

**SPECIALIZED CENTERS OF RESEARCH (SCORs)
on Sex and Gender Factors Affecting Women’s Health**

ADMINISTRATIVE AND REVIEW GUIDELINES

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SPECIALIZED CENTERS OF RESEARCH (SCORs) on Sex and Gender Factors Affecting Women's Health

Office of Research on Women's Health

I. INTRODUCTION

The Office of Research on Women's Health (ORWH) serves as a focal point for women's health research at the NIH. The ORWH promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research. ORWH works in partnership with the NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

Through this partnership, the ORWH announces a new program, Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health, to promote institutional interdisciplinary research in an area important to women's health. A successful SCOR will be a resource that develops and conducts innovative, interdisciplinary research on women's health issues.

The research goals of these centers will address the ORWH research priorities for women's health. A subcommittee of the Coordinating Committee on Research in Women's Health, composed of representatives from NIH institutes and centers reviews the many areas of research opportunities and recommends to ORWH areas which are determined to be of special importance for expanding current initiatives or for developing new research programs as detailed in the Request for Applications for this SCOR program. ORWH also collaborates with the broader scientific, health professional and advocacy communities to encourage meritorious research on women's health and to implement the recommendations from the report, *Agenda for Research on Women's Health for the 21st Century*. This report summarizes a series of national meetings that were held to revise the NIH agenda for research on women's health. (See: <http://www4.od.nih.gov/orwh/report.pdf>)

The following guidelines provide information about the new SCORs, suggestions for preparation of an applications and criteria for review. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) will serve as an administrative center for review and grant administration of this program.

II. PURPOSE AND SCOPE

A SCOR provides the opportunity for investigators to engage in interdisciplinary and collaborative research which is focused on a specific disease or an area within a disease category. It is required that SCOR applications include studies of human subjects and/or human materials as well as basic studies clearly related to a disease area. The foundation of the clinical component should be strongly linked to the basic science projects; the basic science studies

should be driven by the needs of the clinical projects. Thus, a SCOR has a central theme to which all research projects pertain. In addition, a SCOR may include core units to provide services to the various research projects and to support the organizational and administrative aspects of the program.

To meet these objective, each SCOR application is expected to include:

- < a theme for an overall research program for a disease that addresses a critical area of opportunity to advance knowledge and patient care (documented in the program introduction and statement of objectives);
- < a multidisciplinary team of basic and clinical researchers to provide a mutually supportive interaction in meeting the research objectives (documented in the administrative core, in the program introduction and statement of objectives, and in the individual projects and cores);
- < both basic and clinical research projects that develop new approaches, elaborate new and significant hypotheses, and generate improved strategies for approaching current issues relating to the disease investigated (documented in the individual projects and cores).

Each basic or clinical research project is expected to have high scientific merit with clear research objectives and to relate to a theme developed for that SCOR program. Ongoing NIH-funded projects are NOT to be included. The individual projects may be submitted independently for review as R01 projects, but funding of a project approved in a SCOR will take precedence over funding as a R01 or other research application.

Funding may be requested for one or more core resources devoted to performing specialized support activities, such as biochemical analysis, electron microscopy, or data management. A core is defined as a resource shared by multiple investigators that should enhance research productivity and increase the functional capacity of the SCOR. Cores should be designed to provide added dimensions, generating accomplishments greater than that obtainable by the individual projects. Developmental research (for example, development of new assays or procedures) needed to further research efforts of the SCOR investigators are also appropriate for a core.

Specific Requirements

A SCOR is envisioned as a national resource associated with one or more major medical complexes and dedicated to working with the ORWH in furthering the research effort to translate basic research to clinical application. Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals,

laboratories, units of State and local governments, and eligible agencies of the Federal government. An established clinical and basic research program in the disease area should be present. Foreign organizations are not eligible. International collaborations in domestic applications will only be accepted if the resources are clearly shown to be unavailable in the United States.

