Highway, NE, (M/S K–10), telephone 770–488–5000 or fax 770/488–5966.

Dated: July 7, 1998.

Carolyn J. Russell,

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

[FR Doc. 98–18668 Filed 7–13–98; 8:45 am]

BILLING CODE 4861–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Hanford Thyroid Morbidity Study 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 Hanford Thyroid Morbidity Study Advisory Committee (HTMSAC) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, has been renewed for a 2-year period. The charter will now expire June 13, 2000.

FOR FURTHER INFORMATION CONTACT: Henry Falk, M.D., Executive Secretary, HTMSAC, CDC, 4770 Buford Highway, NE, (M/S F–28), telephone 770–488–7300 or fax 770/488–7044.

Dated: July 7, 1998.

Carolyn J. Russell,

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

[FR Doc. 98–18669 Filed 7–13–98; 8:45 am]

BILLING CODE 4861–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99012]

Notice of Availability of Funds; Applied Research Program in Emerging Infections Novel Diagnostic Tests for Infections of Public Health Significance

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for competitive grants and/or cooperative agreements to support applied research on emerging infections. This announcement addresses the development of novel diagnostic tests for infections of public health significance.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION**.)

Authority

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

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Pub. L. 103–227, the Pro-Children's Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day-care, health-care and early childhood development services are provided to children.

Eligible Applicants

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

Only one application will be accepted from any single applicant, organization, government, or agency in each focus area.

Availability of Funds

Approximately $500,000 is available in FY 1999 to fund two to three awards, ranging from $160,000 to $250,000. It is expected the awards will begin on or about February 1, 1999, and will be made for a 12-month budget period within a project period of up to three years. (The funding amounts listed above are for the first 12-month budget period and include both direct and indirect costs.) The funding estimate is subject to change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Specifically, applications are solicited for projects addressing any of the following three areas:

1. Diagnostic Tests of High Sensitivity and Specificity for Use in Clinical Settings

The objective is to encourage the development of highly sensitive and specific diagnostic tests for infectious disease agents of high public health significance for which such tests are not currently available.

2. Development and Evaluation of Improved Tests for Malaria Diagnosis in the U.S.

The objective is to develop and evaluate a malaria diagnostic test that does not require microscopic examination of blood smears and: (a) is at least as sensitive as microscopy (4 parasites per ul. of blood); (b) can detect all 4 known species of human malaria parasites; (c) has a specificity of at least 95 percent; (d) is simple to perform; and (e) can provide results in less than 1 hour.

3. Diagnostic Tests for Field Use

The objective is to encourage the development of field tests for infectious disease agents of high public health significance. Attributes sought in these field tests are: low cost; use with noninvasive or easy to collect specimens; short time-to-result; stable reagents; minimum risks to technicians; sensitivity and specificity appropriate for setting.

Applicants may submit separate applications for projects in one or more of the three focus areas. (See Application Process Section, Application Content area, for detailed instructions.)

Determination of Which Instrument to Use

Applicants must specify the type of award for which they are applying, either grant or cooperative agreement. CDC will review the applications in accordance with the evaluation criteria. Before issuing awards, CDC will determine whether a grant or cooperative agreement is the appropriate instrument based upon the need for substantial CDC involvement in the project. To assist applicants in making a determination as to which type of award to apply for, the following information is provided:

1. Research Project Grants

A research project grant is one in which substantial programmatic involvement by CDC is not anticipated by the recipient during the project period. Applicants for grants must demonstrate an ability to conduct the proposed research with minimal assistance, other than financial support,

from CDC. This would include possessing sufficient resources for clinical, laboratory, and data management services and a level of scientific expertise to achieve the objectives described in their research proposal without substantial technical assistance from CDC.

2. Cooperative Agreements

A cooperative agreement implies that CDC will assist recipients in conducting the proposed research. The application should be presented in a manner that demonstrates the applicant's ability to address the research problem in a collaborative manner with CDC.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of the Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 ''Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act'' (Public Law 105–78) states in Section 503 (a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relations, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

Once expected to be eliminated as a public health problem, infectious diseases remain the leading cause of death worldwide. In the United States (U.S.) and elsewhere, infectious diseases increasingly threaten public health and contribute significantly to the escalating costs of health care.

