NATIONAL PHYSICIANS COOPERATIVE

the Oncofertility® Consortium
www.oncofertility.northwestern.edu

GLOBAL ONCOFERTILITY NETWORK

The Oncofertility Consortium®: Policy and Guidelines Statement

Policy and Operations Manual

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POLICY ON DISCLOSURE OF INDUSTRIAL ACTIVITIES

It is appreciated that scientific investigators have numerous scientific collaborations, both within the **Oncofertility Consortium®** as well as independently of it. It is also understood that these collaborations can represent important adjuncts to the **Oncofertility Consortium®** program in providing technological advances, key scientific opportunities, reagent availability, and potential sources of additional funding of projects of mutual interest. It is also recognized that these activities have the potential for conflict of interest, and it is the purpose of this policy to both maximize expeditious transfer of advances derived from the **Oncofertility Consortium®** into practical use for alleviation of a wide variety of medical conditions, as well as to protect the Consortium and its investigators from both actual conflicts of interest, as well as the appearance of such conflict. The following policies were reviewed at the Steering Committee Meeting on March 12, 2008 with original implementation on April 1, 2008.

The first and most crucial step to avoid conflict of interest or its appearance is full disclosure. This disclosure would take the form of all **Oncofertility Consortium®** Investigators disclosing all relevant collaborations (scientific collaborations, equity arrangements, industry/consultancy/ownership, etc.) to their local Directors. This would be accompanied by the completion of a written form designed to monitor these activities in an objective fashion. All disclosure material for Consortium personnel remains at the Center site. The individual Center Directors would also submit a full disclosure report to the Chairperson of the **Oncofertility Consortium®** Steering Committee. These disclosures would identify the scientific scope of activities, existence of confidentiality agreements, and any potential areas of overlap of these activities with the **Oncofertility Consortium®**. This overlap would specifically include those within their individual Centers, as well as those with other **Oncofertility Consortium®** projects. Following completion of this initial review and disclosure at the individual Center level, the Center Directors would then eliminate those collaborations which were thought to be of little or no impact upon the Centers' programs and request a formal review by the **Oncofertility Consortium®** Steering Committee of those issues deemed to have potential conflict interaction with the Oncofertility Consortium®. The purpose of this general discussion would be full disclosure and a dialogue reviewing potential impact of these considerations, and an assurance that the Steering Committee was generally comfortable with these arrangements. In addition, when requested, ranges of remuneration would be listed in order to give the assurance to the Chairperson of the Steering Committee that these arrangements were not in such a range where the actual levels of remuneration itself could represent a conflict of interest. Following discussion of these issues by the Steering Committee, only additions or deletions of the arrangements would then be reviewed in the future as needed. The same process will be conducted by the **Oncofertility Consortium®** Chairperson for the Center Directors with the exception that Center Directors cannot be present during Steering Committee deliberations that consider their own potential conflict issues. Issues of potential conflict discerned by the judgment of the **Oncofertility Consortium®** Chairperson will be referred by him/her to the NIH for further consideration and decision.

GUIDELINES FOR AUTHORSHIP

Introduction

This document is intended to outline a set of guidelines for distinguishing collaborations that merit co-authorship from those that deserve some other form or recognition. Since it is impossible to establish absolute minimum involvement levels that will be applicable to every situation or circumstance, these are guidelines which should be used to encourage participation at that level which will assure merit as a co-author, rather than serve as exclusionary criteria.

Statement of Policy

1. An author must have participated in the study to an extent that he/she is familiar with all major thrusts of the study, is intimately familiar with those aspects of the study within the individual's scientific competency, and can publicly present and defend those components.

   Hence, determination of inclusion as an author is defined by two major criteria:

   a) participation at some predetermined level (as indicated in the following section), and
   b) willingness to take responsibility for the entire manuscript or those designated parts within their area of expertise.

2. Participation (see 1a above) would normally involve a minimum of two of the following components:

   a) Idea conception or hypothesis(es) development,
   b) Study or experimental design,
   c) Data acquisition or study implementation,
   d) Data analysis or interpretation,
   e) Drafting and/or revising the manuscript.

3. The primary author is responsible for supervising the execution of the project and as such should be familiar with each of the components outlined above. In addition, the primary author is responsible for assigning authorship, and providing copies of at least a semi-final draft to all authors for review and comment prior to submission. He/she should pay serious attention to co-authors' remarks, incorporating appropriate changes.

4. In the event of a dispute about authorship, decisions will be arbitrated by the Steering Committee of the **Oncofertility Consortium®**.

5. Non-critical contributions, technical assistance, or contributions from the above list

but not of sufficient depth or substance to merit authorship can be noted in the acknowledgment section.

