

Conflict of Interest Policy

Purpose:	To avoid the appearance of impropriety, bias, and to ensure that decisions are made in the best interest of the Institute, and that Individuals don't personally profit from their relationship with the Institute.		
Audience:	Regenstrief Institute		
Department:	Legal and Compliance		
Policy Contact:	General Counsel	Responsible Administrator:	Thane Peterson
Effective:	9/20/16	Last updated:	3/8/16
Comments:	Please send comments and revisions to klooney@regenstrief.org		

1. Scope

Individuals (employees, contractors and/or faculty) making decisions or recommendations to guide the Institute, and/or performing work or research in conjunction with or on behalf of the Institute, including supervising Institute employees or contractors involved in research. The scope specifically excludes the Regenstrief Institute Board of Directors, who are subject to the Board's Conflict of Interest Policy, except any Board member who has a role within the Institute that is in addition to or separate from their role on the Board.

2. Policy Statement

2.1. Employees, investigators, and contract workers must conduct the affairs of the Institute in accordance with the highest legal, ethical, and moral standard. Conflicts of interest should be avoided where possible or disclosed and managed. Individuals subject to this policy shall not use their Institute related position to secure personal financial benefits for themselves or any member of their immediate family.

The Institute is committed to avoiding any conflict of interest or appearance thereof between an employee's own personal, professional or financial interests and the interests of Institute and Institute's client, in any and all actions taken by the Individual on behalf of the Institute. To increase transparency and to provide an effective mechanism to manage conflicts of interest, this policy is instructive regarding circumstances which must be disclosed using the forms below.

2.2. Expectations

2.2.1. Each situation will be examined as disclosed on the basis of its particular facts and the nature of the business transaction. The two underlying principles for review are:

2.2.1.1. Preventing the existence of conflicting roles that might bias an individual's judgment; and

2.2.1.2. Preventing unfair competitive advantage.

2.3. Business Relationships: In the event that an Individual or a member of his/her immediate family has any direct or indirect Significant Financial Interest in, or relationship with, any individual or organization which is in or proposes to enter into any business transaction with Institute, including but not limited to transactions involving:

2.3.1. the sale, purchase, lease or rental of any property or other asset;

2.3.2. employment, or delivery of services, personal or otherwise;

2.3.3. the award of any grant, contract, or subcontract; or

2.3.4. the investment or deposit of any funds of Institute,

then such Individual shall complete a Conflict of Interest Disclosure Form and refrain from acting upon the particular business transaction in which he/she has an interest or attempt to influence a decision in the business transaction until a mitigation plan can be put in place. See Figure 1.

2.4. Examples of Potential Conflicts:

2.4.1. Individual or immediate family member owns, in whole or in part, a business entity which does business with the Institute, and the individual or family member is in a position to influence business decisions regarding the business entity.

2.4.2. Individual holds or assumes an executive, officer, or director position in the partnering organization.

2.4.3. Individual participates in consultation activities for the partnering organization or the partnering organizations direct competitors.

2.4.4. Individual receives extramural funding, stipends, or honorariums from the partnering organization in addition to salary support received under the contract in question.

2.5. Gifts: In the course of any Institute business transaction where an Individual is wishing to give or receive a gift valued at greater than \$50.00, he/she must disclose the gift to the Compliance Officer for approval (in the absence of the Compliance Officer, the Executive Operating Officer may approve). No gifts can be made to or received from government employees. No exchange of gifts can be made during open procurements or competitive solicitations, if the Individual is involved in that process. The exchange of cash is never permitted. See Figure 2.

2.6. Outside Engagement: If an Institute employee is participating in or seeking outside engagement (as an employee or contractor whether for a third party or self-employed) in addition to existing Institute employment, the Institute employee shall submit an Outside Employment Disclosure Form, if any of the following conditions exist:

2.6.1. the outside employer is a competitor of Institute,

2.6.2. the outside employer is a provider, payer or vendor, and/or

2.6.3. the work is similar in nature to the current work for which the employee is compensated. Approval for outside employment is valid for one calendar year or until the outside employment changes. Each change in outside employment that requires disclosure will require specific prior approval.

