# [Academic Research Enhancement Award (Parent R15)](http://grants.nih.gov/grants/guide/pa-files/PA-13-313.html)

***Due dates:*** February 25, June 25, and October 25

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise in the funding opportunity announcement [Academic Research Enhancement Award (Parent R15)](http://grants.nih.gov/grants/guide/pa-files/PA-13-313.html). See in particular [Section IV. Application and Submission Information](http://grants.nih.gov/grants/guide/pa-files/PA-13-313.html#_Section_IV._Application_1).

Among the additional guidelines for the R15 application are guidelines concerning the following components:

**Facilities and Other Resources**: Include the following information:

* 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. Include a description of the likely impact of an AREA grant on the PD(s)/PI(s) and the research environment of the institution/academic component.
* Although it is expected that the majority of the research will be directed by the applicant investigator 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.
* If relevant, a statement of institutional support for the proposed research project (e.g., equipment, laboratory space, release time, matching funds, etc.).

**Biographical Sketch**: The PD(s)/PI(s) should include a summary of his or her previous and/or current experience in supervising students in research in the Personal Statement. The PD(s)/PI(s) also should indicate which peer-reviewed publications involved students under his or her supervision.

**Resource Sharing Plans**: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS).

Also visit the [NIH AREA Grant Research Objectives](http://grants.nih.gov/grants/funding/area_grant_objectives.htm) website, where you’ll find the AREA program research topics of particular interest to each NIH Institute/Center. The names of the contacts and their phone numbers and email addresses are available at <http://grants.nih.gov/grants/guide/contacts/parent_R15.html>. Applicants are encouraged to contact the person listed for the particular Institute(s) or Center(s) with research interests relevant to the applicant's proposed topic for additional scientific program information and for pre-application guidance.

# Project summary/abstract

[start text here]

# Project Narrative

[start text here]

# Specific Aims

[start text here]

# Research Strategy

## Significance

[start text here]

## Innovation

[start text here]

## Approach

### Overall Strategy and Rationale

[start text here]

### Preliminary Studies

[start text here]

### Specific Aim 1. [restatement of specific aim]

**Rationale/Hypothesis.** [start text here]

**Experimental Design.** [start text here]

**Methodology.** [start text here]

**Analyses.** [start text here]

**Expected Results and Benchmarks for Success.** [start text here]

**Potential Problems and Alternative Strategies.** [start text here]

### Specific Aim 2. [restatement of specific aim]

**Rationale/Hypothesis.** [start text here]

**Experimental Design.** [start text here]

**Methodology.** [start text here]

**Analyses.** [start text here]

**Expected Results and Benchmarks for Success.** [start text here]

**Potential Problems and Alternative Strategies.** [start text here]

### Project Timeline

[start text here]

# Bibliography and References Cited

[start text here]

# Protection of Human Subjects

## Risks to Human Subjects

***Human Subjects Involvement, Characteristics, and Design***

[start text here]

* 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, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.
* 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. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
* If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention’s 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.

### Sources of Materials

[start text here]

* 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 are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.

### Potential Risks

[start text here]

* Describe the potential risks to subjects (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.

## Adequacy of Protection Against Risks

### Recruitment and Informed Consent

[start text here]

* 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. 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.

### Protections Against Risk

[start text here]

* Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
* Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:
* Additional Protections for Pregnant Women, Human Fetuses and Neonates: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb>
* Additional Protections for Prisoners: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>
* OHRP Subpart C Guidance: <http://www.hhs.gov/ohrp/policy/index.html#prisoners>
* Additional Protections for Children: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>
* OHRP Subpart D Guidance: <http://www.hhs.gov/ohrp/policy/index.html#children>
* Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a general description of the plan for data and safety monitoring of the clinical trials and adverse event reporting to the IRB, the NIH and others, as appropriate, to ensure the safety of subjects (see this section below).

## Potential Benefits of the Proposed Research to Human Subjects and Others

[start text here]

* 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.

## Importance of the Knowledge to be Gained

[start text here]

* Discuss the importance of the knowledge gained or 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

[start text here]

* Only needed if your research includes a clinical trial. The NIH Data and Safety Monitoring Policy is described and referenced in Part II, § 5.3.
* Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (<http://www.fda.gov/>) and also see the following websites for more information related to IND and IDE requirements:
<http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html> (IND)
<http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html> (IDE)
* The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

a. PD/PI (required)

b. Institutional Review Board (IRB) (required)

c. Independent individual/safety officer

d. Designated medical monitor

e. Internal Committee or Board with explicit guidelines

f. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the 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.

* A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. For additional guidance on creating this Plan see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>.

