

Chapter 2

The Planning Grant Application

The Planning Grant

To help potential center directors explore the possibility of obtaining a grant for an AP4 center, the National Cancer Institute (NCI) is offering 1-year, \$50,000 (direct costs) planning grants. Applications for the planning grants are competitive and peer reviewed. These planning grants are to be used by potential AP4 center directors to:

- Hold a meeting to establish a potential collaborative relationship or significantly expand existing partnerships with biotechnology, pharmaceutical, academic, nonprofit, government, and other potential partners.
- Select initial research projects.

The major activity during the period supported by the planning grant is a meeting of potential AP4 center partners to explore the role of each potential partner, define how intellectual property issues will be handled, select initial research projects, and establish a research plan.

The NCI encourages planning applications from academic and nonprofit institutions with a strong record of funded research in cancer intervention discovery and development that have identified an overall theme and/or disease on which to focus their AP4 center. Nonprofit applicants should either have a formal relationship, such as joint faculty appointments, with a degree-granting academic institution, or identify a degree-granting institution as a partner. Prior to submitting a planning application, you should have identified:

- At least two potential pharmaceutical and biotechnology company, academic institution, nonprofit organization, and state and federal government agency partners.
- Several prospective AP4 center researchers with expertise in multiple disciplines (such as chemistry, biology, immunology, and screening technologies).
- Resources from your institution that can be devoted to the potential AP4 center.

NOTE: Every AP4 center is a partnership between an academic or nonprofit institution and at least two partners from the biotechnology and pharmaceutical industries, academic institutions, nonprofit organizations (including disease-specific charities), and government agencies. AP4 center researchers must have expertise in several different disciplines.

Any potential AP4 center director interested in applying for an AP4 center grant must apply first for an AP4 planning grant, because only recipients of a planning grant are eligible to submit an application for an AP4 center. Following the successful completion of the planning year, planning grant recipients may apply for an AP4 center grant, but receipt of an AP4 planning grant does not guarantee that any subsequent application for an AP4 center

will be approved.

The NCI intends to commit approximately \$1.125 million in FY 2004 to fund up to 15 new planning grants in response to the AP4 planning grant request for applications (RFA). Although the NCI currently plans to support this program, awards under this RFA are contingent on the

availability of funds and the receipt of enough meritorious applications. Whether this RFA will be reissued is not known.

Feasibility Study

Before deciding whether to apply for a planning grant, you should conduct a feasibility study to:

1. Ensure that you have identified a research area that addresses an “orphan” cancer (affecting fewer than 200,000 people per year in the United States) or biologically defined subsets of more common tumor types in which a need exists for new, more effective treatment, diagnostic, and prevention interventions;
2. Confirm the availability and commitment of a strong, multidisciplinary team of investigators with appropriate interest and expertise;
3. Make sure that you have a network of existing or potential partners who can be brought into the proposed AP4 center; and
4. Verify the availability of needed institutional resources.

Bring together several interested investigators and, if possible, some potential partners to conduct the feasibility study. Ask all participants to answer the following questions before your meeting:

- Have you identified investigators with the multidisciplinary expertise necessary to conduct intervention-driven research in the needed area?
- Does the center director have appropriate technical, administrative, and entrepreneurial skills and commitment?
- Does the center director have appropriate experience and contacts among existing and potential partners?
- Is the proposed AP4 center’s research focus in an area in which a cancer intervention research need exists?
- Will institutional administrators support a cross-disciplinary research center?
- Does the university or nonprofit organization have appropriate laboratories, equipment, instruments, and students?

In addition, prior to the meeting, collect data on:

- Investigators, students, and facilities that can be brought into the potential AP4 center.
- Colleagues from the biotechnology, pharmaceutical, academic, nonprofit, and government sectors who might become partners of the center.
- Grants, contracts, and consulting experience of the center research team, as an indication of the center’s potential to become self-sustaining.
- Administrative support from relevant department heads (often demonstrated by prior support for multidisciplinary research with other companies and organizations).

At the meeting, begin by briefing the group on the AP4 model and its requirements. Then discuss:

Strengths: Scientific and organizational strengths of the institution and investigators who are likely to participate, including:

- Their experience with the potential partners.
- Research areas in which the institution has recognized expertise.

- Whether the administration has a mission of promoting relations between the institution and corporations, academic institutions, nonprofits, and government agencies.

Weaknesses: Scientific and organizational weaknesses of the institution and investigators who are likely to participate, including:

- Administrative practices that might discourage or prevent investigators from participating in cooperative research with corporate, academic, nonprofit, and government partners.
- Lack of researcher experience at the institution.
- Personality conflicts.

