Items Needed for NIH R03 Application – Updated for Applications Due After May 25, 2016

Use 11 pt. Arial or 12 pt. Times New Roman and at least ½" margins on all sides

☐ **Cover letter**
I can send you a sample if you would like. The letter should contain any of the following information that applies to the application: 1) application title; 2) funding opportunity title.

☐ **Awarding Component Assignment Request (Optional)**
You may request up to three institutes/centers for assignment of your application

Assign to Awarding Component:
Enter preferences for NIH IC assignment in the boxes in the "Assign to" row. Use the column labeled "1" to enter your first choice.

Do Not Assign to Awarding Component:
You may request that your application not be assigned to a specific NIH IC by entering that information in the boxes in the "Do Not Assign To" row.

In most cases, you will only want to make one or two requests; there is no need to make an entry in all six boxes. The hyperlink in this section of the form (http://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents) will take you to a web site where descriptions of the science covered by all NIH institute/centers can be found, including links to other PHS agency information.

☐ **Study Section Assignment Request (Optional)**
You may request up to three SRGs or SEPs for assignment of your application.

For this section, you will need to accurately type in the short abbreviation of the SRG / SEP you wish to request. The hyperlink in this section of the form (http://grants.nih.gov/grants/phs_assignment_information.htm#StudySection) will take you to a site where you can find more information about how to identify CSR and NIH SRGs and SEPs, including their short abbreviations. For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter "ZRG1 HDM-R" if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Assign to Study Section:
Enter the short abbreviations(s) for SRGs / SEPs to which you would like your application assigned in the "Assign to" row. Use one box per individual SRG/ SEP request. Type your first choice in the column labeled "1".

Do Not Assign to Study Section:
If you wish to request that your application not be assigned to a particular SRG/SEP, enter that information in the boxes found in the "Do Not Assign To" row.

In most cases, you will only want to make one or two requests; there is no need to make an entry in all six boxes.

☐ **List individuals who should not review your application and why (Optional) (1000 characters max)**
Provide sufficient information (e.g., name, organizational affiliation) so that the SRO can correctly identify the individual, and provide sufficient information so that the SRO can confirm a conflict of interest for the review. Simply stating "Dr. John Smith is in conflict with my application" is not helpful.

☐ **Identify expertise needed to review your application (Optional) (40 characters/field max)**
Five fields are provided if you wish to identify general or specific types of expertise needed for the review of your application. Do not enter names of individuals you would like to review your application.

☐ **Specific Aims (1 page max)**

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.

☐ **Research Strategy (6 pages max)**

(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 the Resource Sharing Plan attachment, 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.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

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.

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.

☐ **Letters of Support (e.g., consultants)**

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. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.

☐ Vertebrate Animals (if applicable)

If Vertebrate Animals are involved in the project, address each of the following criteria listed below.

1. 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.
2. 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).
3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

Provide a concise, complete description of the animals and proposed procedures.

- The responses to the criteria below must be well-integrated with the other sections. There should be sufficient detail in the responses for peer reviewers and NIH staff to evaluate. Additional details, if any, may be included in the Research Strategy.
- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites.
- An incomplete application will not be considered for review. It will be considered incomplete if the above criteria are not addressed.
- If plans for the use of animals have not been finalized, explain when and how animals are expected to be used.
- If an award is made, the grantee must provide detailed information on the criteria above, and verification of IACUC approval. These must be submitted to the NIH awarding office prior to the involvement of animals.

☐ Protections of Human Subjects (if applicable)

If Human Subjects are involved in the project, address each of the following criteria listed below.

1. Risks to Human Subjects
   a. Human Subjects Involvement, Characteristics, and Design
      - Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.
      - Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant.
      - Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.
      - If relevant, explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.
      - If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, provide details about all planned interventions such as dose, frequency, and administration.
      - List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

   b. Sources of Materials
      - Describe the research material obtained from living individuals in the form of specimens, records, or data.
      - Describe any data that will be collected from human subjects for the project(s) described in the application.
      - Indicate who will have access to individually identifiable private information about human subjects.