NOTE

# Inclusion of Women and Minorities

[start text here]

Targeted/Planned Enrollment

**Study Title:**

**Total Planned Enrollment:**

|  |
| --- |
| **TARGETED/PLANNED ENROLLMENT: Number of Subjects** |
|  | **Sex/Gender** |  |
| **Ethnic Category** | **Females** | **Males** | **Total** |
| Hispanic or Latino |  |  |  |
| Not Hispanic or Latino |  |  |  |
| **Ethnic Category Total of All Subjects\*** |  |  |  |
| **Racial Categories** |  |  |  |
| American Indian/Alaska Native |  |  |  |
| Asian |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |
| Black or African American |  |  |  |
| White |  |  |  |
| **Racial Categories: Total of All Subjects\*** |  |  |  |
| \*The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.” |

# Inclusion of Children

[start text here]

# Vertebrate Animals

If vertebrate animals are involved in the project, address each of the five points below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the five required points below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following five points will result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected. Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.

## Use of Animals

[start text here]

Provide a detailed description of the proposed use of the animals for the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

## Justification

[start text here]

Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

## Veterinary Care

[start text here]

Provide information on the veterinary care of the animals involved.

## Procedures

[start text here]

Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

## Euthanasia

[start text here]

Describe any method of euthanasia to be used and the reason(s) for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

# Select Agent Research

[start text here]

Select Agents are hazardous biological agents and toxins that have been identified by DHHS or 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. CDC maintains a list of these agents. See <http://www.cdc.gov/od/sap/docs/salist.pdf>.

If the activities proposed in the application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at <http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html>.

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

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

1. Identify the Select Agent(s) to be used in the proposed research.

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

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

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

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

• Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s).

• Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

• Describe the biocontainment resources available at all performance sites.

If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.

Reviewers will assess the information provided in this Section, and any questions associated with Select Agent research will need to be addressed prior to award.

# Multiple PD/PI Leadership Plan

[start text here]

For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. 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, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.

# Consortium/Contractual Arrangements

[start text here]

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&R) cover component (Item 17) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

# Letters of Support

[start text here]

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. For consultants, letters should include rate/charge for consulting services.

# Resource Sharing Plan(s)

## Data Sharing Plan

[start text here]

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 FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss data-sharing plans with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See [Data-Sharing Policy](http://grants.nih.gov/grants/policy/data_sharing/) or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

## Sharing Model Organisms

[start text here]

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 appropriate reasons why such sharing is restricted or not possible. See [Sharing Model Organisms Policy](http://grants.nih.gov/grants/policy/model_organism/), and [NIH Guide NOT-OD-04-042](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html).

## Genome-Wide Association Studies (GWAS)

[start text here]

Regardless of the amount requested, 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 provide 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. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](http://www.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html), and <http://grants.nih.gov/grants/gwas/>.

# APPENDIX

Only one copy of appendix material is necessary.

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that are not publicly available (see below for further details and check the FOA for any specific instructions), though not all grant activity codes allow publications to be included in the appendix.

Do not use the appendix to circumvent the page limits of the Research Strategy. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice [NOT-OD-10-077](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-077.html).

Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process.

New, resubmission, renewal, and revision applications may include the following materials in the Appendix (note, however, that some FOAs do not permit publications):

• Publications – **No longer allowed as appendix materials except in the circumstances noted below.** Applicants may submit up to 3 of the following types of publications:

o Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.

o 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 .

o Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.

(Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.)

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

• For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Items that must **not** be included in the appendix:

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

• Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

COVER LETTER

Applicants are encouraged to include a cover letter with the application. This should be printed on letterhead and signed by the PI. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. Request of an assignment (referral) to a particular awarding component(s) (ICs) or [Scientific Review Group (SRG)](http://public.csr.nih.gov/StudySections/IntegratedReviewGroups/Pages/default.aspx). The PHS makes the final determination.
4. List of individuals (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications (see Late Application policy in Section 2.14) include specific information about the timing and nature of the cause of the delay.
7. When submitting a Changed/Corrected Application **after** the submission date, a cover letter is **required** explaining the reason for the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters until after an application is verified; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
8. Explanation of any subaward budget components that are not active for all periods of the proposed grant.
9. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc. To attach the approval documents, append those referenced documents to your Cover Letter File, and upload as one attachment.
10. When submitting a video as part of the application the cover letter must include information about the intent to submit it, if this is not done, a video will not be accepted. See [NOT-OD12-141](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-141.html).

**Suggested Cover Letter Format**

The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to Scientific Review Groups (SRGs). Analysis has shown that requests made by investigators are a valuable source of information in this process. In order to facilitate the use of these requests in conjunction with knowledge management analysis of the content of the application, applicants are requested to use the following format when assignment requests are contained in a cover letter. Following these formatting instructions is crucial for timely assignment as the cover letters are scanned by a computer for routing. (If the letter is formatted incorrectly and the computer can’t read it, the letter must be read by an individual, who then routes the application, which can delay reviewing.)

1. List one request per line.
2. Place Institute/Center (IC) and SRG review requests (if both are made) on separate lines.
3. Place positive and negative requests (if both are made) on separate lines.
4. Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
5. Provide explanations for each request in a separate paragraph.

**Examples:**

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)].