

AANP NIDA MENTORED TRAINING AWARD APPLICATION INSTRUCTIONS

Submission in electronic format is required.

Use English only and avoid jargon and unusual abbreviations. For terms not universally known, spell out the term the first time it is used with the appropriate abbreviation in parentheses; the abbreviation may be used thereafter. Type the application, single-spaced, and stay within the margin limitations indicated on the forms and continuation pages. The type must be clear and readily legible, no smaller than 15 characters per inch (if in doubt, use 12 pt. size font). Application sections and a signed statement of conditions must be submitted as one complete PDF document.

Do **not** submit an incomplete application. **An application will be considered incomplete if it is illegible, if it fails to follow instructions or if the material presented is insufficient to permit an adequate review.** Unless specifically required by these instructions (e.g., human subjects certification, vertebrate animals verification) do **not** send supplementary material. Submit full application to practice@aanp.org.

The application consists of the following sections:

1. LETTER OF INTENT (limit: 1 page)

The Applicant will be the Principal Investigator (PI) of the proposed project. A letter signed by the Applicant (PI) and Mentor should accompany the application. Choose a project title that is descriptive and specifically appropriate, rather than general. In addition to your Mentor, list any associate investigators. Address the following:

- a. Your interest in the topic and this project.
- b. Your perception of your role in the project.
- c. Any additional pertinent experience or interests you wish the committee to consider.

2. ABSTRACT

Provide a brief summary of the project proposal, and any associated activities (e.g., coursework, other technical training). Include rationale, specific aims and significance.

3. PROJECT PROTOCOL (limit: 12 pages)

The National Institutes of Health (NIH) Continuation Format Page is available at www.grants.nih.gov/grants/funding/phs398/phs398.html#.

Please use the following subheadings:

Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability and/or clinical practice in one or more broad fields.

Specific Aims

- State concisely the goals of the proposed project, including the impact that the results of the proposed project will exert on the field(s) involved.
- List succinctly the specific objectives of the project proposed, e.g., create a novel curriculum, challenge an existing paradigm or clinical practice or address a critical barrier to progress in the field.
- Specific Aims are limited to one page.

Innovation

- Explain how the application addresses and seeks to shift current knowledge bases or treatment practices.
- Describe any novel theoretical concepts, dissemination approaches, curricula or instrumentation to be developed or used, and any advantage over existing practices.
- Explain any refinements, improvements or new applications of theoretical concepts, approaches or curricula that will improve the field.

Approach

- Describe the overall strategy, methodology and evaluation to be used to accomplish the specific aims of the project.
- 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.
- Preliminary Studies: Include information on Preliminary Studies and how they will inform the proposed dissemination project. Discuss the PD/PI's preliminary studies, data and/or experience pertinent to this application.

4. DESCRIPTION OF THE TRAINING PLAN (limit: 3 pages)

Describe how the award year will be structured. Outline major goals and objectives and indicate how they will be achieved. Provide a training plan, including the structure and details of the relationship between the applicant and mentor, and how the applicant and mentor will work together to achieve the goals of the award year. Indicate how the mentor will monitor the progress of the trainee.

5. ROLE OF PARTICIPANTS (limit: 1 page)

In addition to the PI, list the mentor and each associate investigator or consultant. Include a brief description of how and to what extent each will be involved in the proposed project.

6. BIOGRAPHICAL SKETCHES

The NIH Biographical Sketch Format Page is available at www.grants.nih.gov/grants/funding/phs398/phs398.html#.

Information is requested for the applicant, mentor and any associate investigators who will be involved with the projects. The five-page NIH format has been adopted.

10. RESOURCES AND ENVIRONMENT

The NIH Resources Format Page is available at www.grants.nih.gov/grants/funding/phs398/phs398.html#.

Describe the facilities available for grant training. If computer access or statistical support is available, it should be described in this section.

11. BUDGET AND JUSTIFICATION

The NIH Form Detailed Budget for Initial Budget Period is available at www.grants.nih.gov/grants/funding/phs398/phs398.html#.

