

HIGH THROUGHPUT TOOLS FOR BRAIN AND BEHAVIOR: SBIR

RELEASE DATE: April 2, 2004

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EXPIRATION DATE: August 2, 2007, unless reissued.

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:

National Institute of Health (NIH)

(<http://www.nih.gov>)

COMPONENTS OF PARTICIPATING ORGANIZATION:

National Institute of Mental Health (NIMH)

(<http://www.nimh.nih.gov>)

National Institute of Neurological Disorders and Stroke (NINDS)

(<http://www.ninds.nih.gov/>)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.242, 93.853

APPLICATION RECEIPT DATE(S): Applications submitted in response to this program announcement will be accepted at the standard application deadlines (April 1, August 1, December 1)

THIS PA CONTAINS THE FOLLOWING INFORMATION:

- o Purpose of the PA
- o Research Objectives
- o Mechanism(s) of Support
- o Project Period and Amount of Award
- o Eligible Institutions
- o Individuals Eligible to Become Principal Investigators
- o Where to Send Inquiries
- o Submitting an Application
- o Peer Review Process
- o Review Criteria
- o Award Criteria
- o Receipt and Review Schedule
- o Required Federal Citations

NOTICE: This program announcement (PA) must be read in conjunction with the current Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications. The solicitation (see <http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf> [PDF] or <http://grants.nih.gov/grants/funding/sbirsttr1/index.doc> [MS Word] contains information about the SBIR and STTR programs, regulations governing the programs, and instructional information for submission. All of the instructions within the

current SBIR/STTR Omnibus Solicitation apply.

PURPOSE OF THE PA

Analytic tools that can screen for particular characteristics at high rates are crucial to discovery science, and increasingly valuable in both basic research (e.g., phenotyping) and applied research (e.g., drug discovery). As such, they are in demand and represent a commercially viable technology, appropriate for funding under the Small Business Innovation Research (SBIR) Program. The intent of this Program Announcement (PA) is to invite applications by small businesses for the commercial development of technologies for high throughput data acquisition and analysis that could aid the research fields of basic behavioral science or neuroscience relevant to the mission of the National Institute of Mental Health (NIMH) and the National Institute of Neurological Disorders and Stroke (NINDS). Only SBIR Phase I, Phase II and Fast Track grant applications are solicited; small business technology transfer (STTR) grant applications are not solicited by this PA.

RESEARCH OBJECTIVES

Many of the common technologies used in neuroscience and behavioral science research require extensive time, labor and cost for acquiring and analyzing data. For example, in drug discovery research the standard pharmacological experiments performed require extensive receptor binding and electrophysiology studies. Likewise, immunohistochemistry/histology studies require the preparation and analysis of multiple individual tissue sections, while studies of behavior require hours of human observation. Therefore, there is a strong need for technologies to be developed that can make data collection and analysis more efficient, without compromising competency.

The past decade has seen many significant advances in technical areas including computer vision, molecular biology, robotics, nanotechnology, microarray fabrication, imaging, etc. The last ten years have also produced tremendous resources and knowledge about neurobiology, its genetic underpinnings, and its expression in behavior. This initiative will bring these technology and biomedical areas together by soliciting applications to develop any of a wide variety of innovative tools for high throughput analysis of data relevant to brain or behavior.

Applications considered responsive to this PA would include those proposing research and development of tools for high throughput measures at any level (or combination of levels) of analysis: from molecules through behavior, including social behavior. The tools would, of course, need to be aimed at rapid acquisition and analysis of data useful to understanding the brain and behavior. While the range of measures by tools appropriate for this PA is wide, responsive applications must propose research and development of tools that would significantly improve the ability to rapidly acquire and analyze the collected data.

Although the greatest demand in the marketplace is likely for data from mouse models, the PA would not place any restrictions on species from which data could be obtained (and many tools would likely not be species-specific). In addition, the PA allows technology development applicable to in vivo or in vitro preparations. The technology must be relevant to neuroscience and/or behavioral science appropriate to the mission of the NIMH and NINDS.

MECHANISM(S) OF SUPPORT

This PA uses the SBIR mechanism, which is a set-aside program. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. Future unsolicited, competing-continuation applications based on this project will compete with all SBIR applications and will be reviewed according to the customary peer review procedures.

This PA uses just-in-time concepts. It also uses the modular budgeting format. Specifically, if you are submitting an application budget of \$100,000 total costs (direct, F&A and fee) or less, use the modular format and instructions as described in the current SBIR/STTR Omnibus Solicitation. Otherwise follow the instructions for non-modular budget research grant applications.

