

**\*\*\* Memorandum \*\*\***

**To:** Charles Grim, Secretary of Health *cg*  
**From:** Bobby Saunkeah, CNDH Research Director *BS*  
**CC:** Kevin Meeks, Deputy Secretary of Health *KM*  
 John Krueger, MD, Undersecretary Medical Staff and Quality *JK*

**Date:** April 23, 2026

**Request:** Review of CNDH Division of Research's *revised* (v.4) draft Standard Operating Guide for addressing Financial Conflicts of Interest (FCOI)

CNDH leadership recently approved the draft FCOI document required for final determination of an NIH award (\$1.8 million over 5 years) for the Tribal IRB Establishment or Enhancement grant (TIRBEE) grant. Working with Chickasaw Nation Grants Office we drafted the proposed document according to the guidelines provided to us; however, the NIH grants compliance officer declined it as well as two subsequent versions. We now have a fourth draft document which is finally deemed satisfactory. We request your review of this revised Standard of Operations Guide (SOG) for official submission.

Your consideration of this revised document is appreciated.

Thank you.

cg Approved \_\_\_\_\_ Declined

\_\_\_\_\_ Need to Discuss

# Chickasaw Nation Department of Health

## Division of Research

### Standard Operating Guide (SOG)

#### Compliance with

#### NIH Financial Conflicts of Interest (FCOI)

#### (42 CFR Part 50 Subpart F)

The Chickasaw Nation Department of Health (CNDH) Division of Research maintains a structured process to ensure compliance with federal Financial Conflicts of Interest (FCOI) regulations as required for National Institutes of Health (NIH) funding under [42 CFR Part 50 Subpart F](#), “Promoting Objectivity in Research” and [45 CFR Part 94](#), “Responsible Prospective Contractors” to promote objectivity in Public Health Service (PHS) funded research for grants, cooperative agreement and research contracts, respectively. The regulations were first published in 1995 and revised the regulations in 2011. This SOG implements the requirements of the 2011 revised FCOI regulation for grants and cooperative agreements.

As recipient of federal and non-federal grants awards, the Chickasaw Nation Department of Health is responsible for compliance with the applicable regulatory requirements set forth by the awarding agency. The Chickasaw Nation Department of Health must also comply with the Uniform Guidance Title 2 Code of Federal Regulations as well as agency-specific adaptations of such. As a prime and pass-through entity, the Chickasaw Nation Department of Health must pass down applicable requirements to any subrecipients of a federal award and adhere to internal guide and code. By achieving regulatory gold standards for all supplemental funding, we will reduce auditable risk and secure future supplemental funding for the Chickasaw People.

The SOG serves as a guide for the internal process of FCOI with the Division of Research and ensures that knowledgeable working staff are fully prepared and trained on the subject matter. The stated regulations apply to all National Institutes of Health (NIH) applications and funded grants, cooperative agreements, and research contracts, excluding the Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and/or awards.

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# 1. Purpose

To establish standards to promote objectivity in research and to ensure the design, conduct or reporting of research will be free from bias resulting from an FCOI. This guide implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. The guide also applies to individuals who meet the regulatory definition of “Investigator” (as defined below) who are planning to participate in, or who participate in NIH-funded research.

## 2. Scope

The Division of Research informs all investigators participating in NIH-funded research of their responsibilities under the FCOI SOG. This includes providing access to the Division’s standard operating guide, explaining disclosure requirements for all significant financial interests (SFIs), both domestic and foreign—and directing investigators to relevant federal regulations and training resources, including those provided by the NIH. This applies to the investigators, contractors, subrecipients, collaborators, Board of Directors, vendors, contract partners, planning to participate in awards, agreements or grants for research.