Indicate how the money will be spent. Justify all major expenditures.

12. OTHER SUPPORT

The NIH Continuation Format Page is available at www.grants.nih.gov/grants/funding/phs398/phs398.html#.

List all current and pending intramural and extramural research funding for the applicant, mentor and co-investigators. For each item, indicate the grant identification number, grant type, PI, funding source, annual direct costs, funding period, percent effort, grant title and brief description of project. For all items, indicate whether there is any scientific or budgetary overlap with the current proposal.

13. ETHICS

If applicable, the NIH Continuation Format Page (with no page limit) is available at www.grants.nih.gov/grants/funding/phs398/phs398.html#.

Human subjects: For all projects involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities and children. The Scientific Review Subcommittee (SRS) (or similar) of each sponsoring organization will assess the adequacy of safeguards of the rights

and welfare of participants and the appropriate inclusion of women, minorities and children, based on the information in the application. This evaluation will be factored into the overall score. The information on the protection of human subjects that you are required to provide in this section is identical to information that you will be required to provide for IRB at your own institution and are required by most Federal agencies. This section must address the following items. These can be copied and pasted directly into your application.

The applicant should include specific measures on how protected health information (as defined by the Human Health Services) will be handled in accordance with the Privacy Rule of the Health Insurance Portability Accountability Act (HIPAA).

1. RISKS TO THE SUBJECTS (if applicable)

a. Human Subjects Involvement and Characteristics

Describe the proposed involvement of human subjects in the work outlined in the Study Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, 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. List any collaborating sites where human subjects research will be performed and describe the role of those sites in performing the proposed project.

b. Sources of Materials

Describe the material obtained from living human subjects in the form of specimens, records or data. Describe any data that will be recorded on the human subjects involved in the project. Describe the linkages to subjects and indicate who will have access to subject identities. Provide information about how the specimens, records or data are collected and whether material or data will be collected specifically for your proposed project.

c. Potential Risks

Describe the potential risks to subjects (physical, psychological, social, legal or other) and assess their likelihood and seriousness to the subjects. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed project.

2. ADEQUACY OF PROTECTION AGAINST RISKS (if applicable)

a. Recruitment and Informed Consent

Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process

for meeting requirements for parental permission and child assent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the method of documenting consent. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. Protection Against Risk

Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. 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 description of the plan for data and safety monitoring of the project and adverse event reporting to ensure the safety of subjects.

3. POTENTIAL BENEFITS OF THE PROPOSED PROJECT TO THE SUBJECTS AND OTHERS (if applicable)

Discuss the potential benefits of the project to the subjects and others.

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED (if applicable)

Discuss the importance of the knowledge gained or to be gained as a result of the proposed project.

Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

5. DATA AND SAFETY MONITORING PLAN (if applicable)

If your project includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan." Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring.

14. LITERATURE CITED

15. APPENDIX

Include letters of support from the mentor, department chairs and associate investigators (required). No page numbering is necessary for the appendix. The appendix can include:

- Up to five publications, manuscripts (*accepted* for publication), abstracts, patents or other printed materials directly relevant to this project. *Do not include manuscripts submitted for publication.*

- Publications in press: Include only a publication list with a link to the publicly available online journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article.
- Manuscripts accepted for publication but not yet published: The entire article should be submitted and may be stapled.
- Manuscripts published but an online journal link is not available: The entire article should be submitted and may be stapled.
- Surveys, questionnaires, data collection instruments, clinical protocols and informed consent documents.
- No photographs or color images may be included in the appendix that are not also represented within the Project Plan.
- Do not use the appendix to circumvent page limitations for project plans. Do not include methods, protocols or figures that should be incorporated within the project description.

16. SIGNED STATEMENT OF CONDITIONS

Sign below and include with your application.

Applicant (*Last, first, middle*): _____

Mentor (*Last, first, middle*): _____