#### **General Questions**

#### Why has the NIDA Director established the Avant-Garde Award?

Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, has a strong commitment to enhancing NIDA's HIV/AIDS research program. The Avant-Garde Award is designed to support novel, innovative, high risk-high payoff research on drug abuse and HIV/AIDS.

#### What distinguishes the NIDA Avant-Garde Award from other programs?

The NIDA Avant-Garde Award is conceptually similar to the NIH Pioneer Award Program but focuses on drug abuse and HIV/AIDS. It differs from other programs in several ways. It is designed to support people with uniquely creative ideas, rather than specific research projects. It is designed to support investigators of exceptional creativity who propose bold and highly innovative new research approaches that cannot be easily supported by other award mechanisms, and that have the potential to produce a major impact on treatment and/or prevention of HIV/AIDS among drug users. The award will provide up to \$500,000 direct costs per year for five years to a select two or three exceptionally creative investigators, to pursue innovative, cutting edge research. The research must be relevant to the Trans-NIH Plan for HIV Related Research (<a href="http://www.oar.nih.gov/public/public.htm">http://www.oar.nih.gov/public/public.htm</a> (see Strategic Plan-FY09 Trans-NIH Plan for HIV-Related Research). The information required in the application is highly abbreviated, and turnaround is accelerated through use of a tailored review process.

#### How does the 2009 Avant-Garde Award process differ from the 2008?

The application process now has two phases. An X02 pre-application process, followed by selected candidates being invited to submit a DP1 application and come to Washington, DC for an interview. The X02 application does not require submission of letters of reference; the DP1 does. The X02 application does not require you to address human subjects and animal welfare issues; the DP1 does. Both X02 and DP1 applications will use Adobe-based forms for application submission. Please see section below on the 2009 application process.

### From which disciplines does NIDA wish to draw applicants for the Avant-Garde Award?

NIDA encourages applications from scientists from all disciplines. Research concepts must be relevant to drug abuse and HIV/AIDS—have the potential to lead to prevention and/or treatment of HIV/AIDS in drug abusers.

Are women and members of underrepresented minority groups encouraged to apply?

Yes. Many minority groups are overrepresented among those living with HIV/AIDS, and there are increasing numbers of infections in women. Outstanding and highly innovative women scientists, as well as outstanding scientists who are members of minority groups underrepresented in biomedical or behavioral research, are strongly encouraged to apply.

#### How much time/effort are recipients expected to devote?

Awardees are expected to commit the major portion (at least 51 percent) of their *research* time/effort to activities supported by the Avant-Garde Award. A **statement of this commitment must be included in the current and pending support section.**Investigators should not apply if they are unable to commit this amount of effort to the project.

# If 50% of my time is devoted to clinical and/or teaching duties, and only 50% to research, how much time/effort would I be expected to devote to Avant-Garde Award activities?

If awardees spend 50% of their time doing research, they would be required to devote the major portion (at least 51 percent) of their *research* time, or 26% of the total time, to Avant-Garde Award activities.

#### Do Avant-Garde Awards include indirect costs?

The institutional indirect costs will be paid in addition to the award. Indirect (facilities and administrative) costs will be determined at the time the award is made.

#### May two or more scientists apply as a team for the Avant-Garde Award?

Since the Avant-Garde Awards are meant to support a person, not a specific project, applications must come from individual investigators, not from teams of investigators.

#### Are these awards renewable?

No. These awards are intended to jump-start or redirect an individual's research program. Awardees are expected to seek future support through traditional routes.

#### What post-award requirements must I fulfill?

You will be required to submit an annual report of your activities during the year, and you may be contacted periodically for at least five years and asked to report on your latest research efforts.

#### Will the Avant-Garde Award program be repeated in FY10?

Yes, it is anticipated that this program will continue in FY10.

#### **Eligibility**

#### Are individuals at all stages of their careers eligible?

Yes, individuals at all career stages are eligible to apply. Those at early to middle stages of their careers, and women and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply.

#### Are foreign scientists eligible?

Yes. However, they must apply from a U.S. institution; non-domestic (foreign) institutions are not eligible.

#### Are non-drug abuse researchers eligible to apply?

HIV/AIDS investigators who have not been previously involved in drug abuse research are encouraged to consider the scientific opportunity to contribute to this field. Investigators should be able to articulate how their research is or could contribute to prevention and treatment of HIV/AIDS among drug abusers.

