

Dated: July 22, 1998.

John L. Williams,

*Director, Procurement and Grants 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 98092]

The Epidemiology of Opportunistic Infections in Bone Marrow Transplant Recipients; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program for The Epidemiology of Opportunistic Infections in Bone Marrow Transplant Recipients. This program addresses the "Healthy People 2000" priority area of Immunization and Infectious Diseases. The purpose of the program is to provide assistance for a study to assess the epidemiology of opportunistic infections (OIs) in bone marrow transplant (BMT) recipients in the mid-1990s. For this study, a BMT is defined as any hematopoietic cell transplant of any type (autologous, syngeneic, or allogeneic), with transplanted cells collected from either the donor's bone marrow or peripheral blood. An OI is defined as any infection which occurs with increased frequency or severity in BMT recipients. The goals of this study are: (a) to identify the important OIs in inpatients and outpatients, both pediatric and adult, and autologous and allogeneic BMT recipients who have received stem cells harvested from donor bone marrow or blood, and (b) to describe recent trends in BMT OI epidemiology to help set priorities for BMT OI prevention strategies.

B. Eligible Applicants

Maximum Competition

Applications may be submitted by public and private nonprofit organizations whose functions include collecting and disseminating national BMT data and coordinating information about OIs in BMT recipients. Eligible applicants must perform or collect OI data on ≤ 100 new BMTs per year in order to maximize the number of BMT recipients under surveillance, and

therefore increase the power of the study.

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 \$140,000 is available in FY 1998 to fund approximately 1-2 awards. It is expected that the average award will be \$70,000 ranging from \$50,000-140,000. It is expected that the awards will begin on or about September 30, 1998 and will be made for a 12-month budget period within a project period of one (1) year. Funding estimates may change.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Develop a plan to identify the important OIs, including new and emerging ones, which have occurred during the mid-1990s in a retrospective cohort of BMT recipients. Previously, important BMT OIs have included cytomegalovirus, influenza A and B, respiratory syncytial virus, *S. pneumoniae*, *Haemophilus influenzae* type b, *Toxoplasma gondii*, *Pneumocystis carinii*, and invasive *Candida spp.* and *Aspergillus spp.* Important OIs in the mid-1990s may include some or all of these agents.

b. Develop case definitions for specific BMT OIs.

c. Design a study to determine the epidemiology of OIs in BMT recipients in the mid-1990s. This should include methods to determine risk factors and incidence rates of important OIs.

d. Develop a plan for quality assurance to ensure completeness and accuracy of data.

e. Interpret, publish, and disseminate findings.

2. CDC Activities

a. Collaborate on planning and designing the study. Assist with the development of OI case definitions.

b. Provide assistance as requested by recipient(s).

c. Collaborate in data management, and in quality assurance.

d. Perform Statistical analysis as requested.

e. In collaboration with recipient(s), assist with interpretation of data.

f. Facilitate dissemination of findings.

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 15 double-spaced pages, printed on one side, with one inch margins, and unredacted 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 PHS398). Forms are in the application kit. On or before August 30, 1998, submit the application to: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98092, Centers for Disease Control and Prevention, Room 300, 255 East Paces Ferry Road, NE., M/S E18, Atlanta, Georgia 30305-2209.

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.

Plan (10 points)

Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities.

Objectives (15 points)

Extent to which applicant describes specific 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.

Methods (30 points)

Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. The extent the proposed plan includes the inclusion of women,

ethnic, and racial groups in the proposed research to include (1) 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 the community and recognition of mutual benefits will be documented.

Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel.

Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and to accomplish the study objectives.

Extent to which the applicant evaluates completeness and accuracy of reported data.

Capacity (35 Points)

Extent to which applicant documents past experience and achievement in successfully completing the types of activities outlined in the Recipient Activities section of this announcement.

Extent to which the applicant has collected OI data on a large number of BMT recipients, including >100 new BMTs performed/year in the mid-1990s.

Extent to which the applicant demonstrates its expertise in infectious diseases, bone marrow transplantation, epidemiology and laboratory practice to diagnose all important OIs, including new and emerging ones in BMT recipients in the mid-1990s.

Extent to which the applicant demonstrates it has collected data on the likely important OIs, as well as possible new and emerging OIs such as *Streptococcus variationist* spp., coagulase-negative *Staphylococcus* spp., etc. Extent to which the applicant demonstrates the ability to determine whether previously reported OIs, such as cytomegalovirus, influenza A and B, respiratory syncytial virus, *S. pneumoniae*, *Haemophilus influenzae* type b, *Toxoplasma gondii*, *Pneumocystis carinii*, invasive *Candida* spp. and *Aspergillus* spp. cytomegalovirus, are still important OIs in the 1990s.

Evaluation (10 Points)

Extent to which applicant provides a detailed and adequate plan for evaluating study results and for

evaluating progress toward achieving project objectives.

Budget (Reviewed, but not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

Does the application adequately address the requirements of 45 CAR Part 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 (quarterly). Progress results should address progress toward overall objectives as represented in the Purpose and Recipient Activities sections of this announcement and include summaries of research results.

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

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

Send all reports to: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 300, 255 East Paces Ferry Road., NE, M/S [E18], Atlanta, GA 30305-2209

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

AR98-1 Human Subjects Requirements

AR98-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR98-9 Paperwork Reduction Act Requirements

AR98-10 Smoke-Free Workplace Requirements

AR98-11 Healthy People 2000

AR98-12 Lobbying Restrictions

AR98-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

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

J. Where To Obtain Additional Information

To receive additional written information call 1-888-GRANTS4. You

will be asked to leave your name, address, and phone number and will need to refer to Announcement 98092. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to Announcement Number 98092 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained by contacting: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98092, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., M/S E18, Atlanta, GA 30305-2209 telephone (404) 842-6872, Email address vxm7@cdc.gov.

See also the CDC home page on the Internet: <http://www.cdc.gov>.

For program technical assistance contact: Clare A. Decoets, M.D., M.P.H., CDC, Mailstop A12, 600 Clifton Rd., NE, Atlanta, GA 30333, Telephone (404) 639-4932, FAX (404) 639-4664, Email address: cad3@cdc.gov.

Dated: July 22, 1998.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Plan for States and Territories (Supplement).

OMB No.: 0970-0114.

Description: The Child Care and Development Block Grant (CCDBG) Act of 1990 requires the States and Territories to submit a biennial Plan (ACF-118) in order to receive Federal funds. The statutorily required Plan provides the public and ACF with a description of, and assurances about, the State's Child Care Program. In 1996, the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) provided additional fiscal resources for child care but required that the funds be spent in accordance