
Procedure Title: Conflict of Interest as Related to Research

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	6/27/17	Executive Lead:	Chief Research Officer
Effective:	6/27/17	Revision History:	.01 – 9/18/18; .02 – 3/7/19; .03 – 1/10/2020; .04 – 01/10/2020; .05 – 11/18/2022
Approved by:	Institutional Review Board		
Procedure Number:	111.03		
Key Words:	COI, Financial, Declaration, Conflicts		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects' research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:

This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU that the PNWU Financial Conflict of Interest (FCOI) Policy applies to all human subject research activity, investigators, and members serving on the Institutional Review Board (IRB).

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Assisting in identifying and disclosing to the Office of Scholarly Activity, the Provost, and/or the Provost's designee or the Institutional Officer at PNWU any new actual or potential conflicts of interest identified at each meeting for any study previously approved or currently undergoing review.
- Ensuring that investigators have filed an updated conflict of interest disclosure form required by PNWU's FCOI policy prior to submission of an application to the IRB to conduct human subjects research; files the annual conflict of interest disclosure form required by PNWU's FCOI policy on a timely basis during the course of any human subject research conducted under the supervision of the IRB; and promptly discloses any actual or potential conflicts of interest that arises during the course of such research, pursuant to the provisions of PNWU's FCOI policy and to the IRB.
- Ensuring that all members serving on the IRB file an annual FCOI disclosure form required by PNWU's FCOI policy on a timely basis, and discloses promptly any actual or potential conflicts of interest that arises during their service as a member of the IRB pursuant to the provisions of PNWU's FCOI policy and to the IRB.
- Ensuring that any actual or potential institutional conflict of interest that may affect any human subjects research conducted under the supervision of the IRB or impact any participant therein is identified in a timely way, is disclosed to the Office of Scholarly Activity (OSA), the Provost and/or their designee, and assists in ensuring that PNWU

appropriately manages, reduces, and/or eliminates any such actual or potential institutional conflict of interest.

- Assisting the Provost and/or their designee in evaluating, managing, reducing, and/or eliminating any actual or potential conflict of interest related to human subjects' research conducted under the supervision of the IRB and in the operations of the IRB.

The Office of Scholarly Activity (OSA) is responsible for:

- Ensuring compliance with PNWU's FCOI policy, as provided in the FCOI policy and this SOP
- Posting this SOP for the PNWU community
- Communicating with PNWU Office of Human Resources regarding declared actual or potential conflicts of interest

The Office of Human Resources is responsible for:

- Supporting the Provost and/or the Provost's designee, the OSA, the IRB, and investigators in ensuring compliance with PNWU's FCOI policy, as appropriate.

The Investigator is responsible for:

- Filing with OSA an FCOI disclosure form prior to submission of an application to the IRB for permission to conduct human subjects research, updating in a timely way any such disclosures as required by PNWU's FCOI policy and disclosing to the OSA and the IRB as soon as the individual becomes aware of any actual or potential conflict of interest as it arises during the conduct of research.

Definitions

Please reference the [Glossary](#) for complete definitions of the following terms and additional terms not listed.

- Academic Conflict of Interest
- Compensation
- Conflict of Commitment
- Conflict of Conscience
- Conflict of Interest
- Conflict Management Plan
- Equity
- Financial Conflict of Interest
- Gift
- Human Subject
- Human Resources
- Immediate Family Member
- Institutional Official (IO)
- Intellectual Property (IP)
- Investigator
- Non-PHS-Funded Investigator
- Public Health Service (PHS)-Funded Investigator
- PHS-Funded Research
- Research Misconduct
- Significant Conflict of Interest
- Significant Financial Conflict of Interest
- Standard Operating Procedure (SOP)

Background Information:

Conflicts of interest pose a threat to scientific integrity by introducing forms of bias that affect the enterprise of science itself. Conflicts of interest may influence the design and conduct of research in ways that render study results unsound, with the potential to misinform the practice of many physicians and allied healthcare providers, to affect adversely the participants in human subjects' research, as well as the health of patients.

Scientific misconduct is not always associated with conflicts of interest; but conflicts of interest increase the chance of scientific misconduct.

