1.25 Financial Conflicts of Interest

1.0 Purpose

The purpose of this policy is to describe the Organization’s procedures for identification, management, and minimization or elimination of financial conflict of interest (COI) of responsible personnel, senior administrators, and the Organization itself that could influence the conduct of research or the integrity of the HRPP.

2.0 Policy

It is the policy of the Organization that:

- 2.1. All potential financial COIs of responsible personnel engaged in non-exempt research (1) within the premises of the Organization, or (2) by any faculty, students, staff or other representatives of the Organization, or by Organizational officials, must be identified and minimized through appropriate management in accordance with a) PHS regulations at 42 CFR 50, Subpart F; b) National Science Foundation (NSF) regulations; c) FDA regulations at 21 CFR 54; d) University of Nebraska Board of Regents Policies #3.2.8.10 and #4.4.2, e) UNMC policy #8010, f) UNO Academic and Research Financial Conflict of Interest Policy, g) Children’s Hospital & Medical Center policy #ADM100, and h) Children’s Hospital & Medical Center Board of Directors Conflict of Interest Policy.
- 2.2. The IRB will interact with the COI Officers, Conflict of Interest Committees (COICs), and/or senior administrators of the applicable components of the Organization who are responsible for compliance and/or COI, in accordance with the above specified regulations and policies to ensure that appropriate COI management plans are in place to protect the rights and welfare of human subjects when investigators, senior administrators, or the Organization itself has a COI.

- 2.3. Any changes in financial interest must be promptly disclosed and managed in accordance with Section 2.1 above.
- 2.4. The Office of Regulatory Affairs will ensure that the organization has adequate policies and procedures to ensure responsible personnel are appropriately trained concerning the identification, disclosure, and management of COI. This includes initial education, immediate re-education when there are policy changes and appropriate re-education when there is noncompliance with the COI policy.

3.0 Definitions

- 3.1. Responsible Personnel: any faculty, students, staff, or other representatives of the Organization listed in Section I of the IRB application who are responsible for the design, conduct, or reporting of research, or the development of proposals to conduct research. This includes: Principal Investigator, Secondary Investigator(s), Participating Personnel, and Protocol Coordinator(s). Data and Administrative Personnel are not considered Responsible Personnel for the purposes of this policy.
- 3.2. Covered Persons: Responsible Personnel, as defined above, and immediate family members of a Covered Person (spouse, dependent children, parents, or anyone that a Covered Person may claim as a dependent under the Internal Revenue Code).
- 3.3. Conflict of Interest (COI): situations when the Covered Persons' direct or indirect personal financial interests or fiduciary duties owed to third parties may compromise, or have the appearance of compromising, a Covered Person's professional judgment or behavior in carrying out his or her research obligations including the individual's obligation to protect the rights and welfare of research subjects. This includes indirect personal financial interests of a Covered Person that may be obtained through third parties such as a Covered Person's immediate family, business relationships, fiduciary relationships, or investments.
- 3.4. Significant Financial Interest: a financial interest of the Covered Person that reasonably appears to be related to the Responsible Person's institutional responsibilities during the course of the research. An interest "related to the research" is one the COI Officer, COI committee, or the IRB reasonably determines could directly and significantly affect the design, conduct or reporting of research. A significant financial interest is defined as (1) anything of monetary value that exceeds $5,000 which the Covered Person has received in the past 12 months preceding the disclosure or intends to or had knowledge of earning during the reporting year; or (2) any equity in a non-publicly traded company.
  - 3.4.1. Financial interests not considered in the determination of "significant financial interest include (1) salary or other remuneration from the Organization, (2) income from seminars, lectures, or teaching engagements sponsored by governmental entities, and (3) income from service on advisory committees or review panels for governmental entities
- 3.5. Non-Significant Financial Interest: any financial interest that does not qualify as a significant financial interest as defined in Section 3.4 of this policy.