The SCOR director is expected to make a commitment of at least 15 percent effort to the overall administration of the program plus 20 percent effort as a principal investigator of a SCOR project. Project and core leaders must commit at least 20 percent effort to each project for which they are responsible.

To be funded, a SCOR must include at least three highly meritorious projects approved for five years. One of these must have the SCOR director as the principal investigator, and the highly meritorious projects must include both basic and clinical research. Note that Sections VII.C & D of these guidelines provide guidance in communicating to reviewers the overall research plan, the role of the projects, and the role of a clinical investigator in the administrative core for translating research to clinical applications.

NIH has policies for the inclusion of women, minorities and children which **must** be addressed in **each** project proposal and in **each** core, even if only to indicate why a full discussion is not applicable. The reviewers will be instructed to address the adequacy of inclusion plans for the work proposed as part of the scientific and technical merit evaluation. Carefully follow the detailed instructions in the Section e, *Human Subjects Research*, of the Research Plan Format and Page Distribution instructions in the PHS 398 (5/01) application guidelines. Section e, *Human Subjects Research*, is covered pages 18-24.

Support for large clinical trials or for applications that contain exclusively clinical investigation or exclusively basic studies will not be provided within this program.

III. PROGRAM ADMINISTRATION/INTERACTION

The ORWH Centers Program Director will facilitate program development and evaluate progress. Restricted travel funds will be added at the time of award to an administrative core for periodic meetings in the Washington D.C. area of the SCOR investigators.

IV. MECHANISM OF SUPPORT

Support of this program will be through the NIH specialized center (P50) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

The direct costs requested cannot exceed \$750,000 in the first year, excluding indirect costs of subcontracts. Applicants may request up to three percent cost of living increases each year. SCOR awards will be issued for a period of up to five (5) years. ORWH will decide whether renew the program after five years.

Applicants are expected to furnish estimates of the time required to achieve specific objectives of the proposed work and a schedule for completion of the work. The SCOR director will plan, direct and implement the research program. Any substantial modifications in the scope or objectives must be agreed upon mutually by the SCOR institution and the ORWH.

V. METHOD OF APPLICATION

A. Preapplication process and letter of intent

The receipt date for a SCOR application will be announced by ORWH through a Request for Applications (RFA) published in the NIH Guide for Grants and Contracts.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) will serve as an administrative center for review and grant administration of this program.

Individuals from institutions with potential interest in applying for a SCOR grant are encouraged to contact the program staff as early as possible after the RFA has been issued. Consultation between program staff and potential applicants prior to submission of the formal application may be useful. Applicants should not construe advice given by the program staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the proposal.

To facilitate Institute planning, applicants are requested to submit a letter of intent on the date listed in the RFA. This letter should provide a descriptive title of the research projects and cores requested and the key participants. The letter of intent, and any inquiries about the program, should be directed to:

Centers Program Director
National Institute of Arthritis and
Musculoskeletal and Skin Diseases
45 Center Drive MSC 6500
Bethesda, Maryland 20892-6500
[Bethesda, MD 20814 (for express/courier service)]
Telephone: (301) 594-5052
FAX: (301) 480-4543

The Institute requests such letters for the purpose of obtaining an indication of the number and

scope of applications to be received. A letter of intent is not binding, will not enter into the review of any proposal subsequently submitted, and is not a requirement for application. For fiscal and administrative matters, contact:

Chief Grants Management Officer
National Institute of Arthritis and
Musculoskeletal and Skin Diseases
45 Center Drive MSC 6500
Bethesda, MD 20892-6500
[Bethesda, MD 20814 (for express/courier service)]
Telephone: (301) 594-3535
FAX: (301) 480-5450

B. Application Procedure

It is desirable for SCOR applications to be arranged in a specified format. This not only makes it easier for reviewers to use, but it can also serve as a checklist for the applicant institution in preparing the application.

Form PHS 398 must be used for the SCOR application and each project and each core should be individually described on this form. Page limitations will apply to the individual projects. The arrangement of materials should follow both the instructions in Form PHS 398 application kit and the more specific instructions detailed in Section VII of these guidelines.

