

## RAPID RESPONSE TO COLLEGE DRINKING PROBLEMS

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

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBERS(S): 93.273

THIS PA CONTAINS THE FOLLOWING INFORMATION:

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### PURPOSE OF THIS PA

The purpose of this Program Announcement (PA) is to provide a rapid funding mechanism for timely research on interventions to prevent or reduce alcohol-related problems among college students. This kind of research most often has a serious urgency with regard to availability or access to data, facilities, or research subjects. The regular grant submission, review, and funding process is lengthy, such that it requires investigators who would conduct such studies to wait a minimum of 9 months after the submission of the application to obtain research support, during which time important data may be lost, appropriate subjects may no longer be available, and the optimal opportunity to directly address a particularly urgent issue or problem may no longer exist.

Applications in response to this Program Announcement can be sent within 6 weeks of the identified event, thus allowing for a much more immediate response on the part of the NIH.

The Federal responsibility for addressing issues related to the excessive use of alcohol and its consequences in these special residential environments rests with several agencies. Therefore, the National Institute on Alcohol Abuse and Alcoholism joins with the Substance Abuse and Mental Health Services Administration, and the National Highway Traffic Safety Administration, Department of Transportation, in support for this Program Announcement. Under this Program Announcement, rapidly developed high quality studies of services or interventions that can capitalize on natural experiments (e.g., unanticipated adverse events, policy changes, new media campaigns) will be supported. Applications may propose to study the

consequences of a change in policies and practices or new prevention approaches that impact drinking in order to inform policy makers about their options to address a problem. Studies to determine and test approaches that might be used to address special serious consequences may also be supported.

There continues to be a need to work closely with college administrators to provide a rapid response to the need for studies that might inform the development of effective policies and actions. It is envisioned that college administrators, recognizing an urgent need to quickly address an alcohol related problem on their campuses, would apply for a grant under this announcement. For applications funded under this announcement, experienced research scientists would be partnered with the applicant institution to assist in the design and evaluation of the proposed intervention. The NIAAA will be involved in identifying appropriate scientists, given the topic to be studied.

The Rapid Response to College Drinking Problems grants described in this Program Announcement are designed to provide a limited amount of support for the immediate implementation of research protocols for rapid intervention, working concurrently with one or more awardees under the Research Partnership Awards for Rapid Response to College Drinking Problems, as described in detail in RFA AA-03-008. Each awardee under this PA is required to partner with an awardee under RFA AA-03-008 (<http://grants.nih.gov/grants/guide/rfa-files/RFA-AA-03-008.html>.) Together, these pairs will work with the NIAAA Staff Collaborator to form individual Steering Committees.

#### RESEARCH OBJECTIVES

Excessive drinking among college students is associated with a variety of negative consequences including fatal and nonfatal injuries; alcohol poisoning; blackouts; academic failure; violence, including rape and assault; unintended pregnancy; sexually transmitted diseases, including HIV/AIDS; property damage; and emotional, vocational, and criminal consequences that could jeopardize future job prospects.

The consequences of excessive and underage drinking affect virtually all college campuses, college communication, and college students, whether they choose to drink or not. It is estimated that 1,400 college students die each year from alcohol-related unintentional injuries, including motor vehicle crashes. The estimates include a half million students injured and more than 600,000 alcohol related assaults. Other problems include sexual abuse, unsafe sex, academic problems, suicide attempts, vandalism, property damage, drunk driving and police involvement. These potential fatal and devastating problems do not address the needs of non-alcohol consuming students who must suffer the consequences (interrupted sleep, assaults, riding in automobiles with intoxicated drivers, etc.) related to the behavior of their peers.

In recognition of the need to address the serious consequences of alcohol abuse among college students, the National Advisory Council to the National Institute on Alcohol Abuse and Alcoholism (NIAAA) established a Task Force on College Drinking in 1998. The Task Force was composed of college Presidents and administrators as well as selected experts in alcohol research. In April, 2002 a report entitled, "A Call to Action: Changing the Culture of Drinking at US Colleges", was released and is available on the NIAAA webpage: <http://www.collegedrinkingprevention.gov>. The report supported the use of comprehensive integrated programs with multiple complementary components that target: (1) individuals, including at-risk or problem drinkers; (2) the

student population as a whole; and (3) the college and the surrounding community.

It is understood that each college environment and student community is different. Differences in ethnic mix, rural vs. urban, private vs. public, etc. can result in different approaches to appropriate interventions. This Program Announcement is intended to provide an opportunity for college administrators to assess the issues and problems that have lead or might lead to emergency and devastating alcohol related problems, to identify an approach that might be appropriate given the unique environment and circumstances, and to design and perform a study of the intervention or prevention service in partnership with research scientists.

