I. PURPOSE

This guideline describes the steps required when reporting and/or documenting conflict of interest (COI). The goal is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of an Investigator. This peer review system relies on the professionalism of each researcher to identify any real or apparent COI that is likely to bias the evaluation of a research.

Note: The Palliative Care Research Cooperative (PCRC) follows the Public Health Service (PHS) 2011 Final Rule regarding COI, specifying disclosure of potential conflicting interests at the *de minimis* value threshold of $5,000. See NOT-OD-11-109: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html).

II. SCOPE

This TOP describes the process for PCRC Full Members, Trainee Members, and non-member Study Principal Investigators, Statisticians, Site Investigators, PCRC Directors, and PCRC Project Leads to report and document COI.

III. DEFINITIONS

Conflict of Interest (COI): A COI is a situation when a researcher, a relative, friend, and/or other professional associate are in a direct or indirect position to gain or lose personally, professionally, or financially from research, and therefore presents a risk of biasing objectivity in the research.

Real Conflict of Interest (RCOI): A RCOI is when a researcher, relative, friend and/or professional associate of the researcher has a financial or other interest in the research that is known and is likely to bias the evaluation of that research, as acknowledged by the researcher.

A researcher will be determined to have a RCOI if he or she, relative, friend and/or professional associate: (a) has received or could receive a direct financial benefit of any amount deriving from the research; (b) has received or could receive a financial benefit from the applicant institution, sponsor and/or investigator that in the aggregate exceeds $5,000 per year and/or more than a 5% ownership interest in a single entity; this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the researchers already existing stock holdings, apart from any direct financial benefit deriving from research: or, (c) has any other interest in the research that is likely to bias the researcher's evaluation of the research or bias findings.

In the case of an independent peer reviewer, regardless of the level of financial involvement or other interest, if the reviewer feels unable to provide objective advice the a RCOI exists and he/she must recuse themselves from the issue.

Researcher: The "investigator", which includes the Principal Investigator (PI) and any of the PI's professional associates participating in PCRC research activities.

Relative: A parent, spouse, sibling, son, daughter or domestic partner of the PI or professional associate participating in PCRC research. If a relative receives or could receive benefits from or provides benefits to the research, it will be treated as a RCOI for the researcher/PI.

Independent Reviewer: A PCRC consultant who reviews potential COIs and provides independent outside advice to the PCRC Steering Committee as to whether a COI exists and how to manage it.

IV. PROCEDURE

1. PCRC Full Members, Trainee Members, and non-member Study Principal Investigators, Statisticians, Site Investigators, PCRC Directors, and PCRC Project Leads participating in PCRC activities:

    - Will complete the PCRC COI Form.

    - The form will be updated annually or more frequently as deemed necessary by the applicable researchers involved in research activities.

    - When a researcher's status changes, it is the responsibility of that investigator and/or research staff researcher personnel to notify the PCRC Project Lead or designee(s).

    - COI forms will be sent out electronically (email) and collected by the PCRC Project Lead. Additional COI forms are available on the PCRC website, for use, as needed. Completed COI forms may be faxed to the PCRC at the main office fax number listed on the PCRC website or emailed to the PCRC Project Lead. The PCRC website will always include updated contact information (http://www.palliativecareresearch.org).

    - All forms will be received and reviewed by the PCRC Project Lead or designee(s). If a form is marked with all "No(s)," the form will be held on file. Forms marked with a "Yes," will be reviewed by an Independent Reviewer.

    - An Independent Reviewer will review the information and decide whether a real COI exists that may prevent a researcher from making an unbiased

decision. The Independent Reviewer will make an expert independent determination of whether a COI exists, document findings, and develop a recommended action plan to manage, reduce or eliminate COI(s). The recommendations of the Independent Reviewer will be submitted to the Steering Committee for action.

- The Steering Committee will enact the recommendations of the Independent Reviewer. In a case where the Steering Committee does not agree, the Committee can elect to engage three additional external reviewers. These three reviewers, in conjunction with the Independent Reviewer, will generate a summary report for the Steering Committee; the majority recommendation will be the course enacted by the Steering Committee.

- In order to ensure transparency, a written summary of the declared potential conflicts will be prepared and distributed within one week prior to each face-to-face PCRC Investigators' and Steering Committee meeting. Printed copies will be distributed to all attendees at the meeting. If there are any corrections to the summary, these can be submitted to the Project Lead who will be responsible for updating and communicating the information.

