

**EFFECTIVE DATE:** The newly revised “Application for a DHHS Public Health Service Grant” (PHS 398, rev. 9/04) instructions and forms are [now](#) available and will be accepted for submission/receipt dates on or after December 1, 2004. All applications received on or after May 10, 2005 must use the new instructions and forms. During the transition period, applications using the previous version (rev. 5/01) of the PHS 398 will be accepted through May 9, 2005. However, after this date, applications submitted using instructions and forms other than the PHS 398 (rev 9/04) will be returned to the applicant

**THESE INSTRUCTIONS AND APPLICATION FORMS (revised 09/2004) SUPERSEDE ALL PREVIOUS EDITIONS.** Carefully read the instructions. Submission of an application that fails to meet the PHS requirements will be grounds for the PHS to return the application without peer review. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

While the instructions are generally applicable, many grant programs, in particular, grant programs of PHS agencies other than NIH, have additional specific instructions. Applicants should contact an official listed in the [table](#) of PHS agencies to obtain the most current information and instructions.

## Research Grant Mechanisms

***The following table summarizes the major mechanisms NIH uses to fund research grants.***

Type (Mechanism)	Description
<b>Research Grants</b>	
<b>Basic Research Grant (R01)</b>	<b>Basic Research Grants</b> are awarded to eligible institutions on behalf of a principal investigator to support a discrete project related to the investigator's area of interest and competence. These grants make up the largest category of NIH funding.
<b>Small Research Grant (R03)</b> <a href="http://grants.nih.gov/grants/funding/r03.htm">http://grants.nih.gov/grants/funding/r03.htm</a>	<b>Small Research Grants</b> support small research projects that can be carried out in a short period of time with limited resources for projects such as pilot or feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology and/or development of new research technology. <i>Not all awarding components accept investigator-initiated R03 applications.</i> Applicants interested in the small research grant program of PHS-awarding components other than NIH should contact an official of the appropriate PHS-awarding component (See <a href="#">Awarding Component Contact Table</a> ).
<b>Academic Research Enhancement Award (AREA) (R15)</b> <a href="http://grants.nih.gov/grants/funding/area.htm">http://grants.nih.gov/grants/funding/area.htm</a>	<b>Academic Research Enhancement Awards</b> provide support to scientists at eligible domestic institutions for small-scale health-related research projects, such as pilot research projects and feasibility studies; development, testing, and refinement of research techniques; and similar discrete research projects that demonstrate research capability. This award is directed toward those smaller public and private colleges and universities that provide undergraduate training for a significant number of the U.S. research scientists. (Applicants should use the PHS 398 with the AREA guidelines.)
<b>Exploratory/Developmental Research Grant (R21/R33)</b> <a href="http://grants.nih.gov/grants/funding/r21.htm">http://grants.nih.gov/grants/funding/r21.htm</a>	<b>Exploratory/Developmental Research Grants</b> seek to broaden the base of inquiry in fundamental biomedical research by encouraging applications for research projects that involve an especially high degree of innovation and novelty. NIH provides pilot-scale support for potentially ground-breaking ideas, methods, and systems that meet the following criteria: they lack sufficient preliminary data for feasibility to be established, their successful demonstration would have a major impact on biomedical research, and they fall within the areas supported by the awarding I/C. <i>Not all awarding components accept R21/R33 applications.</i>

