

Creighton University  
Conflict of Interest Review Committee (CIRC)

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## CIRC PROCEDURES

**Creighton**  
UNIVERSITY

Conflict of Interest Review Committee

<http://www.creighton.edu/researchcompliance/conflictinterest/about/index.php>

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# 1.0 Introduction

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These policies and procedures have been developed to provide the Creighton University research community with an overview of the institutional processes utilized by the Conflict of Interest Review Committee (CIRC) to review financial interests and relationships at Creighton University and address identified conflicts of interest.

The CIRC is responsible for reviewing significant financial interests of Investigators/Support Personnel (as defined in Creighton Policy No. 3.1.10) identified in the Disclosure Form to ensure objectivity in research projects funded through Creighton University by external sources. This review is based on Public Health Service regulations (42 CFR Part 50, Subpart F), the provisions of the National Science Foundation (Grant Policy Manual §150), and other pertinent federal guidance/regulations, as specifically noted herein.

## 2.0 About the Conflict of Interest Review Committee (CIRC)

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### 2.1 PURPOSE OF THE CIRC

Pursuant to University Policy No. 3.1.10, the Conflict of Interest Review Committee (CIRC) is responsible for determining whether a conflict of interest exists based on financial disclosures of Investigators/Support Personnel involved in externally-sponsored projects. In those instances in which the CIRC determines a conflict of interest exists, it must determine the appropriate mechanism(s) to manage, reduce, or eliminate the conflict of interest prior to expenditure of any external funding.

### 2.2 CIRC SCOPE AND AUTHORITY

The CIRC shall review all significant financial interests of an Investigator/Support Personnel and/or his/her Family Members to determine the existence of a potential or actual conflict of interest. The CIRC review shall occur prior to the expenditure of any external funding. The CIRC determines the existence of a potential or actual conflict of interest in research and the manner or means of managing, reducing, or eliminating any potential or actual conflict of interest that is identified. The CIRC has the authority to manage, reduce, or eliminate any potential or actual conflict of interest as a condition of allowing the Investigator/Support Personnel to participate in any externally-sponsored research project, and, by its recommendations to the President, can effect action that withholds or withdraws financial support from externally-sponsored research projects until the conflict of interest is satisfactorily managed, reduced, or eliminated. University administrators (Departmental Chairs, Deans, Provost, Vice Presidents, President) should remind prospective Investigators/Support Personnel of University Policy 3.1.10, “Financial Conflict of Interest in Research,” and the CIRC procedures to enforce the Policy.

### 2.3 SELECTION AND COMPOSITION OF THE CIRC

CIRC members are appointed by the President of the University from the faculty and staff to ensure objectivity and expertise in sponsored research and educational activities. The membership will be composed of voting members representative of the following areas:

- Two representatives from Health Sciences Schools

- One representative from Academic Affairs
- One staff member who is involved in research activities
- One voting member of the Creighton University Institutional Review Board (IRB)
- Research Compliance Officer/Associate Vice Provost for Research and Compliance

The Associate General Counsel shall serve as an ex-officio member, without vote. The Chair(s) is (are) appointed by the President of the University. CIRC members and Chair(s) serve at the pleasure of the President of the University. The CIRC may invite consultants to assist in any review, but consultants shall not vote.

The University provides liability coverage for CIRC members for any legal action arising from their actions and decisions while serving as members of the CIRC.

## **2.4 CIRC MEETINGS**

The CIRC is scheduled to meet monthly or more often as needed, but may not meet if there are no significant financial interests to review. The schedule of regular CIRC meetings is available on the web at <http://www.creighton.edu/researchcompliance/conflictinterest/scheduleofcircmeetings/index.php>. CIRC members may either meet in person or via telephone or e-mail. Prior to each meeting, an agenda is mailed to Investigators/Support Personnel and all CIRC members (and consultants), notifying them of the date, time, and place of the meeting. In addition to the regularly scheduled meetings, the CIRC Chair(s) may call emergency meetings of the CIRC if necessary to review urgent matters.

### **2.4.1 Meeting Materials**

The CIRC shall provide each member with a copy of the following materials approximately 5 to 10 days prior to the regularly scheduled meeting:

- The agenda
- A copy of the minutes from the previous meeting
- A copy of the Disclosure Form completed and signed by each Investigator/Support Personnel.
- Any other information necessary for the meeting.