Applications may be submitted for support as Phase I SBIR (R43) grants; Phase II SBIR (R44) grants; or the SBIR FAST-TRACK option as described in the SBIR/STTR Omnibus Solicitation. Phase II applications in response to this PA will only be accepted as competing continuations of previously funded NIH Phase I SBIR awards.

The Phase II application must be a logical extension of the Phase I research but not necessarily a Phase I project supported in response to this PA.

PROJECT PERIOD AND AMOUNT OF AWARD

The SBIR/STTR Omnibus Solicitation indicates the statutory guidelines of funding support and project duration periods for SBIR and STTR Phase I and Phase II awards. For this PA, budgets up to \$200,000 total costs per year and time periods up to 2 years for Phase I may be requested. Budgets up to \$450,000 total costs per year and up to 3 years may be requested for Phase II. Total costs include direct costs, F&A, and a profit/fee.

ELIGIBLE INSTITUTIONS

Eligibility requirements are described in the SBIR/STTR Omnibus Solicitation. Only small business concerns are eligible to submit applications. A small business concern is one that, on the date of award for both Phase I and Phase II agreements, meets ALL of the criteria as described in the SBIR/STTR Omnibus Solicitation.

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. On an SBIR application, the principal investigator must have his/her primary employment (more than 50%) with the small business at the time of award and for the duration of the project.

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 two areas: scientific/research, and financial or grants management issues:

- o Direct your questions about scientific/research issues to:

Margaret Grabb, Ph.D.
Division of Neuroscience and Basic Behavioral Science
National Institute of Mental Health
6001 Executive Boulevard, Room 7201, MSC 9645
Bethesda, MD 20892-9645
Rockville, MD 20852 (for express or courier service)

Telephone: (301) 443-3563
FAX: (301) 443-1731
Email: mgrabb@mail.nih.gov

Emmeline Edwards, Ph.D.
Systems and Cognitive Neuroscience Cluster
National Institute of neurological Disorders and Stroke
6001 Executive Boulevard, Room 2109, MSC 9521
Bethesda, MD 20892-9521
Rockville, MD 20892 (for express or courier service)
Telephone: (301) 496-9964
FAX: (301) 40202060
Email: ee48r@nih.gov

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

Brian Albertini
Division of Extramural Activities
National Institute of Mental Health
6001 Executive Boulevard, Room 6134, MSC 9605
Bethesda, MD 20892-9605
Telephone: (301) 443-0004
FAX: (301) 443-6885
Email: albertib2@mail.nih.gov

Mr. Aaron Kinchen
Grants Management Branch
National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard, Room 3271
Bethesda, MD 20892
Telephone: (301) 496-7386
FAX: (301) 402-0219
Email: ak284o@nih.gov

SUBMITTING AN APPLICATION

The PHS 398 research grant application must be used for all SBIR/STTR Phase I, Phase II and Fast-Track applications (new and revised.) Effective October 1, 2003, applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Prepare your application in accordance with the SBIR/STTR Omnibus Solicitation and the PHS 398. Helpful information for advice and preparation of the application can be obtained at: <http://grants.nih.gov/grants/funding/sbirgrantsmanship.pdf>. The NIH will

return applications that are not submitted on the 5/2001 version of the PHS 398.

For further assistance contact GrantsInfo, Telephone: (301) 435-0714, Email: GrantsInfo@nih.gov.

The title and number of this PA must be typed on line 2 of the face page of the application.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: This PA uses the modular budgeting format. Specifically, if you are submitting an application budget of \$100,000 total (direct, F&A and fee) or less, use the modular format and instructions as described in the SBIR/STTR Omnibus Solicitation.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five 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 (FOR USPS EXPRESS or REGULAR MAIL)
Bethesda, MD 20817 (FOR EXPRESS/COURIER NON-USPS SERVICE)

APPLICATION PROCESSING: Applications must be received by or mailed on or before the receipt dates described on the first page of this program announcement. 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 unfunded version 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 that are complete will be assigned on the basis of established PHS referral guidelines. Appropriate scientific review groups 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 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 written critique
- o Receive a second level review by the appropriate national advisory council or board

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

ALL SBIR/STTR APPLICATIONS

1. Significance: Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem? What may be the anticipated commercial and societal benefits of the proposed activity? If the aims of the application are achieved, how will scientific knowledge be advanced? Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries? Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs? Will development of this technology increase the rate of analysis for the particular data being measured?

2. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Is the proposed plan a sound approach for establishing technical and commercial feasibility? Does the applicant acknowledge potential problem areas and consider

alternative strategies? Are the milestones and evaluation procedures appropriate?

3. Innovation: Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies? Are the aims original and innovative?

4. Investigators: Is the Principal Investigator capable of coordinating and managing the proposed SBIR/STTR? Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers, including consultants and subcontractors (if any)? Are the relationships of the key personnel to the small business and to other institutions appropriate for the work proposed?