In 1992, the Institute of Medicine of the National Academy of Sciences published a report entitled Emerging Infections, Microbial Threats to Health in the United States highlighting the threat of emerging infections and making specific recommendations to address the threat. This report emphasized a critical leadership role for CDC in a national effort to detect and control infectious disease threats.

In partnership with other Federal agencies, State and local health departments, academic institutions, and others, CDC has developed a plan for revitalizing the nation's ability to identify, contain, and prevent illness from emerging infectious diseases. The plan, ''Addressing Emerging Infectious Disease Threats; A Prevention Strategy for the United States,'' includes applied research as a major objective, stressing the importance of integrating laboratory science and epidemiology to optimize public health practice in the United States (U.S.). CDC has developed an Extramural Applied Research Program in Emerging Infections (EARP) designed to fill gaps in existing support for research in emerging infectious disease surveillance, epidemiology, and prevention. This announcement specifically addresses novel diagnostic methods for infections of public health significance.

Proposals sought under this announcement may span the range from highly sophisticated, sensitive and specific tests that require a well-equipped laboratory and highly trained personnel to robust field tests that are simple, rapid, and can be performed without equipment by minimally trained persons yet provide reliable results. Examples of infections and issues of public health significance to be addressed include, but are not limited to, tuberculosis, malaria, dengue, enterohemorrhagic Escherichia coli other than E. coli O157:H7, antimicrobial resistance (e.g., detecting vancomycin resistance genes in enterococci), and prion disease (e.g., Bovine Spongiform Encephalitis). This announcement focuses on three specific areas:

1. Diagnostic Tests of High Sensitivity and Specificity for Use in Clinical Settings

Despite the recent advances in molecular biology and its applications to diagnostics, significant gaps still remain in infectious disease diagnostics. Commercial companies tend to focus in areas of diagnostics that have a potential for high-volume sales of diagnostic kits. Many published methods have not been adequately validated. Sample preparation procedures tend to be complex and time-consuming; many of the proposed simple sample preparation methods do not yield consistent results. Applications are encouraged that address these and similar issues and target those infectious agents for which there is clear need for better and more rapid diagnostic methods.

Polymerase Chain Reaction (PCR) amplification is being used to detect and identify unculturable organisms directly in human clinical specimens, such as blood, urine, cerebrospinal fluid, and tissues obtained by biopsy or at autopsy. Unfortunately, the success rate of this method is quite low when identification is attempted directly from clinical samples. This is due to the presence of PCR inhibitors in blood and other clinical samples and also, in part, to the often low number of organisms in the samples. For PCR amplification tests to become a valuable rapid identification method for uncultured bacteria, the inhibitors must be identified and removed or overcome, and the sensitivity of the method for a wide variety of human pathogenic bacteria in various clinical samples must be determined.

For many infectious agents, new non-culture methods have been developed that facilitate rapid detection of the pathogen in clinical specimens without its isolation. Because many local, State and Federal surveillance programs depend on the continued availability of pathogenic microorganisms isolated by culture, the Council of State and Territorial Epidemiologists (CSTE) has recently developed a new position statement on this topic. In its position statement, CSTE recommends the Food and Drug Administration require each manufacturer of non-culture tests for infectious agents of public health importance and for which routine characterization (speciation, subtyping or antimicrobial susceptibility testing) provides essential information for public health surveillance or investigation, include in their product insert a statement that positive results must be confirmed by culture. Almost all currently available non-culture

diagnostic tests require the laboratorian to go back to the original specimen or an enrichment culture to attempt to isolate the pathogen. Public health programs will greatly benefit from rapid non-culture diagnostic methods that have built-in algorithms that facilitate the isolation of the pathogen without having to go back to the specimen or an enrichment broth. Such approaches are feasible in techniques that involve selective removal or immobilization of the target pathogen from the specimen without causing its inactivation.

2. Improved Tests for Malaria Diagnosis in the U.S.

Every year, approximately 1,000 cases of malaria are reported in the U.S. Nineteen deaths due to malaria were recorded in the U.S. during the period 1992–1994. Of particular concern, cases of locally-transmitted malaria have been reported on practically an annual basis in densely populated areas (New York City, Houston, and Palm Beach County, Florida). The substantial U.S. public health impact of malaria is very likely to increase in the future due to increased international travel combined with a worldwide resurgence of malaria. Available information indicates that malaria diagnosis is not optimally performed in the U.S. In a recent survey of samples sent to CDC's National Malaria Reference Laboratory (NMRL) by various health institutions (including State health departments, hospitals, and commercial laboratories), the diagnosis made by the NMRL differed from that made at the health institution in 21 percent of the samples. This is due mainly to the fact that the internationally accepted method for diagnosing malaria (the microscopic examination of a Giemsa-stained blood smear) requires a degree of microscopy experience that most clinical laboratorians in the U.S. lack due to their infrequent contact with malaria samples.

