

# **NATIONAL INSTITUTES OF HEALTH SUBMISSION TOOLKIT**

**Includes excerpts and information from the SF424 (R&R) Application  
and Electronic Submission [website](#) of the National Institutes of Health**

**Auburn University  
Proposal Services and Faculty Support  
February 2016**

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## INTRODUCTION

The purpose of this toolkit is to provide a basic understanding of the components and/or requirements of an NIH proposal submission. Note that these are general instructions and specific programs or types of proposals may require deviation from these standard instructions. In all cases, it is very important to review the applicable Request for Proposal (RFP), Program Announcement (PA) or Solicitation to which you are responding.

## BASIC RULES

Refer to [Grants.gov Application Guide](#) (SF 424 R&R) for more information on the topics below.

**Download** the *most recent* Grant Application Package in response to the FOA (funding opportunity announcement) by clicking on “Apply for Grant Electronically” button in FOA.

**Open** the application package:

**Application Filing Name:** insert “PIName\_Deadline Date.” (for PHS and NIH agencies).

**Click on each form under “Mandatory Documents”** on the left side of the Grants.gov selector page;

**Begin** your work.

**Click on each relevant form under “Optional Documents”** on the left side of the Grants.gov selector page;

**Save** your work.

Do not “Save & Submit” – only OSP or an OSP-delegated College-level designee can submit.

**Follow the specifics of each Funding Opportunity Announcement for additional requirements.**

### Conflict of Interest Requirements

Effective August 24, 2012, the Public Health Service (PHS) requires institutions applying for or receiving PHS research funding (including funding from NIH) by means of a grant, cooperative agreement or contract to be in compliance with the following new regulations: “[Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought & Responsible Prospective Contractors](#).” These regulations are commonly referred to as the “FCOI Regulations.” The purpose of the FCOI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under PHS grants, cooperative agreements or contracts will be free from bias resulting from investigator financial conflicts of interest.

The requirements for FCOI compliance include mandatory investigator training (at least every four years) and disclosure of Significant Financial Interests (SFI) at least annually. Detailed information regarding Auburn University’s FCOI policy and procedures are available on the Research Compliance [website](#). The website also includes direct links to the Collaborative Institutional Training Initiative (CITI) [system](#) and COI Smart [system](#) for disclosures.

## FORMAT SPECIFICATIONS

All file attachments must be in PDF format, and should have descriptive filenames of 50 characters or less, using only standard characters. All individual files or components of an NIH proposal must adhere to the following specifications: Font must be Arial, Helvetica, Palatino Linotype, or Georgia, 11 points or larger, and black font color. Symbol fonts may be used to insert Greek letters or other special characters, but the font size requirement still applies. Smaller type may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes: but it must be legible and all text must be in black. Color can be used in figures.

Paper must be standard size (8.5 x 11 inches), with margins of at least one-half inch on all sides. No information should appear in the page margins; including page numbers (NIH will generate page numbers when the proposal is assembled in the eRA Commons after submission).

## PAGE LIMITS

The standard page limits for most NIH proposals are as follows. Please note that individual funding opportunity announcements (FOAs) may contain different guidelines that modify or supersede the standard rules. *Be sure to check the requirements listed in the FOA for the competition for which you are applying!*

Section	Page limit
Introduction ( <i>only</i> for resubmissions/revisions)	1
Specific Aims	1
Research Strategy	6 R03, R13, R21, R36, R41, R43 applications
	12 R01, R15, R18, R21/R33, R24, R25, R33, R34, R42, R44 applications
Biographical Sketches	5
Appendices	<p><b><i>Publications – No longer allowed as appendix materials except in specific circumstances (see <a href="#">SF424 R&amp;R Guide for Guidance</a>)</i></b></p> <p><b><i>Items that must not be included in the appendix: Digital photographs or color images of gels, micrographs, etc. are no longer accepted as Appendix material. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.</i></b></p>