2.7. Conflicts of Interest in Research:

2.7.1. It is the obligation of each Investigator, employee, student, fellow, and contractor to disclose not less than annually all Significant Financial Interests related to their Institute Research responsibilities.

2.7.2. Individuals shall disclose to the Institute annually all Significant Financial Interests that meet the definitions below, and they shall update these disclosures within the annual period and within thirty days of (a) acquiring a

new Significant Financial Interest that reasonably would appear to affect or be affected by their Institute Research Responsibilities, or (b) the end or material alteration of an existing Significant Financial Interest.

2.7.3. Individuals shall not be subject to burdensome or random disclosure requirements; however, this shall not restrict the use of disclosure as a tool for avoiding, resolving, or managing an on-going Conflict of Interest or the compliance with annual monitoring by the Institute.

2.7.4. Disclosures shall be made as designated below. If an Individual is already required to make a research related disclosure through a University, a copy of that disclosure can be provided to the Institute at the same time it is required to be filed and/or updated with a University, but no less frequently than set forth in Section 2.6.2 above.

2.7.5. The Panel will determine whether an Individual's Significant Financial Interest is related to his or her Research or Sponsored Programs activities and, if so, whether the Significant Financial Interest is a Conflict of Interest based upon the following criteria:

2.7.5.1. A Significant Financial Interest is related to Research or Sponsored Programs activities when the Institute reasonably determines that the Significant Financial Interest:

2.7.5.1.1. Could be affected by the Research or Sponsored Program activity; or,

2.7.5.1.2. Is in an entity whose financial interest could be affected by the Research or Sponsored Program activity.

2.8. Conflict Resolution and Management

2.8.1. To the extent possible, all disclosures will be kept confidential unless otherwise required by any applicable policies, audits, or law.

2.8.2. Nothing in this policy shall be construed to permit, even with disclosure, any activity that is prohibited by law.

2.8.3. The Executive Operating Officer and/or Institute Compliance Officer shall review the Disclosure Form and determine if the conflict of interest is manageable. If the conflict of interest is manageable, a Conflict of Interest Mitigation Plan will be created and monitored annually.

2.8.4. If an individual is aware of any other potential conflicts of interest related to a current or pending Institute business transaction(s), the individual is encouraged to speak with his/her manager, other members of management, Organizational Development, or report his/her concerns through the Institute Compliance Officer.

2.8.5. If an individual is engaged in any federally funded program requiring additional training or reporting, the individual shall follow contract requirements.

3. Definitions

3.1. Financial Interest: is anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, salary, commissions, consulting fees, honoraria, equity interests, interests in real or personal property, dividends, royalties, rent, capital gains, intellectual property rights, and forgiveness of debt, other than:

3.1.1. compensation from the Institute, local hospital systems, Indiana University, or Purdue University;

3.1.2. income from seminars, lectures, or other educational activities sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 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;

3.1.3. income from service on advisory committees, or review panels for a public federal, state, or local government agency, an Institution of higher education as defined at 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; or

3.1.4. an interest arising solely by means of investment in a mutual, pension, or other institutional investment fund where the Investigator does not exercise control over the management and investments of such fund.

3.2. Business Transaction: Purchase of goods or services; contracting; subcontracting; commitment of Institute resources.

3.3. Conflict of Interest: An individual who is unable or potentially unable to render impartial assistance or advice because of other activities or relationships with other persons, to Institute or Institute's client(s), or the individual's objectivity in performing the contract work is or might be otherwise impaired, or the individual has an unfair competitive advantage.

3.4. Disclosure Form: A form to capture all relevant information for the Conflict of Interest Committee to render a decision. Information to include: individual, relationship, type of business transaction, value of business transaction, etc

3.5. Individual: For purposes of conflict of interest, one who falls within the scope of this Policy in addition to their spouse, parents, children, brothers, sisters, daughters-in-law, sons-in-law, brothers-and sisters-in-law, fathers- and mothers-in law, stepparents, stepsiblings, stepchildren, and others with whom they are in a personal relationship.

