

received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 4, 2004.

A. Federal Reserve Bank of New York (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045-0001:

1. *J.P. Morgan Chase & Co.*, New York, New York; to engage *de novo* through its subsidiary, Chase FSB, Newark, Delaware, in operating a federal savings bank, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, December 4, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E3-00498 Filed 12-9-03; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Meeting

TIME AND DATE: 11:30 a.m. (EDT); correction, December 15, 2003.

PLACE: 4th Floor, Conference Room, 1250 H Street, NW., Washington, DC.

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice; correction.

SUMMARY: The Federal Retirement Thrift Investment Board published a notice in the **Federal Register** on Friday, December 5, 2003, concerning upcoming Board member meeting.

Correction:

In the **Federal Register** of Friday, December 5, 2003, Vol. 68, No. 234, page 68093, first column, change the time caption to read: 11:30 a.m.

FOR FURTHER INFORMATION CONTACT: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942-1640.

Dated: December 8, 2003.

Elizabeth S. Woodruff,

Secretary to the Board, Federal Retirement Thrift Investment Board.

[FR Doc. 03-30713 Filed 12-8-03; 1:07 pm]

BILLING CODE 6760-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS-0990-0221]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#1 Type of Information Collection Request: Revision of currently approved collection;

Title of Information Collection: Family Planning Annual Report: Forms and Instructions and Supporting Regulations 42 CFR Part 50 and 59; *Form/OMB No.:* OS-0990-0221;

Use: This annual reporting requirement is for family planning service delivery projects authorized and funded under the Population Research and Voluntary Family Planning Programs (Section 1001 Title X of the Public Health Service Act, 42 U.S.C. 300). The Family Planning Annual Report (FPAR) is the only source of annual, uniform reporting by all Title X family planning service grantees. Office of Population Affairs uses FPAR data to monitor compliance with statutory requirements, to comply with accountability and performance requirements of Government Performance and Results Act and HHS plans, and to guide program planning and evaluation.

Frequency: Annually;
Affected Public: State, local, or tribal government;

Annual Number of Respondents: 89;
Total Annual Responses: 89;
Average Burden Per Response: 30 hours;

Total Annual Hours: 2,937.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at <http://www.hhs.gov/oirm/infocollect/pending/> or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Naomi.Cook@hhs.gov or call the Reports Clearance Office on (202) 690-

5522. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OS Paperwork Clearance Officer designated at the following address: Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (0990-0221), Room 531-H, 200 Independence Avenue, SW., Washington DC 20201.

Dated: December 1, 2003.

John P. Burke III,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 03-30551 Filed 12-9-03; 8:45 am]

BILLING CODE 4168-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Studies To Determine the Prevalence of a History of Traumatic Brain Injury (TBI) in an Institutionalized Population

Announcement Type: New.

Funding Opportunity Number: 04062.

Catalog of Federal Domestic

Assistance Number: 93.136.

Key Dates:

Letter of Intent Deadline: January 9, 2004.

Application Deadline: February 18, 2003.

I. Funding Opportunity Description

Authority: This program is authorized under sections 391(a) and 301(a) of the Public Health Service Act (PHS Act) and 42 U.S.C. 241(a) and 280b(a) as amended.

Purpose: The purpose of the program is to fund a cooperative agreement to conduct pilot studies to investigate methods for determining the prevalence of a history of traumatic brain injury (TBI) in an institutionalized population. For purposes of this RFA, "institutionalized" refers to persons who are either incarcerated or residing in a nursing home. Research on only one of these populations should be proposed.

Anecdotal reports suggest that a very large proportion of the prison population may have experienced one or more TBIs, with many of them occurring prior to incarceration. The cognitive deficits that can result from traumatic brain injuries often are not visible, and behavioral and emotional problems associated with TBI may be

attributed to other causes. Thus, prisoners with TBI as well as prison officials may not be aware of the signs, symptoms, and long term problems resulting from TBI, and therefore may not seek or provide appropriate treatment or other interventions. Better methods for identifying incarcerated persons with a history of TBI and related problems could lead to improved management of TBI in this population.