## SPECIFIC RULES FOR COMPLETING PHS/NIH APPLICATIONS

### SF 424 (R&R) Application for Federal Assistance (Cover Page)

- (1) Type is usually "Application"
- (2) Date Submitted – leave blank (will be added prior to submission)
- (3) Date Received by State: leave blank                      Applicant Identifier: leave blank
- (4) (a) Federal Identifier: Use two letter Institute Code and six digit grant # for Resubmission/Renewal (e.g., GM012345) (NIH only)
  - (b) Leave blank
  - (c) Enter the previous Grants.gov tracking number for changed/corrected applications (use eight digit Grants.gov number, e.g. GRANT12345678 (as applicable)
- (5) Applicant Information: Auburn University, Office of Sponsored Programs, VPR&ED, 310 Samford Hall, Auburn University AL 36849-5131, Lee County
  - (a) DUNS #: 066470972
  - (b) Person to be contacted is Ms. Martha M. Taylor, Assistant VP for Research, Office of Sponsored Programs, 310 Samford Hall, Auburn University AL 36849-5131, 334-844-4438, 334-844-5953, [ospadmn@auburn.edu](mailto:ospadmn@auburn.edu)

- (6) EIN #: 63-6000724
- (7) Type of applicant is always **H**: Public/State Controlled Institution of Higher Education
- (8) Type of application – choose as applicable; answer yes or no regarding submission to other agencies
- (9) Auto-filled by the application package
- (10) Auto-filled by the application package; or blank
- (11) Descriptive Title of Project – NIH truncates titles after 81 characters (including spaces), so try to keep the title brief—or else put the important information first. Note that new applications must have different titles from any other project you have previously submitted. A resubmission or a renewal application should normally be given the same name as the previous grant or application. However, if the specific aims of the project have changed significantly, choose a new title. Revision applications must have the same title as the currently funded grant.
- (12) Project Dates: Important – dates must match those on budget forms. For renewal applications, start date must be after end date of current project period
- (13) Congressional District of Applicant – AL-003
- (14) PD/PI Information – fill out completely –include suffix (terminal degree)
- (15) 15.a. + 15.b = 15.c. 15.b. and 15 d. – usually \$0.00 unless there is cost share required or program income
- (16) 16.b. NO (Program is NOT covered by E.O. 12372)
- (17) Check box
- (18) Leave blank
- (19) Authorized Representative: Dr. John M. Mason, Ph.D., VP for Research and Economic Development, Auburn University, Office of Sponsored Programs, VPR&ED, 310 Samford Hall, Auburn University, Lee County, 36849-5131, 334-844-4438, 334-844-5953, [ospadmn@auburn.edu](mailto:ospadmn@auburn.edu)
- (20) Only include as applicable
- (21) Cover letter attachment - Cover letters are not required (except for late applications or when submitting a corrected/changed application after the submission date), but OSP strongly recommends including one with every proposal you submit to NIH. Cover letters will not be shared with peer reviewers. You should include any of the following information that is relevant to the application:
- a. Application title
  - b. Funding opportunity (PA or RFA) and title of the NIH initiative
  - c. Request(s) for assignment/referral to a particular institute or center for funding consideration or Scientific Review Group (SRG). NIH is not obligated to grant these requests, but will consider them.
  - d. List of individuals (i.e., competitors) who should not review the application and why.
  - e. Disciplines involved in the proposed research, if multidisciplinary.

- f. Explanation of any subaward budget components that are not active for all periods of the proposed grant.

To facilitate consideration of your requests, the Division of Receipt and Referral (DRR) of the Center for Scientific Review (CSR) suggests that you list one request per line. If both institute/center and SRG review requests are made, place these on separate lines. If you are making positive (i.e., a request for referral to a specific SRG) and negative (i.e., a request that the proposal not be considered by a particular IC) requests, make these requests on separate lines. Include the name of the IC or SRG, followed by a dash and the acronym. Do not use parentheses. Provide explanations for each request in a separate paragraph.

## PHS 398 Research Plan (for R proposals)

1. **Introduction to application** – Limited to one page. Introductions are only allowed for resubmissions or revisions of previously submitted proposals. Use the introduction to describe the revisions made, and to respond to comments and criticisms presented by the peer reviewers of the previous proposal. If you disagree with any of these, explain why. Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc.). Do not use the numbers associated with these sections in the instructions, as your application may not include all of the sections.
2. **Specific aims** – Limited to one page. State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the 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.

