

The NIH should ensure that proposals for training grants and center grants include appropriate provisions for training and technical assistance in the issues discussed in this report. Where appropriate, the NIH and the Office for Protection from Research Risks (OPRR) should consider using consensus development conferences or workshops to advance discussion of these issues.

Institute of Medicine Review of Research Studies

Recommendation 20. The Department of Health and Human Services should contract with the Institute of Medicine to conduct a comprehensive review and evaluation of the nature and extent of challenge, washout, and placebo controlled studies with subjects with mental disorders that may affect decisionmaking capacity.

Increased Funding To Support Necessary Protections of Human Subjects

Recommendation 21. Compliance with the recommendations set forth in this report will require additional resources. All research sponsors (government, private sector enterprises, and academic institutions) should work together to make these resources available.

FOR FURTHER INFORMATION ABOUT THE REPORT CONTACT: Eric M. Meslin, Ph.D., Executive Director, National Bioethics Advisory Commission or to obtain copies of the report contact: Ms. Patricia Norris, National Bioethics Advisory Commission, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892-7508, telephone 301-402-4242, fax number 301-480-6900. Copies may also be obtained through the NBAC website: www.bioethics.gov.

Dated: February 12, 1999.

Eric M. Meslin,

Executive Director,

National Bioethics Advisory Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (formerly Hospital Infection Control Practices Advisory Committee), Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92-463) of October 6, 1972, that the Healthcare Infection Control Practices

Advisory Committee (HICPAC), National Center for Infectious Diseases (NCID), of the Department of Health and Human Services, has been renewed for a 2-year period through January 19, 2001.

For information, contact Michele Pearson, M.D., Executive Secretary, HICPAC, NCID, CDC, 1600 Clifton Road, m/s A07, Atlanta, Georgia 30333. Telephone 404/639-6400.

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: February 11, 1999.

Carolyn J. Russell,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99017]

Evaluating Potential Exposures To Blood and Risk of Hepatitis C Virus (HCV) Infection Among Persons Without Traditional Risk Factors; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for evaluating potential exposures to blood and risk of hepatitis C virus (HCV) infection among persons without traditional risk factors. This program addresses the "Healthy People 2000" priority area of Immunization and Infectious Diseases. The purpose of the program is to provide assistance for addressing the risk of HCV or hepatitis B virus (HBV) transmission through potential but unproven mucosal or percutaneous exposures to blood in the United States. Specifically, applications are solicited for projects aimed at determining if there is an increased risk of HCV or HBV infection associated with illegal intranasal drug use (e.g., cocaine or heroin), anabolic steroid abuse, tattooing, or body piercing in populations with a low prevalence of illegal injection drug use.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$150,000 is available in FY 1999 to fund one award. It is expected that the award will begin on or about June 1999 and will be made for a 12-month budget period within a project period of one year. The funding estimate may change.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under (Recipient Activities), and CDC will be responsible for the activities listed under (CDC Activities).

Recipient Activities

1. Conduct research to determine if there is a risk of HCV or HBV infection, independent of known risk factors for transmission, associated with percutaneous exposures, such as tattooing, body piercing, or illegal injection of anabolic steroids, or percutaneous exposures, such as use of illegal intranasal drugs.

2. Develop a study protocol to determine the prevalence of potential exposures for bloodborne pathogen transmission (i.e., illegal intranasal drug use, anabolic steroid abuse, tattooing, body piercing) in populations with a low prevalence of illegal injection drug use and their prevalence of HCV and HBV infection.

3. Based on the protocol, conduct an epidemiologic study of the potential association between HCV or HBV infection and illegal intranasal drug use, anabolic steroid abuse, tattooing, and body piercing.

4. Analyze, interpret, and publish results.

CDC Activities

1. Upon request of recipient, provide technical assistance in the design, conduct, and analysis of the research,

including development of the questionnaire and analytic plan.

2. Upon request of recipient, perform serologic testing for HCV and HBV infection and report results back to study investigators.

3. Upon request of recipient, participate in the analysis of the research data and the interpretation and presentation of research findings.

4. If CDC is requested to provide technical assistance in the design of the study, CDC will participate in the development of a research protocol for Internal Review Board (IRB) review by all institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 10 double-spaced pages, printed on one side, with one inch margins, and unreduced font.

F. Submission and Deadline Application

Submit the original and five copies of PHS-398 [(OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398)]. Forms are in the application kit. On or before May 10, 1999, submit the application to: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99017, Centers for Disease Control and Prevention, 2920 Brandywine Road, Mailstop E-18, Atlanta, Georgia 30341-4146.

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Background and Need (10 points): Extent to which applicant demonstrates a clear understanding of the subject area and of the purpose and objectives of this cooperative agreement program.