## 3. Definitions

For the purpose of these policies and procedures, the following definitions apply:

- **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- **Institution** means any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, Public Health Service (e.g., NIH) funding.
- **Institutional Responsibilities:** Professional activities an Investigator performs on behalf of CNDH Division of Research (e.g., research, publication, research consultation, administration, committee memberships, or any other duties defined by their role at the company).
- **Designated Official (DO):** The individual designated by CNDH Division of Research as an Officer to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests, identification of FCOIs per the regulatory criteria provided in 42 CFR 50.604(f), and monitoring staff FCOI training requirements.
  - 1) The research DO is the Undersecretary of Medical Staff and Quality, as appointed/delegated by the Chickasaw Nation Department of Health Secretary.

- **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 research funded by an award or proposed for funding, which may include collaborators or consultants. CNDH Division of Research will consider the individual's role, rather than the title, and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the NIH-funded research.
- **Research:** Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). As used in the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.
- **PHS-Funded Research:** Any activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.
- **PHS:** The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- **NIH:** The biomedical research agency of the PHS.
- **Senior/Key Personnel:** The PD/PI and any other person identified as senior/key personnel by CNDH Division of Research in the grant application, progress report, or any other report submitted to the PHS/NIH by CNDH Division of Research. *This term is defined only as it relates to the public accessibility requirements described under Section 9.*

#### **Significant Financial Interest (SFI):**

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- 1) A **domestic or foreign** 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

appear to be related to the *Investigator's institutional responsibilities* (e.g., research, consulting, etc.) performed on behalf of CNDH:

- i. **Publicly Traded Entity:** A significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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. **Non-Publicly Traded Entity:** A significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - iii. **Intellectual Property Rights and Interests:** A significant financial interest exists upon receipt of income greater than \$5,000 received over the preceding months that is related to such rights and interests (e.g., patents, copyrights).
- 2) Investigators must disclose the occurrence of any **reimbursed or sponsored travel** that exceeds \$5,000 (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel reimbursed or sponsored by the following:
- i. A federal, state, or local government agency located in the United States,
  - ii. A United States Institution of higher education,
  - iii. An academic teaching hospital,
  - iv. A medical center, or
  - v. A research institute affiliated with a United States Institution of Higher Education.
- 3) The term 'significant financial interest' does **not** include,

and therefore, Investigators are not required to disclose, the following types of financial interests:

- i. Salary, royalties, or other remuneration paid by CNDH to the Investigator if the Investigator is currently employed or otherwise appointed by CNDH, including intellectual property rights assigned to CNDH and agreements to share in royalties related to such rights.
  - ii. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
  - iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
  - iv. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, 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.
  - v. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, 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.
- **NOTE: Exclusions above do not apply to Foreign Financial Interests:** Investigators must disclose all foreign financial interests (including income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

#### **4. Significant Financial Interest Investigator Disclosure Requirements**

Investigators will disclose their SFIs that are related to their “*institutional responsibilities*” as defined in the guide.

**The disclosure will not be limited to an Investigator’s research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation.**

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The Investigator SFI Disclosures will be retained by CNDH Division of Research as part of the record maintenance requirements.

**Investigators will disclose their SFIs at the following times:**

- a. **At the time of application:** The Principal Investigator and all other individuals who meet the definition of ‘Investigator’ must disclose their SFIs to CNDH Division of Research’s Designated Official. Any new Investigator who, after applying for NIH funding or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the Designated Official promptly and prior to participation in the project.
- b. **Annually:** Each Investigator participating in research under an NIH award must submit an updated disclosure of SFI at least annually (on or before January 1) during the period of the award. The annual disclosure must include any information not disclosed initially to CNDH Division of Research pursuant to this Guide or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- c. **Ad Hoc Basis - New SFIs During the Award:** Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

**5. Review of SFI Disclosures by CNDH Division of Research Designated Officials**

The Designated Official (DO) will conduct reviews of SFI disclosures. The role to DO will be assigned to the CNDH Chief Medical Officer or as delegated by the CNDH Secretary of Health. The DO will review any SFI identified in a disclosure and compare these interests to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award as explained in Section 6.