- 3.6. Organizational COI: a situation when the Organization itself, or any of its component parts, or any of senior organizational officials, have a financial interest in the design, conduct, or outcome of human subject research. Organizational financial COI includes: a) licensing, technology transfer, patents; b) investments of the Organization; c) gifts to the Organization when the donor has an interest in the research; d) financial interests of senior administrators; e) other financial interests.
- 3.7. COI Committee (COIC): the Committee responsible for reviewing potential conflicts of interest which have been determined to be significant, developing the management plan, and providing the information to the IRB. If a component of the organization does not have a committee per se, COIC hereinafter will mean the Conflict of Interest Officer, or the senior administrator of the applicable components of the Organization who are responsible for compliance and/or COI.

4.0 Procedures for Disclosure of Potential COI

- 4.1. Any Responsible Personnel listed on the IRB application who has a COI must disclose that financial interest in accordance with the applicable policy specified in Section 2.1 above.
- 4.2. Responsible Personnel conducting FDA regulated research must disclose their financial interests in accordance with 21 CFR 54.4.

5.0 COI Management Plan

- 5.1. A COI Management plan will be developed for research where responsible personnel have a significant financial interest.
  - 5.1.1. For multi-institution research where the UNMC IRB is the reviewing IRB, the COI Management plan may be generated by the relying institution, in accordance with the terms of the reliance agreement.
- 5.2. The COI management plan may include an appropriate disclosure of the presence of a financial COI of the Responsible Person(s) in the consent form, in any presentations, publications, or news articles regarding the research, and to all personnel involved in the research including students. Additional management strategies may include (but are not limited to) more frequent and/or independent monitoring of the research; modification of

the research protocol to manage potential bias (for example, through blinding); monitoring of the consent process; divesting or appropriately reducing the financial interest giving rise to the COI; severing relationships existing between the Covered Person and the company or other entity that is the source of the COI; or disqualification of the Covered Person from participation in all or a portion of the research.

- 5.3. In addition to any features required by the COIC and the IRB, the COI management plan will prohibit:
  - 5.3.1. Any arrangement where the value of ownership interests will be affected by the outcome of the research.
  - 5.3.2. Any arrangement where the amount of compensation will be affected by the outcome of the research.

6.0 Review of COI Management Plans

- 6.1. Management plans for responsible personnel with non-significant financial interest will not be reviewed by the convened IRB. The ORA will be notified by the Compliance Office of the management plan, and the investigator’s agreement to abide by it.
- 6.2. Management plans for responsible personnel with significant financial interest will be reviewed by the convened IRB (for FB studies) or by an expedited reviewer (for EP studies).
- 6.3. For management plans reviewed by the convened IRB the following apply:
  - 6.3.1. The full IRB will be provided with the COI management plan approved by the COIC.
  - 6.3.2. The COI Officer, the IRB Executive Chair, the IRB chair or designee will verbally describe the nature of the financial interest, and the specifics of the management plan proposed by the COIC. Note: Members of the full IRB are not provided written copies which detail the specifics of the financial interest but are given ranges of the financial interest (e.g., $5,000 to $9,999; $10,000 to $19,999).
  - 6.3.3. The full IRB must approve the COI Management Plan proposed by the COIC before the protocol is approved and released or may require a more stringent COI management plan. The IRB may not adopt a less stringent plan than that approved by the COIC.
- 6.4. For management plans reviewed by an expedited reviewer, the reviewer may approve the plan, or may refer to the convened IRB if he/she believes that a more stringent COI management plan is required. The expedited reviewer may not adopt a less stringent plan than that approved by the COIC.
- 6.5. Management plans for responsible personnel with significant financial interest who are participating in a study where the Organization relies on an external IRB (CB) will not be reviewed by the convened IRB. The ORA will acknowledge receipt of the plan and will instruct the PI to notify the IRB of record.
- 6.4. In all cases, the COI Management plan may be reviewed by Organizational officials, who may require a more stringent COI management plan. The Organization may not adopt a less stringent plan than that approved by the IRB of record.