Opportunities: Opportunities in the environment that could benefit the potential AP4 center, including:

- Documented need for new, more effective treatment, diagnostic, and prevention interventions in an area that matches the experience, expertise, and interests of the institution, its investigators, and potential partners.
- Support at the institution for research in the target area, such as an endowed chair.
- Environmental factors, such as new government regulations imposed on biotechnology or pharmaceutical companies that have accelerated the need for research in the target area.

Threats: Threats in the environment that might affect the potential AP4 center, including:

- Other centers, investigators, companies, or nonprofits addressing the same target research area.
- Conflict-of-interest laws that make it difficult to work with biotechnology, pharmaceutical, and other potential partners.

The results of this discussion should be summarized for future reference. Based on these results, you should decide whether to:

1. Stop the planning process, without going any further.
2. Develop a plan to diminish the internal weaknesses and external threats identified through the process.
3. Go ahead with your AP4 planning grant application.

Funding Mechanism

The administrative and funding instrument used for the AP4 planning grant is a cooperative agreement (U56)—an assistance mechanism (rather than an acquisition mechanism) in which NCI is actively involved in scientific and/or programmatic activities. Under the cooperative agreement, the NCI supports and/or stimulates the recipient's activities by serving as a partner, but does not direct or have a dominant role in the activities. Rather, it is the academic or nonprofit institution that has the dominant role in, and prime responsibility for, the planning grant activities, although the institution and the NCI program coordinator share specific tasks.

Center Director Rights and Responsibilities

The center director has primary authority and responsibility for defining objectives and approaches. She/he has responsibility and accountability to the center's home institution and the NCI for performance and proper conduct of the activities supported in the AP4 planning grant, in accordance with the terms and conditions of award.

NCI Staff Responsibilities

The NCI participates as a partner in the planning grant and is represented by a coordinator. The NCI coordinator is a scientist from the NCI extramural program, appointed after the award, who participates as a member of the steering committee, interacts scientifically with the center, and facilitates the NCI's role as a center partner. The NCI coordinator has substantial scientific/programmatic involvement in the center that is above and beyond normal program stewardship. For example, during the planning year, the NCI may provide appropriate assistance by helping design activities; providing advice in identifying sources for resources, staff, and other areas; and offering advice in management and technical performance. However, the NCI does not assist in the writing of the AP4 application, in the planning or conduct of the partnership meeting, or in identifying potential partners. In all cases, the NCI's role is to assist with and facilitate, but not direct, activities.

Collaborative Responsibilities

The planning grant is overseen by a unit that consists of a center director, principal investigators, their respective programs, and an NCI coordinator. Foreign institutions may participate as partners but not as the awardee institution, and a foreign scientist may not serve as center director.

A steering committee comprising the AP4 center director, center partners, and the NCI program coordinator as voting members is the governing body of the AP4 center. The steering committee reviews all project status reports, makes go/no go decisions, and recommends new projects. The steering committee may shift funds from one project to another and select candidate molecules for possible clinical development. The AP4 center director chairs the steering committee.

The Letter of Intent

If you plan to submit an application for an AP4 center planning grant, you should first submit a letter of intent that includes the following information:

- Descriptive title of the proposed research.
- Name, address, and telephone number of the center director.
- Names of other key personnel.
- Participating institutions.
- RFA title: Academic Public Private Partnership Program (AP4) Planning Grant.
- RFA number: CA-04-005.

Letters of intent are neither required nor binding, and are not considered in the review of any subsequent application. However, the information in letters of intent allows NCI staff to estimate the potential review workload and plan the review.

Submit the letter of intent for receipt by **October 21, 2003** to:

Jill Johnson
Developmental Therapeutics Program, DCTD
National Cancer Institute
Building EPN, Room 8020

Bethesda, MD 20892
Telephone: 301-496-8720
Fax: 301-402-0831
E-mail: johnsoji@mail.nih.gov

Preparing the Planning Grant Application

To prepare the planning grant application, you should bring together investigators interested in developing an AP4 center. This team will help prepare the application and, if the application is successful, oversee planning year activities. In addition to interested researchers, the team should include someone from the institution's research office. One team member should be responsible for addressing such issues as patent policy, publication delays, membership fees, and cost sharing with appropriate officials at the institution.

The team should meet to brainstorm ideas for the application. Each team member should then take responsibility for drafting a section or sections of the application, which should be distributed for comment. If possible, a grant writer should be identified who will be responsible for ensuring that all sections are completed on time and all comments are integrated.