## **2.4.2 Quorum**

A majority of voting members must be present (in person or via telephone, fax, or other acceptable means) to conduct business of the CIRC. The final Resolution Plan will require a majority vote of CIRC members.

### **2.4.2.1 *Members with a Conflict of Interest***

CIRC members with a conflict of interest in a particular research project subject to the conflict of interest review shall not participate in the Committee's deliberations and voting concerning any Investigator's/Support Personnel's financial interest related to that project. Those with a conflict of interest may provide information requested by the CIRC.

### **2.4.2.2 *Loss of Quorum***

If a quorum is lost at any time during the meeting, the meeting shall be adjourned and no further action taken until a quorum is attained.

## **2.4.3 Attendance**

At the request of the CIRC, Investigators/Support Personnel may be asked to attend the CIRC meeting at which their significant financial interest is reviewed.

## **2.4.4 Minutes**

Minutes of meetings shall including the following information:

- Attendance of members and guests
- CIRC actions taken on each significant financial interest reviewed
- A written summary report describing the nature and amount of any significant financial interest resulting in a conflict of interest, including the Committee's recommendation to manage, reduce, or eliminate the conflict of interest
- Votes on recommendations to manage, reduce, or eliminate the conflict of interest, including the number of members voting for or against, the number of members abstaining from voting, and notation of members who were not present during deliberations or not voting on items with which they have a conflict of interest

## **2.5 CIRC RECORDS**

At a minimum, the CIRC shall retain all financial disclosures, minutes of meetings and written summary reports relating to each identified conflict of interest as follows:

- PHS-Funded Projects – 3 years after the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b).
- NSF-Funded Projects – 3 years beyond the termination or completion of the project, or until the resolution of any NSF action involving those records, whichever is longer.
- All Other Externally-Funded Projects – 3 years after the termination or completion of the project.

## 3.0 Administrative Roles and Responsibilities

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### 3.1 THE UNIVERSITY PRESIDENT

The President of the University is responsible for appointing CIRC members and Chair(s) and supports CIRC decisions.

### 3.2 THE CIRC CHAIR(S)

The CIRC Chair(s) ensure(s) that the CIRC carries out its responsibilities in accordance with federal requirements and these procedures.

### 3.3 THE CIRC

The CIRC reviews all significant financial interests disclosed by Investigators/Support Personnel to determine the existence of a potential or actual conflict of interest. In those instances in which a potential or actual conflict of interest exists, the CIRC is responsible for developing a Resolution Plan to place appropriate determinations to manage, reduce, or eliminate the conflict of interest. In those instances in which the research project involves human subjects, the CIRC will include recommendations and approval from the IRB as part of its Resolution Plan.

### 3.4 THE INVESTIGATOR/SUPPORT PERSONNEL

The Investigator/Support Personnel is responsible for completing and submitting the Disclosure Form in accordance with Policy 3.1.10. In those cases in which the CIRC has determined that a Resolution Plan is necessary, the Investigator/Support Personnel shall sign the Resolution Plan and be bound by its terms. If the Investigator/Support Personnel does not agree with the proposed Resolution Plan, the Investigator/Support Personnel may appeal the determination by submitting a written request to the CIRC for reconsideration, along with any supporting materials. The CIRC shall review the request and supporting materials and issue its final determination, which shall not be subject to further appeal. No project funds will be released until the Investigator/Support Personnel signs the CIRC's Disclosure and a final determination is issued regarding a Resolution Plan. The IRB and Institutional Animal Care and Use Committee (IACUC) may hold projects from being approved until all disclosures have been completed.

## 4.0 Training

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### 4.1 INVESTIGATORS/SUPPORT PERSONNEL

All Investigators/Support Personnel, as defined in University Policy 3.1.10, must complete initial conflict of interest training.

### 4.2 PERSONNEL LISTED ON NIH GRANTS

All Creighton Investigators, faculty, staff, and students responsible for the management, design, conduct, or reporting of National Institutes of Health (NIH)-sponsored research must complete the NIH online conflict of interest. It is the responsibility of each Principal Investigator to ensure that the appropriate individuals who participate on his/her NIH sponsored grants complete the tutorial on conflict of interest.