3.6. Gift: Any tangible item with a value greater than \$50.00 from employee to Vendor/Client or from Vendor/Client to employee. No cash gifts of any kind. No exchange of gifts of any kind with governmental employee (Federal, state or local). Personal gifts among employees are excluded from policy.

3.7. Gift Review Form: A form to capture all the relevant information for the Executive Operating Officer or Compliance Officer to render a decision. Information shall include: employee, type of gift, value of gift, does a relationship, is employee making any financial decision with provider of gift.

3.8. Mitigation Plan: If a conflict of interest can be neutralized or mitigated, the mitigation plan will provide details such as party(s) responsible for oversight, and what type of oversight/monitoring is necessary.

3.9. Outside Engagement: A situation where a paid employee of the Institute is also a paid employee or consultant of another organization (including being self-employed and/or an organization that the Individual owns) where any of the following conditions exist: 1) the other employer is in competition with Institute and/or its subsidiaries, 2) the work conducted is in similar in the work Institute pays the employee to complete, and/or 3) the other employer is a provider or payer.

3.10. Significant Financial Interest: a Financial Interest is a Significant Financial Interest if at the present time OR over the past 12 months, and when aggregated for the employee and the employee's Family Members, meets one of the following tests:

3.10.1. With regard to any publicly traded entity, it is 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, the value of which exceeds \$5,000 from one enterprise or entity;

3.10.2. With regard to any non-publicly traded entity, it is the value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest;

3.10.3. Intellectual property rights and interests totally \$5,000 or more, upon receipt of income related to such rights and interests;

3.10.4. Salary, remuneration, reimbursed or sponsored travel or similar payments which exceed, or are expected to exceed \$5,000 within any one-year period, when aggregated for the member and his or her Family Members

3.11. Relationship: Includes spouses, parents, children, brothers, sisters, daughters-in-law, sons-in-law, brothers-and sisters-in-law, fathers- and mothers-in law, stepparents, stepsiblings, stepchildren, and individuals who are in a personal relationship.

3.12. Vendor: An organization from which Institute does or will be purchasing good or services. This type of business transaction would be an expense to Institute. Definition

3.13. Panel: Potential conflicts of interest related to research will be reviewed by a panel that includes the Executive Operating Officer, the Compliance Officer, and a Center Director (from a Center other than the Individual's Center).

4. Enforcement

Violation of this policy will result in appropriate disciplinary action. Additionally, individuals may be subject to loss of the Institute's information resources access privileges, and civil and/or criminal prosecution.

The administration of the policy and procedure is the responsibility of corporate management and extended staff.

