**Items Needed for NIH R15 Application – Updated for Applications Due After May 25, 2017**

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

* **Cover letter**

OSR can send you a boilerplate. The letter should contain any of the following information that applies to the application: 1) application title; 2) funding opportunity title.

* **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)**

**U**sing 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. 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. Note: interim research products have specific citation requirements: <https://grants.nih.gov/grants/interim_product_faqs.htm#5122>.

* **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.

* **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.”

1. **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 (including interim research products: <https://grants.nih.gov/grants/interim_product_faqs.htm>) 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.

Additional instructions:

* If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this “A. Personal Statement” section.
* Indicate whether you have published or created research products under another name.
* You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application.
* Figures, tables, or graphics are not allowed.

1. **Positions and Honors:** List in chronological order the positions you’ve held that are relevant to this application, concluding with your present position. 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.
2. **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. For each contribution, indicate the following:

* 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 (including interim research products: <https://grants.nih.gov/grants/interim_product_faqs.htm>) 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.

1. **Research Support**. Research Support highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each your qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

List ongoing and completed research projects from the past three years (Federal or non-Federal support) that you want to draw attention to. 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.

* **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)**

1. 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.
2. 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.
3. 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.
  + If your study(s) involves human subjects, the sections on 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, but it must also be addressed here in the "Approach" section of the "Research Strategy" attachment.
  + 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.

* **Protections of Human Subjects (if application involves human subjects)**

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

1. Risks to Human Subjects

1. 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.

1. 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.

1. 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.

1. Adequacy of Protection Against Risks
2. 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.

1. 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.

1. 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.

1. 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.
* **Data and Safety Monitoring Plan (if application involves a clinical trial)**

For all clinical trials (<https://grants.nih.gov/grants/glossary.htm#ClinicalTrial>), NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial and its size and complexity. In this attachment, you must provide a description of the DSMP that you are proposing to establish for each clinical trial proposed, including:

* The overall framework for safety monitoring and what information will be monitored.
* The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
* The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported as required to the Institutional Review Board (IRB), the person or group responsible for monitoring, the funding IC, the NIH Office of Biotechnology Activities (OBA; http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), and the Food and Drug Administration (FDA; http://www.fda.gov/).
* The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the monitoring plan will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
  + PD/PI: While the PD/PI must ensure that the trial is conducted according to the protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
  + Independent safety monitor/Designated medical monitor: a physician or other expert who is independent of the study.
  + Independent Monitoring Committee or Safety Monitoring Committee: A small group of independent investigators and biostatisticians.
  + Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. As noted in Part II Section 5.3, NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the Supplemental Grant Application Instructions II-11 participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
    - If a DSMB is used, please describe the general composition of the Board without naming specific individuals.
* **Inclusion of Women and Minorities (if application involves human subjects)**

**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 of Children (if application involves human subjects)**

**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.

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. 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 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.
* **Vertebrate Animals (if application involves vertebrate animals)**

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.
* **Select Agent Research**

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. 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.”

1. 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 select agent(s).
   * Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s). l
   * Describe the biocontainment resources available at all performance sites.

* **Multiple PD/PI Leadership Plan (if applicable)**

Do not submit a Multiple PD/PI Leadership Plan if you are not submitting a multiple PD/PI application. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes 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 PD/PIs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Multiple PD/PI Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

* **Consortium/Contractual Arrangements (if applicable)**

Contact the Office of Sponsored Research if you plan on including subcontracts in your application. OSR will provide the appropriate boilerplate for this section.

* **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.

* **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**

A maximum of 10 PDF attachments is allowed in the Appendix. The only allowable appendix materials are:

1. For applications proposing clinical trials (unless the FOA provides other instructions for these materials):

* Clinical trial protocols
* Investigator's brochure from Investigational New Drug (IND), as appropriate

1. For all applications:
   * Blank informed consent/assent forms
   * Blank surveys, questionnaires, data collection instruments
   * FOA-specified items.
     + If appendix materials are *required* in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.

* **Budget Narrative**

OSR 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.

* **PHS Assignment Request Form (see below 4 optional sections)**

**Awarding Component Assignment Request (Optional)**

You may request up to three institutes/centers for assignment of your application

Assign to Awarding Component:

Enter up to three preferences for primary 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:

Enter up to three preferences to which you do not want your application assigned. Enter your preferences in the boxes in the “Do Not Assign To Awarding Component” row. Use the column labeled “1” to enter your first choice.

Descriptions of the scientific areas covered by all NIH ICs and links to other PHS agency information can be found at <https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents>. You do not need to make entries in all six boxes of the “Awarding Component Assignment Request” section.

**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 up to three preferences for SRGs/SEPs in the boxes in the “Assign to Study Section” row. Use one box per individual SRG/SEP request. Use the column labeled “1” to enter your first choice.

Do Not Assign to Study Section:

Enter up to three preferences for SRGs/SEPs to which you do not want your application assigned. Enter your preferences in the boxes in the “Do Not Assign To Study Section” row. Use the column labeled “1” to enter your first choice.

You do not need to make entries in all six boxes of the “Awarding Component Assignment Request” section.

**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 scientific areas of 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.