- Careful documentation will be maintained, including annual Project Lead requests for COI reporting, COI forms, Project Lead findings, Independent Reviewer findings, and Steering Committee action.

2. Decisions on Matters of COI
    - This process does not cover every possible situation that could give rise or the perception thereof a COI. For this reason, decisions are arrived in the best interest of the research participants. The Independent Reviewer has latitude and flexibility with respect to rendering decisions.

    - If a researcher wants to appeal a decision made by the Independent Reviewer, the researcher must submit a written appeal detailing the basis for the appeal via email to the Project Lead or designee within ten calendar days of receipt of the decision. Instructions for appeal will be maintained on the PCRC website (http://www.palliativecareresearch.org).

3. Miscellaneous
    - There may be a situation in which a researcher and an individual(s) with whom he/she may directly share income have an affiliation or relationship such that objective impartiality could be questioned. In such instances, the researcher should disclose the nature and extent of such affiliations or relationships on the PCRC COI Form.

4. Penalties for Failure to Comply

- Lack of compliance with this process will be referred to the Independent Reviewer, which will review the issue and recommend action to the Steering Committee.

5. Record Keeping
    - The PCRC Project Lead or designee(s) will maintain records of all forms and related documents for a minimum of three years after the last financial statement has been submitted.

V. REFERENCES

- Section 493A of the Public Health Service Act
- 42 CFR Part 50
- 42 CFR Part 94

VIII. ATTACHMENTS

Attachment 1: PCRC COI Form

VIII. HISTORY OF CHANGE

NA

Palliative Care Research Cooperative (PCRC)
Conflict of Interest Form

<<<<<<<NAME>>>>>>>

Employment: Are you and/or a relative employed by an entity having a commercial interest in a drug, medical device, or treatment that the PCRC has utilized or is utilizing in research?		
□NO □YES	Company:	Description of the conflict(s):
Consultancies/Honoraria: Have you and/or a relative served as a consultant and/or sponsored speaker for a company with a commercial interest in a drug, medical device, or treatment that the PCRC has utilized or is utilizing in research, and received >$5,000 aggregated per year total from the company in the last 3 years?		
□NO □YES	Company:	Description of the conflict(s):
Stock Ownership: When considering stock ownership in a company with a commercial interest in a drug, medical device, or treatment that the PCRC has utilized or is utilizing in research, do you and/or a relative have: • ≥ 5% ownership interest (including stock options) in a start-up company with such a commercial interest, the stock of which is not publicly traded (including stock options but excluding indirect investments through mutual funds and the like) and valued at ≥ $5,000; or, • Ownership valued ≥ $50,000 from any single company in a single year that is publicly traded?		
□NO □YES	Company:	Description of the conflict(s):
Intellectual Property: Do you or any individual with whom you directly share income, have a patent (issued or pending), that is related to a drug, medical device, or treatment that the PCRC has utilized or is utilizing in research; or have you played a substantial role in the development of a drug, medical device, or treatment that PCRC has utilized or is utilizing in research?		
□NO □YES	Company:	Description of the conflict(s):
Research Funding: Have you/or a relative received research funds ≥ $100,000 in the last 3 years from an entity having a commercial interest in a drug, medical device, or treatment that the PCRC has utilized or is utilizing in research?		
□NO □YES	Company:	Description of the conflict(s):
Membership on Board of Director or Advisory Committees: Do you and/or a relative serve in a compensated role on the Board of Directors or an Advisory committee for an entity having a commercial interest in a drug, medical device, or treatment that the PCRC has utilized or is utilizing in research?		
□NO □YES	Company:	Description of the conflict(s):

Miscellaneous: Are there other situations in which you, a relative and/or any individual(s) with whom you directly share income have an affiliation or relationship due to which objective impartiality could be questioned?

Description of the conflict(s):

Other comments (when applicable):

I, <<<<<<<<NAME>>>>>>>, will notify the PCRC Study Co-PIs if:

- A change occurs in any of the above during the tenure of my responsibilities, or
- I discover that an organization with which I am affiliated meets the criteria for a conflict of interest.

I am aware of my responsibilities for maintaining the confidentiality of any non-public information that I receive or become aware of through this activity, and for avoiding using such information for my personal benefit, the benefit of my associates, or the benefit of organizations with which I am connected or with which I have a financial involvement.

Signature:

<<<<Electronic signing>>>