Type (Mechanism)	Description
<p><b>Small Business Innovation Research Grant (SBIR: R43/R44)</b></p> <p><b>Small Business Technology Transfer Grant (STTR: R41/R42)</b></p> <p><a href="http://grants.nih.gov/grants/funding/sbir.htm">http://grants.nih.gov/grants/funding/sbir.htm</a></p>	<p><b>SBIR and STTR grants</b> are made to eligible domestic for-profit small business concerns conducting innovative research that has the potential for commercialization.</p> <p>SBIR/STTR awards are intended to stimulate technological innovation, use small business to meet Federal research and development needs, increase private sector commercialization of innovations derived from Federal research and development, and foster and encourage participation by minority and disadvantaged persons in technological innovation.</p>
<p><b>Program Project Grant (P01)</b></p>	<p><b>Program Project Grants</b> are more complex in scope and budget than the individual basic research (R01) grant. While R01s are awarded to support the work of one principal investigator who, with supporting staff, is addressing a scientific problem, program project grants are available to a group of several investigators with differing areas of expertise who wish to collaborate in research by pooling their talents and resources. Program project grants represent synergistic research programs that are designed to achieve results not attainable by investigators working independently. <i>Not all awarding components accept P01 applications.</i></p>
<p><b>Research Center Grant (P50/P60)</b></p>	<p><b>Research Center Grants</b> serve varying scientific and IC-specific purposes, but they have elements in common. The grants are multidisciplinary in scope and may focus more on an area or discipline of science than on a specific theme or goal. Independent investigators direct the projects and cores. Center grants offer a greater opportunity for scientific interactions and overall progress than with individually-funded projects. <i>Not all awarding components accept P50/P60 applications.</i></p>
<p><b>Scientific Meeting Support (R13)</b></p> <p><a href="http://grants.nih.gov/grants/funding/r13/index.htm">http://grants.nih.gov/grants/funding/r13/index.htm</a></p>	<p>NIH provides support for scientific meetings, conferences, and workshops that are relevant to its scientific mission. Any U.S. institution or organization, including an established scientific or professional society, is eligible to apply. For more information and guidelines, see <a href="http://grants.nih.gov/grants/guide/pa-files/PA-03-176.html">http://grants.nih.gov/grants/guide/pa-files/PA-03-176.html</a>. <i>Applicants must obtain IC approval prior to submission.</i></p>
<p><b>Research Grants to Foreign Institutions and International Organizations</b></p>	<p><a href="http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part12.htm#_Toc54600260">http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part12.htm#_Toc54600260</a>.</p>

Type (Mechanism)	Description
<b>Training, Fellowships and Career Development Programs</b>	
<b>NIH Institutional Ruth L. Kirschstein National Research Service Award (T32/T34/T35)</b> <a href="http://grants.nih.gov/grants/guide/pa-files/PA-00-103.html">http://grants.nih.gov/grants/guide/pa-files/PA-00-103.html</a>	These awards are made to domestic institutions that have the facilities and faculty to provide for research training programs in scientific specialties. Grant funds may be used for personnel, equipment, supplies, trainee stipends (both pre- and postdoctoral), and related costs. See <a href="#">Section IV. Institutional Ruth L. Kirschstein National Research Service Award.</a>
<b>Individual Ruth L. Kirschstein National Research Service Award Fellowships (NRSA: F30/F31/F32/F33)</b> <a href="http://grants.nih.gov/training/nrsa.htm">http://grants.nih.gov/training/nrsa.htm</a>	These fellowships are awarded to qualified individuals at the predoctoral, postdoctoral, or senior investigator level to pursue full-time research training in designated biomedical or behavioral science areas. <b>NRSA APPLICANTS MUST USE PHS 416-1 FORMS/INSTRUCTIONS</b> ( <a href="http://grants.nih.gov/grants/funding/416/phs416.htm">http://grants.nih.gov/grants/funding/416/phs416.htm</a> )
<b>Career Development Award (K Award)</b> <a href="http://grants.nih.gov/training/careerdevelopmentawards.htm">http://grants.nih.gov/training/careerdevelopmentawards.htm</a>	Among NIH components, several types of career development awards are available to research and academic institutions on behalf of scientists who require additional independent or mentored experience in a productive scientific environment in order to further develop their careers in independent biomedical or behavioral research. See <a href="#">Section III. Career Development Awards.</a>
<b>APPLICATIONS AVAILABLE FROM OTHER OFFICES</b>	
<b>International Research Fellowship Award Application (NIH 1541-1)</b>	Fogarty International Center (FIC) (301) 496-1653
<b>Nonresearch Training Grant Application (PHS 6025)</b>	Health Resources and Services Administration (HRSA) (301) 443-6960
<b>Health Services Project Application (5161-1)</b>	Substance Abuse and Mental Health Services Administration (SAMHSA) (301) 436-8451

