Respondents (hospitals)	Number of respondents	Number of responses/respondent	Avg. rurden/response (in hrs)	Total burden (in hrs)
Update Form (Abstract Service Hospitals)	175	2	.03333	12
Quality Control Forms	50	40	.01667	33
Induction Forms	15	1	2	30
Total				2,465

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–16751 Filed 6–30–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99149]

Changing Antimicrobial Prescribing To Reduce Antimicrobial Resistance in Hospitalized Patients; 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 Changing Antimicrobial Prescribing to Reduce Antimicrobial Resistance in Hospitalized Patients. This program addresses the ''Healthy People 2000'' priority area(s) of Immunization and Infectious Diseases.

The impact of antimicrobial resistant infections on patients is considered to be substantial, and the societal cost to the United States (U.S.) has been estimated to be as high as $4 Billion each year. Hospitalized patients are at greatest risk of acquiring these resistant infections. An increasing number of hospitals and other healthcare facilities are reporting the presence of antimicrobial resistant bacteria each year. The knowledge that a defined program to change antimicrobial prescribing activity will reduce the incidence of these infections will benefit all U.S. hospitals in their battle against antimicrobial resistant infections. The proposed study in this program announcement will impart such knowledge to the infection control and hospital community.

The purpose of the program is to assist U.S. healthcare institutions and public health agencies in evaluating the impact of changes in antimicrobial prescribing on the incidence of antimicrobial resistance and other health outcomes among hospitalized patients. Recipients of this award will form a collaborative network of researchers, using similar methodology to allow aggregation of surveillance data from all sites into a multi-site study. The change in antimicrobial prescribing would be considered a part of routine medical practice for the selected patient population groups. Evaluating the impact of routine cycling of available select antimicrobial agents for empiric therapy is the top priority for this collaborative network. Results of this multi-site study will provide other U.S. hospitals with guidance to implement programs to reduce antimicrobial resistance at their institutions. The objective of this program is to measure (see recipient activities) the change in incidence and prevalence of patient colonization and infection with select antimicrobial resistant bacteria of epidemiologic concern in the following scenario:

1. During a time of altered antimicrobial prescription activity (specifically the routine cycling of available antimicrobial agents).

2. In a (1) medical intensive care unit and (2) other target patient population group(s) (e.g., trauma intensive care unit, transplant patients, diabetic patients, etc.).

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 or for-profit organizations participating in the healthcare delivery to patients in hospitals. These hospitals must fulfill the following criteria and provide appropriate documentation (see application instructions) in the application:

1. Have >250 licenced beds.

2. Have a medical intensive care unit in which a limited number (i.e., 1–4) of attending physicians have ultimate responsibility for patient care in that intensive care unit during a typical month (*i.e.,* a closed unit).

3. Have ongoing surveillance in the medical intensive care unit of two types: (1) nosocomial infections and (2) rectal (or stool) surveillance cultures, on admission or at some standard period, for some antimicrobial resistant bacteria.

4. Have access to a clinical microbiology laboratory which can demonstrate proficiency at:

a. Identifying extended-spectrum ''β-lactamase producing enterobactericea.

b. Maintain viable frozen specimens from surveillance samples.

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 $200,000 is available in FY 1999 to fund approximately 3 awards. It is expected that the average award will be $80,000, ranging from $60,000 to $100,000. It is expected that the awards will begin on or about September 30, 1999 and will be made for a 12-month budget period within a project period of up to 3 years. The funding estimate may change.

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

Funding Preferences

To achieve appropriate geographic representation of the study network, funding preference may be given to approved applications that would enhance the geographic diversity of the network (e.g., network ideally comprised of sites from different cities or states).