**The SFI disclosures will be reviewed as described below:**

- a. **Prior to the expenditure of awarded funds (e.g., during the Just-in-Time stage):** The Designated Official(s) will review the Investigator’s SFI(s) prior to the NIH issuing a new award. If an FCOI is identified, CNDH Division of Research will submit an FCOI report to the NIH via the eRA Commons FCOI Module prior to the expenditure

of funds under the new award.

- b. **Annual Disclosure:** The annual disclosure will require the Investigator to disclose updated values of any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest). The Designated Official(s) will review the Investigator's annual disclosure and use the updated information to determine if any changes are needed to an existing management plan. Any changes to an existing management plan will be reported to the NIH when the next Annual FCOI report is due, if applicable.
  
- c. **Ad Hoc Basis – New SFIs During Award Period:** Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the Designated Official(s) will, within 60 days: review the disclosure of SFI, determine whether the SFI is related to the NIH-funded research, determine whether an FCOI exists, 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 the FCOI. CNDH Division of Research will submit the FCOI report to the NIH within 60 days of identifying the FCOI.

#### **6. Guidelines for Determining 'Relatedness' of SFI to PHS/NIH-Funded Research and a Financial Conflict of Interest**

The Designated Official will determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

- a. **Relatedness Test:** An Investigator's SFI is related to the research when the Designated Official reasonably determines the SFI:
  - 1) Could be affected by the PHS/NIH-funded research; or
  - 2) Is in an entity whose financial interest could be affected by the PHS/NIH- funded research.

**Investigator Involvement:** The designated official(s) may involve the Investigator in determining whether an SFI is related to the NIH-funded research.

- b. **FCOI Determination:** A financial conflict of interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. 'Significantly' means that the financial interest would have a material effect on the research.
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## **7. Management of Significant Financial Interests that Pose Financial Conflict of Interest**

If a financial conflict of interest exists, the Designated Official(s) will determine what management conditions and/or strategies will be put in place to manage the FCOI. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Chickasaw Nation's Institutional Review Board,);
- b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d. Modification of the research plan;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g. Severance of relationships that create financial conflicts.

If the Designated Official determines that a conflict exists, it will communicate its determination and the means developed for managing the FCOI in writing to the individual.

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Guide and has agreed, in writing, to comply with any plans determined by the Designated Official(s) necessary to manage the Financial Conflict of Interest. The FCOI Designated Official(s) of CNDH Division of Research will submit the FCOI report to NIH via the eRA Commons FCOI Module.

## **8. Monitoring Investigator Compliance**

CNDH Division of Research will monitor Investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the Investigator disclosed the FCOI

in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Official which will serve as documentation for compliance with the management plan.

### **9. Public Accessibility of the FCOI Guide and FCOI Information Held by Senior/Key Personnel**

**FCOI Guide:** A copy of the FCOI guide is posted on Chickasaw Nation's public website per the NIH requirements in the NIH Grants Guide Statement Section [4.1.10 Financial Conflict of Interest](https://grants.nih.gov/grants/guide/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm) at [https://grants.nih.gov/grants/guide/nihgps/HTML5/section\\_4/4.1.10\\_financial\\_conflict\\_of\\_interest.htm](https://grants.nih.gov/grants/guide/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm).

CNDH Division of Research will ensure public accessibility of its guide by posting the FCOI guide on its publicly accessible website ([Chickasaw Nation Website TBD and link added](#))

**Identified FCOIs held by Senior/Key Personnel:** Prior to the expenditure of any funds under an NIH award, CNDH Division of Research will ensure public accessibility by providing a written response to any requestor within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel;
2. CNDH Division of Research has determined that the SFI is related to the research funded through an award; and
3. CNDH Division of Research has determined that the SFI is a financial conflict of interest.

The information made available via the public website or in a written response will include, at a minimum:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. The approximate dollar value of the Significant Financial Interest in the following ranges:

\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

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The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of Chickasaw Nation's identification of a new FCOI which should be

requested subsequently by the requestor.

If the CNDH Division of Research uses a publicly accessible website to meet this requirement, the information posted will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key personnel related to the NIH-funded research that was not previously disclosed, or
- A new SFI being disclosed by Senior/Key personnel joining the project and determined by the designated official to be related to the research and an FCOI.

