

SUBMITTING AN APPLICATION: Limited Competition for Competing Renewals
(Dietary Supplement Research Centers: Botanicals)

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 9/2004). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTARY INSTRUCTIONS

Special Instructions for Preparing a Competing BRC Grant Application

A. General Information

General instructions for the preparation of NIH grant applications are contained in the standard NIH grant application kit (PHS Form 398, revised August 2004). Even though the PHS 398 is intended primarily for a single research project grant (i.e. R01), many of the general instructions and forms also apply to BRC grant applications. Exceptions are due to unique requirements of BRCs and corresponding modifications of review criteria. Accordingly, the special instructions in this document were prepared for use along with the PHS Form 398 grant application kit. Unless otherwise specified, PHS 398 instructions apply.

B. Detailed Instructions

1. Face Page (Page 1)

The face page is the same as the face page (form page 1) in the PHS 398 kit. In item 1, enter the title of the Center. The title should be descriptive and reflect the thematic focus of the Center. In item 2, insert the RFA number, and enter the title "Dietary Supplement Research Centers: Botanicals". In item 3, indicate the name, degree, and position (or equivalent) title of the BRC Principal Investigator.

2. Description, Performance Sites, and Key Personnel (Page 2)

Page 2 is the same as form page 2 in the PHS 398 application kit. Provide a brief description of the BRC in the space provided, specifically addressing each project and proposed resource core. Fill in all the performance sites and all key professional personnel including all Research Project and Core Leaders and key personnel of the Pilot Research Program and Career Development effort, using continuation pages as required.

3. Table of Contents (Page 3)

Instead of using form page 3 in the PHS 398 application kit, prepare a Table of Contents that identifies by page number all major parts of the BRC application so that each can be readily located. When listing individual projects and core components, identify each by a project or core number, title and responsible investigator (i.e., Research Project

or Core Leader) in the order in which they appear in the application.

For the Table of Contents, it is recommended that applicants follow the format outlined below using continuation pages as needed:

I. Face Page (see Detailed Instructions #1 above)

II. Description, Performance Sites, Key Personnel (see Detailed Instructions #2 above)

III. Table of Contents of Center Grant Application (see Detailed Instructions #3 above)

IV. Initial Program Budget (see Detailed Instruction #4 below)

V. Summary Program Budget (see Detailed Instruction #5 below)

VI. Biographical Sketches (see Detailed Instruction #6 below)

VII. Institutional Commitment (see Detailed Instruction #7 below)

VIII. Center Description (see Detailed Instruction #8 below)

- o Title Page with Principal Investigator

- o Center Overview

- o Center Theme and Botanicals to be Studied

- o Center Organizational Structure

- o Scientific Integration - Interactions and Collaborations

- o Center Director

- o Institutional Resources (unique facilities at applicant institution plus those of other participating institutions, if applicable)

- o Research Plan: including Summary of Research Projects and Cores

- o Literature Cited

IX. Research Projects (see Detailed Description #9 below)

Project 1

- o Title Page with Project Leader

- o Abstract Page

- o Budget/Budget Justification Pages

- o Resources

- o Research Plan

Project 2 (same format as above) etc, for additional projects

X. Core Resources (see Detailed Instruction #10 below)

Core 1 Administrative Core (required)

- o Title Page with Core Leader/Center Director
- o Abstract
- o Budget/Budget Justifications
- o Resources
- o Plan/Interactions/Progress (for competing renewals)

Core 2 (at least one Research Resource Core required)

- o Title Page with Core Leader
- o Abstract Page
- o Budget/Budget Justifications
- o Resources
- o Resource Plan
- o Human Subjects or Vertebrate Animals or "Assurances"
- o Literature Cited

Core 3 (follow format for Core 2) etc., for additional cores

XI. Pilot Research Program (see Detailed Instruction #11 below)

- o Title Page with Pilot Program Leader
- o Program Plan

XII. Training and Career Development (see Detailed Instruction #12 below)

- o Title Page
- o Program Plan

XIII. Checklist

XIV. Appendix

4. Summary Program Budget for the Initial Budget Period

Use PHS 398 form page 4 to present the summary budget for the first year. For each category, show separately the total amounts requested for each research project and core. Applicants may request up to \$1.5 million in the total costs (direct plus facilities and administrative (F & A) cost) for the first year.

If the grant application includes research activities that involve institutions other than the applicant organization, the proposed program represents a consortium effort. It is essential to explain the programmatic, fiscal, and administrative arrangements for such activities. These matters also should be discussed in general terms in the Center Description section of this application and more specifically within descriptions of pertinent projects. Include in the designated blocks on form page 4 the total cost (direct plus F & A cost) associated with such third party participation.

