

## FCOI

### IOWA ONCOLOGY RESEARCH ASSOCIATION (IORA) /

### IOWA-WIDE ONCOLOGY RESEARCH COALITION (IWORC)

## POLICY ON FINANCIAL CONFLICT OF INTEREST IN RESEARCH

### **Introduction**

The IORA/IWORC NCORP, its physician investigators and employees are committed to the principle of open and objective inquiry in the conduct of research. The IORA /IWORC operates on the belief that conflicts of interest should be avoided where possible, or otherwise disclosed and managed.

### **Purpose**

This policy implements federal requirements [42 CFR Part 50 Subpart F] adopted by the Public Health Service [PHS] of the U.S. Department of Health and Human Services [DHHS] pertaining to objectivity in research and the disclosure of financial interests for NIH grants or cooperative agreements. The policy serves to establish standards which provide a reasonable expectation that the design, conduct and report of research is free from bias resulting from financial conflicts of interest.

This policy applies *in addition to* general institutional policies, such as policies on standards of conduct.

### **Definitions**

Institution refers to any organization that is applying for or that receives NIH research funding. For the purposes of this policy, “Institution” refers to the Iowa Oncology Research Association/Iowa-Wide Oncology Research Coalition National Cancer Institute Community Oncology Research Program [IWORC NCORP], which includes the NCORP office in Des Moines as well as all component sites.

Institutional Responsibilities means any of the professional responsibilities of a covered individual on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, or service on an institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest [FCOI] means a Significant Financial Interest [SFI] that could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

Manage means taking action to address an FCOI.

Senior/Key Personnel means the Principal Investigator and any other person identified as Senior / Key Personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution.

## **Section 1 Coverage**

### **1.1 Covered Individuals**

This policy covers all individuals who, regardless of title or position, are responsible for the design, conduct or reporting of research. A person required to file and update financial disclosure statements is henceforth referred to in this policy as a “covered individual”.

The financial interests of a covered individual’s spouse and dependent children must also be reported per federal regulations.

For the Institution, covered individuals include but are not limited to, the Principal Investigator, all rostered IORA CCOP physician investigators and research staff who meet the above definition, including those at affiliate sites of the Institution. When it is questionable as to whether an individual is covered under this policy, the Principal Investigator will make that determination with the advice and counsel of local IRBs and NIH Office of Extramural Research and/or DHHS, if needed.

### **1.2 Sub-Recipients[Affiliate Sites]**

For research that is carried out in cooperation with an entity identified under federal regulations as a “sub-recipient” of the Institution, i.e. affiliate sites, the main Institution must enter into a written agreement with each site which establishes that this policy also pertains to covered individuals at those institutions.

The agreement must specify the time periods for the affiliate sites to report identified financial conflict of interest to the their local IRB and the Institution. The time periods must be sufficient for the review, management, and reporting obligations to be met under federal regulations.

## **Section 2 –Responsibilities of Covered Individuals**

### **2.1 Policy**

Each covered individual must acknowledge in writing annually that the individual is aware of and has read this policy and is aware of the covered individual’s responsibilities regarding disclosure of significant financial interests and of applicable federal regulations. If this policy is revised, covered individuals must also acknowledge in writing they have reviewed the revised policy.

## **2.2 Training**

Each covered individual must complete training in regard to this policy and other applicable policies, regulations, and laws:

- 1) Before engaging in research through the IORA /IWORC
- 2) At least once every four years thereafter
- 3) Immediately if the Institution finds that the individual is not in compliance with this policy or if the Institution revises this policy in a manner that affects the individual's duties.

## **2.3 Disclosure of Significant Financial Interests Related to Institutional Responsibilities**

### **(a) Significant Financial Interests**

The following interests are considered to be significant financial interests and, subject to the exclusions provided by Subsection 2.3b, a covered individual's disclosure statement must include the following information in regard to the covered individual (and those of their spouse and dependent children), *but only in regard to interests that reasonably appear to be related to the individual's institutional responsibilities*:

#### **(i) PAYMENTS RECEIVED FROM OR EQUITY INTEREST IN A PUBLICLY TRADED ENTITY:**

With regard to any 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 the disclosure, when aggregated, exceeds \$5,000. For purpose 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) PAYMENTS RECEIVED FROM A NON-PUBLICLY TRADED ENTITY OR EQUITY INTEREST IN A NON-PUBLICLY TRADED ENTITY:**

With regards to any 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 covered individual (or the covered individual's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest).