Information on SFIs subject to the public accessibility requirement will remain available for at least three years from the most recent update.

## **10. Reporting of Identified Financial Conflicts of Interest**

The CNDH Division of Research has an Authorized Official who serves as the FCOI Signing Official (SO) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. FCOI reports are submitted to the NIH only when a grant or cooperative agreement is active and an FCOI is identified (i.e., no award – no FCOI and no FCOI – no FCOI report). The FCOI Module User Guide is available at [https://www.era.nih.gov/files/fcoi\\_user\\_guide.pdf](https://www.era.nih.gov/files/fcoi_user_guide.pdf) to assist in submitting reports to the NIH.

**INITIAL OR ORIGINAL FCOI (2011 FCOI) REPORT:** The Original FCOI report will include the information required in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ

H.5. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52888>.

- **Prior to the Expenditure of Funds under a new award:** When an FCOI is identified upon the issuance of a new NIH award, the FCOI SO will submit an original report prior to the expenditure of any funds under an NIH award.
- **Within 60 days of Identifying a new FCOI During Award Period:** When an FCOI is identified during the period of an NIH-funded award (e.g., a new SFI is identified for an Investigator, or upon the participation of a new Investigator), CNDH Division of Research will provide to NIH within 60 days of identifying the FCOI, an Original FCOI report regarding the financial conflict of interest.

**ANNUAL FCOI REPORTS:** While the award is ongoing (including any extensions with or without funds), CNDH Division of Research will provide NIH with an annual FCOI report that addresses the status of the previously reported FCOI

(i.e., whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

The Annual FCOI report will be submitted at the same time as the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, if applicable, per the NIH guidance (see NIH’s FAQ H.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52860>). The NIH will send an annual report email notification to the Institution when an annual report is due. Annual FCOI reports are not submitted as part of grant closeout.

**REVISION (or Mitigation) FCOI REPORTS:** Following the completion of a retrospective review, Chickasaw Nation will provide NIH with a Revision if new information is discovered or a Mitigation Report if bias is found.

The types of FCOI reports and their requirements are summarized below:

<b>REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE</b>		
<b>REPORT</b>	<b>CONTENT</b>	<b>REQUIRED WHEN?</b>
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds  (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 Chickasaw Nation 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.

## 11. Training Requirements

Each Investigator will be informed about CNDH Division of Research Financial Conflict of Interest Guide and trained on the Investigator’s responsibility to disclose foreign and domestic SFIs per this guide and the FCOI regulation at 42 CFR Part 50 Subpart F.

FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- a. CNDH Division of Research revises this Guide, or procedures related to this Guide, in any manner that affects the requirements of Investigators;
- b. An Investigator is new to CNDH Division of Research research under an NIH award (training is to be completed prior to his/her participation in the research); or
- c. CNDH Division of Research finds that an Investigator is not in compliance with this Guide or a management plan issued under this Guide (training is to be completed within 30 days in the manner specified by the Designated Official(s)).

To fulfill the FCOI training requirement, CNDH Division of Research requires its Investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at [https://grants.nih.gov/grants/guide/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/guide/coi/tutorial2018/story_html5.html) in accordance with the requirements and expectations of this Guide. All Investigators must print a certification of completion at the end of training and retain it for audit purposes. Additionally, CNDH Division of Research requires its Investigators to review the NIH Virtual Seminar presentation on developing or refining Chickasaw Nation FCOI policies at <https://www.youtube.com/watch?vffD292Y26BX24>.

## **12. Failure to Comply with CNDH Division of Research Financial Conflict of Interest Guide Applicable to Public**

### **Health Service Funded Award**

Whenever Chickasaw Nation identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) will within 60 days: review the SFI, determine whether the SFI is related to research; determine whether an FCOI exists, 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 Chickasaw Nation Module.

