Items Needed for NIH R15 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 (12 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.

In addition, for R15 applications, include the following information in your Research Strategy: Describe how undergraduate and/or graduate students will be exposed to and supervised conducting hands-on research. Describe how students will participate in research activities such as planning, execution and/or analysis of research. Formal training plans (e.g., non-research activities, didactic training, seminars) should not be provided. A sound rationale should be offered as to why the approach and the research team, including undergraduate and/or graduate students, are appropriate to accomplish the specific aims and to make an important scientific contribution.

☐ **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.

☐ **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.

☐ Authentication of Key Biological and/or Chemical Resources (1 page max)

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

- Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

☐ 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*.

In addition, for R15 applications, include the following information in your biographical sketch: The PD(s)/PI(s) should include a summary of his or her previous and/or current experience supervising undergraduate and/or graduate students in research in the Personal Statement. The PD(s)/PI(s) should indicate which peer-reviewed publications or other research products involved undergraduate and/or graduate students under his or her supervision.

☐ **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.

In addition, for R15 applications, include the following information in the Facilities section as part of the AREA Impact Statement:

- A profile of the students of the applicant institution/academic component and any information or estimate of the number who have obtained a baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences during the last five years.
- A description of the special characteristics of the institution/academic component that make it appropriate for an AREA grant, where the goals of the AREA program are to: (1) provide support for meritorious research; (2) strengthen the research environment of schools that have not been major recipients of NIH support; and (3) expose available undergraduate and/or graduate students in such environments to research.
- Description of the likely impact of an AREA grant on the PD(s)/PI(s).
- Description of the likely impact of an AREA grant on the research environment of the institution/academic component.
- Although it is expected that the majority of the research will be directed by the PD(s)/PI(s) and conducted at the grantee institution, limited use of special facilities or equipment at another institution is permitted. For any proposed research sites other than the applicant institution, provide a brief description of the resources and access students will need and have to these resources.
- If relevant, a statement of institutional support for the proposed research project (e.g., equipment, supplies, laboratory space, release time, matching funds, etc.).

☐ 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.

In addition, for R15 applications, include the following information in the budget narrative: Since a primary objective of the AREA program is to expose students to meritorious research, PD(s)/PI(s) must include undergraduate students (preferably, if available from any academic component) and/or graduate students from the applicant institution/applicant component in the proposed research. Indicate aspects of the proposed research in which students will participate. If participating students have not yet been individually identified, the number and academic level of those to be involved should be provided. If there are any Collaborators or Consultants for the project, provide their names, organizational affiliations, and the services they will perform.