Although this Program Announcement is designed to support research on unanticipated opportunities, the following are some of the areas in which research plans might be developed (see Tier 2 and Tier 3 of the Task Force on College Drinking Report, which can be found at the following website: <http://www.collegedrinkingprevention.gov> .) These are in no way meant to be exhaustive or limiting but are examples of topics that might be studied. Such topics might include:

- o The implementation and evaluation of a program of alcohol screening and brief interventions;
- o Changes in campus or community policies and practices to directly address factors contributing to abusive drinking, or they may involve changes in campus systems or structures to promote non-drinking norms;
- o Policies and practices of campus health-care systems and providers with regard to alcohol abuse;
- o Policies directed toward high-risk groups, such as athletes or students in the Greek system;
- o Emergency action plans by campus administrators in response to adverse alcohol-related injuries and deaths;
- o The academic environment, including class and examination schedules and academic standards;
- o Campus policies, such as rules and administrative proclamations regarding alcohol use on campus, in dormitories, and at campus events;
- o Disciplinary procedures, such as parental notification, mandatory counseling, and other sanctions for rule violations;
- o Planning and conducting marketing campaigns aimed at correcting student misperceptions about alcohol use;
- o The formation of a campus and community coalition consisting of community leaders and law enforcement to directly address the problem of student drinking.

The regular peer review process for grant applications does not facilitate the ability to quickly respond to crises related to drinking on college campuses. There is a significant delay between the conceptualization of the grant, submission, review, and final funding. Unless there is a special

mechanism to investigate these naturally-occurring situations, the opportunity to address them in a systematic manner will be missed. Therefore, in response to applications submitted under this Program Announcement and judged to be responsive, a special review group will be convened as rapidly as possible after submission to provide a scientific review. The nine-month and semester academic calendar and the urgency of addressing the campus and individual student needs following an alcohol related emergency are factors that were considered in the development of this Program Announcement.

#### MECHANISM(S) OF SUPPORT

A. This PA will use the NIH U18 award mechanism, which provides for up to \$200,000 in direct costs per year. The total project period for an application submitted in response to this PA may not exceed 3 years. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. Awardees are strongly encouraged to seek outside support to continue these activities after the three year period has ended.

B. This PA uses just-in-time concepts.

C. The NIH U18 is a cooperative agreement award mechanism in which 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 "Cooperative Agreement Terms and Conditions of Award".

#### ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics (small colleges are particularly encouraged to apply):

- o Public or private universities, and colleges
- o Faith-based or community-based organizations

Foreign institutions are not eligible to apply.

#### INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

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.

For this program, the Principal Investigator must be authorized to speak on behalf of administrative policymakers and/or implementers in the college or university (e.g., College President, Dean of Student Affairs, Academic Dean, etc.) Evidence of this authority must be provided through a letter of support if the principal investigator does not directly hold this position of authority.

#### SPECIAL REQUIREMENTS

The applications should include budgetary allowance for attendance at two mandatory meetings per year with NIAAA and other participating Federal agencies. These meetings of all awardees under this PA and those under the [RFA AA-03-008](#) will be held at approximately 6-month intervals in the Washington, D.C. area.

#### COOPERATIVE AGREEMENT TERMS AND CONDITIONS OF AWARD

The following Terms and Conditions will be incorporated into the new award statements and will be provided to the principal investigators and to the appropriate institutional officials at the time 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, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIAAA programmatic involvement with the awardees is anticipated during performance of the activities. Under the cooperative agreement, the NIAAA supports and stimulates the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role. The NIAAA 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.

#### o The Primary Rights and Responsibilities of the Principal Investigator (PI)

The PI Awardee has primary authority and responsibility to define objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusions of their research, career development, and other activities. The PI will:

- Create a Program Advisory Committee (PAC) in consultation with the NIAAA and other participating Federal agencies, and the Staff Scientific Collaborator.
- Coordinate a regular schedule of PAC meetings for review and consultation.
- Implement the approved three-year plan for the planning effort, with periodic updates as needed.
- Coordinate project activities within their institution, with outside collaborators, and with the NIAAA Staff Scientific Collaborator.
- Maintain collaboration and partnership with an established NIAAA investigator and collaborating alcohol research program.
- Accept assistance from the NIAAA Staff Scientific Collaborator in pursuing project goals.
- Awardees will retain custody of and have primary rights to the data developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

o NIAAA Staff Rights and Responsibilities

As per the terms of the cooperative agreement arrangement, the NIAAA will appoint a Program Official and a Staff Scientific Collaborator to participate in the conduct of each U18 Cooperative Agreement Program.

- Program Official

The NIAAA Program Official provides normal program stewardship and reviews the scientific progress of individual research project components, and the use of the core resource facilities among the research projects within each Cooperative Agreement. The Program Official also monitors compliance by the Cooperative Agreement with the operating policies of this PA. The NIAAA Program Official may recommend withholding of support, suspension, or termination of an award for lack of scientific progress or failure to adhere to policies established by the PA or the Award Statement.