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

- a. Failure by the Investigator to disclose a significant financial interest that is determined by CNDH Division of Research to constitute a FCOI;
- b. Failure by CNDH Division of Research to review or manage such an FCOI;
- c. Failure by the Investigator to comply with a management plan;

CNDH Division of Research will, within 120 days of determining non-compliance:

- a. Complete a retrospective review of the Investigator's activities and the PHS/NIH- funded research project to determine whether any NIH- funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;

- b. Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52895>.

If bias is found, CNDH Division of Research shall notify NIH promptly and submit a mitigation report per the regulation at 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. at

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52896> to NIH via the eRA Commons FCOI Module that shall address:

- a. Impact of the bias on the research project, and
- b. CNDH Division of Research plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, CNDH Division of Research will submit FCOI reports annually to NIH in accordance with the NIH guidance as provided in the summary chart above. Depending on the nature of the Financial Conflict of Interest, CNDH Division of Research may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of CNDH Division of Research's independent retrospective review.

If bias is not found, no further action will be taken unless new information is discovered that needs to be reported to the NIH. If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update 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.

### **13. Clinical Research Requirements**

If the Department of Health and Human Services determines that one of its funded clinical research projects, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by CNDH Division of Research, CNDH Division of Research shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

### **14. Subrecipient Requirements**

A subrecipient relationship is established when federal funds flow down from or through CNDH Division of Research to another individual or entity that is not a contract, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to CNDH Division of Research for programmatic outcomes and compliance matters. Subrecipients, including but not

limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to CNDH Division of Research's terms and conditions. CNDH Division of Research will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F and also follow internal subawarding as a pass-through entity policy.

CNDH Division of Research will incorporate, as part of a written agreement with the subrecipient, terms that establish CNDH Division of Research's FCOI Guide or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Guide Statement Section 15.2.1 Written Agreement at [https://grants.nih.gov/grants/guide/nihgps/html5/section\\_15/15.2\\_administrative\\_and\\_other\\_requirements.htm](https://grants.nih.gov/grants/guide/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm).

- a. **If the subrecipient's FCOI guide applies:** The subrecipient institution will certify as part of the agreement with CNDH Division of Research that its guide is in compliance with the federal FCOI regulation. The agreement shall specify the time period for the subrecipient to report all identified FCOIs to CNDH Division of Research (e.g., within 55 days of identification to allow CNDH Division of Research to report within 60 days) to enable CNDH Division of Research to provide timely FCOI reports to the PHS/NIH as required by the regulation. The CNDH Division of Research assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.
- b. **If the subrecipient cannot provide certification:** The agreement shall state that the subrecipient Investigator is subject to CNDH Division of Research's FCOI Guide for disclosing SFI(s) that are directly related to the subrecipient's work for CNDH Division of Research. CNDH Division of Research will require the submission of all Investigator disclosures of SFIs to CNDH Division of Research. The agreement will include sufficient time period(s) to enable CNDH Division of Research to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, CNDH Division of Research will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module.

## 15. Maintenance of Records

CNDH Division of Research and Grant Support Services will keep all records of all Investigator disclosures of financial interests and CNDH Division of Research's review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest), and all actions under this guide or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained for at least three years from the date of

submission of the final expenditures report or, where applicable, from other dates specified in 2 C.F.R. 200.334 for different situations.

CNDH Division of Research will retain records for each competitive segment as provided in the regulation. Management plans will be retained as part of the CNDH Division of Research records.

In addition, Chickasaw Nation will make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the CNDH Division of Research's review of, and response to such disclosure whether or not the disclosure resulted in the CNDH Division of Research's determination of an FCOI per the regulation 42 CFR 50.606(b).

#### **16. Enforcement Actions When an Investigator Fails to Comply with This Guide**

Compliance with this guide is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply with this guide are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.