An estimated 20 to 30 percent of persons hospitalized with moderate to severe TBI are discharged to nursing homes, including those for long-term care. Not all of the persons with TBI who are discharged to nursing homes are elderly, but little is known about the age distribution and other characteristics of this population. Of note, research on a small number of persons with TBI residing in long-term nursing facilities found that, with the proper rehabilitation, they recovered sufficient function to return home or live in a supported community living environment. Better information on the number and characteristics of persons with TBI living in nursing homes, including their functional levels, would inform the development of policies to ensure that they receive appropriate rehabilitation services that can help them return to the community.

This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control (NCIPC):

- Conduct a targeted program of research to reduce injury-related death and disability.

Research Objectives

For research to identify TBI among prisoners:

- To develop valid and reliable measure(s) for ascertaining the history of previous traumatic brain injuries (including those occurring prior to or during incarceration) within a subgroup of the incarcerated population (e.g., adult women or men in prison, or youth in the juvenile justice system), or to validate an existing instrument for use with this population.

- To use these measure(s) to determine the prevalence of a history of TBI in an incarcerated population.

For research to identify persons with TBI in nursing homes:

- To determine the prevalence of persons admitted to nursing homes with a diagnosis of TBI, including those for long-term care, within a state, or

alternatively a defined catchment area, for example, multiple census tracts, multiple counties, or a metropolitan area.

- To determine the functional status and other characteristics of a sample of persons with TBI in long-term care facilities.

Activities

Awardee activities for this program are as follows:

- With assistance from the CDC, prepare a detailed research protocol for Institutional Review Board (IRB) approval by all cooperating institutions participating in the study, including CDC. The protocol shall include but is not limited to the following: A detailed description of a reliable and valid existing instrument(s) for use with the proposed population, or the methods for developing such instrument(s); recruitment and enrollment methods including the informed consent process and consent forms; methods for data handling and storage including methods for ensuring participant confidentiality; data analysis methods; and plans for data dissemination. Specific issues and approaches to conducting research in the proposed institutional setting, including any prior experience, must be described.

- Develop a detailed operations manual documenting study methods.

- Train study personnel.
- Recruit study participants.
- Collect and enter the data.
- Provide case level data, without personal identifiers, to the CDC for use in collaborative analyses.
- Analyze and interpret the data.
- Report study findings, including those in peer-reviewed publications.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide technical assistance where applicable and as necessary for effective study planning and management.
- Assist in the development of a research protocol for Institutional (IRB) review by all cooperating institutions participating in the research. CDC will provide guidance about protocol format and content as well as scientific and human subjects considerations.

- The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

- CDC staff will collaborate in the analysis of data and reporting of findings by participating as co-authors in the preparation of peer-reviewed publications.

- CDC staff will convene routine conference calls with the recipient and conduct a site visit annually or as needed to review progress.

II. Award Information

Type of Award: Cooperative agreement. CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$ 300,000.

Approximate Number of Awards: Two.

Approximate Average Award: \$ 150,000.

Floor of Award Range: \$ 100,000.

Ceiling of Award Range: \$200,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: One year.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.

III. Eligibility Information

1. Eligible Applicants

Applications may be submitted by public and private nonprofit and for profit organizations and by governments and their agencies, such as:

- Public nonprofit organizations
- Private nonprofit organizations
- For profit organizations
- Small, minority, women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian tribes
- Indian tribal organizations
- State and local governments or their

bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

- Political subdivisions of States (in consultation with States)

A *bona fide* agent is an agency/organization identified by the State as

eligible to submit an application under the State eligibility in lieu of a state application. If you are applying as a *bona fide* agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

2. Cost Sharing or Matching

Matching funds are not required for this program.

3. Other Eligibility Requirements

If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

- Is there an appropriate degree of commitment and cooperation from other participating parties as evidenced by letters of support detailing the nature and extent of involvement? Letter(s) of support from appropriate officials from departments of corrections, nursing homes, or other agencies responsible for approving the use of existing data sets containing information on these populations, indicating approval for the research, must be included with the application.

- Does the applicant describe research methods that are feasible and appropriate for the corrections setting?

- Is there evidence of the experience and capacity for all key staff members including Curriculum Vitae (CV) and position descriptions?

- Does the research team include expert(s) with experience conducting TBI research relevant to the proposed study?