The RFA label available in the application package must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

The original and three (3) signed, exact photocopies of the application should be sent or delivered to:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC 7710
Bethesda MD 20892-7710
[Bethesda, MD 20817 (for express/courier service)]

In addition send two (2) copies of the application to:

Chief, Review Branch, EP, NIAMS
Room 5AS.25U
45 Center Drive MSC 6500
Bethesda MD 20892-6500

[Bethesda, MD 20814 (for express/courier service)]

Telephone: (301) 594-4952

All appendix material must be clearly marked with the Center Director and the appropriate project or core. Appendix material should be labeled for each core or project to which it is applicable.

VI. REVIEW PROCEDURE AND CRITERIA

Applicants should keep in mind that the written application is the basis for the merit review. Site visits are not anticipated.

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS and ORWH. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique.
- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score. If the project from the SCOR director is not recommended for further consideration during the review for scientific merit, the entire SCOR application may not be reviewed further. If none of the clinical research projects in a SCOR application is recommended for further consideration, the SCOR application may not be further reviewed.
- o Receive a second level review by the NIAMS National Advisory Council. The ORWH Director and the Advisory Committee for the Office will make the funding decisions.

The review criteria for the overall project are shown below; review criteria for SCOR Leadership, Environment and Resources, individual projects, research cores and the administration core are included in Sections VII.C and D. The overall score may be higher or lower than the “average” of the descriptors based on the assessment of whether the “whole is greater or lesser than the sum of its parts”. Major factors to be considered in the overall evaluation of applications will include:

1. How the proposed SCOR combines basic and clinical research into the scientific goals and research theme;

2. Scientific merit of each proposed project. [Each project will receive a priority score. This score reflects not only the feasibility of the project and adequacy of the experimental design, but also the design of the project to advance both the theme of the SCOR and the interaction between basic research and clinical investigation];
3. Scientific merit of combining the component parts into a SCOR;
4. Technical merit and justification of each core unit;
5. Competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the research program;
6. Adequacy of facilities to perform the proposed research, including laboratory and clinical facilities, instrumentation, and data management systems, when needed;
7. Adequacy of plans for interaction among investigators, and the integration of the various projects and core units;
8. Qualifications, experience and commitment of the SCOR Director and his/her ability to devote time and effort to provide effective leadership;
9. Scientific and administrative structure, including internal and external procedures for monitoring and evaluating the proposed research and for providing ongoing quality control and scientific review;
10. Institutional commitment to the program, and the appropriateness of resources and policies for the administration of a SCOR;
12. Adequacy of plans to include both genders and minorities and their subgroups and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The appropriateness of the budget for the proposed program and its individual components will be considered independently of the factors indicated above.

Since the ORWH is interested in funding only the best research, individual research projects of lesser quality may not be funded, even if approved, under the "umbrella" of the SCOR mechanism. For this reason, each project will be assigned a separate priority score.

VII. SUGGESTED CONTENT ORDER FOR APPLICATIONS

A. Face page, Abstract Page, Table of Contents

PHS 398 is required for all applications. Each budget unit (project or core) should be written in the style and within the page limitation described in the PHS 398 instruction kit. To aid in the review of these applications, the applicant should assemble the component units following the format described below. Applicants may also consult with Program staff concerning the technical aspects of preparing the application.

Face Page of Form PHS 398 . Complete all items on the face page as directed. In the title block, item 1, put "ORWH: SCOR on Sex and Gender Factors Affecting Women's Health". Mark item 2 "yes" and write in the RFA code as listed in the NIH Guide to Grants and Contracts. and "ORWH: SCOR on Sex and Gender Factors Affecting Women's Health" for the title.

Page 2: Describe the **overall** proposed program indicating the goals and objectives of the projects.