FIGURE 1

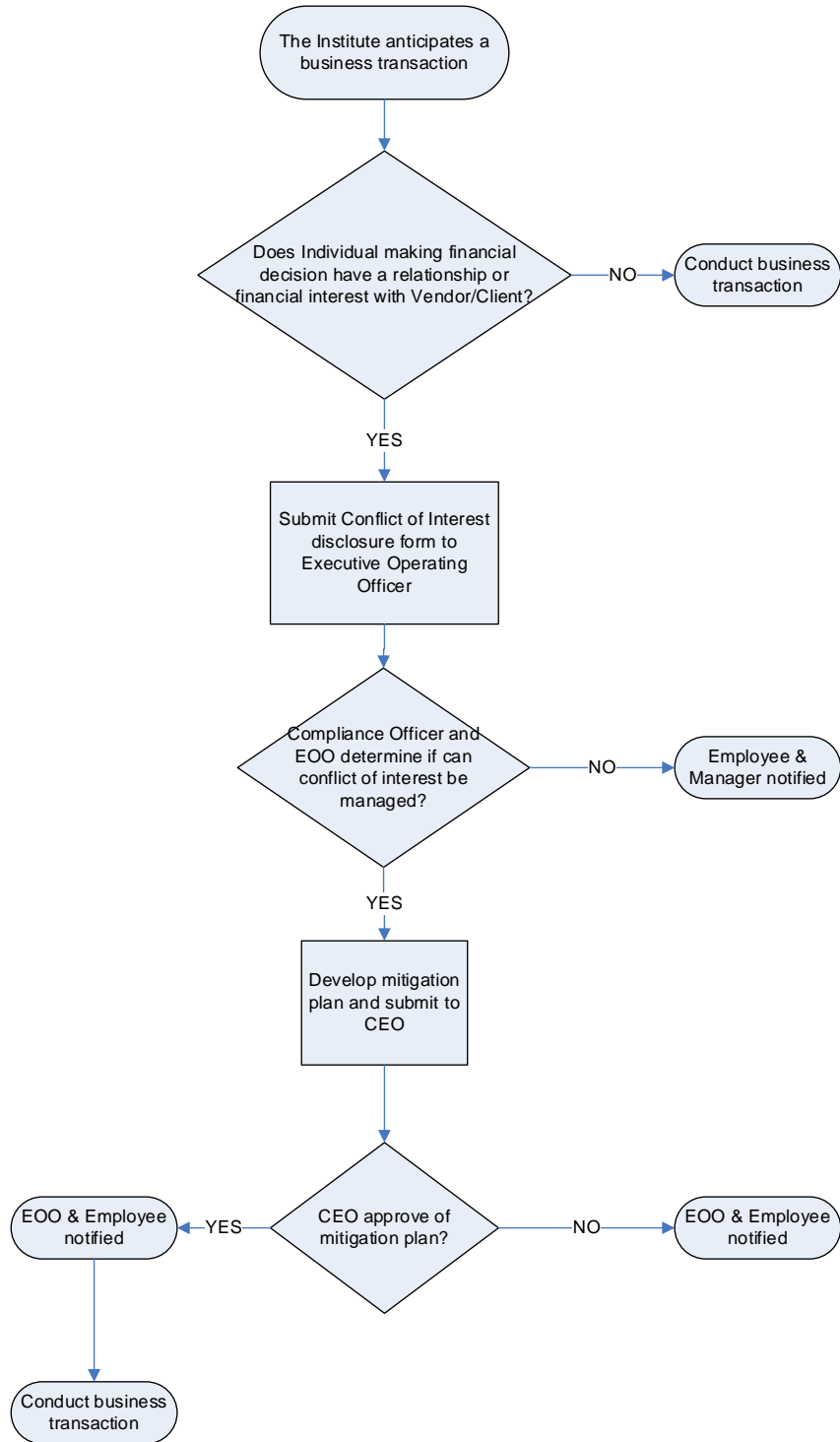


FIGURE 2