- Are the investigators requesting a funding amount that is greater than the upper ceiling of the award range?

- Principal investigators (PI's) are encouraged to submit only one proposal in response to this program announcement. With few exceptions (e.g., research issues needing immediate public health attention), only one application per PI will be funded under this announcement.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

4. 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 CDC programs.

IV. Application and Submission Information

1. Address To Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925-0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770-488-2700. Application forms can be mailed to you.

2. Content and Form of Application Submission

Letter of Intent (LOI)

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, your LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review. Your LOI must be written in the following format:

- Maximum number of pages: Two;
- Font size: 12-point unredlined;
- Paper size: 8.5 by 11 inches;
- Page margin size: One inch;
- Single spaced;
- Printed only on one side of page;
- Written in English, no jargon.

Your LOI must contain the following information:

- Descriptive title of the proposed research;
- Name, address, e-mail, and telephone number of the Principal Investigator;
- Names of other key personnel;
- Participating institutions;
- Number and title of this Program Announcement (PA).

Application

Follow the PHS 398 application instructions for content and formatting

of your application. For further assistance with the PHS 398 application form, contact GrantsInfo, telephone (301) 435-0714, email: GrantsInfo@nih.gov.

Your research plan should address activities to be conducted over the entire project period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered in item 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcomm.htm>.

3. Submission Dates and Times

LOI Deadline Date: January 9, 2004.

Application Deadline Date: February 18, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770-488-2700. Before

calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows: none.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement must be less than 12 months of age.

6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Robin Forbes, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Hwy, NE., Mailstop K-62, Atlanta, GA 30341. Telephone: 770-488-4037; fax: 770-488-1662; email: cipert@cdc.gov.

Application Submission Address: Submit the original and five copies of your application by mail or express delivery service to: Technical Information Management—PA# 04062, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

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

The scientific review group will address and consider each of the

following criteria in assigning the application's overall score, weighting them as appropriate for each application.

The 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.

The criteria are as follows:

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? Does the proposed experiment 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 priority score:

- Does the applicant describe either (a) existing instruments appropriate for use with the proposed population or (b) scientifically sound plans for developing such instrument(s)?
- Does the applicant describe research methods appropriate for a study in the proposed institutional setting?
 - Are there adequate plans for data collection and data management including security of data and assurance of participant confidentiality?
 - Is there a statistical analysis plan appropriate for the study design?

- Does the applicant provide a detailed and appropriate timeline for the study?

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of woman, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) the proposed justification when representation is limited or absent; (3) a statement as to whether the design of the study is adequate to measure differences when warranted; and (4) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

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>.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. This announcement does not use the modular budget format.

2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness for other eligibility requirements by the National Center for Injury Prevention and Control. Incomplete applications and applications that are non-responsive will not advance through the review

process. You will be notified that you did not meet submission requirements.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCIPC in accordance with the review criteria listed above. As part of the initial merit review, all applications will:

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.

- Receive a written critique.
- Receive a second level review by the Science and Program Review Subcommittee (SPRS) of the Advisory Committee for Injury Prevention and Control (ACIPC).

Applications that are complete and responsive to the PA will be subjected to a preliminary evaluation (streamline review) by a peer review committee, the Initial Review Group (IRG) convened by NCIPC, to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRG. CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator or program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

1. The primary review will be a peer review conducted by the IRG. All applications will be reviewed for scientific merit in accordance with the review criteria listed above. Applications will be assigned a priority score based on the National Institutes of Health (NIH) scoring system of 100–500 points.

2. The secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of NCIPC's Advisory Committee for Injury Prevention and Control (ACIPC). The ACIPC Federal agency experts will be invited to attend the secondary review, and will receive modified briefing books (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). ACIPC Federal agency experts will be encouraged to participate in deliberations when applications address overlapping areas of research interest, so that unwarranted duplication in federally-funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the

secondary review in a similar capacity as the ACIPC Federal agency experts to assure that research priorities of the announcement are understood and to provide background regarding current research activities. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered will be the same as those considered by the SPRS.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The secondary review committee has the latitude to recommend to the NCIPC Director, to reach over better-ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

- a. The results of the primary review including the application's priority score as the primary factor in the selection process.
- b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.
- c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010," the Institute of Medicine report, "Reducing the Burden of Injury," and the "CDC Injury Research Agenda."