### 4.3 ONGOING EDUCATION AND RECERTIFICATION

In addition to initial training, recertification can be obtained by completing the CITI Responsible Conduct of Research course.

### 4.4 ADDITIONAL TRAINING

The CIRC may require additional training as needed, addressing such issues as regulatory changes and issues identified through the current CIRC review process.

## 5.0 The CIRC Review Process – Research Conflict of Interest

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The CIRC is responsible for reviewing significant financial interests disclosed and to establish mechanisms to manage, reduce, or eliminate any identified conflicts of interest. There is no single approach to reviewing and dealing with conflicts of interest. The strategies for dealing with conflicts of interest are as numerous as the types of conflicts of interest and are dependent on the particular facts and circumstances involved in each individual case. Therefore, the procedures outlined for review and resolution of conflicts of interest may lead the CIRC to consider other questions not specifically identified in these policies.

### 5.1 DISCLOSURE OF POTENTIAL FINANCIAL CONFLICT OF INTEREST

Any person involved in the design, conduct, or reporting of a research project (Investigator/Support Personnel) is required to complete and submit a Disclosure Form to the Associate Vice Provost for Research and Compliance prior to the initiation of an externally-sponsored research project, a project involving human subjects, or a project involving the use of animals. A Disclosure Form must be submitted at least annually thereafter, or more often if the person's financial interest creates a significant financial interest as defined in University Policy No. 3.1.10.

#### 5.1.1 Update of Disclosure of Potential Financial Conflict of Interest

Investigators/Support Personnel are responsible for updating the most current Disclosure Form on file with the Associate Vice President for Research and Compliance on an annual basis or more often upon obtaining any new or additional financial interest that creates a significant financial interest. See University Policy 3.1.10

### 5.2 INITIAL REVIEW OF DISCLOSURE OF POTENTIAL FINANCIAL CONFLICT OF INTEREST

The Disclosure Form is initially reviewed by the Associate Vice Provost for Research and Compliance, or his/her designee, to determine whether or not a significant financial interest exists, in accordance with University Policy 3.1.10. If the Associate Vice Provost for Research and Compliance identifies a significant financial interest, he/she shall forward the Disclosure Form and any additional information received from the Investigator/Support Personnel to the CIRC Chair(s) and/or the CIRC committee. If the project involves human subjects research, the Associate Vice Provost for Research and Compliance shall also inform the IRB.

## **5.3 CIRC REVIEW PROCESS**

The CIRC shall review all significant financial interests disclosed by Investigators/Support Personnel through the Disclosure Form prior to funding of the research or educational project, or in the case of an existing project, prior to the release of any additional funding. The CIRC reviews any identified significant financial interests to determine the existence of a potential or actual conflict of interest. When the research project involves human subjects, the CIRC shall review any recommendations from the IRB to reconsider its Resolution Plan in those instances where the IRB determines that the CIRC Resolution Plan does not adequately protect human subjects. The IRB shall approve at a convened meeting the Resolution Plan presented by the CIRC, or the IRB may impose additional requirements. The IRB may request a reconsideration of the CIRC's initial decision. The CIRC has the final authority to determine whether any interest and its management allow the research to be approved.

### **5.3.1 CIRC Review Factors - General**

The CIRC shall review the Disclosure Form along with any other information presented to the CIRC by the Associate Vice Provost for Research and Compliance and/or Investigator/Support Personnel. During its review, the CIRC may consider one or more of the following factors in determining the existence of a potential or actual conflict of interest:

- The sponsor financing the research;
- Where and by whom the research study was designed;
- Where and by whom the resulting research data will be analyzed;
- Indication that research results have not been faithfully and accurately reported;
- Indication that the Investigator/Support Personnel in his/her professional role has improperly favored any outside entity or appears to have incentive to do so;
- Whether the Investigator/Support Personnel appears to be subject to incentives that might lead to inappropriate bias or otherwise affect the research results;

- The possibility that the Investigator/Support Personnel's circumstances represent any possible violation of federal, state, or local laws and requirements;
- Impact of the financial interest on the integrity of the research data, including the impact the study outcome may have on the receipt of any compensation;
- Type of financial interest (i.e., proprietary interests, equity interests in the sponsor, receipt of significant payments for other activities, such as grants, equipment, incentive payments);
- Risks to the rights and safety of human subjects for projects involving human subjects;
- Risks to the rights and obligations of students and trainees participating in the project;
- Impact on the availability of research results to the scientific community for use in the public interest;
- Any request by an Investigator/Support Personnel to rebut the presumption that he/she may not conduct human subject research; and
- Any other matter pertaining to the Investigator's/Support Personnel's disclosed financial interest and the externally funded project, including those outlined in HHS guidance 69 F.R. 26393; 26396 (May 12, 2004); <http://www.hhs.gov/ohrp/archive/humansubjects/finreltn/fguid.pdf>.