One solution to this problem would be a diagnostic test that depends, not on the experience and skills of a microscopist, but on more objective, quantifiable criteria. Several malaria diagnostic tests that follow this approach are currently on the market or in various development phases. Such tests identify malaria parasites by nucleic acid fluorescence or by detecting parasite-specific antigens or enzymes. However, none of these tests satisfy all desirable criteria for a malaria diagnostic tool applicable to clinical laboratory practice in the U.S. Such criteria include: (a) sensitivity at least equal to that of microscopy (4) parasites per ul. of blood); (b) detection of all 4 known species of human malaria parasites; (c) specificity above 95 percent; (d) simplicity of performance; and (e) rapidity of execution (results available in less than 1 hour). In addition, none of these tests have been adequately evaluated under strictly controlled conditions in U.S. health facilities.

3. Diagnostic Tests for Field Use

For many infectious agents, there is a critical need for rapid, simple tests that can be performed in the field without access to a sophisticated laboratory and for which minimal sample preparation is required. In the past, many of these tests have been configured on the basis of specific antigen-antibody interactions (e.g., latex agglutination tests, dipstick immunoassays, immunoprecipitation tests) using polyclonal or monoclonal antibodies. However, for the purpose of this announcement, any tests that meet the following criteria will be considered: low cost; use with noninvasive or easy to collect specimens; short time-to-result; stable reagents; minimum risks to technicians; sensitivity and specificity appropriate for setting, and demonstrated need for such tests for the proposed target pathogen.

Purpose

The purpose of the EARP is to provide financial and technical assistance for applied research projects on emerging infections in the U.S. As a component of EARP, the purpose of this grant/cooperative agreement announcement is to provide assistance for projects addressing novel methods for identification of emerging infections.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities) and CDC will be responsible for conducting activities under B. (CDC Activities) for cooperative agreements only:

A. Recipient Activities

1. Diagnostic Tests of High Sensitivity and Specificity for use in Clinical Settings

a. Develop diagnostic tests for use in clinical settings for one or more infectious diseases of high public health significance for which such tests do not currently exist or significantly improve an existing test; OR

b. Develop rapid diagnostic tests for use in clinical settings for one or more infectious diseases of high public health significance. Design the test in such a manner that the etiologic agent may be directly isolated from the matrix that is used for rapid detection of the etiologic agent; OR

c. Systematically develop optimal conditions for the detection of uncultured bacteria from blood, serum, and other clinical specimens, specifically addressing the problem of inhibition of the polymerase chain reaction by sample components. Complete Phase I evaluation of the diagnostic test in a clinical setting and compare against a method which has been previously validated. Demonstrate that the sensitivity and specificity of the test are significantly better than the current benchmark tests. For a.2. and a.3., demonstrate that the target pathogen can be consistently isolated from clinical specimens.

d. Organize independently or collaborate with CDC (for cooperative agreements) to organize more extensive Phase II evaluation of the test in multiple laboratories.

e. Publish and/or otherwise disseminate findings.

2. Development and Evaluation of Improved Tests for Malaria Diagnosis in the U.S.

a. Develop a new diagnostic test or improve currently available test(s) that does not require microscopic examination of blood smears and is:

(1) At least as sensitive as microscopy (4) parasites per ul. of blood).

(2) Can detect all 4 known species of human malaria parasites.

(3) Has a specificity of at least 95 percent.

(4) Is simple to perform.

(5) Can provide results in less than 1 hour.

b. Conduct a first phase of evaluation of the new or improved test(s). This should involve testing clinical samples for malaria under blinded conditions and should use mainly samples collected from non-human primates experimentally infected with human malaria parasites and malaria-infected human blood samples, both of which can be made available by CDC.

c. Collaborate with CDC (for cooperative agreements) to conduct field evaluations of the test(s) in endemic countries (e.g. a large-scale assessment in a short time period where n > = 500) and in U.S. facilities. (The actual U.S. field testing will likely require a longer time period due to low frequency of malaria and should involve collaboration with State health departments, hospitals, and commercial laboratories.)

d. Publish and/or otherwise disseminate results.