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

VI. Award Administration Information

1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

2. Administrative and National Policy Requirements

45 CFR part 74 and 92.

For more information on the Code of Federal Regulations, see the National

Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1—Human Subjects Requirements
- AR-2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-6—Patient Care
- AR-8—Public Health System Reporting Requirements
- AR-9—Paperwork Reduction Act Requirements
- AR-10—Smoke-Free Workplace Requirements
- AR-11—Healthy People 2010
- AR-12—Lobbying Restrictions
- AR-13—Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14—Accounting System Requirements
- AR-15—Proof of Non-Profit Status
- AR-21—Small, Minority, and Women-Owned Business
- AR-22—Research Integrity
- AR-23—States and Faith-Based Organizations
- AR-24—Health Insurance Portability and Accountability Act Requirements
- AR-25—Release and Sharing of Data

Starting with the December 1, 2003, receipt date, all NCIPC funded investigators seeking more than \$500,000 in total costs in a single year are expected to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing/release, including the timeliness and name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing/release may also be appropriate in other sections of the application (*e.g.* background and significance, human subjects requirements, *etc.*) The content of the data sharing/release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing/release plan will not count towards the application page limit and will not factor into the determination of scientific merit or priority scores. 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.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or visiting the NCIPC Internet Web site: at http://www.cdc.gov/ncipc/osp/sharing_policy.htm.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

3. Reporting

You must provide CDC with an original, plus two copies of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925-0001, rev. 5/2001) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be sent to the Grants Management Specialist listed in the "Agency Contacts" section of the announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, PA#04062, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2700.

For scientific/research program technical assistance, contact: William K. Ramsey, Project Officer, Division of Injury and Disability Outcomes and Programs, Centers for Disease Control and Prevention, 4770 Buford Highway, Mail Stop F-41, Chamblee, GA 30341. Telephone: 770-488-1226; e-mail: BRamsey1@cdc.gov.

For questions about peer review, contact: Gwendolyn Cattledge, Scientific Review Administrator, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway, NE., MailStop K-02, Atlanta, GA 30341. Telephone: 770-488-1430; e-mail: gxc8@cdc.gov.

For budget assistance, contact: Angie Nation, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2719; e-mail: aen4@cdc.gov.

Dated: December 4, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03-30583 Filed 12-9-03; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Radiation and Worker Health Advisory Board Meeting; Correction

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

AGENCY: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH), HHS.

ACTION: Correction.

Correction: In the **Federal Register** of November 17, 2003, in DOCID: fr17no03-102, Volume 68, Number 221, Page 64902, concerning the purpose for closing a portion of the meeting of the Advisory Board on Radiation and Worker Health, the notice cited an incorrect reason for the meeting closure. Correct "Matters to be Discussed" to read:

The closed portion of the meeting on the afternoon of December 10th will involve a review and discussion of the Independent Government Cost Estimate (IGCE) for task order contracts and proposals of work for the performance of these task order contracts, which could lead to a revision of the IGCE. These contracts will serve to provide technical support consultation to assist the ABRWH in fulfilling its statutory duty to advise the Secretary of Health and Human Services on the scientific validity and quality of dose estimation and reconstruction efforts under the Energy Employees Occupational Illness Compensation Program Act. These discussions will include reviews of the technical proposals to determine adequacy of the proposed approach, and associated contract cost estimates.

This portion of the meeting will be closed to the public in accordance with provisions set forth regarding subject matter considered confidential under the terms of 5 U.S.C. 552b(c)(9)(B), 48 CFR 5.401(b)(1) and (4), and 48 CFR 7.304(d), and the Determination of the Director of the Management and

Services Office, Centers for Disease Control and Prevention, pursuant to Pub. L. 92-463.

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-6825, fax (513) 533-6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 5, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03-30681 Filed 12-9-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0428]

Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components" dated December 2003. The guidance document recognizes the "Circular of Information for the Use of Human Blood and Blood Components" (the circular) dated July 2002 as acceptable for use by manufacturers of blood and blood components intended for transfusion. The circular will assist manufacturers in complying with the labeling requirements under FDA regulations. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2002.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40),