### May individuals who applied in last year who did not receive awards apply this year?

Yes. Note that all Avant-Garde Award applications must be submitted as "new" applications, regardless of any previous submission to the program.

### Are individuals employed by government agencies, non-academic, and/or for-profit organizations eligible?

Individuals from all organizations that can otherwise apply to the NIH for funding and are willing to abide by the terms and conditions that NIH requires are eligible for this award.

#### Are scientists in the NIH Intramural Program eligible?

No. Because intramural scientists may not receive extramural NIH grants, they may not apply for an Avant-Garde Award.

## Are individuals who have other support eligible? If so, may the awardee remain as principal investigator on his/her grant(s)?

Individuals who have other support are eligible for this award and may continue as principal investigator on other grants. However, awardees are expected to devote at least 51 percent of their research time/effort to this work. Since the Avant-Garde Award is expected to support distinctly new research, awards will not be made simply to enable investigators to expand research projects that are ongoing.

#### Once awarded, is this award transferable if I change institutions next year?

This award may be transferred to another eligible institution according to the same policies and procedures as for traditional research grants. Please note, however, that awards may not be transferred to foreign institutions.

### I have applied for a Pioneer Award for FY09. May I submit the same project as an Avant-Garde application?

No. NIH policy does not allow multiple submissions of essentially the same project. Funding for the same project may not be sought through multiple submissions to the Avant-Garde Award program and any other award program (such as the Pioneer and New Innovator awards) targeting unusually innovative research.

Can the same project be submitted to two programs at the same time? While my Avant-Garde Award pre-application is pending, may I submit the same project for another NIH grant such as an R01? If I have an application pending, may I submit the same project for an Avant-Garde Award?

Avant-Garde Awards are meant to support investigators who intend to pursue projects that are substantially different from those already being pursued in the investigator's lab or elsewhere. Those submitting pre-applications must address explicitly how the proposed research direction will differ from their past or current work and the reviewers will evaluate whether the Avant-Garde Award project is merely incremental or whether it is a "leap" ahead of the work the investigator is already doing. Investigators must also provide compelling justification for the advantage of evaluation by the Avant-Garde Award process rather than by the standard review process. In general, projects that are appropriate for more traditional grant mechanisms are not appropriate for Avant-Garde Award pre-applications. Additionally, the general policy of the Public Health Service, which includes the NIH, does not allow multiple submissions of essentially the same proposal to any of its components.

### I am currently a postdoctoral fellow. Am I eligible to apply for an Avant-Garde Award?

Applicants must be able to show concrete evidence for their claim of innovativeness. This could be very difficult for a postdoctoral fellow who has never conducted independent research. In addition, like all NIH grants, the Avant-Garde Awards will be made to institutions on behalf of investigators. Because most institutions will only authorize grant applications from individuals who are independent investigators, this could present an administrative barrier to applying.

#### **Application Process**

#### Are there significant changes from last year's process?

Yes, the 2009 competition will proceed in two stages, with two separate Funding Opportunity Announcements (FOAs). The first stage is a pre-application stage. The pre-application must be submitted in response to PAR-09-044, which uses the X02 mechanism. The pre-applications will be assessed by a group of external reviewers. Only those investigators whose proposals are judged to be the most outstanding (responsive to review criteria) will be notified of the opportunity to submit full (DP1) applications under RFA-DA-09-011.

The full DP1 application represents the second stage of the process; and although much of the application will be the same as the X02 application, additional information is required. DP1 applicants must arrange for the submission of three reference letters and 2) if applicable, provide information regarding protection of human subjects from research risk and inclusion plans for women, children, and minorities and/or care and use of vertebrate animals. DP1 applicants will also be invited for interviews.

#### Where can I find information about the application process?

Please read the application instructions in PAR 09-044 carefully. If you have questions, e-mail <a href="mailto:avant-garde@nida.nih.gov">avant-garde@nida.nih.gov</a>.

#### What are the dates for submission of X02 applications?

The <u>Grants.gov</u> X02 pre-application in response to PAR-09-044 may be submitted beginning January 27, 2009 and must be successfully received by Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization) on February 27, 2009.

