

# **Specialized Cooperative Centers Program in Reproduction and Infertility Research (SCCPIR)**

**Policy and Operations Manual  
(Effective April 1, 2007)**

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**SPECIALIZED COOPERATIVE CENTERS PROGRAM  
IN REPRODUCTION AND INFERTILITY RESEARCH  
(SCCPIR)**

**MISSION STATEMENT**

THE MISSION OF THE SCCPIR IS TO SUPPORT HIGH QUALITY INSTITUTIONAL RESEARCH PROGRAMS IN THE REPRODUCTIVE SCIENCES THAT WILL FORM A NATIONAL NETWORK OF CENTERS AIMED AT FOSTERING COMMUNICATION, INNOVATION AND RESEARCH EXCELLENCE WITH THE ULTIMATE GOAL OF IMPROVING HUMAN REPRODUCTIVE HEALTH THROUGH ACCELERATED TRANSFER OF BASIC SCIENCE FINDINGS INTO CLINICAL PRACTICE.

**SPECIALIZED COOPERATIVE CENTERS PROGRAM IN  
REPRODUCTION AND INFERTILITY RESEARCH  
(SCCPIR)**

**CONFIDENTIALITY STATEMENT**

All the materials provided on specific projects or cores of the SCCPIR for purposes of review or evaluation must be considered confidential, as are all oral or written exchanges during the Steering Committee review sessions. The technical data contained in proposals or progress documents must be used only for SCCPIR evaluation purposes unless such information becomes available to the reviewer through other channels. Unless specifically authorized, all copies of proposal, progress, or evaluation documents and related information must be returned at the conclusion of the Steering Committee meeting for retention by the SCCPIR.

Individuals participating in the review or evaluation of SCCPIR proposals, projects, or cores shall not reveal any information concerning the review or evaluation underway except to individuals participating in the same review or evaluation proceedings. Unauthorized divulgence of information before any activity being reviewed or evaluated reaches public disclosure can cause unnecessary embarrassment and complications for the reviewers, the investigators, and the participating members of the SCCPIR and NICHD.

I acknowledge and agree to the conditions stated above:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

# **SPECIALIZED COOPERATIVE CENTERS PROGRAM IN REPRODUCTION AND INFERTILITY RESEARCH (SCCPIR)**

## **POLICY ON DISCLOSURE OF INDUSTRIAL ACTIVITIES**

It is appreciated that scientific investigators have numerous scientific collaborations, both within the SCCPIR as well as independent of it. It is also understood that these collaborations can represent important adjuncts to the SCCPIR 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 SCCPIR into practical use for alleviation of a wide variety of medical conditions, as well as to protect the Program and its investigators from both actual conflicts of interest, as well as the appearance of such conflict. Therefore, it is with both of these thoughts in mind that the following policies were put into place following a review of these considerations at the Steering Committee Meeting of May 12, 1998.

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 Center Investigators disclosing all relevant collaborations (scientific collaborations, equity arrangements, industry/consultancy/ownership, etc.) to their Center 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 Center personnel remains at the Center site. The individual Center Directors would also submit a full disclosure report to the Chairperson of the SCCPIR 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 SCCPIR. This overlap would specifically include those within their individual Centers, as well as those with other SCCPIR Centers. 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 SCCPIR Steering Committee of those issues deemed to have potential conflict interaction with the SCCPIR. 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 SCCPIR 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 judgement of the SCCPIR Chairperson will be referred by him/her to the NICHD for further consideration and decision.

# **SPECIALIZED COOPERATIVE CENTERS PROGRAM IN REPRODUCTION AND INFERTILITY RESEARCH (SCCPIR)**

## **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 SCCPIR.

5. Noncritical 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 provision (e.g., antibody, probe, cDNA),
- 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.

# **SPECIALIZED COOPERATIVE CENTERS PROGRAM IN REPRODUCTION AND INFERTILITY RESEARCH (SCCPIR)**

## **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:

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

### **3. Programmatic Involvement of the Research Coordinator**

The degree of programmatic involvement of the Research Coordinator is as follows:

- o Participating in the overall coordination of the Centers Program with the Steering Committee.