Procedure:

1. An institution may face a conflict among its multiple duties to protect human subjects. To ensure the integrity of research and its compliance with applicable laws and regulations, and the institution's legitimate interest in the financial health and economic viability of the enterprise, PNWU ensures that the responsibility for human subjects research does not overlap or coincide with responsibility for those institutional financial interests that may be directly affected by the outcome of the research.
2. No research, sponsored program, or technology transfer activities occurring at PNWU shall be adversely affected by the financial interests of University personnel carrying out those activities.
3. Prior to participating in a research project, sponsored program, or technology transfer activity, PNWU personnel having an actual or potential conflict of interest shall promptly disclose the details pursuant to provisions of PNWU's FCOI policy and the IRB through its application and renewal process.
4. Conflicts of Interest may be either financial or nonfinancial and indirect or direct. Conflicts of interest are not always prohibited because not all interests cause conflicts that impact research.
5. Actual and potential conflicts must be recognized, managed, reduced, or eliminated so that they do not adversely affect participant protections or the credibility of the human research protections program.
6. When investigators have specific financial relationships or other nonfinancial interests in research, the disclosure must be declared.
7. Financial Relationships: Institutions and individuals involved in human subjects research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property. When a financial interest is disclosed, the disclosure is reviewed as provided in PNWU's FCOI policy and this SOP.
8. Nonfinancial Interests: Private interests in outside organizations can result in COI. Examples of private interests include unpaid leadership positions; membership on boards of directors; and membership in companies, clubs, societies, and organizations such as trade unions and voluntary organizations that members of the public might reasonably think could influence the decision-making process. Also, non-financial interests may include personal relationships with researchers or the topic of research. When such nonfinancial interests are disclosed, the disclosure is reviewed as provided in PNWU's general conflict of interest policy and the IRB when such actual or potential conflicts of interest may impact the conduct of human subjects' research.

9. Investigator or other study staff conflicts: Any investigator or other person responsible for the design, conduct, or reporting of research (including spouses and dependent children) that may have an actual or potential conflict of interest with any proposed human subjects research must disclose such actual or potential conflict of interest in a timely way pursuant to PNWU's FCOI policy and directly to the IRB.
10. Each investigator shall disclose:
 - a. All interests that would reasonably appear to be directly and significantly affected by the funded research or educational activities; or
 - b. Actual or potential conflicts of interest as required by PNWU's FCOI policy.
11. All of the above information must be disclosed:
 - a. at the time, the IRB proposal is submitted.
 - b. on an annual basis during the project annual renewal.
 - c. as soon as the investigator becomes aware of the conflict with regard to ongoing research projects.
12. When a new investigator seeks to join an ongoing human subjects' research project any actual or potential conflicts of interest shall be disclosed and resolved prior to joining the project.
13. The Provost and/or the Provost's designee, with the assistance of the IRB committee, as appropriate, will determine whether any disclosed actual or potential conflict can be effectively managed, reduced, or eliminated.
14. The PNWU IRB has final authority to decide whether the research can be continued and/or approved.
15. Examples of how conflicts of interest might be addressed include the following:
 - a. Public disclosure of significant interests via the consent process
 - b. Monitoring of research by independent reviewers
 - c. Modification of the research plan
 - d. Disqualification from participation in all or a portion of the research
 - e. Divestiture of significant interests
16. No IRB member, their spouse or dependent children, or consultant may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.
17. An IRB member (their spouse and dependent children) or consultant is considered to have a conflicting interest when any of the following are true:
 - a. There is actual or potential conflict of interest as provided in the PNWU FCOI policy.
 - b. There is an external reporting structure related to the research.
 - c. They are involved in the design, conduct, or reporting of the research.
 - d. They assist in the development of the study.
 - e. They have a personal or professional relationship with the other members listed on the study (e.g., relationship, employer).
 - f. The IRB member or consultant believes that they will be unable to impartially review a research protocol.
 - g. Or, if the IRB member has identified him or herself for any other reason as having a conflicting interest.
 - h. The co-investigator is a student of the IRB member.

18. The IRB chair and staff will request disclosures of conflict of interest at regularly scheduled meetings from all members.
19. At regularly scheduled meetings, IRB members will determine if a conflict exists by reviewing the agenda that lists the names of all investigators and sponsors. The following statement is read at the start of each convened meeting by the IRB Chair (or Vice Chair in the Chair's absence), and it is also printed on the meeting agenda.

"Any member who has a conflict with any of the protocols discussed at this meeting should either recuse her/himself from the discussion and vote for that protocol or else abstain from the vote. If you are unsure whether you have an actual conflict, or are unsure as to what constitutes a conflict, you are welcome to discuss it with me (IRB Chair) in private and our conversation will be considered confidential."

Members will make disclosures orally and the IRB staff will note them in the minutes. If a conflict is disclosed, when the study is reviewed, the member with the conflict is required to leave the meeting for deliberation and voting. If assigned as a reviewer for a study in which the member has a conflict, the member is responsible for declining the review so that another reviewer may be assigned. This policy also pertains to reviews conducted through the expedited process.