5. Environment: Is there sufficient access to resources (e.g., equipment, facilities)? Does the scientific and technological 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?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be applied to ALL applications 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 additional information and criteria included in the section on Federal Citations, below).
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

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. Plans for the recruitment and retention of subjects will also be evaluated. (See additional information and Inclusion Criteria in the sections on Federal Citations, below).

Human Subjects:

1. Protection of Human Subjects from Research Risks - for all studies involving

human subjects. See instructions and "Guidance for Preparing the Human Subjects Research Section." If an exemption is claimed, is it appropriate for the work proposed? If no exemption is claimed, are the applicant's responses to the six required points appropriate? Are human subjects placed at risk by the proposed study? If so, are the risks reasonable in relation to the anticipated benefits to the subjects and others? Are the risks reasonable in relation to the importance of the knowledge that reasonably may be expected to be gained? Are the plans proposed for the protection of human subjects adequate?

2. Inclusion of Women Plan - for clinical research only. Does the applicant propose a plan for the inclusion of both genders that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent? Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?

3. Inclusion of Minorities Plan - for clinical research only. Does the applicant propose a plan for the inclusion of minorities that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent? Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?

4. Inclusion of Children Plan - for all studies involving human subjects. Does the applicant describe an acceptable plan in which the representation of children of all ages (under the age of 21) is scientifically appropriate and recruitment/retention is addressed realistically? If not, does the applicant provide an appropriate justification for their exclusion?

5. Data and Safety Monitoring Plan - for clinical trials only. Does the applicant describe a Data and Safety Monitoring Plan that defines the general structure of the monitoring entity and mechanisms for reporting Adverse Events to the NIH and the IRB?

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the required five items described under Vertebrate Animals (section f of the Research Plan instructions) will be assessed.

BIOHAZARDS: Is the use of materials or procedures that are potentially hazardous to research personnel and/or the environment proposed? Is the proposed protection adequate?

ADDITIONAL REVIEW CONSIDERATIONS: The following items may be also be considered by reviewers but will not be included in the determination of scientific merit.

SHARING RESEARCH DATA: Applicants requesting \$500,000 or more in direct costs in any year of the proposed research must include a data sharing plan in their application (http://grants.nih.gov/grants/policy/data_sharing.) The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or priority score.

BUDGET: The reasonableness of the proposed budget may be considered. For all applications, is the percent effort listed for the PI appropriate for the work proposed? On applications requesting up to \$100,000 total costs, is the overall budget realistic and justified in terms of the aims and methods proposed? On applications requesting over \$100,000 in total costs, is each budget category realistic and justified in terms of the aims and methods?

PERIOD OF SUPPORT: The appropriateness of the requested period of support in relation to the proposed research.

PHASE II APPLICATIONS: In addition to the above review criteria:

1. How well did the applicant demonstrate progress toward meeting the Phase I objectives, demonstrating feasibility, and providing a solid foundation for the proposed Phase II activity?
2. Did the applicant submit a concise Commercialization Plan that adequately addresses the seven areas described in the Research Plan item J?
3. Does the project carry a high degree of commercial potential, as described in the Commercialization Plan?

AMENDED APPLICATIONS

In addition to the above criteria, the following criteria will be applied to revised applications.

1. Are the responses to comments from the previous SRG review adequate?
2. Are the improvements in the revised application appropriate?

PHASE I/PHASE II FAST-TRACK APPLICATION REVIEW CRITERIA: For Phase I/Phase II Fast Track applications, the following criteria also will be applied:

1. Does the Phase I application specify clear, appropriate, measurable goals (milestones) that should be achieved prior to initiating Phase II?
2. Did the applicant submit a concise Commercialization Plan that adequately addresses the seven areas described in the Research Plan, item J?
3. To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources that would enhance the likelihood for commercialization?
4. Does the project carry a high degree of commercial potential, as described in the Commercialization Plan?

Phase I and Phase II Fast-Track applications that satisfy all of the review criteria will receive a single rating. Failure to provide clear, measurable goals may be sufficient reason for the scientific review group to exclude the Phase II application from Fast-Track review.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended SBIR and STTR 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

For FAST-TRACK applications, the Phase II portion may not be funded until a Phase I final report and other documents necessary for continuation have been received and assessed by program staff that the Phase I milestones have been successfully achieved.

RECEIPT AND REVIEW SCHEDULE

See http://grants.nih.gov/grants/funding/sbirsttr_receipt_dates.htm

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://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). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

SHARING RESEARCH DATA: Starting with the October 1, 2003 receipt date, 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). Investigators should seek guidance from their institutions, on issues related to institutional policies, 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.

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 are available at

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>.

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 (see <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.

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.

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 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.