- Provide information about how the specimens, records, and/or data will be collected, managed, and protected, as well as whether any individually identifiable private information will be collected specifically for the proposed research project.

c. Potential Risks
   - Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
   - Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research. When alternative treatments or procedures are possible, the rationale for the proposed approach should be clear.

2. Adequacy of Protection Against Risks
   a. Recruitment and Informed Consent
      - Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
      - Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
      - If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

   b. Protections Against Risk
      - Describe planned procedures for protecting against or minimizing all potential risks identified, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
      - Describe how proposed research involving vulnerable populations meets the additional regulatory requirements described in the HHS regulations, Subparts B, C or D.
      - Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
      - Where appropriate, describe plans for handling incidental findings that may be uncovered as a result of the research, such as incidental findings from research imaging, results of screening tests, or misattributed paternity.

3. Potential Benefits of the Proposed Research to Human Subjects and Others
   - Discuss the potential benefits of the research to research participants and others.
   - Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
   - Please note that financial compensation of subjects should not be presented as a benefit of participation in research.

4. Importance of the Knowledge to be Gained
   - Discuss the importance of the knowledge to be gained as a result of the proposed research.
   - Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

☐ Inclusion of Women and Minorities (if applicable)

This section is required for all studies meeting the NIH definition for clinical research, not just clinical trials:

Clinical Research. NIH defines human clinical research as research with human subjects that is: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health

services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

It is important to provide a detailed plan of who will be included (and/or excluded) and how the distributions of individuals on the basis of sex/gender, race, and ethnicity are justified in the context of the scientific goals of the application. Simply stating that certain individuals will not be excluded or that individuals of either sex/gender or any race/ethnicity are eligible is not sufficient. Details about why the individuals are the appropriate individuals to accomplish the scientific goals of the study should be provided.

In this section, address, at a minimum, the following four points:

1. Describe the planned distribution of subjects by sex/gender, race, and ethnicity for each proposed study and complete the format in the PHS Inclusion Enrollment Report.
2. Describe the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. Provide a compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial, or ethnic group that comprises the population under study.
4. Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects. This is particularly important if difficulty recruiting certain groups is anticipated.

Additional Considerations for justifying inclusion:

There may be reasons why the proposed sample is limited by sex/gender, race, and/or ethnicity. This should be addressed as part of the four points detailed above.

- Inclusion of certain individuals would be inappropriate with respect to their health;
- The research question addressed is only relevant to certain groups or there is a gap in the research area;
- Evidence from prior research strongly demonstrates no difference on the basis of sex/gender, race, and/or ethnicity; Supplemental Grant Application Instructions II-13
- Sufficient data already exist with regard to the outcome of comparable studies in the excluded group(s) and duplication is not needed in this study;
- A certain group or groups is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects (e.g., uniquely valuable stored specimens or existing datasets are limited by sex/gender, race, and/or ethnicity; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens); and/or
- Representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete sex/gender documentation are used), and this does not compromise the scientific objectives of the research.
- In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. This should be considered when developing outreach plans. Establishing collaborations or other arrangements to recruit may be necessary.

Additional guidance for research utilizing existing datasets or resources:

- Inclusion must be addressed when conducting NIH-defined clinical research, even if the samples or data have already been collected as part of a different study. Details about the sex/gender, race, and ethnicity composition of the existing dataset/resource should be provided and justified as appropriate to the scientific goals of the proposed study.
- For the purposes of inclusion policy, an existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the NIH definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated. More information about what is considered an existing dataset or resource for inclusion policy is available here: http://grants.nih.gov/grants/funding/women_min/datasets_faq.htm

☐ Inclusion Enrollment Report (if applicable)

- The PHS Inclusion Enrollment Report form (see attached form) is used for all applications involving NIH-defined clinical research:

  > Clinical Research. NIH defines human clinical research as research with human subjects that is: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

- This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.
- NOTE: This report format should NOT be used for collecting data from study participants.
- See Page R-78 in the attached "Research Instructions for NIH and Other PHS Agencies" regarding how to fill out this form.