## Submission Dates, Review, and Award Cycles

Types of Applications	Cycle I	Cycle II	Cycle III
<b>Application Submission Dates</b>			
<b>Institutional Ruth L. Kirschstein National Research Service (Kirschstein-NRSA) Awards*</b> (All new, competing continuation, supplemental and revised applications)	January 10	May 10	September 10
<b>Academic Research Enhancement Award (AREA)</b> (All new, competing continuation, and revised applications <i>except</i> those involving AIDS-related research)	January 25	May 25	September 25
<b>New Research Grants (e.g., R01) and Career Development Awards (K series)</b>	February 1	June 1	October 1
<b>Program Project Grants and Center Grants (P series)</b> (All new, competing continuation, supplemental and revised applications)	February 1	June 1	October 1
<b>Competing Continuation, Supplemental and Revised: Research Grants and Career Development Awards**</b>	March 1	July 1	November 1
<b>Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants</b> (All new, supplemental, and revised applications <i>except</i> AIDS and AIDS-Related applications)	April 1	August 1	December 1
<b>Conference Grants and Conference Cooperative Agreements</b> (All new, competing continuation, supplemental and revised applications)	April 15	August 15	December 15
<b>AIDS and AIDS-Related Grants</b> (All new, competing continuations, supplemental and revised applications; <i>includes</i> AIDS and AIDS-Related SBIR/STTR)	May 1	September 1	January 2
<b>RFAs and PARs</b>	<b>Special submission dates: Check the specific NIH Guide announcement.</b>		
<b>Review and Award Schedule</b>			
<b>Scientific Merit Review</b>	June - July	Oct - Nov	Feb - Mar
<b>Advisory Council Review</b>	Sept - Oct	Jan - Feb	May - June
<b>Earliest Project Start Date***</b>	December	April	July

\* Many NIH Institutes and Centers use only one or two of the submission dates for Institutional NRSA awards. Please check the program announcement for "Institutional Research Training Grants (T32)" at <http://grants.nih.gov/training/nrsa.htm>.

\*\* Some ICs have different submission dates for revised Career Development Award applications. Check with the appropriate IC.

**\*\*\* Awarding components may not always be able to honor the requested start date of an application. Therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.**

## Format Specifications

Follow font and format specifications. Otherwise, application processing may be delayed, or the application may be returned to the applicant without review.

### Font

- Use an Arial, Helvetica, Palatino Linotype or Georgia typeface and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.
- Print must be clear and legible.

### Page Margins

- Use standard size (8 ½" x 11") sheets of paper.
- Use at least one-half inch margins (top, bottom, left, and right) for all pages, including continuation pages.

### Application Paging

- The application must be single-sided and single-spaced.
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).
- Do not include unnumbered pages.

### Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

- You may use a smaller type size but it must be in black ink, readily legible, and follow the font typeface requirement.

### Photographs and Images

- Do not include photographs or other materials that are not printed directly on the application page in the body of the application. Pictures or other materials that are glued or taped onto application pages are incompatible with the current duplication/scanning process.
- You may include black-and-white or color images in the six (6) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

### Copies

- Original (signed by principal investigator and an authorized organizational official) and five exact, legible, single-sided photocopies
- Do not use photo reduction.
- The application must contain only material that reproduces well when photocopied in black and white. Glossy photographs or other materials that cannot be photocopied must be submitted in five collated sets as appendices (see [Section I-8 Appendix](#)). Note: Full-sized glossy photographs may be included in the appendix; however, a photo copy of each must also be included within the page limitations of the Research Plan.

### Grantsmanship

- Use English and avoid jargon.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

## Page Limitations and Content Requirements

All applications and proposals for NIH funding must be self-contained within specified page limitations.