If, after reviewing the information, there is genuine cause for concern that a conflict of interest exists, the CIRC must ascertain whether appropriate controls are currently in place to deal with possible conflicts of interest and, if not, what controls may need to be established to manage, reduce, or eliminate the conflict of interest. During this phase of the review, the following questions may be addressed:

- Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the institution?
- Will the research work plan receive independent peer review prior to its initiation?

- Are there mechanisms in place to prevent the introduction of bias into research projects (i.e., Is the protocol double-blinded? Are research subjects randomly selected?)?
- Will the project be supervised by someone with authority and no conflicting interest?
- Are there means to verify research results (e.g., independent corroboration in another lab, FDA review)?
- Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
- Will the product of the collaborative effort with an outside party be published in the peer-reviewed scientific literature?

If, after this review, it is determined that a potential or actual conflict of interest exists that has not already been adequately addressed, a summary report shall be prepared describing the nature and amount of the financial interest, as well as a Resolution Plan to manage, reduce, or eliminate the conflict of interest to allow the Investigator/Support Personnel to participate in the research or educational project.

### **5.3.2 CIRC Review Factors for Research Projects Involving Human Subjects**

The significant financial interest(s) of an Investigator/Support Personnel involved in human subjects research may present real or perceived risks to the welfare of human subjects and may require additional review. Therefore, when reviewing an Investigator's/Support Personnel's Disclosure Form for projects involving human subjects research, the CIRC will include the following criteria, as well as criteria in Section 5.3.1 above, as part of its review.

#### **5.3.2.1 *Participation When a Significant Financial Interest Exists***

It is presumed that an Investigator/Support Personnel may not participate in human subjects research while he/she has a significant financial interest in the project.

#### **5.3.2.2 *CIRC Exemptions***

The CIRC may grant an exception on a case-by-case basis upon a showing of compelling circumstances or facts to support a finding that the Investigator/Support Personnel with a

significant financial interest be permitted to conduct human subjects research. In its review, the CIRC shall consider the following factors:

- The nature of the project (i.e., double-blind, placebo-controlled, multi-center);
- The magnitude of the interest;
- The degree to which the project is related to the interest;
- The extent to which the conflict of interest could be directly or substantially affected by the project; and
- The degree of risk to human subjects involved.

The CIRC's review shall also consider the extent to which the conflict of interest can be effectively managed and overseen. These compelling circumstances or facts shall be consistent with the rights and welfare of human subjects. A determination from the IRB, in accordance with federal regulations, that the human subjects research involves "no more than minimal risk" may be used as compelling circumstances or facts.

### **5.3.3 Full Committee Review**

All significant financial interests shall be reviewed by the full Committee.

#### **5.3.3.1 Review Process**

After full Committee review, the CIRC shall make one of the following determinations:

- No potential or actual conflict of interest exists and no further action is necessary
- A potential or actual conflict of interest exists and appropriate controls already exist to manage, reduce, or eliminate the conflict of interest.
- A potential or actual conflict of interest exists that is not adequately addressed and a Resolution Plan is prepared to satisfactorily manage, reduce, or eliminate the identified conflict of interest so that the Investigator/Support Personnel may participate in the research or educational project.
- A potential or actual conflict of interest exists and it is not possible to implement a plan to satisfactorily manage, reduce, or eliminate the identified conflict of interest in such a manner as to allow the Investigator/Support Personnel to participate in the research or educational project.

- In the case of National Science Foundation (NSF) projects, a potential or actual conflict of interest exists, but it is determined that the placement of restrictions or conditions will be ineffective or inequitable and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, in which case the CIRC may allow the Investigator/Support Personnel to participate without placing any conditions or restrictions after the office of NSF has been notified of the CIRC's determination.