#### **(iii) INTELLECTUAL PROPERTY AND ROYALTIES:**

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

#### **(iv) TRAVEL:**

Covered individuals also must disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the covered individual and not reimbursed to the covered individual so that the exact monetary value may not be readily available) within the preceding twelve months, related to their institutional responsibilities. The following details must be disclosed: a) the purpose of the trip, 2) the identity of the sponsor, 3) the destination and duration. The Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest (FCOI) with PHS-funded research.

### (b)Exclusions

The following interests are **NOT** significant financial interests and need not be disclosed on the disclosure statement:

- (i) Salary, royalties, or other remuneration paid by the Institution to the covered individual, if the covered individual is currently employed or otherwise appointed by the Institution.
- (ii) Income from seminars, lectures, or teaching engagements sponsored by a federal , state or local government , an Institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
- (iii) Income from service on an advisory committee or review panel for a federal, state or local government, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic or teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
- (iv) Income from investment vehicles such as mutual funds, or retirement accounts, as long as the covered individual does not directly control the investment decisions made in those accounts.
- (v) Travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

### **2.4 When to Submit Disclosure Statements**

A covered individual shall submit or update a financial interest disclosure statement:

- (i) Not later than the 30<sup>th</sup> day after initial employment or the 30<sup>th</sup> day after becoming a physician investigator. The statement should cover the twelve months preceding the date of disclosure.
- (ii) Annually no later than August 15<sup>th</sup>. The Institution's COI Committee will notify covered individuals 45 days by mail and / or email before the annual disclosure statement is due.
- (iii) No later than the 30<sup>th</sup> day after acquiring a new financial interest that requires disclosure as noted in Section 2.3a, such as receiving payments, an equity interest, intellectual property rights or royalties that would require disclosure on an annual financial interest statement.

### **2.5 Disclosure Guidelines**

In making disclosures, the covered individual will:

- (i) When describing a source, provide the name of the source.
- (ii) Distinguish among information pertaining to the covered individual and covered family members whose financial interests are also disclosed by the covered individual.

Disclosure will be accomplished by completing the Financial Disclosure Form and submitting it to the IORA CCOP Designated FCOI Official.

In determining whether research or a financial interest should be disclosed, the covered individual should resolve the question in favor of disclosure.

## **Section 3 Institutional Responsibilities**

### **3.1 Designated Conflict of Interest Official**

The designated Conflict of Interest Official for the Institution is the Regulatory Coordinator who will perform the initial review of all financial conflict of interest forms. This Official will report findings directly to the Institution's Conflict of Interest Committee and the local Institutional Review Boards.

### **3.2 Conflict of Interest Committee**

The Conflict of Interest Committee for the Institution shall provide advice on policy development, assist with training and review conflict of interest issues. Members of the Committee will include the Administrator, Principal Investigator, and Research Integrity Officer as well as the COI Official.

### **3.3 Training**

The IORA/IWORC Principal Investigator, Administrator, COI Official and Research Integrity Officer are responsible for the development[and revision, if applicable]of the training program as well as ensuring that appropriate staff and investigators participate in training per federal regulations and institutional policy.

### **3.4 Determination of Financial Conflict of Interest**

- (i) Within 30 days after receipt, the designated Conflict of Interest Official will make an initial review of all financial disclosure forms. The Official will submit forms that identify significant financial interests or potential conflicts of interest to the Institution's Conflict of Interest Committee for further review.
- (ii) After the Institution's Conflict of Interest Committee has fully reviewed the submitted forms, the Committee will determine whether any significant financial interest disclosed is related to research in which the covered individual is engaged and if so, whether a financial conflict of interest exists according to the definitions in Sections 2.3a and 2.3b.
- (iii) The Institution's Conflict of Interest Official will also submit all disclosure forms to the local Institutional Review Boards [IRBs] per the IRB's policy. Both the Institution and the local IRBs will review financial disclosure forms. Although this results in a duplication of reviews, it is the policy of the Institution that if there is conflicting interpretations or doubt as to whether a financial conflict of interest exists, the question should be resolved in favor of the existence of a financial conflict of interest.

### **3.5 Management of Financial Conflict of Interest**

Timely, complete and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment at the Institution and a covered individual who does not comply with this policy is subject to discipline, including termination of employment. For a covered individual who is not an employee of the Institution, compliance with this policy is a condition of participating with the Institution in the capacity that qualifies the person as a covered individual.

If it is determined by the Institution's Conflict of Interest committee and/or the local IRBs that a covered individual has a financial conflict of interest, a management plan governing that conflict of interest will be developed and implemented within 60 days.