Observe the page number limitations given in [Table 1](#). Only in cases involving interdependent multiple subprojects (e.g., Program Projects and Multi-Center Clinical Trials) will the PHS accept applications that exceed the page number limitations. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See [Agency Contact Table](#).) The page number limitations may also be different for other specialized grant applications (e.g., R03 and R21 applications). Consult and follow the additional instructions for those applications.

## Page Limitations and Content Requirements

Section	Page Limit	Content
<a href="#">Introduction</a> - New applications - Revised applications - Revised Phase I SBIR/STTR applications - Supplemental applications	Not required/Not to be submitted 3 1 1	See <a href="#">Instructions</a>
<a href="#">Research Plan</a> - Sections A-D  - Sections E-J	25* * Some exclusions for competing continuation applications * SBIR/STTR: See <a href="#">Section V</a>  none	Text including all figures, charts, tables, and diagrams
<a href="#">Biographical Sketches</a>	4	No more than four pages for each person listed as Key Personnel. Items A and B together may not exceed 2 pages.
<a href="#">Literature Cited</a>	none	Complete citations, including titles and all authors
<a href="#">Appendix</a>	none  Phase I SBIR/STTR: Not permitted unless specifically requested by NIH.	No more than 10 publications (including <i>accepted</i> manuscripts); photographs (include a copy in the Research Plan); questionnaires; and other materials that do not photocopy well.
<a href="#">PAs and RFAs</a>	Page limitations specified in the PA and RFA announcement in the <i>NIH Guide</i> take precedence.	See specific instructions in PAs and RFAs published in the <i>NIH Guide</i> .

## DECISION TABLE FOR HUMAN SUBJECTS RESEARCH, PROTECTION AND THE INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

	Criteria and Answers to Questions 1 thru 5				
Scenarios with linked instructions	<a href="#">1. Human Subjects Research</a>	<a href="#">2. Exempt from HHS Human Subjects Regulations</a>	<a href="#">3. Clinical Research</a>	<a href="#">4. Clinical Trial</a>	<a href="#">5. NIH-Defined Phase III Clinical Trial</a>
<b><a href="#">A</a></b> <b><a href="#">No Human Subjects</a></b>	No	N/A	N/A	N/A	N/A
Requirements for Scenario A: - Indicate "No Human Subjects Research" If Human Subjects is "Yes," see Scenarios B-F below.					
<b><a href="#">B</a></b> <b><a href="#">Human Subjects/E-4</a></b>	Yes	Yes Exemption: 4	No	N/A	N/A
Requirements for Scenario B: - Indicate Exemption 4 (E-4) and include justification that E-4 is appropriate.					
<b><a href="#">C</a></b> <b><a href="#">Human Subjects/ Other Exemptions</a></b>	Yes	Yes Exemptions: 1, 2, 3, 5, 6	Yes	N/A	N/A
Requirements for Scenario C: - Indicate Exemption number(s) and include justification that the designated exemption(s) is appropriate. - Address "Inclusion of Women and Minorities" - Address "Inclusion of Children"					
<b><a href="#">D</a></b> <b><a href="#">Clinical Research</a></b>	Yes	No	Yes	No	N/A
Requirements for Scenario D: - Address Protection of Human Subjects - Address "Inclusion of Women and Minorities" - Address "Inclusion of Children" "Targeted/Planned Enrollment Table(s)" for each new study/ protocol (New applications; Competing Continuation applications; Competing Supplements) - "Inclusion Enrollment Report Table(s)" (Competing Continuations; Competing Supplements)					
<b><a href="#">E</a></b> <b><a href="#">Clinical Trials</a></b>	Yes	No	Yes	Yes	No
Requirements for Scenario E: - All requirements in Scenario D - Data and Safety Monitoring Plan - Note: Some trials may require a Data and Safety Monitoring Board, based on risk					
<b><a href="#">F</a></b> <b><a href="#">NIH-Defined Phase III Clinical Trial</a></b>	Yes	No	Yes	Yes	Yes
Requirements for Scenario F: - All requirements in Scenario E Increased requirements for Inclusion of Women and Minorities in Clinical Research					

## Budget Instructions

### MODULAR FORMAT

The following instructions are applicable to **certain** research grant applications requesting **\$250,000 or less per year for direct costs**. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application.

