

# Part I Overview Information

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## Department of Health and Human Services

### Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov>)

### Components of Participating Organizations

National Institute on Alcohol Abuse and Alcoholism (NIAAA), (<http://www.niaaa.nih.gov>)

**Title:** Underage Drinking: Building Health Care System Responses

### Announcement Type

New

**Request For Applications (RFA) Number:** RFA-AA-06-003

### Catalog of Federal Domestic Assistance Number(s)

93.273

### Key Dates

Release Date: June 24, 2005

Letters of Intent Receipt Date(s): November 19, 2005

Application Receipt Dates(s): December 19, 2005

Peer Review Date(s): February/March 2006

Council Review Date(s): May 2006

Earliest Anticipated Start Date: July 1, 2006 .

Additional Information To Be Available Date (Url Activation Date): N/A

Expiration Date: December 20, 2005

### Due Dates for E.O. 12372

Not Applicable

## Additional Overview Content

### Executive Summary

This is Phase I of a two-part RFA. It solicits applications for cooperative agreements (U01s) to enable rural and small urban health care systems to become platforms for research programs on underage drinking. More specifically NIAAA seeks to fund such systems: (1) to assess the extent of underage drinking the areas they serve (Phase 1) and (2) develop capacity for intervening with this problem. Phase 2 will fund systems that have successfully completed Phase 1 to implement and evaluate interventions designed to address underage alcohol consumption in the areas they serve.

- It is anticipated that approximately \$2,000,000 will be awarded.
- Three to five awards are anticipated .
- The awards will use the U01 mechanism.
- Eligible organizations include for-profit organizations, non-profit organizations, public or private institutions, such as universities, colleges, hospitals, and laboratories, units of State government, units of local government, eligible agencies of the Federal government, domestic institutions, faith-based or community-based organizations
- Eligible principal investigators include individuals with the skills knowledge, and resources necessary to carry out the proposed research are invited to work with their institutions to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.
- Applicants may submit more than one application, provided they are scientifically distinct.
- See [Section IV.1](#) for application materials.
- Telecommunications for the hearing impaired is available at: TTY 301-451-0088

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# Part II - Full Text of Announcement

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## Section I. Funding Opportunity Description

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### 1. Research Objectives

#### Purpose of this RFA

As part of a two-phase RFA program, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is seeking research grant applications that will stimulate the primary care health delivery system in rural and small urban areas (hereafter referred to as "rural areas") in the United States to address the critical public health issue of underage drinking. The purpose of these grants is to enhance alcohol research expertise and promote infrastructure development in rural primary health delivery systems to facilitate their participation in community-based empirical research on underage drinking. To accomplish this goal, this RFA solicits Phase I applications for cooperative agreements (U01s) which will assist rural health care systems in developing their capacity to engage in research on underage drinking. The intention of NIAAA is to provide funding to enable such systems: (1) to evaluate and upgrade their capacity to assess the extent of underage drinking in the areas they serve and to evaluate and strengthen their capacity to intervene to reduce this underage drinking in Phase I; and (2) to prospectively study the development of alcohol use and alcohol-related problems among the youth in the areas they serve and to implement and evaluate interventions designed to address this underage drinking in Phase II (which will be addressed in a future RFA). Phase I emphasizes evaluation and upgrading of research capacity among primary care health delivery systems, and is the subject of this RFA. Phase II will emphasize translation of research on underage drinking to empirically-based interventions and evaluations of the effectiveness of these interventions and will be addressed in a future RFA.

#### Background

Alcohol consumption is associated with significant morbidity and mortality in youth. According to the 2002 National Survey on Drug Use and Health (NSDUH) (SAMHSA, 2003), about 40% percent of youth 12 to 20 years of age reported binge drinking in the past 30 days, that is, drinking five or more drinks on at least one occasion. This translates into more than 7,000,000 youth. NSDUH data suggest an even more serious problem in rural than in nonrural areas, in particular among young adolescents (SAMHSA, 2004). For example, in 2002, the binge drinking rate was 4% among 12 or 13 year old rural youth as compared with 1.6% among nonrural youth of the same age. The same pattern held for youth ages 14 or 15 (12% versus 9%) and for youth ages 16 or 17 (25% versus 21%). Not only are these youth at high risk for acute negative physical and social consequences due to their alcohol consumption, they are also at increased risk for long-term consequences including alcohol dependence and derailed academic and vocational trajectories.