3. Diagnostic Tests for Field Use

a. Develop diagnostic tests for use under field conditions for one or more infectious diseases of high public health significance for which such tests are needed but do not currently exist or significantly improve an existing test.

b. Complete limited evaluation of the diagnostic test under field conditions and compare against a method which has been previously validated. Demonstrate that the sensitivity and specificity of the test are acceptable and appropriate for use in field settings.

c. Organize independently or collaborate with CDC (cooperative agreements) to organize more extensive Phase II evaluation of the test.

d. Publish and/or otherwise disseminate findings.

B. CDC Activities (for Cooperative Agreements)

1. Provide technical assistance in the design and conduct of the research.

2. Perform selected laboratory tests, as appropriate and necessary.

3. Participate in data management, the analysis of research data, and the interpretation and presentation of research findings.

4. Provide biological materials (e.g., strains, reagents, etc.) as necessary for studies.

Technical Reporting Requirements

Narrative progress reports are required semiannually. The first semiannual report is required with each year's noncompeting continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project). The second semiannual report is due along with the Financial Status Report (FSR) (see next paragraph) 90 days after the end of each budget period and should cover activities from the date of previous report. Progress reports should address the status of progress toward specific project objectives and should include copies of any publications resulting from the project.

An original and two copies of the FSR are required no later than 90 days after the end of each budget period. A final performance report and FSR are due no later than 90 days after the end of the project period.

Application Process

1. Pre-Application Letter of Intent

In order to assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit application(s) are encouraged to inform CDC of their intention to do so as soon as possible but not later than 10 business days prior to the application due date. Notification should include: (1) name and address of institution; (2) name, address, and phone number of contact person; and (3) which focus area(s) application(s) will be submitted under. Notification can be provided by facsimile, postal mail, or electronic mail (E-mail) to Bala Swaminathan, Ph.D., National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, N.E., Mailstop C–7, Atlanta, GA 30333, Facsimile (404) 639–3333, Internet bas5@cdc.gov.

2. Application Content

Applicants may apply for assistance for projects in one or more of the three separate focus areas identified under PURPOSE and PROGRAM REQUIREMENTS sections. IF APPLICANT IS APPLYING FOR ASSISTANCE FOR MORE THAN ONE FOCUS AREA, A SEPARATE AND COMPLETE APPLICATION MUST BE SUBMITTED FOR EACH FOCUS AREA AND INDICATE WHETHER APPLYING FOR A GRANT OR COOPERATIVE AGREEMENT.

All applicants must develop their application(s) in accordance with PHS Form 398, information contained in this grant/cooperative agreement announcement, AND the attached errata sheet instructions. In order to ensure an objective, impartial, and prompt review, applications must conform to these instructions:

a. General Instructions

1. The original and five (5) complete copies of the application must be UNSTAPLED and UNBOUND.

2. ALL pages must be clearly numbered, and a complete index to the application and its appendices must be included.

3. All typewritten materials must be single-spaced, using a font no smaller than size 12. All supplemental pages of the application (i.e., in addition to the PHS 398 form) must be on the 8 ½″ by 11″ white paper.

4. All pages must be printed on ONE side only, with at least 1″ margins, headers, and footers.

b. Special Instructions

The application narrative must not exceed 10 pages (excluding budget and appendices). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below. (REMINDER: IF PROPOSING PROJECTS UNDER MULTIPLE FOCUS AREAS, SUBMIT A SEPARATE AND COMPLETE APPLICATION FOR EACH PROJECT AND INDICATE WHETHER APPLYING FOR GRANT OR COOPERATIVE AGREEMENT):

3. Abstract

a. Provide a brief (two pages maximum) abstract of the project. Clearly identify:

1. The specific focus area being addressed;

2. The project period proposed (not to exceed three years as indicated in AVAILABILITY OF FUNDS section); and

3. The type of award that is being applied for, grant or cooperative agreement.

4. Background and Need

Discuss the background and need for the proposed project. Demonstrate a clear understanding of the background, purpose, and objectives of the focus area.