Note consortium/contractual F&A costs are not factored into this DC limit. They may be requested in addition to the \$250,000 limit.

- Applicable only to R01, R03, R15, and R21 applications.
- Use for research grant applications requesting \$250,000 or less in direct costs, exclusive of any consortium F&A costs.
- Submit only the Modular Budget Format Page ([MS WORD](#) or [PDF](#)).
- Do *not* submit Form Pages 4 and 5. Use these as internal “worksheets” only in the development of the total direct costs to be shown on the Modular Budget Format Page and in Item 7a of the Face Page.
- Refer to the Modular Budget Samples:

Same Modules each year

[MS Word](#) or [PDF](#)

Variable Modules each year

[MS Word](#) or [PDF](#)

#### Direct Costs.

**Modular, With Consortium/Contractual Costs.** On the Modular Budget Format Page, enter separately the Direct Costs less (**actual**) Consortium F&A, **actual** Consortium F&A, and Total Direct Costs requested for each year. The budget figures from the "DC less Consortium F&A" row are used for Face Page Items 7a. and 8a. **When consortium/contractual costs are involved, the figures for each year in the "DC less Consortium F&A" row must be in \$25,000 increments and ≤ \$250,000.**

**Modular, Without Consortium/Contractual Costs.** If your budget does not include consortium/contractual costs complete only the "Total Direct Costs" row. From this row, use "Initial Period" figure for Face Page Item 7a, and "Sum Total" figure for Face Page Item 8a. **When no consortium/contractual costs are involved, the figures for each year in the "Total Direct Costs" row must be in \$25,000 increments and ≤ \$250,000.**

**For all modular budgets,** request total direct costs (in **modules of \$25,000 as described above**), reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year. Provide an additional narrative budget justification for any variation in the number of modules requested.

NIH may request (prior to award) additional budget justification in exceptional circumstances. For further information, see

<http://grants.nih.gov/grants/funding/modular/modular.htm> and [http://grants.nih.gov/grants/funding/modular/modular\\_review.htm](http://grants.nih.gov/grants/funding/modular/modular_review.htm).

#### Budget Justification.

**Personnel.** List **all** personnel, including names, percent of effort and roles on the project. No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation when estimating the number of modules. For guidance on current salary limitations, see the

[NIH Guide for Grants and Contracts](#) on the NIH grants website or contact your office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. This limit should also be used when estimating the number of modules. See: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html>.

**Consortium/contractual costs.** Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the **total** consortium/contractual costs must be included in the overall requested modular direct cost amount.

While all NIH ICs use modular formats, not all of the other PHS agencies accept modular budgets. If you are submitting an application to an agency other than NIH, be sure to read the instructions in the funding announcement to determine whether the application should be submitted in the modular format, or contact an official at the appropriate PHS awarding component (see [Agency Contact Table](#)).

## NON-MODULAR FORMAT

The following instructions are applicable to all applications requesting **more than \$250,000 direct costs per year**. **Note consortium/ contractual F&A costs are no longer factored into this DC limit. If you exceed the \$250,000 level by only the amount of consortium F&A costs, you are still required to use the modular format.** Detailed categorical budget information for preparing the budget for the “Initial Budget Period” and the “Entire Proposed Period of Support” is to be submitted with the application.