3. **Research strategy** – Depending on the type of application you are submitting, you are allowed either 6 or 12 pages for this section (see the table on page 3).
  - a. **Significance.**
    - ✓ Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
    - ✓ Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
    - ✓ Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
    - ✓ Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
  - b. **Innovation.**
    - ✓ Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
    - ✓ Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
    - ✓ Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

c. *Approach.*

- ✓ Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
- ✓ Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
- ✓ Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- ✓ Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- ✓ If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- ✓ Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
- ✓ If your study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample. Please refer to [NOT-OD-1502](#) for further consideration of NIH expectations about sex as a biological variable.
- ✓ Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- ✓ If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

NOTE: Additional guidance on the new requirements in Rigor and Reproducibility can be found at: <http://grants.nih.gov/reproducibility/index.htm>

**As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.**

***Preliminary Studies for New Applications:***

For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.

### ***Progress Report for Renewal and Revision:***

Applications. For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. For any studies meeting the NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children etc.) as part of the progress report, particularly if relevant to studies proposed in the renewal or revision application. You should not submit a Cumulative Inclusion Enrollment Report form unless the enrollment is part of the renewal or revision application. A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment; do not include that information here.

#### ***4. Progress report publication list.***

- ✓ Include for competitive renewals only. List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at:

[http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm).

#### ***5. Human Subjects***

- ✓ Complete this section if you answered “yes” to the question “are human subjects involved?” on the R&R Other Project Information form). Instructions on completing this section can be found in the DHHS/PHS [Supplemental Grant Application Instructions](#) (Section 5). NOTE: if you checked “yes” on the R&R Other Project Information page, all three sections (5-7) are necessary even if the answer is “Not applicable.”

#### ***6. As applicable.***

#### ***7. As applicable.***

### **Other Research Plan Sections**

#### ***8. Vertebrate Animals***

- ✓ If you checked “yes” on the R&R Other Project Information page, this section is necessary. If Vertebrate Animals are involved in the project, address each of the criteria below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the criteria below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following criteria will result in the application being designated as incomplete and it will not be considered.



If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, the grantee must submit to the NIH awarding office detailed information as required in the criteria below and verification of IACUC approval prior to the involvement of animals.

The criteria are as follows:

- I. Description of Procedures: Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the “Research Strategy” section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
- II. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
- III. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.
- IV. Euthanasia: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>

#### 9. Select Agent Research

- ✓ Explain as applicable. If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the select agent(s) to be used in the proposed research.

2. Provide the registration status of all entities\* where select agent(s) will be used.

- If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.

*\*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”*

3. Provide a description of all facilities where the select agent(s) will be used.

- Describe the procedures that will be used to monitor possession, use and transfer of the select agent(s).
- Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
- Describe the biocontainment resources available at all performance sites.

#### 10. Multiple PD/PI Leadership Plan

- ✓ For projects designating multiple PDs/Pis, a leadership plan must be included. The rationale for choosing a multiple PD/PI approach should be described. The governance and organization of the

leadership team and the research project should be described, including communication plans, the process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and for other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

#### 11. Consortium/Contractual Arrangements

- ✓ Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium or 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.

#### 12. Letters of Support

- ✓ Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated.

#### 13. Resource Sharing Plan(s)

- ✓ Not required for all applications – read the terms of each specific PA to which you plan to apply.

#### 14. Appendix

- ✓ A maximum of 10 PDF attachments is allowed. If more than 10 are needed, combine the remaining information into attachment number 10. If you have multiple items, include a summary sheet listing all of the items as the first appendix.

#### **Publications – Only 3 allowed, and only under the following circumstances:**

- **Manuscripts and/or abstracts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
- **Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:** The entire article should be submitted as a PDF attachment.
- **Patents directly relevant to the project:** The entire document should be submitted as a PDF attachment.

#### **Not Allowed in Appendix**

**Photographs or color images of gels, micrographs, etc.,** are no longer accepted as Appendix material. These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.

**Publications with URLs or PMCs** are not allowed; rather, they should be included in the

Bibliography and References cited section, Progress Report Publications List, and/or Biographical Sketch section.