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## 17. Responsibilities and Regulatory Citation

The CNDH Division of Research Responsibilities:	Regulatory Citation
Inform each Investigator of the:	42 CFR 50.604(b)
<ul style="list-style-type: none"> <li>• CNDH Division of Research's standard operating guide</li> </ul>	
<ul style="list-style-type: none"> <li>• Investigator's disclosure responsibilities of all foreign and domestic significant financial interests (SFI) per the SFI definition and NIH's FAQs E.9, and E.20</li> </ul>	
<ul style="list-style-type: none"> <li>• Federal regulation (See NIH's <a href="#">FAQ L.L</a>, "FCOI Training" tutorial and other training resources on NIH's <a href="#">FCOI Training website</a>)</li> </ul>	
Require each NIH-supported Investigator to complete FCOI training:	42 CFR 50.604(b)
<ul style="list-style-type: none"> <li>• Prior to engaging in research related to any NIH-funded grant</li> </ul>	
<ul style="list-style-type: none"> <li>• At least every four (4) years</li> </ul>	
<ul style="list-style-type: none"> <li>• Immediately, if:               <ul style="list-style-type: none"> <li>○ CNDH Division of Research revises its FCOI policy that affects requirements of Investigators</li> <li>○ An Investigator is new to research at the Chickasaw Nation</li> <li>○ An Investigator is not in compliance with the training guidance</li> </ul> </li> </ul>	
Trainees may complete <a href="#">CITI Program COI training</a> or NIH's <a href="#">FCOI Training Webpage</a> at <a href="#">FCOI Training   grants.nih.gov</a> to satisfy the training requirements related to the Federal regulation.	
<b>Disclosure, Review and Monitoring Requirements</b>	<b>Regulatory Citation</b>
Require each Investigator to disclose their foreign and domestic Significant Financial Interests (SFIs) (see FAQs D.8, and E.26) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities <sup>1</sup> (e.g., research, research consultation, teaching, professional practice, etc.) that meet the regulatory definition of SFI:	42 CFR 50.603
<ul style="list-style-type: none"> <li>• No later than at the time of application for NIH-funded research (see FAQ D.35)</li> </ul>	
<ul style="list-style-type: none"> <li>• At least annually during the period of the award</li> </ul>	
<ul style="list-style-type: none"> <li>• Within thirty (30) days of discovering or acquiring a new SFI</li> </ul>	
Designate CNDH Division of Research official(s) to:	42 CFR 50.604(d)
<ul style="list-style-type: none"> <li>• Solicit and review Investigator SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's Chickasaw Nation responsibilities for a determination of FCOI</li> </ul>	
Provide adequate guidelines consistent with the regulation for the designated official(s) to determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is an FCOI.	42 CFR 50.604(f)

<p>NOTE: An SFI is related to PHS/NIH-funded research when the CNDH Division of Research through its designated official(s), reasonably determines that the SFI:</p> <ul style="list-style-type: none"> <li>• could be affected by the PHS/NIH-funded research; or</li> <li>• is in an entity whose financial interest could be affected by the research.</li> </ul> <p>The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.</p> <p>An FCOI exists when the CNDH Division of Research, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.</p>	
<ul style="list-style-type: none"> <li>• Include the examples of conditions or restrictions that might be imposed to manage conflicts of interest (e.g., full public disclosure, appointment of an independent monitor, modification of the research plan, etc.). See regulation and NIH's <a href="#">FAQ F.1</a> for more information on how to manage an FCOI).</li> </ul> <p>Adding additional conditions to manage an FCOI is at the CNDH Division of Research's discretion.</p>	<a href="#">42 CFR 50.605(a)(1)</a>
<p>Require the designated official(s), prior to CNDH Division of Research's expenditure of funds, to:</p> <ul style="list-style-type: none"> <li>• Review all Investigator SFI disclosures</li> <li>• Determine if any SFIs relate to the Investigator's NIH-funded research</li> <li>• Determine if an FCOI exists (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)</li> <li>• Develop and implement a management plan to manage the FCOI(s)</li> </ul>	<a href="#">42 CFR 50.605(a)(1)</a>
<p>Require when an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the CNDH Division of Research's designated official(s) will:</p> <ul style="list-style-type: none"> <li>• Review disclosure(s) of SFIs within 60 days</li> <li>• Determine whether the SFI is related to the Investigator's NIH-funded research</li> <li>• Determine whether an FCOI exists; and, if so, implement at least on an interim basis a management plan that shall specify the actions that have and/or will be taken to manage the FCOI</li> </ul>	<a href="#">42 CFR 50.605(a)(2)</a>
<p>Require whenever the CNDH Division of Research identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the CNDH Division of Research during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) will:</p> <ul style="list-style-type: none"> <li>• Review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research</li> <li>• Determine whether an FCOI exists; and if so, implement at least on an interim basis a management plan that specifies the actions that have and/or will be taken to manage the FCOI going forward</li> </ul>	<a href="#">42 CFR 50.605(a)(3)(i)-(iii)</a>
<p>Take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.</p>	<a href="#">42 CFR 50.604 (g)</a> <a href="#">42 CFR 50.605(a)(4)</a>