Figure 2-1: Preparing the planning application*

Self-assessment:

1. Determine whether or not there are sufficient potential AP4 center partners interested in the focus area of the potential AP4 center.
2. Ensure that strong leadership (especially from the center director) is available in technical, administrative, multidisciplinary, and collaborative issues.
3. Determine whether the center director is experienced; has sufficient contacts among potential academic, nonprofit, corporate, and government partners; and has the trust and respect of colleagues.
4. Identify investigators and colleagues who are willing to help.
5. Identify potential AP4 center partners from the biotechnology, pharmaceutical, academic, nonprofit, and government fields.
6. Match partner resources to the needs of the potential AP4 center.
7. Make sure that all potential partners understand the AP4 model.
8. Obtain administrative support from the institution (and ensure that the president's office is aware of plans for the AP4 center).
9. Ensure that commitment from the institution, researchers, and potential partners is strong.

If the above self-assessment is positive:

10. Submit a letter of intent to the NCI.
11. Convene a group of two or three investigators and the center director to prepare the planning application.
12. Convene a larger group to plan the center and advise the team writing the planning application. This group should include representatives of the institution's research office, administration, and potential partners.
13. Distribute copies of the planning application to administrators at the institution.
14. Gather documentation on patent policy, publication policies, center structure, membership fees, and cost sharing.
15. Identify potential research areas and three initial projects.
16. Obtain letters of interest from at least two potential partners.
17. Write the planning application.
18. Submit the planning application to the NIH for peer review.

*Adapted from Gray and Walters, pp. 41-42.

The grant writer should then edit the application for consistency and completeness. Alternatively, the center director can draft the entire application and then distribute it to team members for comment.

Content of the Planning Grant Application

The planning grant application should reflect the unique combination of the proposing institution's research interests, capabilities, and the potential for working with multidisciplinary partners. Discuss these features in the application in sufficient detail to facilitate review in accordance with AP4 planning grant requirements. Elements of a successful planning grant application include the following:

Introduction

- Research needs on which the proposed AP4 center will focus.
- Goals of the planning year.
- Capabilities of the institution to address research needs, including investigators and infrastructure, and commitment to the success of the proposed AP4 center.

Background and Significance

- Why the prospective AP4 center's research focus was selected.
- Relevant experience of the:
 - Institution.
 - Center director.
 - Other investigators.
 - Potential partners (at least two must be identified).
- Capabilities of the institution, including:
 - Amount of research space available for the proposed AP4 center.
 - Amount of administrative (office) space available for the proposed AP4 center.
 - Types of equipment (computers, laboratory equipment, and others).
 - Names and areas of expertise of investigators.
 - Institutional programs of relevance to the potential AP4 center.
- Center organization, including:
 - Management plan.
 - Staffing (number of staff and their roles).
 - Operational procedures, which could include:
 - Patent policy.
 - Publication delays.
 - Membership fees.
 - Cost sharing.
 - Budget and sources of funding for the proposed AP4 center, including how the center will plan to obtain at least \$300,000 a year from sources other than the NCI.

Center Administration

- Role of the proposed center director in the AP4 center.
- Roles of other researchers in performing the proposed AP4 center studies.

Activities

- Process and criteria to be used during the planning year to recruit partners and select projects for the AP4 center application.
- Planning for the partners meeting.
- Format and content of the partners meeting to explore the role of each potential partner, discuss how intellectual property issues will be handled, select initial research projects, and establish a research plan.
- One- to 2-page summaries of at least three sample proposed projects involving orphan malignancies addressing
 - How each project will affect the diagnosis, prevention, imaging, or treatment of a specific cancer.
 - How the proposed research activities are appropriate to the potential AP4 center’s environment.
- Process to be used to select the center evaluator, who will be responsible for conducting surveys on center performance and project progress. The evaluator must be external to the center and may be retained on a contractual basis.

Budget

- Include costs for the planning meeting and investigator time.
- Specify other sources of funds to be used in the planning year.

Partner Letters

- At least two letters of interest in a potential AP4 center from potential partners are required. These letters are not viewed as full or formal commitments, but as a basis for further discussion. NCI recognizes that the final AP4 center application may contain commitments from a subset of these, or additional potential partners. The letters should be signed by someone who can eventually authorize the provision of funds to the AP4 center. Letters from potential center partners should state that:
 - The proposed research agenda of the center is concordant with the organization.
 - The organization will consider joining if the center is formed.

Planning Grant Application Format

The planning application must be submitted on the Public Health Service (PHS) 398 form, available at most institutional offices of sponsored research; from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301-435-0714, e-mail: grantsinfo@nih.gov; and on the Internet at <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

Application instructions for the AP4 planning application have been modified to reflect NIH’s streamlining “modular grant” and “just-in-time” efforts. Information on the modular format for budget planning is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>. According to the just-in-time concept, applicants may submit certain information only when the

possibility exists that an award will be granted. These concepts were implemented to reduce the administrative burden on applicants, reviewers, and NCI staff.

