## 1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for the identification and management of IRB member, IRB consultant, and IRB staff potential conflicts of interest.

## 2.0 Policy

It is the policy of the Organization that all potential financial and non-financial conflicts of interest that IRB members, IRB consultants, and IRB staff must be self-identified to the best of the individual's knowledge and appropriately managed to prevent such conflicts from interfering with the objectivity and validity of the expedited or full board review process. The Organization does not require disclosure of the specifics of the conflict unless an exception is requested.

## 3.0 Definitions

**3.1** ***Covered Persons:*** Covered persons are IRB members, IRB consultants, IRB staff 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).

**3.2** ***Potential Conflicts of Interest:*** The following are financial and non-financial conflicts of interest that exclude IRB members, IRB staff, and IRB consultants from participating in the IRB review of protocols, amendments, adverse event reports, unanticipated problems involving risk to the subject or others, noncompliance, complaints, or other problems that are related to the conduct of human subject research. In addition, IRB staff who have any of the conflicts listed below are excluded from serving as the key IRB administrator assigned to process the study in question.

**A.** The covered person serves as an investigator and is, accordingly, listed on the IRB application or is serving as a scientific/medical advisor to the PI.

**B.** The covered person is an advisor, or a direct supervisor, of a trainee's (e.g., medical, graduate or undergraduate student) research.

**C.** The covered person has a financial interest (in any amount) defined as: 1) salary, royalties (or a commitment for future royalties), consulting fees, honoraria, gift(s), or other payments that has been received in the last twelve months, will be received while the research is being conducted or will be received within twelve months after the research is completed; or 2) an equity interest in the sponsor of the research. Mutual funds are excluded.

**D.** The covered person holds a position as director, officer, partner, trustee, or any other significant position in the company sponsoring the research or has held such a position in the past twelve months.

**E.** The covered person holds patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving the Organization as described in *HRPP policy #1.1, Section 3.1.*

**F.** The covered person has a financial interest (as defined above) in a company which has a marketed product, or is in the process of developing a new product which is, or will be, in direct market competition with the product in the protocol under IRB review.

**G.** The covered person has a personal relationship, or a conflict, with any research personnel listed on the IRB application which would potentially cause the IRB member, in his/her opinion, to be less than objective in their review.

**H.** If a covered person is listed on the IRB application as a participating physician or other study personnel and will be involved in both obtaining and documenting informed consent as well as providing clinical care, that individual may serve as a primary or secondary IRB reviewer and participate in the discussion. Such IRB member reviewers, however, are required to abstain from voting.

*Note: In the following instances the covered person does **not** have a conflict of interest:*
*1) The individual serves on the sponsor's scientific advisory board for an area unrelated to the research under review.*

*2) The individual serves on an NIH study section or FDA advisory committee, where it has been determined by the NIH/FDA that a conflict does not exist.*

*3) The individual is listed on the IRB application as a participating physician or other study personnel and the **only** involvement in the protocol is in the context of providing clinical care to subjects. The individual will not obtain and document informed consent or be included as an author on any publications arising from the research.*

## 4.0 Procedures for identification and management of conflict of interest

**4.1** All IRB members must notify the IRB Executive Chair/designee of a potential conflict of interest in advance of the IRB meeting or upon assignment as an expedited reviewer for any action under review (i.e., review of new research, changes, continuing review, adverse events, unanticipated problems involving risk to subjects or others, and noncompliance). If the IRB member is uncertain if a potential conflict of interest exists, they are encouraged to consult with the IRB Executive Chair/designee.

**4.2** Whenever a prospective consultant is asked to review a protocol, he/she will be provided with a copy of this policy and will be excluded from serving as a consultant if a conflict exists. Consultants must certify in writing that they do not have a conflict of interest.

**4.3** Prior to the beginning of each meeting, IRB members will be asked to declare the existence of any undisclosed conflicts, but are not required to describe the nature of the conflict.

**4.4** All IRB staff must immediately notify the IRB Executive Chair/designee if a conflict exists. The IRB Executive Chair/designee will determine what action is necessary.

**4.5** When an IRB member has a conflict of interest, he/she must be absent from the meeting room during the discussion and voting phases of the review of the protocol in question. The IRB member may not vote on any protocol where he/she has a conflict of interest as defined above. Upon request of the IRB the member may provide information or respond to questions. The absent member is not counted towards determination of quorum during the vote on the protocol in question.

**4.6** If an IRB member has a conflict of interest as defined by Section 3.2 of this policy, but in their opinion, the conflict will not interfere with the objectivity and validity of the review, the member may request approval of an exception to allow them to serve as a reviewer and be granted voting privileges. In such cases, the following procedure must be followed:

**A.** The IRB member must disclose the specifics of the conflict to the IRB Executive Chair/designee.

**B.** The IRB member must indicate whether they wish to serve as follows: (1) assignment as a primary or secondary reviewer with or without voting privileges; or (2) no assignment as a primary or secondary reviewer, but with voting privileges.

**C.** The IRB Executive Committee will review the conflict and determine whether or not the exception will be granted.

**D.** The full IRB will be notified that an exception has been granted and may request further details. The full IRB has the authority to overturn approval of an exception.

**4.7** The IRB meeting minutes will specifically record that COI is the reason any IRB member is out of the room and did not vote.