5. Capacity and Personnel

Describe applicant's past experience in conducting activities similar to that being proposed. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project. Include *in an appendix* curriculum vitae for all professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project. Provide *in an appendix*, letters of support from all key participating non-applicant organizations, individuals, etc. (if any), which clearly indicate their commitment to participate as described in the operational plan. Do not include letters of support from CDC personnel. Letters of support from CDC will not be accepted. Award of a cooperative agreement implies CDC participation as outlined in the PROGRAM REQUIREMENTS section of this announcement.

6. Objectives and Technical Approach

Present specific objectives for the proposed project which are measurable and time-phased and are consistent with the Background, Purpose, and Recipient Activities for the specific focus area. Present a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses these objectives (if proposing

a multi-year project, provide a detailed description of first-year activities and a brief overview of subsequent-year activities). Clearly identify specific assigned responsibilities for all key professional personnel. Include a clear description of applicant's technical approach/methods which are directly relevant to the above objectives. Describe specific study protocols or plans for the development of study protocols. Describe the nature and extent of collaboration with CDC (if proposing a cooperative agreement) and/or others during various phases of the project. Describe in detail a plan for evaluating progress toward achieving process and outcome project objectives.

7. Budget

Provide a line-item budget and accompanying detailed, line-by-line justification for the first year of the project that demonstrates the request is consistent with the purpose and objectives of this program. If requesting a multi-year project, provide estimated total budget (direct plus indirect) for subsequent years. If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities to be performed by contractor; (4) period of performance; and (5) method of contractor selection (e.g., sole-source or competitive solicitation).

8. Human Subjects

Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, describe adequate procedures for the protection of human subjects. Also, ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (10 Points)

Extent to which applicant demonstrates a clear understanding of the background, purpose, and objectives of the focus area being addressed. Extent to which applicant demonstrates that the proposed project addresses an emerging infectious disease issue of public health importance.

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 participating 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. If requesting a grant (versus a cooperative agreement), the extent to which applicant demonstrates that they can accomplish the project without substantial technical assistance from CDC.

3. Objectives and Technical Approach (45 Points Total)

a. Extent to which applicant describes measurable and time-phased objectives of the proposed project which are consistent with the purpose of the focus area being addressed. (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 programmatic focus area being addressed. 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 feasible, 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. Extent to which applicant clearly describes collaboration with CDC (if proposing a cooperative agreement) and/or others during various phases of the project. If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHHS) regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1) protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the ORG has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable, and (5) protections appear adequate that women, racial and ethnic minority populations are appropriately represented in applications involving human research. (30 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives. (5 points)

4. Budget (not Scored)

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

Executive Order 12372 Review

This program is not subject to Executive Order 12372 Review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the grant/ cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any

component of IHS will be involved or will support the research. If the Native American community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC)and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Application Submission and Deadline

The original and five copies of each application PHS Form 398 must be submitted to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 300, Mailstop E–18, Atlanta, GA 30305, on or before October 1, 1998.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1. a. or 1. b. above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888-GRANTS (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. (Please refer to Announcement Number 99012.) You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie M. Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 314, Mailstop E–18, Atlanta, GA 30305, telephone (404) 842–6546, Facsimile (404) 842–6513, Internet oxb3@cdc.gov.

Programmatic technical assistance may be obtained from Bala Swaminathan, Ph.D., National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, N.E., Mailstop C–07, Atlanta, GA 30333, Telephone (404) 639–3669, Facsimile (404) 639–3333, Internet bas5@cdc.gov.

Please refer to Announcement Number 99012 when requesting information regarding this program.

You may obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the **INTRODUCTION** through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone: (202) 512–1800.

Dated: July 8, 1998.

John L. Williams,

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

[FR Doc. 98–18667 Filed 7–13–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payments in Excess of the Poverty Income Level from a State Program Funded under Part A of Title IV of the Social Security Act.

OMB No.: 0970–0040.

Description: This information is collected to meet the statutory requirements of section 1124 of Title I of the Elementary and Secondary Education Act (as amended by PL 103–382). It is collected by DHHS from State public welfare agencies and turned over to the Department of Education which uses it to arrive at the formula for allocating Title I grant funds to State and Local elementary and secondary schools for the purpose of providing educational assistance to disadvantaged children.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–4125	52	1	264	13,746