This includes efforts to improve and strengthen inter- and intra-center cooperation amongst the research projects of the Centers, particularly as it pertains to translational research activities within and between centers. As a means of improving inter-center cooperation, the Research Coordinator will directly participate in the activities of the smaller collaborative groups established by the Steering Committee comprised of subprojects and/or cores focused on a particular reproductive research topic area. The Research Coordinator will also assist the research efforts of the Centers Program by facilitating access to fiscal and intellectual resources provided by industry, private foundations and NIH intramural scientists. The Research Coordinator will, as required, help reprogram research efforts, including options to modify or terminate them, by mutual consent between the Centers Program and NICHD. In the event of disagreements among the Program participants, the Research Coordinator will assist in forming an arbitration panel as discussed below.

- o Interacting with each individual center awardee evaluating objectives and research goals of that particular center, deciding optimal research approaches and protocol designs, and contributing to the adjustment of research protocols or approaches as warranted. The Research Coordinator will assist and facilitate this process and not direct it. The Research Coordinator will also provide assistance in reviewing and commenting on all major transitional changes of an individual center's activities prior to implementation to assure consistency with required goals of the Centers Program.

- o Retaining the option to recommend the withholding of support from a Center subproject or core materially failing to meet the technical performance requirements established by the Centers Program. This includes identifying jointly with participants of the Steering Committee the need to add additional research subprojects or service cores to Centers or to phase out a Center subproject or core when performance standards have not been met; and

- o Participating, where warranted, in data analyses, interpretations, and the dissemination of study findings to the research community and health care recipients including co- authorship of the publication of results of studies conducted by the Centers.

#### **4. Guidance and Management Structures**

Overall Coordination of the Centers Program consistent with the stated intent of the RFA will be done by a Steering Committee consisting of the Principal Investigators from each of the participating Centers and one NICHD staff member from the RSB, CPR, NICHD, who will be the Research Coordinator. A member of the NICHD grants management staff will serve as a nonvoting advisor to the Committee. A chairperson for the Steering Committee will be chosen by a majority vote of the Principal Investigators. The Steering Committee meetings will be convened at least once per year. The purpose of these meetings is to share scientific information, assess scientific progress, identify new research opportunities and potential avenues of collaborations such as with industry, private foundations and/or NIH intramural scientists, establish priorities that will accelerate the translation of preclinical findings into clinical applications, reallocate resources and conduct the business of the cooperative research program. In anticipation that some centers will have common research interests that address a specific basic and/or clinical research problem, it is envisioned that research focus groups will be formed

to conduct coordinated research activities recommended by the Steering Committee. The Steering Committee will approve multicenter protocols on specific research activities. As needed, the Steering Committee will develop a publication policy regarding joint authorship of research reports derived from such collaborative efforts.

## **5. Arbitration**

When agreement between an awardee and NTCHD staff 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 NICHD 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.

## **ADMINISTRATIVE GUIDANCE FOR STAFF PARTICIPATION IN THE COOPERATIVE AGREEMENT MECHANISM**

The following guidance is established to clarify the participation and responsibilities of NICHD staff for the review, administrative and scientific involvement and management of co-operative agreements. Since a major feature of this mechanism, which sets it apart from a grant, is the substantial scientific-programmatic involvement of staff, it is important that safeguards be in place for the administrative and scientific management, which would guard against any real or apparent conflict of interest. The Institute recognizes the potential conflict of interest that exists when a Federal employee serves in an activity that combines his/her responsibility for making financial control decisions with that individual's opportunity to provide scientific input or receive scientific recognition. Such activity would constitute a conflict of interest under the Ethics rules and could include a criminal violation on using one's official position for personal gain.

The definitions and/or responsibilities listed below will be observed by NICHD staff while participating in the cooperative agreement mechanisms.

### **NICHD PROJECT SCIENTIST/SCIENTIFIC COORDINATOR:**

This individual will provide the support and/or stimulation of the recipients activities by involvement in and otherwise working jointly with the award recipient/s in a partner role, but not to assume direction, prime responsibility, or a dominant role in the activity. This involvement during the conduct of the project would be support such as technical assistance, advice, coordination, and/or other assistance activities. While this position indicates substantial collaboration with the grantee, it is also the responsibility of the Project Scientist/Scientific Coordinator to routinely advise the NICHD Program Official of the progress of the project and any significant difficulties encountered in the performance of the project. In addition to the programmatic involvement in the research with the grantee, this position will serve as the initial NICHD contact point for all matters except those which pertain to fiscal or administrative issues. While these matters may be discussed at this level, the official channel is through the Office of Grants and Contracts for consideration by the Program Fiscal Official. Documentation of the participation of the Project Scientist/Project Coordinator in the project, describing the events and nature of the substantial involvements during each grant budget year, must become a part of the official grant file. Otherwise a brief summary of the project scientist/scientific coordinator's involvement at the end of each budget period must be submitted for the official grant file.