☐ Inclusion of Children (if applicable)

Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the age-appropriate inclusion or exclusion of children in the proposed research project. This section is required for all studies meeting the NIH definition for clinical research, not just clinical trials:

> Clinical Research. NIH defines human clinical research as research with human subjects that is: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

It is important to provide a detailed plan of who will be included (and/or excluded) based on age. Details about why the individuals in the given age/age range are the appropriate individuals to accomplish the scientific goals of the study should be provided.

Instructions for this item of the Research Plan including addressing the following points:

- Describe the age(s) or age range of all individuals to be included in the proposed study.
- Specifically discuss whether children under the age of 18 (as a whole or a subset of individuals under 18) will be included or excluded.
- The description of the plan should include a rationale for selecting a specific age range of children.
- The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR part 46 Subpart D) apply and must be addressed under the Protections Against Risk subheading (4.1.2.b).

Justifications for Exclusion of Children

For the purposes of this policy, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group should be justified in this section. It is expected that children will be included in all NIH defined clinical research unless one or more of the following exclusionary circumstances apply:

- The research topic to be studied is not relevant to children.

- Laws or regulations bar the inclusion of children in the research.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
- A separate, age-specific study in children is warranted and preferable. Examples include:
  - The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
  - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
  - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should Supplemental Grant Application Instructions II-17 not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
- Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
- Other special cases can be justified by the investigator and assessed by the review group and the Institute/Center Director to determine if acceptable.

☐ Resource Sharing Plan

(Note: we typically include boilerplate language addressing this section whether it is required or not. Please let me know if you would like me to send you a copy to adapt.)

NIH considers the sharing of unique research resources developed through NIH sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

1. *Data Sharing Plan*: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1- paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and 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.

2. *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible.

3. *Genome Wide Association Studies (GWAS):* Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition.

☐ Appendix

1. Applicants may submit up to 3 of the following types of publications:

a. **Manuscripts and/or abstracts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
b. **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.
c. **Patents directly relevant to the project:** The entire document should be submitted as a PDF attachment.

2. Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.

☐ Biographical Sketch (5 pages max)

Please see attached samples / instructions. Include biographical sketches for you and any other person considered "Senior/Key Personnel" or "Other Significant Contributor."

A. **Personal Statement:** Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C).

You may cite **up to four** publications or research products that highlight your experience and qualifications for this project. Research products can include audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

B. **Positions and Honors:** List in chronological order positions held since the completion of your most recent degree, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee. List any relevant academic and professional achievements and honors. In particular:

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on clinical licensure and specialty board certification, if applicable.
- Include present membership on any Federal Government public advisory committee.

C. **Contributions to Science.** Briefly describe **up to five** of your most significant contributions to science.

Each contribution should be no longer than one half page, including citations. These contributions do not have to be related to this project. 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.
- You may cite up to four papers accepted for publication or research products that are relevant to the contribution.
  - Research products can include audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.
  - These citations do not have to be authored by you.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required, and reviewers are not required to look at the list.

D. **Research Support**. List both selected ongoing and completed research projects for the past three years (Federal or non-Federal support). Briefly indicate the overall goals of the projects and your responsibilities. *Do not include number of person months or direct costs*.

☐ **Project Summary / Abstract (30 lines max)**

The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. **This section must be no longer than 30 lines of text.**

☐ **Project Narrative (2-3 sentences max)**

Using no more than two or three sentences, describe the relevance of this research to **public health**. For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.

☐ **Bibliography / References Cited**

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. 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. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references 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.

☐ **Facilities and Other Resources**

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. See http://grants.nih.gov/grants/new_investigators/.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about select agents must be described in the Research Plan, Select Agent Research.

☐ **Equipment**

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.

☐ **Budget Narrative**

I will create a draft "skeleton" of the budget narrative for you to edit / fill in details once the budget is finalized.