PHS 398 grant application instructions are available electronically on the grants.nih.gov website in rich text file (RTF) and portable document file (PDF) format. RTF files can be opened and altered with most common word processors. In addition, many word processing programs allow users to save a document in RTF when they select “Save As....” However, changes to PDF versions of the form can only be saved on computers with certain types of Adobe Acrobat software, such as Adobe Acrobat Professional.

The grants.nih.gov website provides detailed instructions on completing the PHS 398 application form, as well as examples of some sections of the form. Before you begin writing your grant application, read the PHS 398 instructions carefully and become familiar with all requirements and necessary certifications. In addition to reading this handbook, read the RFA for the AP4 planning grant (CA-04-005) carefully. Ask your colleagues for copies of successful NIH grant applications to gain a more concrete idea of what each section should include, because incomplete applications are returned without review.

Before writing your planning grant application, you should also review carefully the requirements of the actual AP4 center application (see Chapter 5 of this handbook), as well as how to implement an AP4 center (Chapters 6–9 of this handbook).

Note: The summary in this section of certain key components of the PHS 398 form is intended to show you how to use the PHS 398 form to describe your plans for an AP4 planning grant. However, these instructions are NOT intended to substitute for reading all of the RFA and PHS 398 instructions carefully.

The PHS 398 form includes the following sections:

Form Page 1: Face Page

- Project title.
- RFA title: Academic Public Private Partnership Program (AP4) Planning Grant.
- RFA number: CA-04-005.
- Center director's name and address.
- Dates and total costs of AP4 center planning project.
- Signatures of center director and applicant organization representative.

Form Page 2: Description, Performance Sites, and Key Personnel

- Performance site.
- List of key personnel, including potential center evaluators.

Form Page 3: Research Grant Table of Contents

- Page numbers of each section of the application.

Form Page 4: Detailed Budget for Initial Budget Period

- Do not complete page 4, as it is not required for the AP4 planning application and will not be accepted with the application.

Form Page 5: Budget for Entire Proposed Period of Support

- Do not complete page 5, as it is not required for the AP4 planning application and will not be accepted with the application.

Budget Justification Page for Modular Research Grant Applications

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant application format, which simplifies the preparation of the budget by limiting the level of budgetary detail required. More information on modular grant applications is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

- Indicate the total direct costs requested.
- List all personnel, but do not provide individual salary information.
- List all individuals/organizations with whom consortium or contractual arrangements have been made, their roles, and the estimated total cost of these arrangements.

Biographical Sketch Format Page (each biographical sketch may not exceed 4 pages)

- Name.
- Education/training.
- Positions and honors.
- Selected peer-reviewed publications or manuscripts in press (in chronological order).
- Research support.

Resources Format Page

- Computer resources.
- Office space.
- Major equipment.

Research Plan (limit of 25 pages for sections a–d)

- a. Specific aims (1 page recommended)—Could address the roles of potential partners, organization of the partners meeting, and anticipated results of the planning period.
- b. Background and significance (2–3 pages recommended)—Could address the center director, other investigators, and partners, as well as the background and significance of the proposed AP4 center’s research focus.
- c. Preliminary studies/progress report (6–8 pages recommended)—Could address other activities by investigators and/or potential partners that are relevant to the proposed AP4 center projects, resources provided by potential partners, and experience of the center director, other investigators, and potential partners.
- d. Research design and methods (13–16 pages recommended)—Describe how specific aims will be accomplished by planning and implementing the partners meeting, other planning activities for the prospective AP4 center, and three or more sample projects.
- e. Human subjects research (because the planning grant does not involve human subjects research, this is not applicable).
- f. Vertebrate animal research (because the planning grant does not involve vertebrate animal research, this is not applicable).
- g. Literature cited.
- h. Letters from at least two potential partners.

Checklist Form Page

- Type of application.
- Program income.
- Assurances/certifications.
- Facilities and administrative costs.
- Smoke-free workplace.

Personal Data Form Page

- Race and ethnicity of center director.

Other Support Format Page

- List active and pending support for center director and key personnel.

When the application is ready, affix the RFA label available in the PHS 398 form to the bottom of the application's face page. If you do not use this label, it might not reach the review committee in time for review. The RFA label is also available at:
<<http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>>.