### **NICHD PROGRAM FISCAL OFFICIAL:**

This is the NICHD individual responsible for the administrative and fiscal review and recommendation within the program area. This is the position within the program office which reviews and recommends approval of the budget and relevant communications including all supplements, competing and noncompeting applications from the principal investigators/grantee institutions. The NICHD Program Fiscal Official will interact with the Project Scientist/Project Coordinator to identify the most optimal lines of communication with the Principal Investigator/s.

**NICHD BRANCH CHIEF:**

This position would be responsible for approvals usually vested with this position as it relates to grant reviews and recommendations. In addition, specifically related to the cooperative agreement mechanism, the Branch Chief will be the next level of approval above the NICHD Program Official. In some instances, this individual may serve as the Program Official.

**NICHD CENTER DIRECTOR:**

Where appropriate will be the next level of approval above the Branch Chief.

**NICHD GRANTS MANAGEMENT SPECIALIST (GMS):**

The grants management specialist is primarily responsible for the administrative and fiscal management of the cooperative agreement. Specifically, the GMS verifies certifications and assurances and assures compliance with established policies and procedures and makes recommendations relative to the above. The review of the applications, primarily the budget, is the responsibility of the GMS and is accomplished in collaboration with the program official and project scientist. The GMS serves as the focal point for receiving and responding to all correspondence related to business management activities of the cooperative agreement. The GMS with the assistance of the program official and project scientist develops any award specific terms and conditions and is responsible for the preparation of the official Notice of Grant Award.

**NICHD GRANTS MANAGEMENT OFFICER (GMO):**

The Grants Management Officer has the overall responsibility for monitoring the cooperative agreement process, including the internal operating procedures associated with the business management aspects of the cooperative agreement. The GMO shall also advise, interpret administrative policies and procedures, and assist management and program officials in developing, implementing, and evaluating program plans, strategies, regulations, announcements, guidelines, procedures, etc. applicable to the cooperative agreement. This individual has signatory responsibility for notices of: awards, amendments, -suspensions, terminations, and correspondence related to the administrative and business management of the cooperative agreement.

**NICHD SCIENTIFIC REVIEW ADMINISTRATOR (SRA):**

The Scientific Review Administrator is responsible for managing the review panel meeting. This includes determinations of conflicts of interest of reviewers as well as NIH staff. The SRA is responsible for all arrangements for IRG review panel meetings and serves as the focal point for communications with the panel members.

**INFORMATION RECEIPT POINTS:**

The usual grant procedure for receipt and handling of official correspondence, applications, etc., from/to the Principal Investigator/Grantee Institution, will be followed. The only two differences would be 1) the additional information and reporting of the Program Scientists/Program Coordinator to the Program Official on meetings, status, and overall progress of the cooperative agreement; and 2) the communication between the Principal Investigator and the Program Scientist/Program Coordinator to conduct that business which is relevant to the purpose and responsibilities of that position for the programmatic involvement.

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**DUTIES OF THE SCCPIR 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 SCCPIR.
4. Serves as liaison between the Steering Committee and NICHD staff (other than the NICHD Research Coordinator member of the Steering Committee). As liaison, conveys information (i.e., meeting minutes) or formal action requests from the Steering Committee to the NICHD, as well as information or responses from the NICHD to the Steering Committee. Approves and certifies by signature, those SCCPIR support documents to be submitted with an annual noncompeting, continuation application of the individual SCCPIR center grants that provide assurance for Steering Committee approval of recommended major changes in science directions or budgetary allocations.
5. Reviews and approves the SCCPIR Research Coordinator's Annual Report to the NICHD.
6. Reviews and approves the Disclosure of Potential Conflict of Interest circumstances submitted by the SCCPIR Center Directors, and forwards to the NICHD any issues requiring further consideration and decision.