(a) A management plan must be in the form of a written agreement and must include the following elements:

- (i) Role and duties of the conflicted individual
- (ii) Conditions of the management plan, as noted below
- (iii) How the plan is designed to safeguard objectivity in the research project
- (iv) How the plan will be monitored to ensure a covered individual's compliance

The covered individual must acknowledge in writing receipt of the plan and understanding of the requirements of the plan and required actions.

(b) A management plan may impose any condition and prescribe any action necessary to manage a financial conflict of interest, including an action reducing or eliminating the financial conflict of interest, to ensure that the design, conduct or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be taken include:

- (i) Public disclosure of the conflict of interest in presentations or publications
- (ii) Direct disclosure of the conflict of interest to research participants
- (iii) Monitoring of the research by independent Ethics Committee or IRB
- (iv) Modifications of the research plan
- (v) Limitation of the covered individual's involvement; change of personnel or personnel responsibilities or disqualification of a covered individual from participation in all or a portion of the research

Management plans will be submitted to the local IRBs for their review and approval.

### **3.6 Enforcement**

Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the Institution will be considered a deviation from accepted standards of conducting research.

Alleged violations of this policy will be investigated by the Institution's Conflict of Interest Committee and the local IRBs, which will make recommendations for action to the Institution's Board of Directors. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed by the Conflict of Interest Committee. If institutional officials determine that the policy has been violated, sanctions may be imposed including termination.

If the failure of a covered individual to comply with the Institution's FCOI policy or an FCOI management plan appears to have biased the design, conduct or reporting of the NIH research, the Institution shall promptly notify the NIH and local IRBs of the corrective action taken or to be taken. The NIH 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 promote and maintain appropriate objectivity in NIH funded research projects.

If the NIH 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 a covered individual with an FCOI that was not managed or reported by the Institution, the Institution shall require the covered individual involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

### **3.7 Dispute Resolution**

Any dispute between a covered individual and the Institution will be resolved by the local IRBs' Conflict of Interest Committee and if necessary, appropriate federal agencies.

### **3.8 Posting of Financial Conflict of Information**

This policy and each update of this policy will be posted for public viewing on the Institution's website at [www.iora.org](http://www.iora.org).

### **3.9 Senior / Key Personnel FCOI**

Identified FCOIs held by Senior / Key Personnel must also be publicly accessible on the Institution's website at [www.iora.org](http://www.iora.org). The information must be updated annually and updated within 60 days after discovery of a newly identified FCOI. The information must be posted for three years from the date the information was most recently updated.

For each financial conflict of interest that is found to exist for Senior / Key Personnel, the Institution will make the following information available to the public on the Institution's website at [www.iora.org](http://www.iora.org)

- (i) The covered individual's name, title and role
- (ii) The name of the entity in which the financial interest is held
- (iii) The nature of the financial interest that constitutes a conflict (e.g. equity, consulting fees, travel reimbursement)
- (iv) The approximate value of the financial interest or a statement that the interest is one whose value cannot be readily determined.

### **3.10 Reporting Requirements to NIH**

FCOI Reports, including all required reporting elements, will be submitted for the Institution and its subrecipients to the NIH through eRA Commons FCOI Module, as required by regulations:

- (i) Before the expenditure of any funds under a PHS-funded research project
- (ii) Within 60 days of identification for a covered individual who is new to the research Institution
- (iii) Within 60 days for newly identified financial conflict of interest

In addition to the FCOI Report, the Institution must, within 120 days of determination of noncompliance, complete a retrospective review of the covered individual's activities to determine whether any NIH-funded research conducted during the period of noncompliance was biased in the design, conduct or reporting of such research. Based on the results of the retrospective review, if appropriate, the previously submitted FCOI report will be updated, specifying the actions that will be taken to manage the FCOI going forward. The Institution's Conflict of Interest Committee, in collaboration with the local IRBs, will develop the correction action plan for the noncompliance.

If bias is found with the design, conduct or reporting of NIH-funded research by a covered individual of the Institution or its subrecipients, a Mitigation Report will also be completed and submitted per federal regulations. The Mitigation Report must include the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

#### **Section 4 Records**

All records of disclosures and associated activities will be maintained securely and confidentially in a password protected database accessible by the Conflict of Interest official and Research Integrity Officer of the Institution.

All records will be maintained for three years from the date the final expenditures report is submitted to the NIH.

#### **Section 5 Institutional Contact Information**

For questions, concerns or additional information, please contact the IORA Administrator at 515-241-3305.