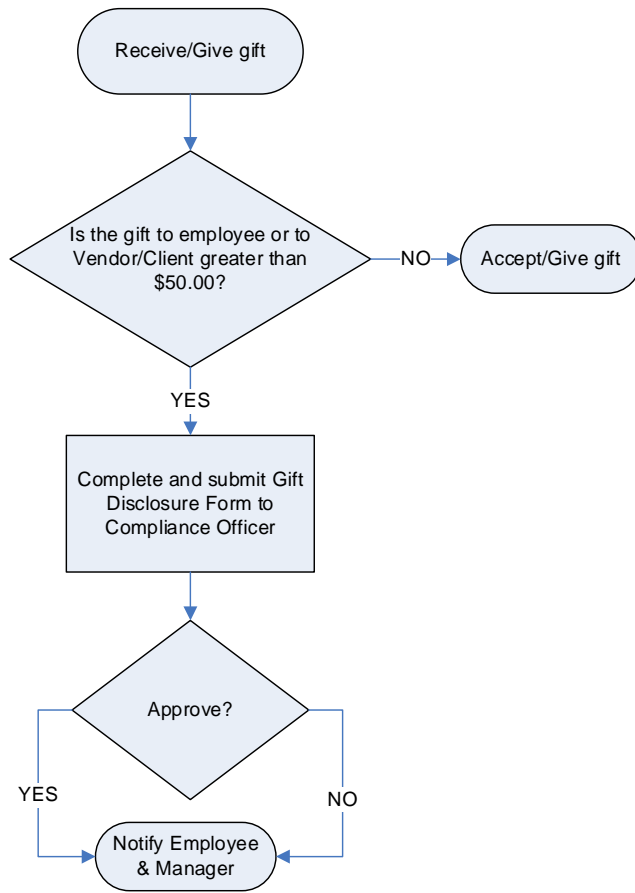


FIGURE 3