#### What are the dates for submission of full DP1 applications?

Following review of X02 applications, a small number of applicants will be invited to submit full DP1 applications. **DP1 applications may be submitted beginning May 2, 2009 and must be submitted by June 2, 2009 no later than 5:00 p.m. local time**. The **three letters of reference** may be submitted **beginning May 2, 2009** and must be submitted **no later than 5:00 p.m. Eastern Time, June 2, 2009** at <a href="https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp">https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp</a>.

Application materials will not be accepted after that time and applications that are not complete will not be evaluated. Applications with fewer than three letters of recommendation will be viewed as incomplete.

#### What must be done before I submit an application to Grants.gov?

**Important:** You should immediately check with your sponsored research office to determine whether your institution is registered with Grants.gov. Please note that the

registration process could take up to two weeks. The institution's Authorized Organizational Representative (AOR) is responsible for completing the registration process.

If your institution is not already registered, it must first register with the Central Contractor Registry (the Credential Provider) at <a href="http://www.ccr.gov/">http://www.ccr.gov/</a> and then with Grants.gov at <a href="http://www.grants.gov/GetStarted">http://www.grants.gov/GetStarted</a>.

Both the institution and the applicant must also complete a one-time registration in the NIH eRA Commons in order to submit applications to NIH. Institutional officials are responsible for registering investigators in the eRA Commons. You should work with your AOR (also known as Signing Official in the eRA Commons) to determine your own institution's process for registration.

#### Where can I find help registering for Grants.gov?

For help with the Grants.gov registration process, contact Grants.gov customer support at 1-800-518-4726 (Toll Free), Monday–Friday, 7:00 a.m. to 9:00 p.m. (Eastern Time), or at <a href="mailto:support@grants.gov">support@grants.gov</a>.

#### Where can I find help in submitting my application to Grants.gov?

For help with the technical aspects of submitting an application to Grants.gov, check the resources available on the Grants.gov website first (<a href="http://grants.gov">http://grants.gov</a>). If you need assistance, contract Grants.gov customer support at 1-800-518-4726 (Toll Free), Monday through Friday, 7:00 a.m.—9:00 p.m. (Eastern Time), or at <a href="mailto:support@grants.gov">support@grants.gov</a>.

#### Where can I find help in registering for the eRA Commons?

Step-by-step directions for registering with eRA Commons are available at <a href="http://era.nih.gov/ElectronicReceipt/files/Grantee\_Registration\_Process\_for\_Commons.pdf">http://era.nih.gov/ElectronicReceipt/files/Grantee\_Registration\_Process\_for\_Commons.pdf</a>

For questions regarding the Commons registration process, contact the NIH eRA Commons help desk at phone: 301-402-7469 or 866-504-9552 (Toll Free); 301-451-5939 (TTY) business hours Monday–Friday, 7:00 a.m.–8:00 p.m. (Eastern Time).

#### Where can I find additional information about electronic submission?

There are informative frequently asked questions at <a href="http://era.nih.gov/ElectronicReceipt/faq\_prepare.htm#2">http://era.nih.gov/ElectronicReceipt/faq\_prepare.htm#2</a>

#### Where can I find information about the use of Adobe forms?

http://www.grants.gov/applicants/app\_help\_reso.jsp#faqs has information about the transition to Adobe forms and <a href="http://www.grants.gov/help/download\_software.jsp">http://www.grants.gov/help/download\_software.jsp</a> has information on compatible versions of Adobe Reader.

Information on the NIH transition to use of Adobe forms is available at <a href="http://era.nih.gov/ElectronicReceipt/adobe\_transition.htm">http://era.nih.gov/ElectronicReceipt/adobe\_transition.htm</a>

### Whom do I contact if I have questions about programmatic aspects of the Avant-Garde Award?

For questions of a programmatic nature, please e-mail avant-garde@nida.nih.gov.

### Is there a limit to the number of applications that can be submitted by an institution?

There is no limit to the number of applications that an institution can submit. However, an investigator may submit only one application.

#### **Grants.Gov Submission Documents**

What format should I use for the documents submitted with my pre-application to Grants.gov (abstract, essay, biosketch, current research support)?

All documents must be in PDF format. Other formatting requirements are in the <u>Application Guide (PDF)</u>, Section 2.6, Format Specifications for Text (PDF) Attachments.

For the **biographical sketch**, use the sample *format* on the <u>Biographical Sketch Format</u> <u>Page</u> (MS Word) in Part I, Section 4.5.2, of the Application Guide. Omit Section C, Research Support. The biographical sketch must not exceed two pages.

