National Heart, Lung, and Blood Institute

National Institutes of Health

U.S. Public Health Service, DHHS

SPECIAL INSTRUCTIONS for

Specialized Centers of Clinically Oriented Research (SCCOR)

GRANT APPLICATIONS

November 2004

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A. Introduction

These instructions provide information needed for preparation of an application for a National Heart, Lung, and Blood Institute (NHLBI) Specialized Center of Clinically Oriented Research (SCCOR). They are intended as a companion to an RFA for a SCCOR and PHS Form 398. Additional information about the SCCOR program can be found on the NHLBI website at Specialized Centers of Clinically Oriented Research (SCCOR)—Program Description (http://www.nhlbi.nih.gov/funding/policies/sccor_desc.htm) and Specialized Centers of Clinically Oriented Research (SCCOR)—Frequently Asked Questions (http://www.nhlbi.nih.gov/funding/policies/sccor_qa.htm).

Note: This is NOT a solicitation for SCCOR applications and the SCCOR mechanism is NOT used to support investigator-initiated research. SCCOR applications are solicited by the NHLBI in a Request for Applications (RFA) in the NIH Guide, which can be found at http://grants.nih.gov/grants/guide/index.html and on the NHLBI website at http://www.nhlbi.nih.gov/funding/inits/index.htm#rfa.

B. General Information

General instructions for preparation of NIH grant applications are contained in the most recent standard NIH grant application (PHS Form 398, which is available at http://grants.nih.gov/grants/funding/phs398/phs398.pdf). It is also usually available at an applicant institution's business office. Even though the application is intended primarily for the regular research project grant, some of the **general** instructions and forms in it also apply to SCCOR grant applications. However, SCCOR grants have special characteristics. Accordingly, the **specific** instructions in this document were prepared for use with the grant application. If questions arise, it is recommended that applicants contact Institute staff. To the extent possible, the staff is prepared to discuss plans for developing an application. Inquiries about preparation of SCCOR applications should be addressed to the individuals listed in the RFA under the section Agency Contacts.

C. Specific Instructions for Specialized Centers of Clinically Oriented Research (SCCOR) Applications

1. FACE PAGE (Form Page 1)*

   - Type "NHLBI SCCOR" in the top left-hand corner of the face page above the words "GRANT APPLICATION." Enter in Item 1 the title of the SCCOR program. In Item 2, check "YES" and insert the RFA Number and Title: Specialized Center of Clinically Oriented Research. In item 3, indicate the name, degree(s), and position (or equivalent) title of the SCCOR Director. Complete the rest of the page according to the instructions in the application, including the signature of the appropriate institution officials. Be sure to attach the **RFA label** , found in the application, to the bottom of the face page on the original application. Failure to use the RFA label could result in delayed processing of your application, such that it may not reach the review committee in sufficient time for review.

*Refers to appropriate form in the NIH grant application (PHS 398).

2. DESCRIPTION, PERFORMANCE SITES, AND KEY PERSONNEL (Form Page 2)

   - Provide a brief description of the proposed SCCOR in the space provided. Fill in the performance site(s) and the key professional personnel on this form.

3. RESEARCH GRANT TABLE OF CONTENTS

   - Do **not** use Form Page 3 provided in the application. **Instead**, prepare a table of contents that identifies by page number all major parts of the SCCOR so that they can be readily located. When listing individual projects and core(s), identify each by a number, title, and responsible investigator in the order in which they appear in the application. Pages should be numbered sequentially throughout the entire application.

4. DETAILED BUDGET FOR INITIAL BUDGET PERIOD (Form Page 4)

   - A detailed budget will be required for **EACH PROJECT AND EACH CORE UNIT** in their respective sections of the application. (See later under Research Plan)

   - To aid in the review of your application, it is suggested that you incorporate a detailed budget for all requested support for the first year using Form Page 4 (See Sample Table 1 at the end of this document for an example). For each category, such as “Personnel,” “Equipment,” “Travel,” and “Other Expenses,” give the amount requested for **EACH PROJECT AND CORE UNIT** with subtotals. If contractual arrangements or “purchased services” involving other institutions or organizations are anticipated (as in project 5 in Sample Table 1), include total (direct and facilities and administrative) costs associated with such third-party participation in the “Consortium/Contractual Costs” category. In addition, a complete budget for a consortium project is to be developed and identified as such. The published policy governing consortia should be available in the business office of the grantee institution. If clarification is required, communicate with the Grants Operations Branch, Division of Extramural Affairs, NHLBI, at 301-435-0166.