**Reporting Requirements to NIH**

**Regulatory Citation**

<p>Send initial, annual (i.e., ongoing) and revised FCOI reports for the CNDH Division of Research's Investigators and those of its subrecipients, if applicable, including all required information defined in the regulation and in NIH's <a href="#">FAQ H.5</a>, to the NIH via the eRA Commons FCOI Module, as required by the regulation and as stated below:</p> <ul style="list-style-type: none"> <li>• Prior to the expenditure of funds</li> <li>• Within sixty (60) days of identification for an Investigator who is newly participating in the project</li> </ul>	<p><a href="#">42 CFR 50.604(h)</a></p> <p><a href="#">42 CFR 50.605(b)</a></p>
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<ul style="list-style-type: none"> <li>• Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators</li> </ul>	
<ul style="list-style-type: none"> <li>• At least annually (at the same time the CNDH Division of Research is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). <i>The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.</li> </ul>	<u>42 CFR 50.605(a)(3)(iii)</u>
<ul style="list-style-type: none"> <li>• Based on the results of a retrospective review, notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation report includes the key elements of the Retrospective review plus information to explain what action(s) have been or will be taken to mitigate the effects of the bias (i.e., <i>a description of the impact of the bias on the research project and the Chickasaw Nation Division of Research's plan of action(s) taken to eliminate or mitigate the effect of the bias.</i>)</li> </ul>	<u>42 CFR 50.605(a)(3)(iii)</u>
<ul style="list-style-type: none"> <li>• To ensure compliance with retrospective review and bias mitigation reporting requirements, the policy and/or procedures should include all the key elements documented in the retrospective review as well as the elements of a mitigation report that must be submitted to NIH.</li> </ul>	
Notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with the CNDH Division of Research's FCOI standard operating guide or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.	<u>42 CFR 50.606(a)</u>
Notify NIH promptly and take corrective action for noncompliance with the CNDH Division of Research's FCOI standard operating guide.	

**Maintenance of Records**

**Regulatory Citation**

Maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the CNDH Division of Research's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable,:	<u>42 CFR 50.604(i)</u>
<ul style="list-style-type: none"> <li>• For at least three (3) years from the date the final expenditures report (Final Federal Financial Report) is submitted</li> </ul>	
<ul style="list-style-type: none"> <li>• Or, where applicable, from other dates specified in <u>45 CFR 75.361</u> for different situations</li> </ul>	

**Enforcement Mechanisms and Remedies and Noncompliance**

**Regulatory Citation**

Abide by existing enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).	<u>42 CFR 50.604(j)</u>
Complete a retrospective review (see FAQs in <u>Section 1</u> ) within 120 days of the CNDH Division of Research's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:	<u>42 CFR 50.605(a)(3)(ii)(A)</u>
<ul style="list-style-type: none"> <li>• Failure by the Investigator to disclose an SFI that is determined by the CNDH Division of Research to constitute a financial conflict of interest</li> </ul>	
<ul style="list-style-type: none"> <li>• Failure by the CNDH Division of Research to review or manage such a financial conflict of interest</li> </ul>	
<ul style="list-style-type: none"> <li>• Failure by the Investigator to comply with the financial conflict of interest management plan</li> </ul>	
Document the retrospective review which shall include at a minimum the following key elements:	<u>42 CFR 50.605(a)(3)(ii)(B)</u>
<ul style="list-style-type: none"> <li>• Project Number</li> <li>• Project Title</li> <li>• PD/PI or contact PD/PI if multiple PD/PI model is used</li> </ul>	