2. Capacity (45 points): Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed, as evidenced by curriculum vitae, publications, etc. If applicable, extent to which applicant includes letters of support from non-applicant organizations, individuals, etc., and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 points total):

a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and goals of this cooperative agreement program and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all "Recipient Activities" for the specific project area being addressed in the application. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the approach/methods are appropriate and adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for 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. (30 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives.

If the proposed project involves notifiable conditions, the degree to which applicant describes an adequate process for providing necessary information to appropriate State and/or local health departments. (5 points)

4. Budget: (not scored) Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

5. Human Subjects: Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects?

___ Yes ___ No

Comments: _____

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. progress reports (semiannual)
2. Financial and final Performance reports, no more than 90 days after the end of the project period.

Send all reports to: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Mailstop E-18, Atlanta, GA 30341-4146.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2000
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act Sections 301(a) [42 U.S.C. 241 (a)], 317(k)(2), [42 U.S.C. 247b(k)(1)] and [247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

To obtain additional information, contact: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99017, Centers for Disease Control and Prevention, 2920 Brandywine Road,

Mailstop E-18, Atlanta, GA 30341-4146, telephone (770) 488-2751, Fax (770) 488-2777, Email address: ayw3@cdc.gov.

See also the CDC Home Page on the Internet for applicable forms: <http://www.cdc.gov>.

For program technical assistance, contact Rob Lyerla, Ph.D., Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Viral and Rickettsial Diseases, Hepatitis Branch, 1600 Clifton Rd N.E., Mailstop G37, Atlanta, GA 30333, Phone: 404-639-3048, E-mail address: rfl8@cdc.gov

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

Dated: February 12, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-4093 Filed 2-18-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

The Advisory Council for Elimination of Tuberculosis: Meeting

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 council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.-5 p.m., March 10, 1999. 8:30 a.m.-12 p.m., March 11, 1999.

Place: Corporate Square Office Park, Corporate Square Boulevard, Building 11, Room 1413, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters to be Discussed: Agenda items include revisiting the 1989 TB elimination strategic plan; discussion of combined

preparations of TB drugs; update on contact studies; and follow-up on TB vaccine issues. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Beth Wolfe, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E-07, Atlanta, Georgia 30333, telephone 404/639-8008.

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: February 11, 1999.

Carolyn J. Russell,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families (ACF)

[Program Announcement No. OCSE 99SIP-1]

Child Support Enforcement Demonstration and Special Projects—Special Improvement Projects

AGENCY: Office of Child Support Enforcement (OCSE), ACF, DHHS.

ACTION: Notice.

SUMMARY: The OCSE invites eligible applicants to submit competitive grant applications for special improvement projects which further the national child support mission, vision, and goals which are: all children to have parentage established; all children in IV-D cases to have financial and medical orders; and all children in IV-D cases to receive financial and medical support. Applications will be screened and evaluated as indicated in this program announcement. Awards will be contingent on the outcome of the competition and the availability of funds.

DATES: The closing date for submission of applications is April 20, 1999. See Part IV of this announcement for more information on submitting applications.

ADDRESSES: Application kits (Forms 424, 424A-B; Certifications; and Administration for Children and Families Uniform Project Description [UPD]) containing the necessary forms and instructions to apply for a grant

under this program announcement are available from: Administration for Children and Families, Office of Child Support Enforcement, Division of State and Local Assistance, 370 L'Enfant Promenade, SW, 4th Floor, East Wing, Washington, DC 20447 (This is not the mailing ADDRESS for submission of applications, See Part IV, B.); or contact Jean Robinson, Program Analyst, phone (202) 401-5330, FAX (202) 401-5559; e-mail, jrobinson@acf.dhhs.gov.

FOR FURTHER INFORMATION CONTACT:

Administration for Children and Families (ACF), OCSE, Susan A. Greenblatt at (202) 401-4849, for specific questions regarding the application or program concerns regarding the announcement.

SUPPLEMENTARY INFORMATION: This program announcement consists of four parts:

Part I: Background—program purpose, program objectives, legislative authority, funding availability, and CFDA Number.

Part II: Project and Applicant Eligibility—eligible applicants, project priorities, and project and budget periods.

Part III: The Review Process—intergovernmental review, initial ACF screening, competitive review and evaluation criteria, and funding reconsideration.

Part IV: The Application—application development, and application submission.

Paperwork Reduction Act of 1995 (Pub. L. 104-13): Public reporting burden for this collection of information is estimated to average 20 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

The following information collections within this Program Announcement are approved under the following currently valid OMB control numbers: 424 (0348-0043); 424A (0348-0044); 424B (0348-0040); Disclosure of Lobbying Activities (0348-0046); Uniform Project Description (0970-0139 Expiration date 10/31/00).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Part I. Background

A. Program Purpose and Objectives

To fund a number of special improvement projects which further the national child support mission to ensure that all children receive financial and