- Use for research grant applications requesting more than \$250,000 direct costs per year, exclusive of consortium F&A costs.
- Submit Form Page 4 and Form Page 5.
- **If you are requesting a budget of \$500,000 direct costs or more for any year, you must obtain prior approval from Institute/Center staff.** Note this limit is exclusive of any consortium F&A costs. If the "Subtotal Direct Costs" on Form Page 5 equals or exceeds \$500,000 in any year, prior approval is required. (See [Policy on the Acceptance for Review of Unsolicited Applications That Request \\$500,000 or More in Direct Costs](#).)
- Form Page 4 reflects the total direct costs, which includes the total costs of any contractual costs, requested for the *initial* (first 12 months) budget period. (F&A costs are requested on the Checklist Page.)
- Form Page 5 reflects the total direct costs for the *entire* project period. This form also is used to prepare the *narrative budget justification*.
- Submit a separate detailed budget (Form Page 4) for each participating consortium/contractual organization. For each, label that page accordingly. If consortium activity exceeds one year, also include Form Page 5. See [Consortium/Contractual Costs](#) for specific instructions.

If the proposed budget is \$250,000 direct costs per year or less (excluding any consortium F&A costs), skip the following instructions for Form Page 4 and Form Page 5. Use the ‘Modular Budget Format Page’ only and follow the specific [Budget Instructions for Modular Grant Applications](#)

## ***Policy on the Acceptance for Review of Unsolicited Applications That Request \$500,000 or More in Direct Costs***

Applicants must seek agreement to accept assignment from Institute/Center staff at least six weeks prior to the anticipated submission of any application requesting \$500,000 or more in direct costs for any year. Note for the purposes of determining whether or not this policy applies, this \$500,000 limit now excludes any consortium F&A costs.

The NIH supports research projects with large budgets but needs to consider such awards as early as possible in the budget and program planning process. Regardless of the merit of the application or the budget justification, unanticipated requests for unusually high amounts of direct costs are difficult for NIH to manage. It is in the best interest of all parties if applicants anticipating large direct costs contact the appropriate NIH program staff as early as possible to ensure that an Institute/Center (IC) would be willing to accept the application.

Applicants must seek agreement from IC staff at least six weeks prior to the anticipated submission of any application requesting \$500,000 or more in direct costs for any year. Note for the purposes of determining whether or not this policy applies, this limit now excludes any consortium F&A costs. If the proposed budget excluding consortium F&A costs equals or exceeds the \$500,000 level, then prior approval is required. If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than \$500,000, then approval should be sought even earlier.

This prior acceptance policy does not apply to applications submitted in response to RFAs or in response to other Announcements that include specific budgetary limits. Such applications must be responsive to any budgetary limits specified; however, any specified budgetary limit now excludes consortium F&A costs.

### **PROCEDURES**

- **An applicant planning to submit a grant application with \$500,000 or more in direct costs for any year (excluding consortium F&A costs) is required to contact in writing or by telephone NIH IC program staff. This contact should be made during the development process of the application but no later than six weeks before the anticipated submission date. If the IC is willing to accept assignment of the application for consideration of funding, the staff will notify the Center for Scientific Review before the application is submitted.**
- **The principal investigator must include a cover letter with the application. That cover letter must identify the program staff member contacted and the Institute/Center that has agreed to accept assignment of the application.**
- **An application received without indication of prior staff concurrence and identification of program staff contacted will be returned to the applicant without review. Therefore, NIH strongly encourages applicants to contact appropriate IC staff at the earliest possible time.**

For additional information about this policy, contact the program staff at any Institute/Center. Applicants who are uncertain about which IC may have the greatest interest in the research for which support is sought should contact the NIH CSR Receipt and Referral Office at (301) 435-0715.

## Key Personnel

In addition to the principal investigator (PI), Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Key Personnel. **Consultants should also be included if they meet the same definition.**

Key Personnel must devote measurable effort to the project whether or not salaries are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Key Personnel.

**Start with the principal investigator.** List the principal investigator's **last name first**. All other Key Personnel should be listed in **alphabetical order**, last name first. For each individual provide name, eRA Commons User Name (if known), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

**Other Significant Contributors.** This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion.

However, if an award is to be made, Other Support information will not be required or accepted since considerations of overlap do not apply to these individuals.

Should the level of involvement change for an individual listed in this category, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

## Biographical Sketch

### [FORMAT PAGE \(MS WORD OR PDF\)](#)

Follow the instructions on the Biographical Sketch Format Page. This section must contain the biographical sketches of all **Key Personnel and Other Significant Contributors**, including consultants, following the order as listed on Form Page 2.