Table of Contents: Discard this page from Form PHS 398 and write a Table of Contents appropriate for the SCOR grant application. This is paginated to follow the list of Key Personnel. **Do not use letters (e.g. 4a, 4b, 4c, etc.)** The Table of Contents should list all projects and cores for which funding is sought. Each project and core should be listed by the title and Principal Investigator. Specifically list the locations of the checklist and the various requested supporting documents, e.g. animal and human subject assurances, other support, and bibliographies.

B. Budgets and Other Supporting Forms

Budget: See Exhibits I, II and III. To aid in the review of your application, it is suggested that the forms found as pages 4 and 5 in PHS Form 398 be used for all budgets. Justify and document all costs for current and future years throughout.

The **overall** Center budget, "Summary Center Budget," is to be presented first using PHS Form 398 page 4 entitled "Detailed Budget for First 12-Month Period" (see Exhibit I). Note that no details need be given for the individual categories. To provide budget information in a format that is clear to reviewers and therefore provides the most positive review possible, presentation of a consolidated budget for the first 12 months in a tabular form such as the sample shown as Exhibit II is suggested. Page 5 of PHS Form 398, "Budget Estimates for All Years of Support Requested Direct Costs Only", should then follow, a composite like that in Exhibit I, summarizing all individual budgets (see suggested format in Exhibit III). For the purpose of establishing future year budget requests, the applicant should use cost escalations of 3% or less.

Both first 12 month and 5 year **individual** budgets, should be included *in the sections for each project and core*. Details and justifications for all budget items must be part of the individual budgets. Read carefully pages 10 - 14 of the Instructions for PHS 398 on how to prepare budget pages and justifications.

- < This grant mechanism is not intended for the acquisition of costly equipment which should be funded through other sources. Under unusual circumstances, where costly items of equipment are requested, the application must document available equipment within the institution and provide clear justification.

Biographical Sketches: Biographical sketches are required for all professional level personnel who are listed with a percent effort (including consultants) in the SCOR application. The forms found in Form PHS 398 should be used. Place individual sketches in alphabetical order after the budget pages. These pages should not be duplicated in the individual component projects and cores. Note that research support is now included in the biographical sketches. These pages should not be duplicated in the individual projects and cores.

Assurance Documentation: See sample suggested table, Exhibit IV. In addition to the assurance pages, a master table listing the status of human subject and the animal usage approval dates will aid in the timely processing of your application. The IRB approval is not required by NIH at the time that the application is submitted, but will be requested if the intent is to fund the specific project.

C. Overall Research Plan, Leadership & Resources

Using continuation pages, substitute the following for the Research Plan instructions of Form PHS 398. **Note - this section is intended to be read by all reviewers, even if they are not assigned to projects within this application. Therefore it is important to provide a succinct, yet comprehensive overall research plan.** This section on Overall Research Plan, Leadership & Resources should not exceed 25 pages.

1. Program Introduction and Statement of Objectives

State the research theme that is the focus of the application. Describe the rationale for the proposed research program, and explain the strategy for achieving the objectives of the overall program, how each project and core unit relates to the strategy, and how the projects and cores relate to one another. Describe which are the clinical research projects and the rationale for each within the SCOR theme. Describe the nature of the multidisciplinary team and approach.

It is important to indicate prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, and to predict the anticipated unique advantages that would be gained by the research within the proposed SCOR.

2. SCOR Leadership

The emphasis in this section should be on the qualification of the SCOR leadership. Describe the qualifications of the SCOR Director to lead the program.

Review criteria for SCOR leadership:

- C Does the Director have the leadership and research qualifications to lead the SCOR? Do the projects and cores included in the application reflect this leadership?

3. Environment and Resources

Briefly describe the features of the institutional environment that are or would be relevant to the effective implementation of the proposed 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. Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SCOR staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

Review Criteria for Environment and Resources:

- C Is there evidence of a supportive institutional environment for the proposed SCOR? Does the proposed SCOR utilize available resources well? Is there support and commitment from the institutional authorities?