5. Summary Program Budget for Entire Project Period

Use PHS 398 form page 5 to show the total BRC budget requested for each of the five years. Justifications for increases in succeeding years should not be included here; they should be delineated in the detailed budgets for individual projects and cores. Current NIH practice limits overall budget escalation per year to 3 percent cost-of-living.

6. Biographical Sketches

Prepare biographical sketches as described in the PHS 398 application kit. Begin with the Principal Investigator/BRC Director and then proceed in alphabetical order. Biographical sketches are required for all key personnel participating in the individual BRC projects and cores, including consultants.

7. Institutional Commitment

In two pages or less, describe how the institution will make the BRC an area of high priority. For example, describe the space, personnel and other resources that the institution will make available to ensure that the BRC exists in an appropriate environment for conducting an effective research program. Outline plans for the commitment of future resources in space and personnel to strengthen the research capability of the BRC. The application should describe how the institution will participate in overseeing research progress and generally assuming a high level of accountability for the success of the BRC in achieving research goals and objectives.

A letter of institutional commitment from the Dean or another person of similar rank should be included. If the application is a consortium effort, similar letters of support from participating institutions should be included.

8. Center Description (25 page limit not including description of institutional resources or literature citations.

The order of the items listed in the table of contents may be changed in the application, but all topics should be included.

Title Page:

A title page with the name of the BRC and Center Director on a plain piece of paper.

Center Overview:

Provide a concise description of the BRC.

Center Theme and Botanicals to be Studied:

Discuss the rationale for the thematic focus of the Center and for the selection of botanicals to be studied. Discuss the scientific

significance of the research to be conducted as well as the potential for the research to be translated into practical benefits for human health.

Center Organizational Structure:

Discuss the overall breadth of the administrative and scientific capabilities of the BRC to address critical research needs related to botanical dietary supplement ingredients. Explain how the organization of the BRC will maximize the potential to achieve research objectives. Include an organizational chart showing the relation of key center components (e.g., Research Projects and Cores). Describe the role of the External Advisory Committee and the Internal Steering Committee.

Scientific Integration - Interactions and Collaborations:

Discuss how interactions will be maintained and fostered among researchers within the research projects and among researchers within the research cores (e.g., nature and frequency of project and core meetings). Describe how the core resources will be integrated effectively into the program to maximize the research capability of the BRC. Describe how the projects and cores will function collectively to produce a truly interdisciplinary collaborative program in which the whole is greater than the sum of its parts. If applicable, describe how the effects of geographic separation will be overcome to maximize critical scientific interactions. Include a table showing an estimate of the allocation of core effort (percent) for each of the proposed research projects.

Center Director:

Describe the authority, scientific and administrative experience of the principal investigator to provide leadership and direction to the BRC. Describe the processes and chain of responsibility for scientific decision-making and day-to-day administration and management of the BRC. If a co-Director will be appointed at the applicant institution, the justification and responsibilities of the co-Director should be described.

Institutional Facilities and Resources:

Describe the institutional facilities and resources available to BRC scientists at the applicant institution. If there are multiple performance sites, then resources available at each site should be described. Summarize the special features of the institutional facilities and resources that make this application strong and/or unique.

Research Plan, including a Summary of Projects and Cores:

This important section provides the group of investigators an opportunity to give conceptual wholeness to the overall program by giving a statement of the research objectives and by laying out a broad strategy for addressing them. In this section, the applicant summarizes the overall research plan for the multi-project application. The application should be viewed as a collection of complementary research projects, each capable of standing on its own scientific merit but accomplishing more as part of a center grant than as an isolated R01 award. The aims of each project and core should be summarized along with a concise plan to achieve the stated objectives.

In 10 pages or less, applicants should address overall progress of the BRC in meeting research objectives during the last project period, as well as describing the evolution of project goals over time.

9. Research Projects (Follow PHS 398 page limitations; five additional pages allowed for competing renewals, excluding literature citations.) Page limitations specified for individual R01 grant applications in the PHS 398 application kit must be followed for individual research project plans. For each research project provide the following:

- o A title page with a project number, a title for the project, the Project Leader and co-investigators on a plain piece of paper.
- o An abstract of the research plan. Follow PHS 398 instructions for all sections of this page.

o Budget Pages

The detailed budget for the first year and the overall budgets for each succeeding year for each research project should be presented separately using the PHS form pages 4 and 5.