If the individual is registered in the eRA Commons, include the assigned Commons User Name. This data item is currently optional. (For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.)

Use the sample *format* on the Biographical Sketch Format Page to prepare this section for **all** (modular *and* other) grant applications.

The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. See sample [MS Word](#) or [PDF](#). **This 4-page limit includes the table at the top of the first page.**

Complete the educational block at the top of the format page, and complete sections A, B, and C.

- A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- B. Selected peer-reviewed publications or manuscripts in press (in chronological order).** Do not include manuscripts submitted or in preparation.
- C. Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). *Begin with the projects that are most relevant to the research proposed in this application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. **Note: Do not include percent of effort or direct costs.**

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you *after* peer review. This information will be used to check that the proposed research has not already been Federally-funded.

Information on Other Support beyond that required in the biographical sketch should NOT be submitted with the application. Otherwise, the application processing may be delayed or the application may be returned to the applicant without review. For additional information and policy on Other Support, see [Part III: Policies, Assurances, Definitions and Other Information](#).

## Research Plan

### No Specific Form Page

### Use Continuation Page ([MS Word](#) | [PDF](#))

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). The format for preparing this section is provided below. Be specific and informative, and avoid redundancies. For grant writing tips, see [http://grants.nih.gov/grants/grant\\_tips.htm](http://grants.nih.gov/grants/grant_tips.htm).

### Introduction (Revised or Supplemental Applications Only)

Refer to the section on [Revised Applications](#). All revised (amended) and supplemental applications must include an Introduction. The Introduction may not exceed three pages for revised applications or one page for supplemental applications. *Insert the Introduction at the very beginning of the Research Plan.*

### Page Limitations

**Do not exceed 25 pages for *Items A-D*.** All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit. Be succinct and remember that there is no requirement to use all 25-pages allotted to *Items A-D* of the Research Plan.

**Follow page limitations as specified in PAs and RFAs.**

**SBIR/STTR applicants:** See [Section V](#) and the [SBIR/STTR Solicitation](#) for specific instructions.

Do not include photographs or other materials that are not printed *directly* on the application page in the body of the application. Pictures or other materials that are glued or taped onto application pages are incompatible with the current duplication/scanning process.

Full-sized glossy photographs of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan (see [Section I.C.8 Appendix](#)).

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site as it could compromise their anonymity.

The 25-page limit will be strictly enforced. Application processing may be delayed or the application may be returned to the applicant without review.

### Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (\*) in the left-hand margin and providing the page numbers before "A. Specific Aims" in the Research Plan.

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction

does not limit the Government's right to use the information if it is obtained without restriction from another source.

## Content of Research Plan

The PHS recommends the following format and page distribution. Organize *Items a-d* of the Research Plan to answer these questions: *What do you intend to do? Why is the work important? What has already been done? How are you going to do the work?*

Do not exceed 25 pages for Items A-D, including all tables and figures.

### **A. Specific Aims**

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. **One page is recommended.**

### **B. Background and Significance**

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. **Two to three pages are recommended.**

### **C. Preliminary Studies/Progress Report**

*Preliminary Studies.* For new applications, use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.

Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), and Phase I Small Business Research Grants (R41/R43), peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

*Progress Report for Competing Continuation and Supplemental Applications.* A Progress Report must be provided for competing continuation and supplemental applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Discuss any changes in the specific aims as a result of budget reductions. Include the complete references to appropriate publications and manuscripts accepted for publication (not part of the page limitations). Include five collated sets, single-sided, of all Appendix material, in the same package with the application, following all copies of the application (see [Section I.C.8](#)).

If the competing continuation or supplemental application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender.

See "[What Form Should PIs Use for Population Tracking? \(New Versus Old\)](#)" ([PDF](#) or [MS Word](#)) for more detailed instructions on which Target and Enrollment Report or Table to use.

Provide a succinct account of published and unpublished results, indicating progress toward their achievement.