Currently, the primary health care system is not sufficiently addressing the issue of underage drinking. Because screening for alcohol problems among youth is not routine, health care service organizations do not have an accurate estimate of the extent of underage alcohol consumption in the communities they serve. Although adolescents may be difficult to access and time in the physician's or other health care professional's office may be limited, primary health care systems, in partnership with the communities they serve, can play a vital role in addressing alcohol consumption by youth under the age of 21. Primary care practitioners can play a vital role in screening for alcohol, the psychoactive substance most often used by youth. As already mentioned, alcohol use by youth is associated with considerable negative consequences, including substantial physical morbidity and mortality. Despite the magnitude of the problem, only 40% of a national sample of pediatricians and family doctors reported that they screened their adolescent patients for alcohol use and only 52% provided alcohol education (Marcell et al. 2002). The situation may be even worse in rural areas where primary care may be less available and the need to deliver early adolescent prevention services greater (ibid).

#### Problems to Overcome

Because adolescents are in one of the physically healthiest periods of the lifespan, they may not regularly interface with primary health care practitioners. This lack of contact may be exacerbated among youth of lower socio-economic status (SES) and/or of rural residence, since for them access may be more difficult due to economic constraints and distance. Nonetheless, NIAAA believes that efforts to overcome barriers should be made, and that health care providers can play an essential role in combating underage drinking in this country. In addition, research with youth populations is challenging and requires special resources and expertise.

## Structure of the Project

The project will be structured as a cooperative agreement with two phases, each of which will have a separate, independent call for applications. The first phase of grant support provides three years of limited funding for capacity building by relevant health care systems. In Phase I, successful applicants will assess the extent of underage drinking in their community and develop their skills and capacity for undertaking intervention research. Activities of this phase include, but are not limited to, developing the ability to: collect and analyze data; access the population of interest; establish community partnerships; establish working relationships between community health delivery systems and established alcohol researchers or investigators at research intensive institutions, as necessary; and overcome barriers to intervening with youth about alcohol consumption. At the conclusion of the initial three-year funding period, the grantee should have developed skills and partnerships and have collected data to support a Phase II application. In Phase II, primary health care systems that have the necessary components in place will be funded, after peer review, to: (a) comprehensively and longitudinally assess rural youth with varying alcohol risk profiles in order to monitor the developmental progression of alcohol use, abuse, and dependence and; (b) design and pilot test interventions for such rural youth at risk in their affiliated clinical and community settings. The RFA for Phase II will be released during the early part of the third year of Phase I. During the third year of Phase I, Phase I grantees will be encouraged to plan and submit, by the middle of the third Phase I project year, an application for Phase II. Up to five years of support will be provided in Phase II, and applications for additional periods may be considered subsequently. A final meeting of Phase I grantees will be held at the end of Phase I, at which grantees will present the results of their Phase I process. This will result in conference report, the purpose of which will be to inform and guide similar entities about the procedures and processes involved in gearing up for the type of research involved in Phase II, should such an entity decide to enlarge its research focus.

This Request for Applications (RFA) invites applications for Phase I of the program from sites interested in building capacity and becoming a Health Center Based Program (HCBP). Applicant health care systems may include those that are accustomed to carrying out research on alcohol-related problems. We also welcome applications from health care systems that may not be accustomed to doing so. In the latter instance, a long-term committed partnership between the rural primary health care delivery system and one or more established alcohol researchers or investigators from research intensive institutions, will be necessary. It will be the applicant's responsibility to designate their collaborator(s) and describe in detail plans for collaboration in the application.

## Specific Areas of Interest

- This request for applications is directed towards entities in the primary health care system that serve rural populations and that have the following characteristics:
- They are multi-disciplinary (i.e. they must have two or more of the following components: medicine (allopathic or osteopathic), emergency medicine, dentistry, allied health, nursing, pharmacy, clinical psychology, social work and public health).
- Their extended health care networks reach and influence many parts of the communities they serve.
- They provide community leadership for prevention and intervention of adolescent health problems.
- They have the potential to screen for alcohol use among young people, possibly in conjunction with screening for other problem behaviors.