- NIAAA Staff Scientific Collaborator

The NIAAA Staff Scientific Collaborator will have substantial scientific-programmatic involvement with the awardees through providing technical assistance, advice, and coordination above and beyond normal program stewardship of research grants. The NIAAA Staff Scientific Collaborator will:

- a) facilitate the coordination necessary to manage this complex project;
- b) participate as a non-voting member of the PAC;
- c) participate in monitoring progress of ongoing studies;
- d) participate in planning and implementing efforts to disseminate information;
- e) provide instruction in faculty development activities;
- f) participate in data interpretation and, when appropriate, in the preparation of publications and presentations.

The NIAAA Staff 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.

o Arbitration Process

Any disagreement that may arise on scientific or programmatic matters between U18 awardees and the NIAAA may be brought to arbitration before an arbitration panel. The arbitration panel will be composed of three members. One member will be chosen by the awardee. A second member will be selected by the NIAAA. The third member, having expertise in the relevant scientific area, will be chosen by the two selected members. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with the PHS regulations at 42 CFR Part 50, Subpart D and HHS regulation at 45 CFR Part 16.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA 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.

o Direct your questions about scientific/research issues to:

Peggy Murray

Director, International and Health Education Programs Branch  
Office of Collaborative Research  
National Institute on Alcohol Abuse and Alcoholism  
Willco Building, Suite 302  
6000 Executive Boulevard, MSC 7003  
Bethesda, MD 20892-7003  
Telephone: (301) 443-2594  
FAX: (301) 480-2358  
Email: [pmurray@mail.nih.gov](mailto:pmurray@mail.nih.gov)

o Direct your inquiries about peer review issues to:

Eugene G. Hayunga, Ph.D.  
Chief, Extramural Project Review Branch  
National Institute on Alcohol Abuse and Alcoholism  
Willco Building, Suite 409  
6000 Executive Boulevard, MSC 7003  
Bethesda, MD 20892-7003  
Telephone: (301) 443-4375  
FAX: (301) 443-6077  
Email: [hayungae@mail.nih.gov](mailto:hayungae@mail.nih.gov)

o Direct your questions about financial or grants management matters to:

Judy Fox  
Chief, Grants Management Branch  
Office of Scientific Affairs  
National Institute on Alcohol Abuse and Alcoholism  
Willco Building, Suite 504  
6000 Executive Boulevard, MSC 7003  
Bethesda, MD 20892-7003  
(301) 443-4704 (telephone)  
(301) 443-3891 (fax)  
Email: [jsimons@willco.niaaa.nih.gov](mailto:jsimons@willco.niaaa.nih.gov)

#### SUBMITTING AN APPLICATION

RAPID applications involve expedited peer review and funding consideration processes. Potential applicants are strongly encouraged to contact the Program Officer, at the address listed under WHERE TO SEND INQUIRIES, before submitting a RAPID application to determine whether the proposed work meets the guidelines of this program, whether requested RAPID funding is likely to be available, and whether the idea should be considered for initial submission as a fully developed application. Inquiries not meeting the RAPID guidelines may be guided to other grant mechanisms and to program contacts to discuss alternatives.

To meet the goals of the RAPID program, applications should be submitted within approximately 6 weeks of the identified event that prompted a rapid response and/or intervention. RAPID applications will be handled on an expedited external peer review and award basis to meet the goals of this program.

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714,

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at any time during the year.

SENDING AN APPLICATION TO THE NIH: 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  
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Eugene Hayunga, Ph.D.  
Extramural Project Review Branch  
Attn: PA No. PAR-03-133  
Office of Scientific Affairs  
National Institute on Alcohol Abuse and Alcoholism  
6000 Executive Boulevard, Room 409, MSC 7003  
Bethesda, MD 20892-7003  
Rockville, MD 20852 (for express/courier service)

APPLICATION PROCESSING: The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

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

#### PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

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

- o Receive a written critique
- o 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
- o Receive a second level review by the National Advisory Council on Alcohol Abuse and Alcoholism.

#### REVIEW CRITERIA



The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your 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 be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

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

**INNOVATION:** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

**INVESTIGATOR:** Is the investigator 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 (if any)?

**ENVIRONMENT:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

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

- o Suitability of the project to the RAPID award criteria, as described in this Announcement.

- o Evidence of commitment from service providers, communities, or others and the extent to which the project director will be working with members of the university community.

- o Extent to which the applicant demonstrates an adequate participatory

planning process which involves individuals reflective of the target population in the preparation of the application, planned implementation of the project, and data interpretations.

- o Demonstrated commitment to work with designated alcohol researchers in refining a research protocol to address the defined problem.

- o Authority of the project director and qualifications of the study coordinator and other key personnel, including any proposed consultants and subcontractors.

- o Adequacy and availability of core resources to support the proposed project.

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 criteria in the sections on Federal Citations, below).

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 Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section (f) of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

#### ADDITIONAL CONSIDERATIONS

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

#### AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

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

#### REQUIRED FEDERAL CITATIONS

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://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components

involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

**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 - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<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 RESEARCH INVOLVING HUMAN SUBJECTS:** The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

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 that is available at <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 proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

**PUBLIC 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 public 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 PA 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). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

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 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 42 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.

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National Institutes of Health (NIH)

9000 Rockville Pike

Bethesda, Maryland 20892