For the **list of current and pending support**, use the format shown in the Application Guide (MS Word, or PDF), Section 3.1.1.8. Pre-applications with documents that exceed page limits will be considered non-responsive and will not be evaluated.

### Does the five-page essay replace the traditional "Research Plan" (with "Specific Aims") or is it to be submitted in addition to that section?

The five-page essay replaces the traditional 25-page "Research Plan" section required for most other NIH grant applications. The requirements of the Avant-Garde Award preapplication are very different from those of most other NIH grants. Read the application instructions and review criteria in the FOAs carefully.

In my essay, may I include citations to key publications? If so, what is the appropriate format?

Yes, you may include citations in the essay, as long as they fit within the three to five page limit. The citations may be in any format.

#### In my essay, may I include figures and illustrations?

Yes, you may include figures and illustrations in the essay, as long as they fit within the 3–5 page limit. Note, however, that links to animations/movies are not allowed.

#### In my essay, may I include links to Web sites to provide more information?

No, investigators must explain their proposed research in the 3–5 page essay.

#### May I submit a journal article?

No, applicants are required to submit a one-page description of their most significant research accomplishment, and no publications or other work products will be accepted.

The pre-application package that I downloaded from Grants.Gov does not include budget pages. Are detailed budgets required? Where do I indicate indirect costs? A budget of "0" (zero) must be entered. No awards will be made from the pre-application phase.

#### Where do I submit the various required sections of the pre-application?

- Abstract upload on Item 6, Research & Related Other Project Information Component form.
- Public Health Relevancy Statement upload on Item 7, Project Narrative, on the Other Project Information component of the pre-application.
- Essay upload as an attachment in the Research Design and Methods section of the Research Plan Component. Omit the Specific Aims, Background and Significance, and Preliminary Studies Sections.
- Description of my most significant accomplishment upload on Item 11, Other Attachments, on the Research & Related Other Project Information Component.
- Biographical sketch upload on Senior/Key Person Profile Component where indicated.
- List of current and pending support upload on Senior/Key Person Profile Component where indicated.
- Effort Commitment Statement—include with current and pending support.

#### Where do I designate the area of science for my application?

You should designate the area of science at the top of the abstract page. The Avant-Garde award is using only one application package, but putting the area of science in the abstract will facilitate assigning your application for review.

#### What are the areas of science?

Foundational Research

01 Natural History and Epidemiology

02 Etiology and Pathogenesis

Prevention Research

03 Microbicides

04 Vaccines

05 Behavioral and Social Science

Therapeutics

06 Therapeutics

#### **Letters of Reference**

#### Are letters of reference required for pre-applications (X02)?

No. Letters of reference are not required and will not be accepted for pre-applications. Reference letters will be required for those submitting full applications to RFA DA-09-011.

#### **Evaluation and Selection of Awardees**

#### How will awardees be selected?

Pre-applications (X02) will undergo an administrative review to ensure that they are complete and responsive to the PAR. A multidisciplinary group of outside experts will evaluate X02 applications using the following criteria:

- The scientific problem to be addressed: The biomedical or behavioral significance/importance of the problem; the likelihood that, if successful, the project will have a significant impact on HIV/AIDS (open new avenues of research and/or impact prevention and treatment); and the innovativeness of the project.
- The investigator: Evidence for the investigator's claim of innovativeness/creativity (taking into account the applicant's career stage) and the demonstrated ability of the investigator to devote at least 51% of his/her research effort on to activities supported by the Avant-Garde Award.
- The suitability for Avant Garde Award mechanism: Evidence that the proposed project carries much higher levels of risk and potential impact than typical of NIDA-supported research projects and evidence that the proposed project represents a distinctly new scientific direction.

All candidates will be provided with summaries of the reviewers' evaluations of each criterion. Those candidates who are identified as the most outstanding will be invited to submit DP1 applications under RFA DA09-011. These candidates will also be invited to the Washington, D.C. area to be interviewed by a distinguished panel of outside experts. The National Advisory Council on Drug Abuse will conduct the final level of review. The Director, NIDA, will make the final selection of awardees based on the evaluations by the outside experts, the recommendations of the Council, and programmatic considerations. Final selections will be publicly announced, and awards will be made, by the end of September 2009.