### PHS 398 Cover Page Supplement

1. **PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR:** Auto-filled from SF424 R&R Cover Page.
2. **HUMAN SUBJECTS:** Mark clinical trial and NIH Phase III if applicable.
3. **DISCLOSURE PERMISSION STATEMENT:** check Yes or No, depending upon PI's preference.
4. **PROGRAM INCOME:** Usually no.
5. **HUMAN EMBRYONIC STEM CELLS:** Usually no for AU.
6. **INVENTIONS AND PATENTS:** Required only for renewal applications.
7. **CHANGE OF INVESTIGATOR/CHANGE OF INSTITUTION:** As applicable.

### Research and Related Senior/Key Personnel Profile (Expanded)

- For each Senior/Key Person and other [significant contributors](#), complete contact information. **Include eRA Commons UserName in "Credential" field for all PD/PIs.**
- Alphabetize Senior/Key Persons by Project Role/Project Category (according to effort on project). Other Significant Contributors (those without measureable effort) are then listed in alphabetical order.
- "Co-PD/PI" is not accepted by NIH; Use "Other" and "Investigator" or "Co-Investigator"
- For multiple PD/PI grants, **all** PIs are called "PD/PI", contact PI is listed under "PROFILE- PD/PI" and other PIs are listed in Senior/Key Person 1, 2, etc. in alpha order. Include required Multiple PD/PI Leadership Plan in PHS 398 Research Plan #10.
- **Biosketch:** five-page limit; refer to this [website](#) for forms, instructions and sample.
  - A. *Personal Statement.* Briefly describe why your experience and qualifications make you particularly well-suited for your role in the project.
  - B. *Positions and Honors.* List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any public advisory committee to the federal government.
  - C. *Contributions to Science.* Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US

National Library of Medicine.

- D. *Research Support.* List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Don't confuse this section with the Other Support (current and pending support) section. C&P information is not required at proposal stage, but will be requested as "Just-in-Time" information if NIH anticipates making an award. The Research Support section in the biographical sketch is to highlight your accomplishments as a scientist, together with those of your colleagues.

## Research and Related Other Project Information

1. **HUMANS:** If yes, then check 1.a. yes or no regarding exemption; if 1.a is no, check yes for "pending." Insert Human Subject Assurance Number: 00001104
2. **ANIMALS:** If yes and review is pending, check yes and leave date blank. Enter Animal Welfare Assurance number A3152-01
3. **PROPRIETARY/PRIVILEGED INFORMATION:** As applicable (Yes or No). Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "*The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.*" This field is required.
4. **ENVIRONMENTAL QUESTIONS:** As applicable (Yes or No) [4a-4d]. Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer "No" to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, the box marked "Yes" should be checked and an explanation provided.
5. **DESIGNATION AS HISTORIC PLACE:** As Applicable (Yes or No). If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes box and then provide an explanation in the box provided in 5.a. Otherwise, check the No box. This field is required.
6. **FOREIGN COLLABORATORS:** As applicable (Yes or No). Identify countries 6(a) and optional explanation 6(b).
7. **PROJECT SUMMARY/ABSTRACT:** Intended as a summary of the proposed activity suitable for public presentation or dissemination. It should contain a statement of objectives and methods to be employed,

and should be written so as to be informative to other persons working in the same or related fields and, insofar as possible, to a scientifically literate lay reader. Do not include any proprietary or confidential information in the project summary, as it will be available for public viewing. This section is meant to serve as a succinct and accurate description of the proposed work, when separated from the application. This section cannot be longer than 30 lines of text.

8. **PROJECT NARRATIVE:** The second part of the project summary. It should address the relevance of the proposed research to public health in no more than two or three sentences. Write this section in plain language that can be understood by a lay audience.
9. **BIBLIOGRAPHY/REFERENCES CITED:** Provide a bibliography of any and all references cited in the research strategy. Each reference must include the names of all authors (in the same order in which they appear on the publication), the article and journal title, book title, volume number, page numbers (both starting and ending), and year of publication. Include only bibliographic citations. If any of your own work was funded directly by an NIH grant or cooperative agreement active in fiscal year 2008 or beyond and was accepted for publication in a peer-reviewed journal on or after April 7, 2008, you must include the PubMed Central reference number (PMCID) at the end of any citation of such works in any subsequent proposals to the NIH. See <http://publicaccess.nih.gov/> for further details about compliance with this policy.
10. **FACILITIES AND OTHER RESOURCES (ENVIRONMENT):** Information in this section is used to assess the adequacy of the organizational resources available to perform the proposed research. Identify the facilities to be used (laboratory, animal, computer, office, clinical, and other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are pertinent to the proposed research. Provide any information describing other resources available to the project (i.e., machine shops, electronics shops, etc.) and the extent to which they would be available to the project.  
  