6. Specifically excluded as meriting authorship are the following, if they transpire in the absence of additional contributions as listed in section 2 above:

    a) Patient referral,
    b) Reagent or tissue provision (e.g., antibody, probe, cDNA, tissue),
    c) Data collection or computer analysis and/o graphing,
    d) "Honorary" authorship for repayment for some type of support not directly related to the study or included within section 2 above.

7. **All peer reviewed publications must contain an attribution of membership in the Oncofertility Consortium® and including the P50 *and* the specific grant and project number (if applicable) and must be submitted to PubMed Central for an ID # (PMCID).**

For full papers: This research was supported by the Oncofertility Consortium® [NIH P50 HD076188 and (number or numbers, if supported by more than one, and individual project number, if applicable)].

For abstracts: This research was supported by the Oncofertility Consortium® [NIH P50 HD076188 and (number or numbers, if supported by more than one, and project number, if applicable].

If a publication does not permit a specific grant number to be listed, then cite "This work was supported by the Center for Reproductive Health After Disease [NIH P50HD076188] from the National Institutes of Health National Center for Translational Research in Reproduction and Infertility (NCTRI)"

All peer reviewed publications that were supported by NIH funds need to be submitted to PubMed Central for an ID # (PMCID). Detailed instructions about how to submit articles to PubMed Central can be found at http://www.pubmedcentral.nih.gov/.

TERMS OF AWARD

The following Terms and Conditions of Award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS, PHS, and NIH grant regulations, policies and procedures, with particular emphasis on HHS regulations at 45 CFR Part 74 and 92. Business management aspects of these awards will be administered by the NICHD Grants Management Branch in accordance with HHS, PHS, and NIH grant administration requirements.

1. **Purpose**
   The purpose of these cooperative agreements is to support a coordinated research program of specialized centers pursuing high quality reproductive research with the ultimate goal of facilitating and accelerating translation of basic science knowledge into clinical applications which can be used to regulate fertility or diagnose and treat infertility or reproductive disorders that impact on fertility.

2. **Authorities and Responsibilities of Awardees**
   The primary authorities and responsibilities of the awardees are to participate cooperatively with the Steering Committee in the following activities:

   - Pursuit of research objectives consistent with the research scope of the RFA and research approved during the initial peer review;
   - Conduct experiments and collect the resulting data;
   - Analyze, interpret and present results and plans to the Steering Committee for approved activities;
   - Publish results, conclusions, and interpretation of the studies.

   The awardees will agree to: 1) accept the coordinating role of the Steering Committee which includes evaluating objectives and research goals of the **Oncofertility Consortium®**, and recommending modification, deletion or addition of protocols within the Centers Program; 2) follow any common protocols in which they participate for multicenter projects that are approved by the Steering Committee; and 3) accept the cooperative nature of the group process, including the establishment, where appropriate, of smaller collaborative groups comprised of interacting subprojects and/or cores focused on a particular reproductive research topic area.

   Awardees will retain custody of and primary rights to their data developed under the award subject to current government policies regarding rights of access as consistent with current HHS, PHS, and NIH policies.

4. Arbitration

When agreement between awardees cannot be reached on scientific/ programmatic issues that may arise after the award, an arbitration panel will be formed. The panel will consist of one person selected by the Principal Investigator, one person selected by NIH staff, and a third person selected by these two members. The decision of the arbitration panel, by majority vote, will be binding. This special arbitration procedure in no way affects the right of an awardee to appeal an adverse action in accordance with PHS regulations at 42 CFR Part *50,* Subpart D, and HHS regulations at *45* CFR Part 16.

DUTIES OF THE ONCOFERTILITY CONSORTIUM®
STEERING COMMITTEE CHAIRPERSON

1. Approves the content of the agenda for each Steering Committee Meeting.

2. Guides the general conduct of the Steering Committee Meeting.

3. Recommends, as required, activation of the formal arbitration process specified for the **Oncofertility Consortium®**.

4. Serves as liaison between the Steering Committee and NIH staff. As liaison, conveys information (i.e. meeting minutes) or formal action requests from the Steering Committee to the NIH, as well as information or responses from the NIH to the Steering Committee. Approves and certifies by signature, the **Oncofertility Consortium®** support documents to be submitted with an annual noncompeting, continuation application of individual **Oncofertility Consortium®** project grants that provide assurance for Steering Committee approval of recommended major changes in science directions or budgetary allocations.

5. Reviews and approves the **Oncofertility Consortium®** Research Coordinator's Annual Report to the NIH.

6. Reviews and approves the Disclosure of Potential Conflict of Interest circumstances submitted by the **Oncofertility Consortium®** Center Directors, and forwards to the NIH any issues requiring further consideration and decision.