNP identifies subsequent to NCNP's initial FCOI report during an ongoing Applicable Research project, NCNP will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the financial conflict of interest. When such an FCOI report involves noncompliance related to a significant financial interest, pursuant to paragraph (c) of the previous section, NCNP also is required to complete a retrospective review and to report this to the PHS Awarding Component. If the Financial Conflict of Interest involves Investigator noncompliance with these Guidelines or a management plan, NCNP shall complete any required retrospective review within 120 days of the determination of noncompliance and shall submit any required retrospective review results or mitigation reports to the PHS Awarding Component in accordance with applicable PHS requirements.

(c) Any FCOI report required under paragraphs (a) and (b) of this section will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of NCNP's management plan.

(d) NCNP will provide the PHS Awarding Component with an annual FCOI report on the status of financial conflicts of interest and any changes to the management plan for the ongoing Applicable Research for which NCNP has previously reported a financial conflict of interest.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	**CONTENT**	**REQUIRED WHEN?**
New FCOI Report (Initial submission	Grant Number, PI, Name of Entity with FCOI, Nature of	(1) Prior to expenditure of funds

	FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

5. **Remedies**

(1) If NCNP receives a request from the PHS Awarding Component or HHS for an inquiry or remedies regarding compliance with the Federal FCOI Regulations, NCNP will respond in good faith to the request.

(2) In the event of a violation of the provisions of the Guidelines, remedies to be taken may include suspension of PHS funding or suspension of Applicable Research.

(3) Investigator Noncompliance

Failure to comply with these Guidelines, disclosure requirements, training requirements, or an approved management plan may result in corrective action, including but not limited to:

- mandatory retraining;
- increased monitoring;
- removal from the research project;
- restriction of eligibility to participate in PHS-funded research;
- disciplinary action under NCNP personnel regulations; and
- other actions deemed appropriate by NCNP.

6. **Maintaining records**

NCNP shall maintain all records relating to Investigator disclosures of financial interests, reviews of disclosures, determinations of Financial Conflicts of Interest, management plans, retrospective reviews, mitigation reports, and actions taken under these Guidelines for at least three years from the date of submission of the final expenditures report or from such other date specified 2 CFR 200.334 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR4acc10e7e3b676f/section-200.334) for different situations. The Institution will retain records for each competitive segment as provided in the regulation and this Policy.

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7. **Clinical Research**

If the Department of Health and Human Services determines that any PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with an unmanaged or unreported Financial Conflict of Interest, NCNP shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and shall request an addendum to previously published presentations where appropriate.

8. **Public access**

(1) NCNP shall maintain these Guidelines on a publicly accessible website.

(2) For Senior/Key Personnel identified as having a Financial Conflict of Interest, NCNP shall make available information concerning the FCOI, as required by applicable PHS regulations, within five business days of a written request. SFI of Senior/Key personnel will be made available to the public if: 1) The SFI was disclosed and is still held by the Senior/Key Personnel as defined by this policy; 2) The Institution has determined that the SFI is related to the PHS/NIH-funded research; and 3) The Institution determines that the SFI is a financial conflict of interest. Information concerning disclosed Financial Conflicts of Interest held by Senior/Key Personnel will remain publicly available for at least three years from the date the information was most recently updated.

(3) Information made publicly available shall include:

- Investigator name;
- Investigator title and role in the research project;
- name of the entity in which the Significant Financial Interest is held;
- nature of the Significant Financial Interest; and
- approximate dollar value (or statement that the value cannot readily be determined).

9. **Subrecipient**

1. If NCNP carries out PHS-funded research through a subrecipient, NCNP shall incorporate into a written agreement with the subrecipient terms establishing whether the FCOI policy of NCNP or that of the subrecipient will apply to the subrecipient's Investigators.

2. **If the subrecipient's FCOI policy applies**: The subrecipient institution must certify as part of the agreement that its policy complies with the federal FCOI regulation. The agreement will specify the timeframe for the subrecipient to report all identified FCOIs to NCNP in time for NCNP to meet NIH reporting deadlines (i.e., before the subrecipient expends funds and within 60 days of the subrecipient identifying an FCOI). Typically, this means requiring

subrecipients to report FCOIs to the NCNP within 50 or 55 days of identification when an FCOI is identified during the period of an award to meet the 60-day reporting deadline. When a subrecipient reports an identified FCOI to NCNP, it must include the required information in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ currently numbered H.5. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888. The NCNP will submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

3. **If the subrecipient cannot certify compliance**: The agreement will specify that the NCNP's FCOI Policy applies. In this case, subrecipient Investigators must disclose their SFIs to NCNP. The written agreement will specify the time period(s) for the subrecipient to submit all Investigator SFI disclosures to the recipient Institution. The SFI disclosure must include SFIs that are **directly related to the subrecipient's work for the NCNP.** The agreement will allow sufficient time for the NCNP to review SFIs, manage, and timely report any resulting FCOIs per the regulation. When an FCOI is identified, NCNP will implement a management plan, monitor the subrecipient Investigator's compliance with the management plan, and submit the required subrecipient FCOI report to NIH via the eRA Commons FCOI.