Submit a signed, typewritten original of the application, including the checklist and three signed photocopies, in one package to:

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

At the same time, send two additional copies of the application to:

Referral Officer
National Cancer Institute
6116 Executive Blvd, Room 8041, MSC 8329
Bethesda, MD 20892-8329
Rockville, MD 20852 (for express/courier service)

Figure 2-2: AP4 planning grant timetable

Letter of Intent Receipt Date: **October 21, 2003**
Application Receipt Date: **November 20, 2003**
Peer Review Date: **February 2004**
Earliest Anticipated Start Date: **June 2004**

Applications hand-delivered by individuals to the NCI are no longer accepted, except for courier deliveries (i.e., FedEx, UPS, DHL, etc.).

Letters of intent must be received on or before **October 21, 2003**. Applications must be received on or before **November 20, 2003**. If an

application is received after that date, it will be returned without review. Although receipt of an application is not immediately acknowledged, the NCI generally notifies applicants of the review and funding assignment within 8 weeks.

Review Criteria

Upon receipt, applications are reviewed for completeness by the NIH and for responsiveness by the NCI. Incomplete and/or nonresponsive applications are returned to the applicant without further consideration.

All applications that are complete and responsive to the RFA are evaluated for merit, in accordance with the review criteria below, by a peer review group convened by the NCI. The reviewers base their reviews, in part, on whether or not the research approach takes advantage of the latest technologies, allowing the center to change the way molecules and other intervention technologies are discovered and developed. As part of the review process:

- All applicants receive a written critique of their applications.
- Only those applications deemed to have the highest merit—generally the top half of the applications under review—are discussed and assigned a priority score.

The goals of all research supported by NIH are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will discuss specific aspects of the application (see Figures 2-3) to judge the likelihood that the proposed planning program will have a substantial impact on the pursuit of these goals.

Figure 2-3: Review criteria for AP4 planning applications

- Significance
- Approach
- Innovation
- Investigators
- Environment

The peer review group will consider each of the following criteria in assigning the application's overall score. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, a center director may propose an approach to planning the potential partners meeting that is not innovative but is essential to achieving the goals of the planning process.

Significance:

- Does the application demonstrate the ability to plan and organize an AP4 center within the 1-year planning period?
- Does the application propose new partnerships and/or a significant expansion of existing partnerships?
- Do the sample proposed projects address one or more orphan malignancies?

Approach:

- Are the proposed strategies for the planning year (including the potential partners meeting and the development of the AP4 center application) appropriate for establishing new partnerships and/or significantly expanding existing ones?
- Are the proposed processes and criteria for organizing the proposed AP4 center and selecting partners and projects adequate, well integrated, and appropriate for the orphan cancer(s) to be addressed?
- Do letters of interest from potential AP4 center partners support the priorities and objectives of the AP4 center planning process?
- Are the proposed methods for securing resources (space, budget, staffing) for the proposed center adequate?

Innovation:

- Does the proposed AP4 center involve novel concepts, approaches, or methods?
- Does the proposed center involve new partnerships or new projects for an existing partnership?

Investigator:

- Does the proposed center director have strong scientific and administrative leadership ability?
- Are the roles of other proposed researchers appropriate to their qualifications and experience?
- Are the sample projects appropriate to the experience level of the center director and other researchers (if any)?
- Do the researchers involved in the planning grant represent an appropriate range of disciplines?

Environment:

- Does the scientific environment in which the proposed work will be done contribute to the probability of success?
- Is there evidence of strong institutional commitment and support?

Next Steps

Once you have received notification of a center planning grant award, you should make final preparations for your planning year activities. For example, meet with other interested investigators at your institution to identify steps that need to be completed during the planning year, and begin implementing those steps. Start identifying possible dates for the partners meeting and verifying the availability of meeting participants on those dates. Finalize administrative arrangements with your institution and other participants in the planning activities.

You must now begin to identify and implement the planning activities listed in your application. Instructions on how to do so are provided in the next chapter of this handbook.

References

- Gray D.O., Walters S.G. *Managing the Industry/University Cooperative Research Center: A Guide for Directors and Other Stakeholders*. Columbus, OH: Battelle Press, 1998.
- Heaven C. Developing a Plan for Identifying Local Needs and Resources. *Community Tool Box: Bringing Solutions to Light*. Available at:
<http://ctb.ku.edu/tools/EN/sub_section_main_1019.htm>. Accessed May 19, 2003.

Helpful Websites

Instructions on completing the PHS 398 grant application form:

<<http://grants.nih.gov/grants/funding/phs398/phs398.html>>.

Instructions on preparing a modular budget:

<<http://grants.nih.gov/grants/funding/modular/modular.htm>>.

RFA mailing label: <<http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>>.