These entities include, but are not limited to, academic health centers serving rural populations.

All applicants for this solicitation must provide, at a minimum:

- the approximate number and percent of youth aged 8 to 20 in their area who are served by the applicant health center on an annual basis, and any information that may be available on prevalence of alcohol problems and other risk behaviors (e.g. tobacco use, early sexual activity) among these youth;
- the approximate number and percent of youth served by other health care professionals associated with the applicant health center (e.g. school nurses, developmental clinicians), and any information that may be available on prevalence of alcohol problems and other risk behaviors among these youth;
- a detailed description of federal, state and locally supported programs in place as a resource for addressing underage alcohol consumption and other risk behaviors;
- a detailed description of the nature of the existing interface between the health center professionals and the community. Examples include, but are not limited to, relationships with other community systems such as the school system, social services, juvenile justice, the religious community, as well as other settings in which youth may receive social, health or educational services (e.g., 4H Boy and Girl Scouts and other youth serving organizations).

In their application, those responding to this RFA for Phase 1 of the program should describe their plans to accomplish the following:

1. Develop a program to evaluate their current infrastructure, the community of rural youth currently served, and appropriate interventions to address the underage drinking problem in rural community youth. This program should include, but is not limited to:

- providing information on the characteristics of the sample of community youth routinely seen in the academic health center, including actual alcohol consumption of juvenile patients, other risk behaviors, individual risk factors predisposing to problems with alcohol, and individual “resilience” or other positive/protective factors that may offset or mitigate risk;
- providing comprehensive information on the characteristics of the population of underage drinkers in community-based service settings relevant to primary health care;
- providing comprehensive information on the characteristics of the underage population in the community that is at greatest risk for alcohol-related problems;
- documenting the proportion of adolescents with various characteristics who are served in different venues (e.g. school nurse, pediatrician).
- reviewing the empirical intervention research, evaluating programs for application in rural youth and adapting these as necessary for implementation in the community.

2. Develop the appropriate infrastructure to undertake Phase II. This should include but is not limited to:

- exploring which practitioners in which venues are most likely to interface with the greatest numbers of adolescents;
- evaluating the feasibility that the health center service delivery system and associated entities can increase access to youth and follow them over time, as well as pilot test research-based interventions for them, in particular for those individuals who are at high risk for alcohol-related problems;
- enhancing alliances between physicians and other health care professionals in the community who interface with youth such as psychologists or dentists;
- describing potential options for partnerships, coalitions, consortia, and other collaborative interactions between the health care entities and community;
- enhancing the community infrastructure as needed to link relevant service sectors both within and outside the academic health center;
- demonstrating the ability to establish the leadership of their primary health care system in mobilizing multiple community sectors to address underage drinking in their area of service.
- demonstrating the ability to implement an empirically-based intervention to address underage drinking in their area of service.

By the end of Phase I, the necessary infrastructure to apply for and carry out a Phase II project must be in place. More specifically, at the end of Phase I successful grantees will be able to demonstrate that they have developed the expertise and necessary infrastructure to undertake research programs that include data collection, as well as intervention and the evaluation of this intervention in their communities. This capacity should be amply demonstrated in a variety of ways including, but not restricted to (1) provision of an operational plan for mobilizing the community to combat the problem of underage drinking accompanied by signed agreements indicating willingness to participate from all coalition partners (e.g. agencies, community officials, etc.), (2) provision of data (including, but not limited to, agreed upon measures common to all sites) from pilot studies in which samples of community youth are reached in various venues, and (3) provision of plans for an empirically-based intervention program appropriate for implementation in their community. At the conclusion of Phase I, NIAAA will sponsor a meeting at which all grantees will present the process and results of their capacity building experience.

### **The Role of NIAAA**

The NIAAA staff role in these cooperative agreements will extend beyond the level normally required for stewardship of a grant because of the need for some coordination across sites. Approximately six months post-award, NIAAA will sponsor a meeting of the awardees, the purpose of which will be to share information on progress, to decide on certain common data elements to be collected across all sites, and to provide technical assistance and support as needed to further develop the programs. As already described, NIAAA will sponsor another meeting at the conclusion of Phase I at which each site will present the results of its Phase I process. Applicants should include costs for these two meetings in their budgets.