5. BUDGET FOR ENTIRE PROPOSED PERIOD (Form Page 5)

   - Use Form Page 5 in the application to show the total SCCOR budget by category requested for each of the 5 years. Justifications for increases in succeeding years should **not** be included here; they should be delineated in the **detailed** budget for **individual** projects.

6. BIOGRAPHICAL SKETCH (Biographical Sketch Format Page)

   - Prepare biographical sketches as described in the application; they should be placed in alphabetical order immediately after the summary budget information. Biographical sketches are required for all professional personnel participating in the individual SCCOR projects and core(s). A form entitled "Biographical Sketch Format Page" is provided in the PHS 398 application.

     See the PHS 398 instructions for completing the “OTHER SUPPORT Section.”

7. RESOURCES

   - See section 8.b. below, Resources.

8. RESEARCH PLAN

   - Each project should follow the format for the PHS Form 398 and provide supplementary information when necessary for each section as indicated below. Describe each research project and each core unit in the same detail required for an individual research project grant application, so that the scientific merit can be judged on the basis of the written proposal. Keep in mind that the application will be reviewed by experts who can judge, collectively, all areas represented in the application but who may not be familiar, individually, with each area of research proposed. Therefore, the description of a project should be concise yet explicit enough to enable experts in related areas to understand the main thrust of each project.

   - Page limitations specified for individual (R01) grant applications in PHS Form 398 apply to each project and core unit section. Additional information concerning collaboration and integration between projects and cores and the contribution of each component to the program's specific goals should be succinct. It is the responsibility of the principal investigator to ensure that each component is presented as succinctly as possible. Unnecessarily long, wordy, or confusing presentations are usually perceived as indicative of premature or poorly planned research. The bibliography is not counted toward the 25-page limitation per project.

   - Full-size glossy photographs of materials such as electron micrographs or gels may be sent to the Scientific Review Administrator (SRA) for distribution to the reviewers, provided a photocopy (which could be reduced in size from the glossy photograph in the appendix) is included within the 25-page limit of sections a-d of the Research Plan. All other graphs, diagrams, tables, and charts must be included within the 25-page limit of sections a-d in the Research Plan. The appendix is not to be used to circumvent the page limitations in the Research Plan. The appendix will not be duplicated with the rest of the application. Therefore, material in the appendix should be sent directly to the SRA. (The SRA will instruct the applicant as when to send extra materials.)

The following sections should precede the individual projects.

a. Program Introduction and Statement of Objectives

   - A SCCOR should be viewed as a group of interrelated research projects, each of which is not only individually meritorious scientifically but is also complementary to the other projects in your research program and contributes to the integrating theme. The theme of your proposed SCCOR should be established in the first few sentences of the general introduction.

   - Describe the rationale for your proposed total research program. Explain the strategy for achieving the objectives of your overall program and how each research project and core unit relates to that strategy.

- The general introduction of your overall program description is the appropriate place to indicate any prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, to describe anticipated unique advantages that would be gained by the research within your proposed SCCOR, to describe how the projects are synergistic and mutually reinforcing, and to explain how the projects collectively would enhance the stated objective of your proposed research.

b. Resources

- Briefly describe the features of the institutional environment that are relevant to the effective implementation of your overall program. As appropriate, describe available resources such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consultative resources. The information requested here supplants the Resources Format Page in the PHS Form 398 grant application, which is NOT to be used in describing your overall SCCOR program.

c. Organizational and Administrative Structure of a SCCOR

- Describe in detail and by diagram, if appropriate, the chain of responsibility for decision-making and administration, beginning at the level of SCCOR Director and including investigators responsible for the direction of the research projects and core units. The Director of the overall SCCOR is called the principal investigator; the leaders of the individual projects in a SCCOR are project leaders. Indicate where, in the chain of responsibility, advisory groups (internal and external consultants) would be used.

- Advisory groups: Provide a description of the function of advisory groups (internal and external) used to provide advice and quality control. Identify the expertise needed but do not identify by name the external consultants serving on the advisory groups.

- Specific managerial responsibilities: Indicate who would be responsible for assisting the SCCOR Director with the day-to-day administrative details, program coordination, and the planning and evaluation of the program.

- Relation of the SCCOR organization to the administration of the applicant institution : Describe the relation between your proposed SCCOR and other existing research, academic, and administrative units of the applicant institution such as schools, centers, institutions, departments, and central administration.