7.0 Management of COI in Research Conducted by Subgrantees, Contractors, and Collaborators

- 7.1. If the research is conducted at an external site and involves subgrantees, external contractors or collaborators with any financial interest related to the research, the PI must provide verification to the ORA that the individual(s) are in compliance with the external institution’s COI policy which meets the requirements of 42 CFR 50.604.
- 7.2. If the external site does not have a COI policy which meets the requirements of 42 CFR 50.604 the requirements of the applicable policy under Section 2.1 above must be met.

8.0 Documentation of COI Management

- 8.1. The COI Management Plan approved by the IRB will be maintained in the protocol file in the ORA for no less than seven years following cessation of the outside activity to which they relate.

9.0 Management of Organizational Financial COI

- 9.1. Organizational financial COI may occur when the Organization itself, or any of its component parts, or any senior organizational officials, have a financial interest in the design, conduct, or outcome of human subject research.
- 9.2. In accordance with Board of Regents Policies 3.2.8.10 and 4.4.2, the University of Nebraska may accept royalties, equity, or other forms of compensation when technology is licensed, or new companies are formed to commercialize University technology.
- 9.3. Every potential Organizational COI must be reported to the appropriate COI Officer as soon as it is identified.
- 9.4. Organizational COI may be identified through:
  - 9.4.1. the required disclosure of financial interest of the Responsible Personnel at the time the IRB application is submitted.
  - 9.4.2. the required annual disclosure of financial interest of senior administrators when it relates to human subject research.
  - 9.4.3. review by technology transfer officials or other officials at organizational components.
- 9.5. If an Organizational COI is identified the COI Officer of the involved component shall convene a group of senior Organizational officials and unaffiliated individuals, appointed by the appropriate Chancellor, CEO or designee, to review the potential Organizational COI and propose any required management plans for approval.
- 9.6. Initial review of non-exempt human subject research for which an organizational COI has been identified will be performed by the convened IRB.
- 9.7. The COI Officer will provide the full IRB with the COI committee's approved COI Management Plan.
- 9.8. The COI Officer or the IRB Executive Chair/designee will describe the nature of the financial interest, and the specifics of the management plan proposed by the COIC.
- 9.9. The IRB will review the management plan and if any concerns are identified, these will be conveyed to the COI officer for further consideration and action.
- 9.10. The IRB must be assured that any Organizational COI is appropriately managed in the interest of the safety and welfare of human subjects.
- 9.11. Organizational COI management plans approved by the IRB will be maintained in the ORA for no less than seven years following cessation of the activity.

DOCUMENT HISTORY:

? Written: 4/14/2016 (Approved: 4/14/2016) - original author not recorded (previous policy #3.12)

? Revised: 6/13/2018 - revision not documented

? Revised 12/8/2022 - Clarified that the ORA is only responsible for assuring the organization has adequate policies and procedures to ensure responsible personnel are appropriately trained (as opposed to the actual training); revised definition of covered persons to match that in HRPP 1.7; clarified definition of Organizational COI; delete specific FDA requirements under 21 CFR 54.4; clarified that, for multi-institution research where the UNMC IRB is the reviewing IRB, the COI Management plan may be generated by the relying institution; clarified that management plan may (but not "must") include disclosure; clarified process for management plans associated with non-significant FCOI; deleted list of possible management options by COIC; clarified process for expedited review as opposed to convened IRB review; clarified process for review of management plans when organization relies on an external IRB; added requirement that initial review of non-exempt human subject research for which an organizational COI has been identified will be

performed by the convened IRB; added “senior organizational officials” to definition of Organizational COI.{Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board voted and approved: 12/27/2022, 1/13/2023, 1/19/2023, 2/2/2023

? Revised: 6/1/2023 – added examples of possible management options by COIC (section 5.2) as per AAHRPP {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised:8/31/2023 - updated CHMC COI policy name from #ADM100 to ID 13201440. {Robert Lewis - IRB Assoc}

? Revised 1/22/2024 – clarified that an interest “related to the research” is one the COI Officer, COI committee, or the IRB reasonably determines could directly and significantly affect the design, conduct or reporting of research (section 3.4). {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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