## Phase II Program

Funding for Phase I does not imply or guarantee funding for Phase II, although all Phase I grantees are eligible to apply. A future, separate solicitation will be issued for Phase II. Applicants for the second phase will be asked to demonstrate their ability in the following areas:

- comprehensive access to organized venues which allow for interfacing with rural area youth;
- capacity to coordinate the delivery of interventions in community organizations and systems where rural area youth congregate including but not limited to schools and extra-curricular settings;
- understanding of and plans for dealing with the issue of individual differences in risk that may require differential or tailored interventions based on risk and protective factors including, but not limited to, family history and personality characteristics.
- implementation of increased outreach to rural area youth, for example by interfacing with them in non-traditional settings;
- capacity to enhance and capitalize on community partnerships to achieve maximum impact;
- management of the necessary infrastructure to deliver empirically-based underage drinking prevention and brief intervention in this type of setting to reduce risk and minimize adverse outcomes;
- evaluation of the interventions instituted, including but not limited to, surveillance of key measures pre-, during and post-intervention.

## References

Substance Abuse and Mental Health Services Administration. (2003). Results from the 2002 National Survey on Drug Use and Health: National Findings. Office of Applied Studies, NHSDA Series H-22, DHHS Publication No. SMA 03-3836. Rockville, MD.

Marcell AV, Halpern-Felsher B, Coriell M, Millstein S. (2002). Physicians' Attitudes and Beliefs Concerning Alcohol Abuse Prevention in Adolescents. *Am J Prev Med* 2002 Jan; 22(1): 49-55.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

## Section II. Award Information

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### 1. Mechanism(s) of Support

This funding opportunity will use the U01 award mechanism(s).

As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

The NIH U01 is a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Principal Investigator retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator, as described under the [Section VI. 2. Administrative Requirements](#), "Cooperative Agreement Terms and Conditions of Award".

### 2. Funds Available

- The total amount of funding for Phase 1 is anticipated to be approximately \$2,000,000.
- The anticipated number of awards is 3 to 5.
- The expected amount for individual awards is \$250,000 to \$400,000.
- The anticipated start dates are July FY06 and the periods of performance for the awards is three years.

The NIAAA intends to commit approximately \$2,000,000 dollars in FY 06 to fund 3 to 5 new and/or competing continuation grants in response to this RFA. An applicant may request a project period of three years and a budget for direct costs up to \$400,000 dollars per year.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see [NOT-OD-05-004](#).

## Section III. Eligibility Information

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### 1. Eligible Applicants

#### 1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Eligible agencies of the Federal government
- Domestic Institutions
- Faith-based or community-based organizations

#### 1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

### 2. Cost Sharing or Matching

Cost sharing is not required under this program, as described in:

The most current Grants Policy Statement can be found at:

[http://grants.nih.gov/grants/policy/nihgps\\_2003/nihgps\\_Part2.htm#matching\\_or\\_cost\\_sharing](http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_Part2.htm#matching_or_cost_sharing).

### 3. Other-Special Eligibility Criteria

This request for applications is directed towards entities in the primary health care system. To apply for this solicitation, an entity must serve a rural population and have the following characteristics:

- It must be multi-disciplinary (i.e. it must have two or more of the following components: medicine (allopathic or osteopathic), dentistry, allied health, nursing, pharmacy, social work and public health).
- Its extended health care network must reach and influence many parts of the community it serves.
- Through documented collaborative/working relationships with other entities in the community served, it can provide community leadership for prevention and intervention of adolescent health problems.

## Section IV. Application and Submission Information

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### 1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Telecommunications for the hearing impaired: TTY 301-451-0088.

## 2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

## 3. Submission Dates and Times

Applications must be received on or before the receipt date described below ([Section IV.3.A](#)). Submission times N/A.