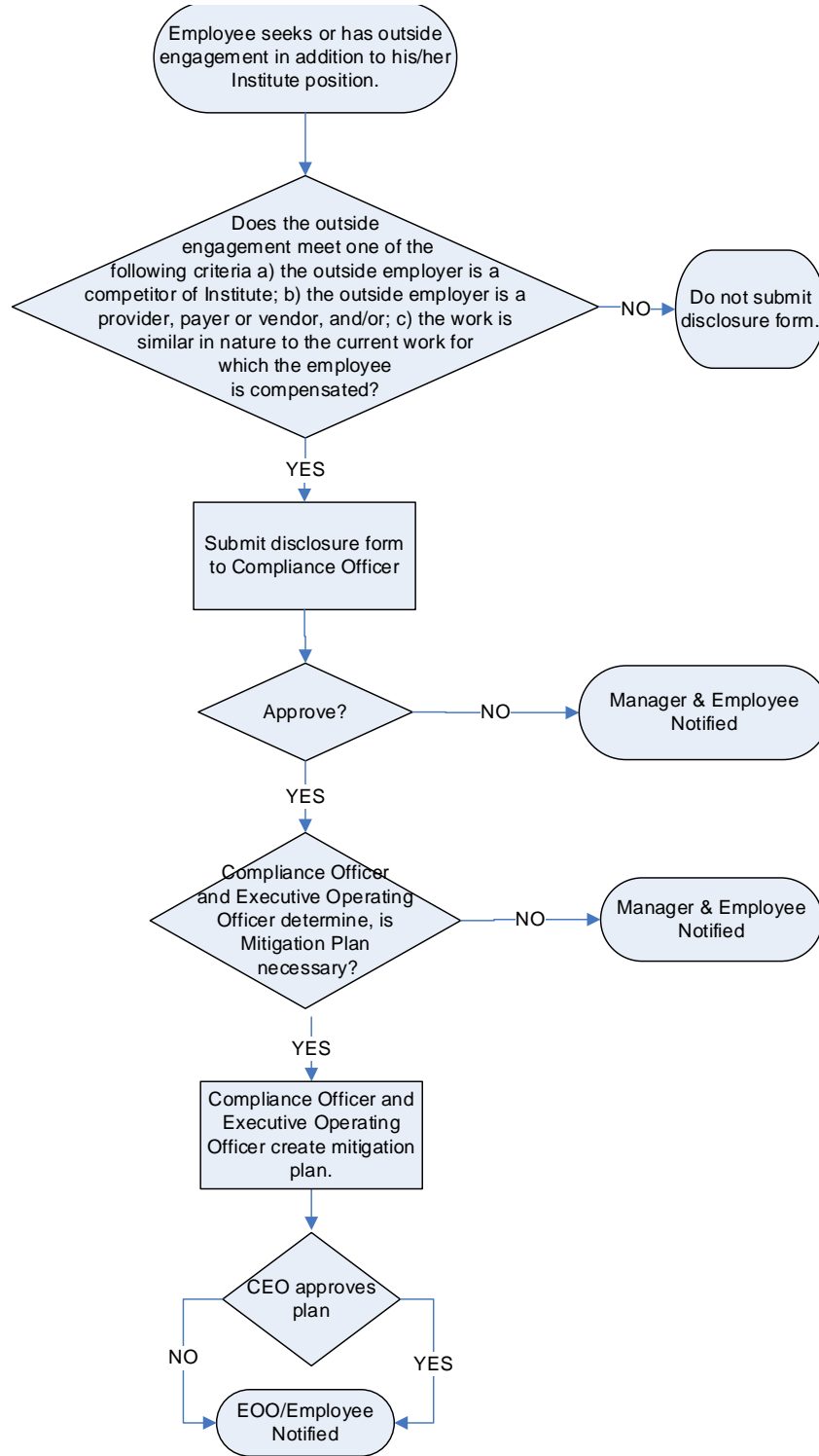
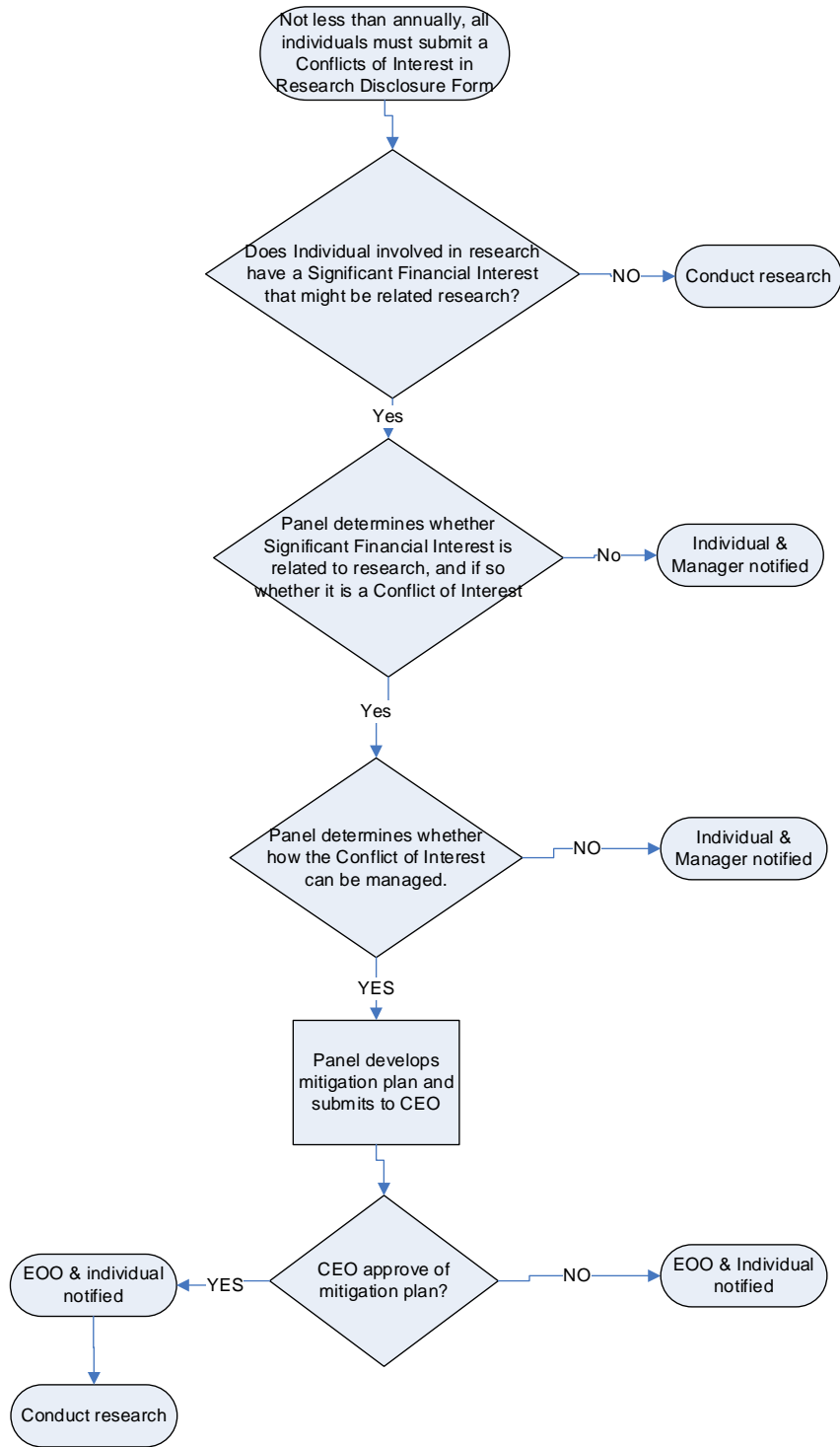