List the titles and complete references to all publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Up to 10 such publications may be included in the five collated sets of appendices.

The publications portion of the competing continuation and supplemental applications Progress Report is not included in the 25-page limit.

**Six to eight pages are recommended** for the narrative portion of the Preliminary Studies/ Progress Report.

#### **D. Research Design and Methods**

Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Section i, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no requirement that all 25 pages allotted for *items A-D* be used.

#### **E. Human Subjects Research**

The following human subject information applies even if you are obtaining specimens from collaborators or if you are subcontracting the human research to another organization.

Also refer to Part II of the PHS 398: [Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan](#) if your proposed research will involve [human subjects](#).

For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. This evaluation will be a part of the Approach criterion. The evaluation of the inclusion plans will be factored into the overall score that the SRGs award for scientific and technical merit of the application.

Much of the information on the protection of human subjects that you are required to provide in this section of the PHS 398 is identical to information that you will be required to provide for IRB review at your own institution.

The research described in your application may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research.

If research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, then your answer is “Yes” even if the research is exempt from regulations for the protection of human subjects.

To assist you in filling out this section of the application, a Decision Table is provided below that presents six possible scenarios, and links to instructions for providing

information on human subjects protection from research risks, and the inclusion of women, minorities and children. All research **projects** will fall into one of these six scenarios.

Determining which scenario best matches your proposed research depends on your answers to the following five questions:

[Question 1: Does your proposed research involve human subjects?](#)

[Question 2: Does your proposed human subjects research meet the criteria for one or more of the exemptions in the HHS Regulations \(45 CFR Part 46\)?](#)

[Question 3: Does your proposed research meet the definition of Clinical Research?](#)

[Question 4: Does your proposed research include a Clinical Trial?](#)

[Question 5: Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?](#)

Click on the questions, and when you have the answer for the five questions proceed to the table above, and select the scenario that best matches your responses. Follow the instructions provided for the scenario you choose. If you need additional guidance then click on the questions, the column heading in the table below, or links within the scenario and you will be provided additional information and guidance.

**For Clinical Research, place the Target/Planned Enrollment Table(s) under the heading "Inclusion of Women and Minorities," immediately in front of the heading "Inclusion of Children." See [Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan](#).**

When you have completed this section of the application proceed to [Section F. Vertebrate Animals](#).

#### **F. Vertebrate Animals.**

If you have marked Item 5 on the Face Page of the application "Yes," create a section heading entitled "Vertebrate Animals." Place it immediately following the Research Design and Methods section of the application (or after Item e, if applicable.)

Failure to address the following elements will result in the application being designated as incomplete and it will be grounds for the PHS either to defer the application from the peer review round or to potentially negatively affect the application's priority score.

Under the Vertebrate Animals heading address the following five points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

#### **G. Literature Cited.**

List all references. The list may include, but may not replace, the list of publications required in the Progress Report for competing continuation applications.

Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication.

See example at: <http://www.niaid.nih.gov/ncn/grants/app/app.pdf>

The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

#### **H. Consortium/Contractual Arrangements.**

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/ contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

The signature of the authorized organizational official on the Face Page signifies that the applicant and all proposed consortium participants understand and agree to the following statement: The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy. A separate statement is no longer required.

#### **I. Resource Sharing.**

(1) Data Sharing Plan: Investigators seeking \$500,000 or more in direct costs in any year must include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See [Data-Sharing Policy](#) or [http://grants.nih.gov/grants/policy/data\\_sharing/index.htm](http://grants.nih.gov/grants/policy/data_sharing/index.htm).

(2) Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. Note unlike the data sharing requirement above, this requirement is for all applications **where the development of model organisms is anticipated**. See [Sharing Model Organisms Policy](#). **If model organisms are not planned as part of the research proposal, omit this section.**

*These descriptions are not included in the Research Plan page limits.*

#### **J. Consultants.**

Attach appropriate letters here from all individuals confirming their roles in the project and rate/charge for consulting services. **Do not place these letters in the Appendix.**