20. Educational materials are available for IRB members and investigators to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects' research. In addition to disclosing conflicts of interest, PHS Investigators must also complete Financial Conflict of Interest (FCOI) training once at least every four years using the CITI Training Program Conflict of Interest training module. Non-PHS Investigators are encouraged to take the training as needed.
21. Any IRB member (including IRB chair and IRB consultants) that has an actual or potential conflict of interest may participate in or be invited to the meeting to answer questions about the research; however, the member will be excused during the IRB deliberations and voting. If a chair is excused from the meeting due to a possible COI, the vice-chair or if also excused, another qualified IRB member will take over the deliberations for that particular project in the absence of the chairs.
22. If an IRB member is excused from the meeting due to an actual or potential conflict of interest, a quorum must be present, or the meeting must be postponed from further action until a valid quorum is obtained.
23. The conflict of interest SOP applies to each IRB member for all types of reviews.
24. Conflict of interest also applies to the institutional official (IO).
 - If the IO is listed on a research study as an investigator, the PNWU provost would serve as the IO for this study.
 - If the IO and Provost are both listed as investigators on a study, the president of PNWU will serve as the IO.
25. Conflict of interest also applies to institutional conflict of interest, meaning if PNWU has equity and/or stake in the processes and outcome of a specific research study, these conflicts must be declared in the IRB application upon submission. Nonaffiliated IRB members will be assigned to review the study to minimize the institutional influence or coercion of affiliated IRB members.

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
3. National Institutes of Health Office of Extramural Research. Financial Conflict of Interest. Retrieved on: March 7, 2019. Available at: <https://grants.nih.gov/grants/policy/coi/index.htm>
4. ERA Commons Financial Conflict of Interest (FCOI) External User Guide. eRA Commons Version 3.36.5 Document Version 4.13.4 July 24, 2018. Retrieved on: March 7, 2019. Available at https://era.nih.gov/files/fcoi_user_guide.pdf
5. [PNWU Financial Conflicts of Interest Policy](#)

Appendices:

Conflict of Interest Statement Form (from IRB application and renewal process)

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00/6.7.2017	M. McCarroll	New Standard Operating Procedure
.01/7.2.2018	M. McCarroll	Minor changes to 6.16
.02/3-7-2019	M. McCarroll	Updated for the Revised Common Rule and Updated to include all types of conflicts of interest
.03/4-4-2019	M. McCarroll	Put into the new PNWU SOP Format
.04 /1-10-2020	C. Case	Removed references to Digital Measures. All IRB reporting of research conflicts of interest will be reported via the IRB Application and renewal process.
.05 / 12-8-2022	B. Roach/M. Cutchin	References to the new Financial Conflict of Interest Policy (FCOI) have been added throughout the SOP; added information about the review and determination process for potential or actual conflicts of interest; added annual FCOI disclosure process for members of the IRB; expanded information about declared conflicts of interest by members of the IRB at IRB Committee Meetings.

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CONFLICT OF INTEREST STATEMENT

Name: Click here to enter text.	Study Role: Click here to enter text.
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Protocol Information:	Study Title: Click here to enter text.	
	Study Sponsor/Device Manufacturer: Click here to enter text.	<input type="checkbox"/> N/A
	IDE/IND#: Click here to enter text. <input type="checkbox"/> N/A	501K#: Click here to enter text. <input type="checkbox"/> N/A

Conflict of Commitment:

1. Do you have adequate time available to carry out all study duties? <input type="checkbox"/> Yes <input type="checkbox"/> No If NO, what changes will be made to allow for adequate time to carry out required study duties? Click here to enter text.

Academic Conflict of Interest/Intellectual Bias

1. Do you have an academic conflict of interest/conflict of intellectual bias that will interfere with the research process for the purpose of intangible personal gain? <input type="checkbox"/> Yes <input type="checkbox"/> No If YES, explain: Click here to enter text.

Conflict of Conscience:

1. Are there any parts of the protocol OR studies duties that would be in conflict of your belief ? <input type="checkbox"/> Yes <input type="checkbox"/> No
If YES, will you be able to carry out the required studies duties without bias? <input type="checkbox"/> Yes <input type="checkbox"/> No
If NO, will certain study duties be delegated to another study team member? <input type="checkbox"/> Yes <input type="checkbox"/> No If YES, provide the name of study team member Click here to enter text.

I understand that it is my responsibility to report any changes to the statements above while this study is open and enrolling subjects.

Printed Name: _____

Signature: _____ Date: _____