FIGURE 4



5. Related Information

POL-ADM-061 Code of Conduct Policy

Indiana University Policies on Conflicts of Interest

POL-ADM-023 Corrective Action Policy

6. Revision History

Date	Description of revision	Author
9/17/15	Policy drafted	K.Looney
9/20/16	Policy Approved	

Any Individual involved in a business transaction and believing to have a conflict of interest or an appearance of a conflict of interest must complete this form. This form must be submitted to the Compliance officer.

Name of Individual:
Description of Institute business transaction:
Name of Client or Vendor:
Do you or any member of your immediate family have any ownership interest in the Client of Vendor named above? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.
Do you or any member of your immediate family serve as a paid consultant, officer, administrator, or board member for the named Client or Vendor above? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.
Have you and a member of your immediate family together received in the last 12 months or will receive in the next 12 months more than \$5,000 (in cash or of monetary value) from the Client or Vendor named above? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.
Is there anything not covered in the above questions that you believe might constitute a conflict of interest or creates the appearance of being a conflict of interest related to the Institute business transaction? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No

3. Certification

By signing below, I hereby certifies that all of the information contained on this form and hereby attached is true and correct to the best of my knowledge and that I have made reasonable efforts to assure that accurate and complete information has been provided.

Signature Date

TO BE COMPLETED BY EOO and/or Institute COMPLIANCE OFFICER
This form has been reviewed and a mitigation plan is:

Required

Not Required

Signature

Title

Date

Gift Review Form

This form is to be completed by any Individual that wishes to receive or give a gift valued at greater than \$50 that is related to their role with the Institute. No cash gifts can be given or accepted. No gifts of any kind may be given to any governmental employee.

Individual Name	
Position	
Center	
Phone Number	

I would like to:

<input type="checkbox"/> Give Gift to:	<input type="checkbox"/> Receive Gift from:
--	---

Name		Name	
Client/Vendor name		Client/Vendor name	
Address		Address	
City, State ZIP		City, State ZIP	
Phone number		Phone number	

Description of Gift	
Estimated Value	
Describe any Institute business transactions pending or planned between provider/recipient of gift.	

By signing below, I hereby certifies that all of the information contained on this form and hereby attached is true and correct to the best of my knowledge and I have made reasonable efforts to assure that accurate and complete information has been provided. This gift was not solicited.

Signature Date

TO BE COMPLETED BY EXECUTIVE OPERATING OFFICER OR COMPLIANCE OFFICER		
I have reviewed this Gift Review form and determined the gift is: <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved		
_____ Signature	_____ Title	_____ Date

Any employee that is engaged in or seeking outside engagement must complete this form. This form must be submitted to the Compliance Officer

Name of Employee:
Name of Outside Engagement (entity that will be paying you with money, equity, etc.):
Attach a copy of current Institute job description.
Attach a copy of outside engagement responsibilities.
Will you be conducting any business transactions at Institute that involve the outside employer? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.
Will you be conducting any business transactions at the outside employer that involve Institute? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.
Are your current Institute job responsibilities similar in nature to those for the outside engagement? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.

4. Certification

By signing below, I hereby certifies that all of the information contained on this form and hereby attached is true and correct to the best of my knowledge and that I have made reasonable efforts to assure that accurate and complete information has been provided.

Signature Date

TO BE COMPLETED BY EXECUTIVE OPERATING OFFICER OR COMPLIANCE OFFICER	
This form has been reviewed and a mitigation plan is: <input type="checkbox"/> Required <input type="checkbox"/> Not Required	
Title: _____	Date _____

Conflict of Interest in Research Disclosure Form

Name: _____ Phone: _____

Email: _____

Current Employer: _____

I currently participate in research activities: Yes No _____ If no, you do not have to complete the rest of the form.