### 3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: November 19, 2005

Application Receipt Date(s): December 19, 2005

Peer Review Date: February/March 2006

Council Review Date: May 2006

Earliest Anticipated Start Date: July 1, 2006

#### 3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Tina Vanderveen, Ph.D.  
Office of Extramural Activities  
National Institute on Alcohol Abuse and Alcoholism  
5635 Fishers Lane Room 3039  
Bethesda, MD 20892  
Telephone: (301) 443-2531  
FAX:301-443-6077  
Email: [tvanderv@mail.nih.gov](mailto:tvanderv@mail.nih.gov)

### 3.B. Sending an Application to the NIH

Applications must be prepared using the research grant applications found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive, Room 1040, MSC 7710  
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)  
Bethesda, MD 20817 (for express/courier service; non-USPS service)

Personal deliveries of applications are no longer permitted (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html>).

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Tina Vanderveen, Ph.D.  
Office of Extramural Activities  
National Institute on Alcohol Abuse and Alcoholism  
5635 Fishers Lane Room 3039  
Bethesda, MD 20892  
Telephone: (301) 443-2531  
FAX: 301-443-6077  
Email: [tvanderv@mail.nih.gov](mailto:tvanderv@mail.nih.gov)

**Using the RFA Label:** The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/labels.pdf>.

### 3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above ([Section IV.3.A.](#)). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by the CSR and responsiveness by the NIAAA. Incomplete and non-responsive applications will not be reviewed.

If the application is not responsive to the RFA, NIH staff may contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next appropriate NIH review cycle.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

### 4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

### 5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

Pre-Award Costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_Part6.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part6.htm).

To facilitate the interaction among NIAAA staff and investigators, and to better coordinate this program, it is anticipated that an annual meeting will be held within the commuting area of Bethesda, Maryland. The Principal Investigator is expected to attend these meetings and travel funds should be included in the budget. By accepting an award, the applicant organization and key personnel agree to abide by this condition.

## 6. Other Submission Requirements

There are special requirements and provisions that are required in instances where none of partners in the application is an established alcohol research investigator or an investigator at a research intensive institution.

- Provision of appropriate letters of support
- Demonstration of a collaborating partnership with an active alcohol research program.
- Description of the collaborative process, methods and means of communication.

For all applications, regardless of the need to establish and document research partnerships, a further requirement is that recipients are to participate in an annual meeting. Travel costs for this purpose should be included in the grant application.

### Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy ([http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing)).

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

### Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (NIH Grants Policy Statement [http://grants.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants.nih.gov/grants/policy/nihgps_2003/index.htm) and [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_Part7.htm#\\_Toc54600131](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm#_Toc54600131)). Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

## Section V. Application Review Information

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### 1. Criteria

Only the review criteria described below will be considered in the review process.

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

## 2. Review and Selection Process

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIAAA in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- Receive a written critique
- Receive a second level of review by NIAAA National Advisory Council.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

**Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

**Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

**Investigators:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? In instances where the principal investigator is not an established alcohol research investigator (see 6. Other Submission Requirements), is the plan to establish a collaborative process to support the alcohol research appropriate and is the documentation of the plan adequate?

**Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

### 2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

**Protection of Human Subjects from Research Risk:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

**Inclusion of Women, Minorities and Children in Research:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

### 2.B. Additional Review Considerations

**Budget:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

## 2.C. Sharing Research Data

**Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy.

[http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing).

## 2.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement [http://grants.nih.gov/grants/policy/nihgps/part\\_ii\\_5.htm#availofrr](http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr) and [http://ott.od.nih.gov/RTguide\\_final.html](http://ott.od.nih.gov/RTguide_final.html)). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

Program staff will be responsible for the administrative review of the plan for sharing research resources.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the awardee before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590). See [Section VI.3. Reporting](#).

## 3. Anticipated Announcement and Award Dates

The earliest anticipated award date is July 1, 2006.

# Section VI. Award Administration Information

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## 1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General ([http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_part4.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm)).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the Notice of Award will be generated via email notification from the awarding component to the grantee business official (designated in item 14 on the Application Face Page). If a grantee is not email enabled, a hard copy of the Notice of Award will be mailed to the business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also [Section IV.5. Funding Restrictions](#).

## 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General ([http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part4.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm)) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities ([http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_part9.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm)).

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

## 2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement U01, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined above.