<ul style="list-style-type: none"> <li>Name of the Investigator with the FCOI</li> <li>Name of the entity with which the Investigator has an FCOI</li> <li>Reasons for the retrospective review</li> <li>Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)</li> <li>Findings of the review</li> <li>Conclusions of the review</li> </ul>	
Ensure that in any case in which the Department of Health and Human Services determines that an NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the CNDH Division of Research as required by the regulation, the CNDH Division of Research shall require the Investigator involved to:	42 CFR 50.606(c)
<ul style="list-style-type: none"> <li>Disclose the FCOI in each public presentation of the results of the research, and</li> <li>Request an addendum to previously published presentations.</li> </ul>	

Subrecipient Requirements	Regulatory Citation
Address FCOI subrecipient requirements (See <a href="#">FAQ K.1</a> ) including compliance with NIH subaward/consortium written agreement requirements provided in the NIH Grants Policy Statement Section 15.2.1:	42 CFR 50.604(c) (also see NIH Grants Policy Statement 15.2.1)
<ul style="list-style-type: none"> <li>Establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.</li> </ul>	42 CFR 50.604(c)(1)(i)-(iii)
<ul style="list-style-type: none"> <li>Obtain a certification from the subrecipient that its FCOI policy complies with the regulation.</li> </ul>	
<ul style="list-style-type: none"> <li>Include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation.</li> </ul>	
<ul style="list-style-type: none"> <li>Alternatively, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.</li> </ul>	

Public Accessibility Requirements	Regulatory Citation
Make the CNDH Division of Research's FCOI Standard Operating Guide accessible by email request to <a href="mailto:ChickasawNationIRB@chickasaw.net">ChickasawNationIRB@chickasaw.net</a> , and available on the Chickasaw Nation's OneAegis IRB Manager system.	42 CFR 50.604(a) (also see NIH GPS 4.1.10)
Make available information concerning identified FCOIs held by appropriate personnel (as defined by the regulation, not the NIH Grants Policy Statement), accessible prior to the expenditure of funds. See FAQs in <a href="#">Section G.1</a> .	42 CFR 50.605(a)(5)(i)-(iv)
The accessible information will:	
<ul style="list-style-type: none"> <li>Include the minimum elements as provided in the regulation</li> <li>Made available within five (5) business days of a written request per CNDH approval processes</li> <li>Be reviewed at least annually (written requests should include the updated information)</li> <li>Remain available for three (3) years from the date the information was most recently updated</li> </ul>	

## 18. References

- A. Chickasaw Nation Department of Health Research Integrity Policy
- B. NIH's email address to send FCOI-related inquiries: [FCOICompliance@mail.nih.gov](mailto:FCOICompliance@mail.nih.gov)
- C. FCOI Regulation 42 CFR Part 50 Subpart F: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- D. Financial Conflict of Interest: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>

- E. FCOI Training: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>
- F. FCOI Frequently Asked Questions (FAQs): <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff3875>
- G. Information for Foreign Grants: <https://grants.nih.gov/new-to-nih/information-for/foreign-grants>
- H. NIH's Welcome Wagon Letter: <https://grants.nih.gov/policy-and-compliance/welcome-wagon>
- I. NIH Grants Policy Statement: <https://grants.nih.gov/policy/nihgps/index.htm>
- J. NIH Guide for Grants and Contracts: <https://grants.nih.gov/funding/guide.htm>
- K. NIH Extramural Nexus:  
<https://public.govdelivery.com/accounts/USNIHOER/subscriber/new?qsppfCODERED>

## **19. Attachments**

- A. [CNDH Research FCIO Disclosure Form](#)
- B. [CNDH Research Policy](#)