- Consortium arrangements: If a SCCOR application includes research activities that involve institutions other than the sponsoring organization, it is considered a consortium effort. Such activities may be included in a SCCOR grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. The published policy governing consortia is available in the business offices of

institutions that are eligible to receive Federal grants-in-aid. Consult the latest published policy governing consortia before developing the application. If clarification of the policy is needed, contact the Grants Operations Branch, Division of Extramural Affairs, NHLBI, at 301-435-0166. Principal investigators of SCCORs should exercise great diligence in preserving the interactions of the participants and the integration of the consortium projects with those of the parent institution.

- Designation of replacement for SCCOR DIRECTOR : Describe the procedure for appointing a replacement for the SCCOR Director, should the need arise. The NHLBI must approve the replacement of the SCCOR Director.

Individual Projects

a. Title and number each research project so that it can be readily distinguished from any other project in the program. An individual ABSTRACT should be prepared for each project in the SCCOR as would be required for an R01 (Individual Research Grant). The title must NOT exceed 56 characters/spaces. DO NOT provide a face page (i.e., PHS Form 398 face page) for individual projects. Provide the name and academic title of the project leader and each participating investigator.
b. The budget for each research project must be presented according to the instructions indicated for PHS Form 398; use Form Pages 4 and 5. A detailed budget is required for the first and all subsequent years. Include budget requests and explicit detailed budget justifications for all years.
c. Research Plan: State the overall objective of the proposed research and explain the relation of the research project to the central theme of the SCCOR and how the project relates to, and both complements and supplements, the other research projects and core units in the program. Indicate the relevance of the research project to the theme of the SCCOR. In addition, specify the overall biomedical significance of the work proposed.

    i. Specific Aims

        - List the specific aims of the research project for the total period of requested support. Indicate the general priority of each aim in the overall research plan.

    ii. Background and Significance

        - Review the most significant previous work and describe the current status of research in this field; document with complete references.

    iii. Preliminary Studies

        - Refer to PHS Form 398 Instructions for Preliminary Studies.

    iv. Research Design and Methods

        - Give details of the research plan, including a description of the experiment or other work proposed; present the methods and techniques to be used; note

the limitations, if any, of the procedures proposed. Insofar as possible, describe the experiments in the sequence in which they would be conducted. (It is important to convey to the reader that the proposed effort would require the time requested for the project period.)

v. Human Subjects Research

- The NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear and compelling rationale should be provided. The policy can be found in the NIH Guide for Grants and Contracts of March 18, 1994 , Volume 23, Number 11 and available on the web at: http://grants.nih.gov/grants/guide/notice-files/NOT-0D-00-048.html.

- The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design sample size appropriate for the scientific objectives of the study. This information should be included in PHS Form 398 in section 9, a-d of the Research Plan AND summarized in section 9, e, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, the NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of U.S. racial/ethnic populations (i.e., American Indian/Alaska Native, Asian, Native Hawaiian or other Pacific Islander, Black or African American, White, and Hispanic or Latino). The rationale for studies on single racial/minority population groups should be provided.

- It is the policy of the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998 . All investigators proposing research involving human subjects should read the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998 , and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

- For the purpose of grant applications, the NIH policy for research on human subjects includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders, or conditions.

- The usual NIH policies concerning research on human subjects also apply. PHS Form 398 should be followed for human subjects information.

- For foreign components, the policy on inclusion of women and children applies fully. Because the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the U.S. populations, including minorities.

- If the required information on research on human subjects is not contained within the application, the application will be returned without review.

- Include a Data and Safety Monitoring Plan in the application that describes the organizational structures and procedures that will be employed to ensure the safety of participants and validity and integrity of the data according to NIH policy that can be found at http://grants.nih.gov/grants/guide/notice-files/not98-084.html. Funds should be requested in the Administrative Core budget for support of a Data and Safety Monitoring Board, if appropriate.

vi. Vertebrate Animals (see PHS Form 398 Instructions)

- If animals are involved, indicate what kinds are to be used and whether nonhuman primates are to be used, listing the special justifications for their use, and indicate all details for the care, use, treatment, and dispatch of all animals.

vii. Literature Cited

- Include a complete citation for each reference in the text. TITLES OF REFERENCE PUBLICATIONS SHOULD BE INCLUDED.

viii. Consortium/Contractual Arrangements and/or Collaborative Arrangements (See PHS Form 398 Instructions)

- Describe the collaboration of investigators within your SCCOR. Describe in detail any other collaborative arrangements anticipated, either within the applicant institution or between institutions.

ix. Consultants (see PHS Form 398 Instructions)

- Provide a justification for consultants and attach letters from all individuals confirming their roles in the project.