D. Presentation of Budgeted Components with Review Criteria

1. Projects

Using Form PHS 398, name and number each project sequentially so that it can be readily distinguished from other projects in the program. Each research project should be clearly identified by the same title as that provided in the Table of Contents. The project should begin with the abstract and budget pages and should follow the instructions for Form PHS 398. Describe each section in the same detail and format as required for a regular research grant application so that the scientific merit can be judged on the basis of the written proposal. Adhere to the page restrictions indicated in the instructions for Form PHS 398. **Begin each project with a short section that clearly states how that project contributes to the theme of the SCOR as**

a whole. If it is a clinical research project, describe the rationale of including it as a clinical research project within the theme of the SCOR.

The budget for each research project should reflect the instructions for Form PHS 398. A detailed budget is required for the first year; budget estimates are required for all subsequent years of support. Explicit and detailed budget justifications must be included for all years. Budget pages must be labeled so that they can be readily associated with the particular projects to which they apply. The project principal investigator should devote at least 20 percent effort to the research.

For projects including human subjects, carefully follow the detailed instructions in the Section e, *Human Subjects Research*, of the Research Plan Format and Page Distribution instructions in the PHS 398 (5/01) application guidelines, pages 18-24.

Review Criteria for individual projects:

(1) Significance

Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach

Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation

Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

(6) Collaboration

Does the project advance the theme of the SCOR and contribute to the interaction of basic research and clinical investigation?

(7) Protections

Are the proposed plans for protection for humans, animals, or the environment, to the extent they may be adversely affected by the proposed project, adequately described?

(8) Inclusion

Are there adequate plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research? Are there adequate plans for the recruitment and retention of subjects?

(9) Data sharing.

Are there appropriate plans to to share data, if appropriate?

(10) Budget

Is the proposed budget and the requested period of support in relation to the proposed research reasonable?

2. Research Cores

Each core must be written using Grant Application Form PHS 398. Name and assign a letter designation to each unit. An abstract should be written for each core.

A core may be a unit designed just for the SCOR projects or may be an institutional core unit. However, funds may only be requested for SCOR use, and the core must serve a minimum of two projects within the SCOR, with no project dominating use of the core. The core principal investigator should devote at least 20 percent effort to the core. Describe the core unit and the various services it would provide. The justification for the core must include the value added by having services provided through the core rather than by the individual projects. Describe the personnel, facilities, management and any special arrangements such as cooperation with other established cores. The techniques to be used and the quality control procedures should be documented and justified. Indicate which core services each project would utilize. It is helpful in presenting the scope of the core to prepare a table indicating the research projects each core unit will serve and the estimated proportion of the cost (in dollars) of the core unit associated with each research project (see **Exhibit V**).

Each core using human subjects must include a discussion of the composition of women and minority subjects and the inclusion of children.

Review Criteria for proposed cores:

- C Will the core have utility to at least two of the SCOR projects?
- C Are the quality of services high? Are there procedures for quality control? Is the core cost effective?
- C Do the services offered best fit within a core structure? If this is an add on to a preexisting core, what is the benefit to the SCOR over direct purchase of services from the existing core?
- C Are the personnel appropriate?
- C Are the facilities and equipment adequate? Is there institutional commitment to the core?

Other factors included in the evaluation:

- C Protections: Are the proposed plans for protection for humans, animals, or the environment, to the extent they may be adversely affected by the proposed project, adequately described?
- C Inclusion: Are there adequate plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research? Are there adequate plans for the recruitment and retention of subjects?
- C Data sharing: Are there appropriate plans to to share data, if appropriate
- C Budget: Is the proposed budget and the requested period of support in relation to the proposed research reasonable?

3. Administrative Core

The purpose of a SCOR is to expedite development and application of new knowledge of specific importance to diseases withing the mission of the institute. The Administrative Core is responsible for the overall administration of the SCOR. Describe in detail, and by diagram if appropriate, the chain of responsibility for decision-making and administration. Include to whom the program director reports and the administrative structure as it relates to the investigators responsible for the research projects and core units. If advisory groups will be used, indicate their specific functions and to whom they report.