O Resources

Follow PHS 398 instructions for Resources. If there are multiple performance sites, then resources available at each site should be described.

o Research Plan

Use the PHS 398 instructions for the Research Plan (Items a-i). The Research Plan should include sufficient information needed for evaluation of the project, independent of any other documentation. Detailed interactions between projects and cores not illustrated in the organizational chart under the Center Description section should be provided in this section.

- o For competing renewals a) describe the scientific accomplishments for each research project proposed in the last grant term (i.e., from date of original center award to present.) Do not repeat information included as preliminary data under the Research Plan section. Limit this narrative to three pages plus publication citations for each project. Citations are limited to published articles or those in press; do not include submitted articles or those in preparation. b) If the applicant proposes to renew and/or expand a research project funded in the last grant term, provide a justification (e.g., Project Leader met original research objectives and developed additional research aims and/or identified new research opportunities during the course of conducting proposed research).

10. Core Resources (allow ten pages per core excluding literature citations, excluding literature citations)

The BRC must include an Administrative Core and at least one scientific Research Resource Core that clearly enhance the specialized research of the BRC. The Administrative Core should include plans for overseeing the Pilot Research Program as well as training and career development efforts. Scientific cores must serve at least two R01 level projects. For each Core Resource, whether administrative or scientific, provide the following information:

o A title page with the core resource number, a title for the core, the names of the Core Leader and co-investigators on a plain piece of paper.

o An abstract of the Core Resource, using form page 2 of the PHS 398 application kit as described for research projects in item 9, above. The abstract should describe the nature and purpose of the resource. The bottom sections of form page 2 should include performance sites and all key professional personnel as instructed.

o Budget Pages

Use same format as in item 9, above, for research projects.

o Resources

Use same format as in item 9, above, for research projects.

o Resource Plan (Plan/Interactions/Progress for competing renewal applications). As appropriate for the proposed Core, use the plan format suggested for research projects in the PHS application kit (sections a-d). At a minimum, the application should state the specific aims of the core; preliminary studies should also be included if appropriate.

Describe the nature of the resource and its importance to the specialized research of the BRC; describe the projected operation of the core, placing special emphasis on cost effectiveness and/or quality control factors; describe the qualifications of the individual(s) assigned to administer/operate the resource.

For competing renewal applications, describe the past performance of the resource core in relation to accomplishing the original BRC research goals.

o Human Subjects and Vertebrate Animals

If applicable, provide information on human subjects and/or vertebrate animals (sections e-f) following instructions in the PHS 398 application kit.

11. Pilot Research Program (5 pages for the program summary, plus an additional 5 pages for program progress)

The Pilot Research Program should be incorporated into the Administrative Core activities, but listed separately in the table of contents.

o Title Page with "Pilot Research Program" and the name of the program leader on a plain piece of paper.

o A program plan containing the following elements: a) A description of the process used by the BRC to solicit, review and fund pilot studies within the BRC institution(s); b) A description of how the BRC will work with pilot study grantees to promote the submission of new applications for peer-reviewed research relevant to the BRC.

o For competing renewal applications, provide a summary identifying the achievements of all pilot projects (ongoing or terminated) supported during the last project term. Identify the pilot project grantee; list

the publications and/or grant submissions resulting from the research; and/or describe how pilot projects improved prospects of R01 level projects.

12. Training and Career Development

Although the BRC does not provide special funds for a training and career development program, the BRC is expected to provide a rich environment for these activities. This section of the application should include:

- o A title

- o A summary of the program containing the following elements: a) List potential funding sources for research training and career development for the BRC; b) Describe plans for seeking funding; c) Provide a brief description of prospective mentors who will interact directly with candidates.

- o For competing renewal applications, list all of the individuals supported by training and career development awards during the past term of the grant. The present position and recent accomplishments of these individuals (e.g., funded grants, publications) should also be described to demonstrate how the BRC has contributed to their research careers.

13. Checklist

Complete the checklist as required in the PHS 398 application kit.

14. Appendix Material

As an additional requirement for this RFA, provide five copies of a single appendix for the entire document. Order of materials in the appendix should follow that of the application (Center Description, Research Project #1, #2, #3, Core #1, #2, etc.). Each section should be clearly labeled.

Appendix materials should be limited and should not be used to circumvent the page limits for the research plans. Copies of appendix material will only be provided to the primary reviewers of the application and will not be reproduced for wider distribution among all reviewers. The following materials may be included in the appendix:

Up to TEN publications per project or core, limited to including manuscripts (published or accepted for publication), abstracts, patents, or other printed materials directly relevant to the project.

Data collection instruments. These may be stapled as sets.

Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25-page limit of items a-d of the research plan.

USING THE RFA LABEL: The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. 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. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at:

<http://grants.nih.gov/grants/funding/phs398/labels.pdf>.