9. APPENDIX

- The following instructions replace, in part, those given in grant application Form 398. Appendix material should NOT be included as part of the grant application but may be submitted as additional material at the same time reprints are requested by the Scientific Review Administrator.

10. FORMAT FOR A CORE UNIT

A core unit is defined as a resource for the SCCOR that provides centralized services to two or more of the research projects.

a. Title of core unit

- Title and assign a LETTER designation to each core so that it can be readily distinguished from any other core unit. Do NOT exceed 56 characters/spaces for its title.

b. Names and titles of investigators

- Provide the name and academic title of the core unit leader and each participating investigator.

c. Resources

- Describe the Resources available for each core unit, see Resources section in PHS Form 398. Follow the sample format and instructions on the Resources Format Page in the PHS Form 398 when completing information on resources available for each core unit.

d. Description of core unit

- Describe the function of the core unit as a resource to the SCCOR. This section must present clearly the facilities, techniques, and professional skills that the core unit would provide. As justification for the core unit, indicate briefly the specific research projects that would use the resources of the core unit. A core unit is principally designed as a service or resource component; it would be highly unusual to include research in a core unit (a possible exception would be methodology development). Please contact the Institute staff if you require guidance on this issue.

e. Budget for core unit

- Present the budget for each core unit in the format and according to the instructions indicated for Form 398, use Form Pages 4 and 5. A budget for the entire proposed project period is required for all subsequent years of support (direct costs only). Include explicit and detailed budget justifications for all years.

f. Relation of core units to research projects

- To aid in the review of your application it is recommended that you prepare in tabular form information concerning the research projects that each core unit would serve and the proportion of the cost of the core unit associated with each research project involved, according to the format presented in Sample Table 2 in the Illustrations. If you have a collaborative Data Management Core, it is not necessary to proportion the cost of the core unit for each research project.

Illustrations

- Sample Table 1 is an example of how to fill in Form 398 (Form Page 4).

- Sample Table 2 is an example of how to indicate the relationship of the cores to the projects and is suggested for use to help the reviewers in the evaluation of your SCCOR grant application.

TABLE 1

Principal Investigator/Program Director (Last, First, Middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY

FROM THROUGH

PERSONNEL *(Applicant organization only)* DOLLAR AMOUNT REQUESTED *(omit cents)*

NAME	ROLE ON PROJECT	TYPE APPT. *(months)*	% EFFORT ON PROJ.	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
Project 1					120,000	12,000	132,000
Project 2					80,000	8,000	88,000
Project 3					100,000	10,500	110,500
Project 4					60,000	6,000	66,000
Core Unit A					88,000	8,800	96,800
Core Unit B					40,000	4,000	44,000
SUBTOTALS				→	**488,000**	**49,300**	**537,300**

CONSULTANT COSTS Project 2 ($4,000), Core Unit A ($8,000)	12,000
EQUIPMENT *(Itemize)* Project 1 ($16,000), Project 2 ($8,000), Project 3 ($4,000), Project 4 ($6,000), Core Unit A ($6,000), Core Unit B ($8,000)	48,000
SUPPLIES *(Itemize by category)* Project 1 ($56,800), Project 2 ($8,000), Project 3 ($46,000), Project 4 ($35,600), Core Unit A ($6,600), Core Unit B ($72,800)	225,800
TRAVEL CORE A (Domestic - $12,000, Foreign - $4,000)	16,000

PATIENT CARE COSTS	INPATIENT Project 4	80,000
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		

OTHER EXPENSES *(Itemize by category)* Project 1 ($4,000), Project 2 ($6,000), Project 3 ($7,600), Project 4 ($4,400), Core Unit A ($6,000), Core Unit B ($8,800)	36,800
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	**$ 955,900**

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	180,800
Project 5	FACILITIES AND ADMINISTRATIVE COSTS	80,000

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)* →	**$ 1,216,700**
SBIR/STTR Only: FEE REQUESTED	

TABLE 2

Relation of Core Units to Research Projects

Projects	Core Unit A	Core Unit B
Project 1	$ 23,080	$ 27,600
Project 2	23,080	24,000
Project 3	23,080	40,000
Project 4	23,080	24,000
Project 5	23,080	18,000
Totals	$115,400	$133,600