The administrative core must include a clinical investigator who is responsible for the translation of basic research to clinical research to assure a mutually supportive interaction between scientists conducting basic research and those performing clinical investigation. The

qualifications of the clinical investigator and the plan to promote patient based research should be described.

The SCOR director is expected to make a commitment of at least 15 percent effort to the overall administration of the program plus 20 percent effort as a principal investigator of a SCOR project. Administrative support personnel may be budgeted in at no more than one full time equivalent (FTE) which may be divided among one or more positions. This FTE must be fully justified.

Indicate who would be responsible for assisting the program director with the day-to-day administrative details, program coordination, and planning and evaluation of the program, and who would be in charge in the absence of the director. Describe procedures for appointing a replacement for the program director if the need should arise.

Review Criteria for the Administrative Core:

- C Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the SCOR Director for the effective management of the SCOR program?
- C Is there a clinical investigator named in the Administrative Core who will be responsible for the translation of basic research to clinical research? Is there a plan to promote patient based research?
- C Is the management proposed appropriate for scientific administration as well as fiscal administration, procurement, property and personnel management, planning, budgeting, etc.?
- C Is there a plan for the establishment and maintenance of internal communication and cooperation among the SCOR investigators? Are there plans for outside review and input?

VIII. REPORTING REQUIREMENTS AND ANNUAL EVALUATION

An annual non-competing continuation application, which includes a progress report, is due two months before the anniversary date of the award. The progress reports are used by the ORWH and advisory committees to review the Center and its progress. They serve to document in detail the achievement of the objectives outlined in the initial application and award; they also serve as an important source of data for program staff in preparing annual reports, planning programs, and communicating scientific accomplishments. These progress reports should include the following:

- A summary (equivalent to no more than 2-4 single-spaced typewritten pages) of the goals and significant activities of the SCOR. This summary should be prepared for a general audience.
 - A discussion of the effectiveness of the SCOR grant in furthering the goals of the program. This should include a summary listing of the specific accomplishments that can be attributed to the SCOR grant. List what has been accomplished with the SCOR grant which would not have been done without it; e.g., new research funding, personnel recruited, notable research breakthroughs, and so forth.
- C A discussion of any problems which impede accomplishment of the stated goals.
- C Itemize any collaborative efforts which the SCOR has established and is conducting with other programs for women's health.
- C A summary of each active SCOR project and core unit, including the title, principal investigator and key personnel, their percent effort, budgets, description, and progress, using the format found in PHS Form 2590. The progress report should describe the original objectives of the project, progress to date, and papers published. **It is important that the significance and utility of each project be discussed in the summary description in a manner which can be understood by an individual who is not familiar with the specific area of science involved.**
- C Special attention should be given the section on Human Subjects, as described on pages 9-11 in PHS 2590, Instructions for the Non-competing Grant Progress Reports. Note the revised Enrollment Table (Enrollment Report Format Page, PHS 2590). The minimum racial/ethnic data required for the progress report on each clinical research project is described on pages 23-24 in the PHS 398 guidelines. For NIH-Defined Phase III Clinical Trials, note especially the requirement for an appropriate data analysis plan of the intervention effect in sex/gender and/or racial/ethnic subgroups.

- C Budget pages for each project and core unit. In conjunction with the programmatic description, this report should describe allocations in the usual budget categories (i.e., personnel, equipment, travel, etc.) as well as total expenditures. Separate pages should be used for each project and each core unit, in addition to a composite budget for the entire SCOR.

- C A summary table listing all human subject approval dates and animal usage approval dates such as shown in Exhibit IV.