Address how the research environment will contribute to the probability of success of the proposed research. Also note any unique features or resources that would contribute to the probable success of the research proposed. For an Early Stage Investigator, describe the institutional investment (start-up funding, course release, graduate assistants, etc.) in the success of the investigator.
11. **EQUIPMENT:** Major items  $\geq$  \$5000; List major items of equipment available for the project, together with their location and pertinent capabilities, if appropriate.
12. **OTHER ATTACHMENTS:** Use for additional project information (a) not already provided or (b) in accordance with FOA.

### **Project/Performance Site Location(s)**

- Name all applicable sites, starting with Auburn and including consortium sites as appropriate.
- List Congressional District for each site as two-letter state and three-digit district: (AL-003 for AU). If program/performance site is outside the US, enter 00-000.

- Do not check box (AU is not an individual).

## OPTIONAL DOCUMENTS

Budget is mandatory, but you must select either a Modular Budget ( $\leq$ \$250K/ annual **Direct Costs**) or a detailed Research & Related Budget ( $>$  \$250K/annual **Direct Costs**) for each application.

### PHS 398 Modular Budget – under \$250K in annual Direct Costs

The National Institutes of Health (NIH) maintains [modular budgeting guidelines](#) for many of its applications. Under these guidelines for application under \$250,000, no detailed budgets are provided to NIH, although details on personnel, subcontracts are provided in a budget justification. Amounts requested per year cannot (currently) exceed \$250,000 in direct costs and funding must be requested in \$25,000 increments.

Please note that while NIH does not require submission of a detailed budget when submitting a modular budget, a detailed internal budget is required for institutional review purposes.

### ***Instructions***

Enter dates – must be the same as Cover Page project periods.

- A. Direct Costs: enter as required (see [PHS SF424 \(R&R\) Guide](#))
- B. Indirect Costs:
  - a. Type of Direct Costs: Modified Total Direct Costs (MTDC)
  - b. Cognizant Agency (Agency Name, POC Name and Phone Number):  
DHHS, Phat Chau, 301-492-4855  
Use latest [DHHS Agreement](#) date: 8/21/2015  
Complete for **EACH** budget period.
- C. Total Direct & Indirect Costs – must equal Cover Page.

### ***Cumulative Budget Information (Justification)***

1. Attach Personnel Justification PDF file
  - i. Begin with PI, list and justify all personnel including OSCs. Include effort in calendar months, OR academic and summer months. Do not use % for effort.
  - ii. Do NOT justify any other expenses.
2. Attach Consortium justification PDF file – use only if necessary
  - i. Include annual direct costs for each year.
3. Attach Additional Narrative Justification PDF file only if you have a variation in the number of modules you are requesting, or if equipment purchase is involved.

### **Research & Related Budget – over \$250K in annual Direct Costs**

Follow instructions carefully in [PHS SF424 \(R&R\) Guide](#)

1. Do not use 0.0 effort – effort must be a minimum of .12 months for Key Personnel.
2. Do not include Other Significant Contributors on budget pages but DO include them in the Budget Justification.

3. Attach budget justification in year 01 (you will not be able to proceed to next period without this step).
4. Do NOT change PD/PI role to anything else – this will cause error
5. Do not forget to include effort for Senior/Key Persons in each year.
6. Remember dates for each year.
7. Include Cognizant Agency info in each year.
8. Do not use Participant Support Costs for anything other than Conference Grants.

**R & R Subaward Budget**

1. Extract a budget and email it to each of the proposed consortium/subawardee contacts to complete.
2. When returned, check carefully for the following:
  - a. Dates match prime proposal dates
  - b. DUNS number of each institution has been completed (ending with four zeros).
  - c. Format is in .pdf format.
  - d. Budget Justification is attached in .pdf format.
3. Attach .pdf file for each consortium using name of institution as filename in Attachment 1, 2, etc. (i.e. Baylor.pdf, Columbia.pdf)