**ADMINISTRATIVE APPROVAL:**
Ernest D. Prentice, PhD. Associate Vice Chancellor for Academic Affairs and Institutional Official
Bruce G. Gordon, MD IRB Executive Chair

## 1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's procedures for identification, management, and minimization or elimination of financial conflict (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

**2.1** It is the policy of the Organization that all potential financial COIs of responsible personnel engaged in non-exempt research under oversight of the Organization's IRBs and 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; and d) the University of Nebraska Board of Regents Policies #3.2.8.10 and #4.4.2, e) the *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, COICs, and senior administrators of the applicable components of the Organization 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 in accordance with Section 2.1 above.

**2.4** The IRB will ensure that 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***: Responsible Personnel are defined as those study personnel 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: PI, 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, are considered Covered Persons for the purposes of this policy. In addition, <u>any</u> financial interest related to the research accruing to the immediate family, including the following: spouse, child, brother, sister, grandchild, or grandparent, by blood, marriage, or adoption of the Covered Person are bound by this policy.

**3.3** ***Conflict of Interest (COI):*** A COI refers to 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 significant financial interest means 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. A significant financial interest is defined as anything of monetary value that exceeds $5,000 which the Covered Person has received in the past 12 months preceding the disclosure, or any equity in a non-publicly traded company.

**3.5** ***Non-Significant Financial Interest:*** The Covered Person has a non-significant financial interest defined as any financial interest that does not qualify as a significant financial interest as defined in Section 3.4 of this policy.

**3.6** ***Financial Interests not Considered:*** The following are financial interests that are not covered by this policy:

**A.** Salary or other remuneration from the Organization

**B.** Income from seminars, lectures, or teaching engagements sponsored by governmental entities

**C.** Income from service on advisory committees or review panels for governmental entities

**3.7** ***Organizational COI:*** 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.

**3.8** ***COI Committees (COICs):*** The UNMC COIC, UNO COIC, and the CHMC COI Office are 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.

**3.9** ***IRB COI Administrator:*** The IRB COI Administrator is the individual assigned responsibility for facilitating IRB review of COI management plans.

## 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 by also submitting Form FDA 3455 to the sponsor. The IRB does not require a copy of this form.

## 5.0 COI Management Plan

**5.1** The COI management plan will include an appropriate disclosure of the financial interest(s) of the Responsible Person(s) in the consent form as well as in any presentations, publications, or news articles (e.g., *UNMC Today*).

**5.2** The COI management plan may also include any of the following in consideration of the nature and magnitude of the financial interest of the Covered Person:

**A.** More frequent monitoring of the research

**B.** Independent monitoring of the research

**C.** Modification of the research protocol to manage potential bias through means such as blinding; modifying the scope of the project; and setting timetables for delivery of the product.

**D.** Designation of a peer or supervising co-investigator with no COI in the project to assume the lead investigative role.

**E.** Monitoring of the consent process.

**F.** Divesting or appropriately reducing the financial interest giving rise to the COI with restrictions on re-investment for an appropriate period to provide for publication and critique of the completed research.

**G.** Severing relationships existing between the Covered Person and the company or other entity that is the source of the COI.

**H.** Removing contract terms which create the COI. For example, under no circumstances shall UNMC engage in projects where payment is defined by the outcome of the research.

**I.** Disqualification from participation in all or a portion of the research (e.g., may not enroll human subjects, obtain informed consent or analyze data).

**J.** Any additional management strategies as determined by the appropriate COIC and/or the IRB.

**5.3** The following are strictly prohibited:

**A.** Any arrangement where the value of ownership interests will be affected by the outcome of the research.

**B.** Any arrangement where the amount of compensation will be affected by the outcome of the research.

## 6.0 Full IRB Review of Significant Risk COI Management Plans

**6.1** The COI Officer will provide the full IRB with the committee's approved COI Management Plan.

**6.2** The COI Officer or the IRB Executive Chair/designee will verbally describe the nature of the financial interest, and the specifics of the COIC management plan.
*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…). It is the position of the Organization that the financial interests of its employees should remain as confidential as possible.*

**6.3** The full IRB must approve the COI Management Plan before the protocol is approved and released.

**6.4** The IRB may require a more stringent COI management plan, but may not adopt a less stringent plan approved by the COIC.

**6.5** Organizational officials cannot overrule the IRB's determination.

## 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 (7) 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, has 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.

**A.** Organizational COI may be identified through the required disclosure of financial interest of the Responsible Personnel at the time the IRB application is submitted.

**B.** Organizational COI may be identified through the required annual disclosure of financial interest of senior administrators when it relates to human subject research.

**C.** Organization COI may be identified by technology transfer officials or other officials at UNMC, UNO, and CHMC.

**9.4** When Organizational COI is identified communication will be carried out with appropriate officials in order to ascertain the specifics of the Organizational COI.

**9.5** The COI Officer of Component shall convene a group of senior Organizational officials and unaffiliated individual(s) who will be appointed by the appropriate Chancellor, CEO or designee to review the potential Organizational COI and propose any required management plans for approval.

**9.6** The COI Officer will provide the approved management plan to the ORA.

**9.7** 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.

**9.8** The IRB must be assured that any Organizational COI is appropriately managed in the interest of the safety and welfare of human subjects.

**9.9** Organizational COI management plans approved by the IRB will be maintained in the ORA for no less than seven (7) years following cessation of the activity.

**ADMINISTRATIVE APPROVAL:**
Ernest D. Prentice, PhD. Associate Vice Chancellor for Academic Affairs and Institutional Official
Bruce G. Gordon, MD IRB Executive Chair