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM

THROUGH

PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						

SUBTOTALS →

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CONSULTANT COSTS

EQUIPMENT (Itemize)

SUPPLIES (Itemize by category)

TRAVEL

PATIENT CARE COSTS

INPATIENT

OUTPATIENT

ALTERATIONS AND RENOVATIONS (Itemize by category)

OTHER EXPENSES (Itemize by category)

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$

CONSORTIUM/CONTRACTUAL COSTS

DIRECT COSTS

FACILITIES AND ADMINISTRATION COSTS

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page) →

\$

SBIR/STTR Only: FIXED FEE REQUESTED

EXHIBIT II SAMPLE OF SUGGESTED FORMAT

CONSOLIDATED BUDGET FOR THE FIRST YEAR OF REQUESTED SUPPORT

BUDGET CATEGORY	CORE A	CORE B	Project 1	Project 2	Project 3	Project 4	TOTAL ALL UNITS
PERSONNEL							
CONSULTANT COSTS							
EQUIPMENT							
SUPPLIES							
TRAVEL							
INPATIENT COSTS							
OUTPATIENT COSTS							
ALTERATIONS/RENOVATIONS							
OTHER EXPENSES							
SUBTOTAL DIRECT COSTS							
CONSORTIUM/ CONTRACT COSTS							
TOTAL DIRECT COSTS							

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD (from Form Page 4)	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>						
CONSULTANT COSTS						
EQUIPMENT						
SUPPLIES						
TRAVEL						
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES						
SUBTOTAL DIRECT COSTS						
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
	F&A					
TOTAL DIRECT COSTS						

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD (Item 8a, Face Page) _____

\$

**SBIR/STTR Only
Fixed Fee Requested**

SBIR/STTR Only: Total Fixed Fee Requested for Entire Proposed Phase II Period

(Add Total Fixed Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

EXHIBIT IV *SAMPLE OF SUGGESTED FORMAT*

HUMAN SUBJECTS AND VERTEBRATE ANIMAL APPROVAL DATES

GENERAL:

1. Initial application: IACUC review dates may be listed as pending when the application is submitted, but IACUC review must be completed before the NIH review. If IACUC certifications are not submitted as part of the application, they MUST be submitted to the Scientific Review Administrator prior to the review of the application. However, IRB approval and certification is not required with the submission or prior to review and may be listed as pending prior to the review.
2. Initial funding: This table may need updating. The NIH no longer requires IRB approval and certification prior to NIH review. This information will be required when a decision is made to fund the application.
3. Yearly progress reports: This table should be updated and included with each yearly progress report.

SPECIFIC:

Please make a table for each Performance Site. If there is only one performance site, then only one table is needed. A certification letter must be attached for each project using Human Subjects. Each letter should include the registered IRB number from the Office of Human Research Protections.

Performance Site: University A			
Principal Investigator	Project	Human Subjects IRB Approval Date (Attach certification letter)	IACUC Approval Date
Dr. A	1	9/5/2002	Not Applicable
Dr. B	2	Not Applicable	9/9/2002
Dr. C	3	8/5/2002	Not Applicable
Dr. E	5	Not Applicable	9/9/2002
Dr. B	Core A	Not Applicable	9/2/2002
Dr. D	Core B	Not Applicable	Not Applicable

Performance Site: University B Human Subjects assurance number: Animal welfare assurance number.			
Principal Investigator	Project	Human Subjects IRB Approval Date (Attach certification letter)	IACUC Approval Date
Dr. X	1 (subproject)	9/6/2002	Not Applicable
Dr. D	4	8/5/2002	9/2/2002
Dr. Y	Core B (subproject)	Not Applicable	8/30/2002

EXHIBIT V SAMPLE OF SUGGESTED FORMAT

DISTRIBUTION OF CORE UNIT COSTS AMONG RESEARCH PROJECTS

PROJECTS	CORE A	CORE B	CORE C	CORE D
P 1	\$ 3,000		\$ 1,500	
P 2	\$ 4,000	\$ 6,000	\$ 1,500	
P 3	\$ 3,000		\$ 2,500	\$ 5,500
P 4	\$ 10,000	\$ 6,000	\$ 1,500	\$ 2,500
TOTALS	\$ 20,000	\$ 12,000	\$ 7,000	\$ 8,000

Only those supply costs and other expenses specific to a project are to be listed. Personnel and equipment maintenance costs should not be prorated.