Policy Acknowledgement

I have read the Regenstrief Institute Conflicts of Interest Policy and understand the purpose of this disclosure.

Signature: _____

Date: _____

Current Research Projects:

Project Name	Role on Project	Funding Source

Disclosure

Please answer the questions below by clicking the checkboxes. If you answer "Yes" for any question, please complete Section 4 for each external interest. If you answer "No" to all questions, please skip Section 4, complete Section 5, and submit the form to the Compliance Officer.

1. During the past twelve months, did you and/or your immediate family members receive any monetary or other compensation exceeding \$5,000 in value from an external (non-Regenstrief) entity that was not related to your Regenstrief responsibilities? Compensation includes, but is not limited to: consulting fees, honoraria, speaking fees, travel, stocks, or gifts. Yes No
2. During the past twelve months, did you and/or your immediate family members receive any research funding, monetary or other compensation from an external (non-Regenstrief) entity that was related to your Regenstrief responsibilities or from an entity that operates in areas related to Regenstrief's business or research? This could include, but is not limited to, participation in other research projects funded by the sponsor, either through the Institute or another organization. Yes No
3. Did you and/or your family members hold, at some point during the past twelve months, an ownership interest any external organization which does work in areas relating to Regenstrief's business or research or your Regenstrief responsibilities, that when aggregated together represents an equity interest that exceeds \$5,000 in values? Yes No

4. In the past twelve months, did you and/or your family members hold or assume an executive, officer, or director position with any external organization which does work in areas relating to Regenstrief's business or research or your Regenstrief responsibilities ? Yes No

Conflict Details

As applicable, provide additional details related to the conflicts identified above. For each applicable item, complete all requested information. When completed, complete Section 5 and submit to the Compliance Officer.

Indicate the name of the entity providing compensation and describe the business of this entity:

Type of remuneration:*

- Compensation
 Equity Ownership
 Intellectual property rights or interests
 Travel

Purpose of Travel:

Destination:

Duration of Travel:

Please provide a brief narrative of how your disclosed external relationship with the above noted entity does or does not relate to your Regenstrief responsibilities:

Please provide a brief description of your role and responsibilities or ownership interest in the entity, including any applicable titles for which you and/or your Family Members will receive compensation.

Please indicate the aggregate annual amount of compensation (including the total value of any compensation, sponsored or reimbursed travel, intellectual property rights or interest and any other remuneration received or expected to be received from the entity) (please note that amounts of \$5,000 or less need not be reported)

Please indicate the aggregate fair market value of **ownership interest** (please note that amounts under \$5,000 need not be reported)

When did/will the compensation and or travel occur?

If you are providing consulting for the entity listed above, please check all relevant boxes below.

- My consultant work for the above entity was a one-time engagement.

- My consultant work for the above entity is ad hoc.
- My consultant work for the above entity is contractual.

Is the disclosed interest royalties or licensing fees? If so, please describe the intellectual property to which the payments are related and how it is or is not related to your Regenstrief responsibilities.

Products and/or services made by the above noted entity in which I have a financial relationship are being used during performance of my Regenstrief responsibilities.

- Yes
- No

If you have received additional research funding, please describe this funding below and outline any relationship to the current Regenstrief responsibilities.

Please describe any conflicts not accounted for above.

Attestation

By signing below, I hereby certifies that all of the information contained on this form and hereby attached is true and correct to the best of my knowledge and that I have made reasonable efforts to assure that accurate and complete information has been provided.

Signature: _____ Date: _____

TO BE COMPLETED BY EXECUTIVE OPERATING OFFICER OR COMPLIANCE OFFICER	
<p>This form has been reviewed and a mitigation plan is:</p> <p> <input type="checkbox"/> Required <input type="checkbox"/> Not Required </p>	
Title: _____	Date _____