All actions taken by the CIRC are recorded in the minutes. The CIRC shall summarize any determinations of a potential or actual conflict of interest. The Investigator/Support Personnel shall be given a written summary of the CIRC's determination along with any recommended Resolution Plan. A copy of the CIRC's written summary and Resolution Plan, if any, shall also be given to the Associate Vice Provost for Research and Compliance and the Investigator's/Support Personnel's Dean, no later than 30 days after its determination. If the research project involves human subjects, a copy of the CIRC's written summary and Resolution Plan shall also be given to the IRB.

#### **5.3.4 CIRC Determinations/Resolution Plan Provisions to Deal with Conflicts of Interest**

If the CIRC determines that there is a potential or actual conflict of interest that does not currently have appropriate controls to address the conflict of interest, it may nonetheless allow the Investigator/Support Personnel to participate in the research or educational project subject to restrictions as outlined in a written Resolution Plan to manage, reduce, or eliminate the conflict of interest. Such restrictions may include, but are not limited to, one or more of the following:

- a. Disclosure – disclosure includes, but is not limited to, (i) public disclosure of the significant financial interest(s) in all relevant publications and all presentations (whether or not academic presentations), (ii) disclosure to members of the project, and (iii) disclosure to human subjects through informed consent.
- b. Monitoring – appointment of independent reviewer(s) or independent data and safety monitoring committee or similar body to monitor the project. Monitoring may include reviewing abstracts and manuscripts before submission for publication, and review of protocols, subject accrual, complications, and other issues.
- c. Modification – modification of the project such that the main purpose of the project is not compromised.

- d. Limiting the Role of the Investigator/Support Personnel with Significant Financial Interest(s) – limitations may include prohibiting the Investigator/Support Personnel from (i) serving as the Principal Investigator; (ii) analyzing the data; (iii) selecting or enrolling human subjects; (iv) determining whether an adverse event report is required; or (v) any other limitation capable of managing, reducing, or eliminating the conflict.
- e. Divestiture – allow the Investigator/Support Personnel to proceed with the project subject to the sale or disposal of all or a portion of specified financial interests to reduce or eliminate financial conflicts.
- f. Severance of Relationships – requiring the Investigator/Support Personnel or his/her Family Member to sever relationships that create actual or potential conflicts, such as relinquishing a seat on a board of directors or terminating a consulting agreement with an outside entity during the course of the project.
- g. Restrictions on Equity Interests – requiring the Investigator/Support Personnel or his/her Family Member to place stock in escrow until a trigger date specified by the CIRC, or requiring options, warrants, and similar interests not be exercised without prior written approval of the CIRC (and IRB, if human subjects are involved).
- h. Any other conditions or restrictions that will contribute to the management, reduction, or elimination of the Conflict of Interest, consistent with applicable policies, regulations, and laws.

#### **5.3.4.1 Additional Requirements for Research Involving Human Subjects**

In all cases in which an Investigator/Support Personnel with a significant financial interest is allowed to participate in human subjects research, the CIRC shall require that the significant financial interest be disclosed as described below:

- Generally. The Significant Financial Interest shall be disclosed as follows: (i) to research subjects; (ii) to state and federal officials where required by statute or regulation; (iii) to research sponsors; (iv) to editors of any publication to which the Investigator/Support Personnel submits a manuscript concerning the research; (v) in any substantive public communication of the research results, whether oral or written; and (vi) and in any other manner as may be determined by the CIRC.
- Multi-Center Trials. Disclosure should be made to the Principal Investigator or external funding sponsor of a multi-center trial.

- Informed Consent Form. The informed consent form shall contain the disclosure of the conflict of interest and shall indicate that additional information (including the CIRC summary report and Resolution Plan) will be provided to human research subjects upon request.

The CIRC shall specify the monitoring procedures or other conditions to be implemented when an Investigator/Support Personnel with a conflict of interest is permitted to participate in human subjects research.

### **5.3.5 Appeal of CIRC Determination and/or Resolution Plan**

If the Investigator/Support Personnel does not agree with the proposed Resolution Plan, the Investigator/Support Personnel may appeal the determination by submitting a written request to the CIRC for reconsideration, along with any supporting materials. The CIRC shall review the request and supporting materials and issue its final determination, which shall not be subject to further appeal.