### 2.A.1. Principal Investigator Rights and Responsibilities

The Principal Investigator will have the primary responsibility for: planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator. The PIs will:

- Coordinate a regular schedule of meetings with NIAAA staff for review and consultation.
- Implement the approved three year research plan, with periodic updates as needed.
- Coordinate project activities within their institutions, with research collaborators and with the NIAAA staff.
- As necessary, maintain collaborative partnership with an established alcohol research investigator and NIAAA Scientific Collaborator.
- Accept assistance and seek input from NIAAA staff to inform the pursuit of project goals.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

### 2.A.2. NIH Responsibilities

Per the terms of the cooperative agreement arrangement, the NIAAA will appoint a Program Official or Director and a Project Scientific Collaborator to participate in the conduct of each U01.

An NIH Project Scientific Collaborator will have substantial scientific and programmatic involvement that is above and beyond the normal stewardship role in awards, as described below because of the need for some coordination across sites. The NIAAA Project Scientific Collaborator will: a) facilitate the coordination necessary to manage these complex collaborative projects; b) participate in monitoring progress of ongoing research and research capacity; c) participate in data interpretation and, when appropriate, in the preparation of publications and presentations. The NIAAA Scientific Collaborator is subject to the same publication/ authorship policies governing all participants in the study, as well as to the official NIH Publication Policy governing extramural employees.

Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

### 2.A.3. Collaborative Responsibilities

About six months post-award, NIAAA will sponsor a meeting of the awardees, the purpose of which will be to share information on progress and to decide on certain common data elements to be collected across all sites. The Awardees and the NIH Project Scientific Collaborator will each have a vote in this decision. Awardees will be required to incorporate these common data elements

At the conclusion of Phase I, NIAAA will sponsor another meeting at which each site will present the results of their Phase I process.

### 2.A.4. Arbitration Process

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16.

### 3. Reporting

The Annual Report is due two months prior to the grant anniversary date. For the awards of this program, there is no specific page limit or format requirement on the progress report at this time; the parameters of the project report will be determined at the 6 month meeting so that certain common elements can be incorporated and so that the information presented across sites will be comparable. The progress reports will include at least the following information: an overview of the major achievements made in the previous year including status on meeting the milestones, and accomplishing the research objectives, outreach development goals, training activities and data collection objectives of the project.

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (<http://grants.nih.gov/grants/funding/2590/2590.htm>) and financial statements as required in the NIH Grants Policy Statement.

## Section VII. Agency Contacts

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We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

### 1. Scientific/Research Contacts:

Judith Arroyo, Ph.D.  
Division of Epidemiology and Prevention Research  
National Institute on Alcohol Abuse and Alcoholism  
5635 Fishers Lane Room 2079  
Bethesda, MD 20892  
Telephone: (301) 402-0717  
FAX:301-443-8614  
Email: [jarroyo@mail.nih.gov](mailto:jarroyo@mail.nih.gov)

### 2. Peer Review Contacts:

Extramural Project Review Branch  
Office of Extramural Activities  
Attn: RFA-AA-06-003  
National Institute on Alcohol Abuse and Alcoholism  
5635 Fishers Lane Room 3039  
Bethesda, MD 20892  
Telephone: (301) 443-2531  
FAX: 301-443-3891  
Email: [tvanerv@mail.nih.gov](mailto:tvanerv@mail.nih.gov)

### 3. Financial or Grants Management Contacts:

Ms. Judy Fox  
Chief, Grants Management Branch  
National Institute on Alcohol Abuse and Alcoholism  
5635 Fishers Lane  
Bethesda, MD 20892  
Telephone: (301) 443-4704  
FAX: 301-443-3891  
Email: [jfox@mail.nih.gov](mailto:jfox@mail.nih.gov)

## Section VIII. Other Information

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### Required Federal Citations

#### Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

#### Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

#### Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

#### Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible ([http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing)).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

#### Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see [http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement [http://grants.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants.nih.gov/grants/policy/nihgps_2003/index.htm)). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

#### Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

**Inclusion of Children as Participants in Clinical Research:**

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

**Required Education on the Protection of Human Subject Participants:**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

**Human Embryonic Stem Cells (hESC):**

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

**Access to Research Data through the Freedom of Information Act:**

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm). Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**Standards for Privacy of Individually Identifiable Health Information:**

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

**URLs in NIH Grant Applications or Appendices:**

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

**Healthy People 2010:**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

**Authority and Regulations:**

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at

<http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

**Loan Repayment Programs:**

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov>.

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Department of Health  
and Human Services



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