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 consensus among appropriate patient-care, pharmacy and infection control personnel towards

changing antimicrobial prescribing practices in (1) the medical intensive care unit, and (2) a second target patient population group (e.g., trauma intensive care unit, respiratory care unit, other). Implement this change in antimicrobial prescribing practice, specifically a cycling program. Characteristics of the cycling program should include cycling between classes of agents with similar spectrum of coverage available for empiric treatment of patients at a defined interval. This should also include provisions to ensure the safety of all patients affected by this change in medical practice, and maintain the spirit of a multi-center study as part of a collaborative network.

b. Prior to and during the periods of changes in antimicrobial prescribing,

1. Enhance existing surveillance activities in the medical intensive care unit including routine rectal or stool cultures on all patients upon admission to the unit in a manner to minimize laboratory burden and maximize ability to detect colonization with target organisms upon admission and before discharge from the unit. This may include combining data with results of routine clinical cultures of eligible patients.

2. Obtain basic demographic, severity of illness, exposure, and outcome data on patients in the intensive care unit.

c. Monitor antimicrobial use in the medical intensive care unit and second target patient population group. Document changes in dispensed antimicrobials throughout the study period.

d. Demonstrate infection control activities remain similar throughout the study period (i.e., barrier precautions, hand washing frequency) through periodic observational studies of healthcare workers in the target patient population group.

e. Obtain technical assistance, if needed.

f. Monitor and evaluate scientific and operational accomplishments and progress in achieving the purpose of this program.

g. Participate in the development of a research protocol for IRB review by all cooperating institutions participating in the research project.

h. As part of the study network manage, analyze, and interpret surveillance and observational data; provide select data for aggregation among study network; publish and disseminate important information in collaboration with the study network.

2. CDC Activities

a. Provide consultation, scientific and technical assistance in protocol development and in general operation of the study network. The CDC IRB will also review and approve the protocol initially and on at least an annual basis until the research project is completed.

b. Participate in analysis and interpretation of aggregate surveillance data from study network.

c. Assist in monitoring and evaluating scientific and operational accomplishments of the study network and progress in achieving the purpose and overall goals of this program.

d. As needed, perform laboratory evaluation of specimens or isolates (e.g., molecular epidemiologic studies, evaluation of diagnostic tools) obtained as part of this program.

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.

Applications should address the following topics in the order presented:

1. Understanding the objectives of the study network and program.

2. Description of the target population groups.

3. Description of existing capacity. There are several things applicants could do to document their capacity to perform the recipient activities:

a. Demonstration of capacity to alter physician prescribing activity in an intensive care unit may include (in decreasing order of strength):

1. Previous publication (peer-reviewed or abstract) of a trial of routine cycling of antimicrobial agents in an intensive care unit (in appendix).

2. Photocopies of memorandum or internal documents which cite the successful institution of an antimicrobial control program in the intensive care unit (in appendix).

3. Letters of support from pharmacy, critical care, or infectious disease departments which cite that alteration of prescribing activity in an intensive care unit has been (or is planned to be) accomplished (in appendix).

b. Provide in an appendix to the application a list of the rates of antimicrobial resistance among the bacteria listed in the eligibility criteria (from routine clinical cultures or surveillance cultures) among patients in the medical intensive unit or the hospital.

4. Operational plan. This should include a description of the change in antimicrobial prescribing (i.e., description of best possible cycling practice based on relevant surveillance data and patient population)

5. Evaluation plan.

6. Budget.

7. Appendix.

Applicant's operational plan should clearly address all recipient activities. The narrative (excluding budget, budget narrative, appendices, and required forms) should be no more than 20 double-spaced pages, printed on one side, with one inch margins, and unreduced font (10 or 12 point). The following information should be presented in appendicies: Letters of support or memorandum (see application content above), curricula vitae (CV) of co-investigators, and budget. Also, for purposes of meeting the eligibility requirement, there are several means in which applicants may provide documentation of eligibility in the appendix:

1. Demonstrate the medical intensive care unit is a closed unit (i.e., a unit in which a limited number of physicians are responsible for patient care in that unit) by submitting a letter from the appropriate department describing which clinicians have primary responsibility for patient care in the medical intensive care unit.

2. Demonstrate ongoing surveillance of nosocomial infections or antimicrobial resistance in the medical intensive care unit by submitting a letter from the infection control department describing the type of surveillance currently performed in the medical intensive care unit, including any surveillance cultures done routinely.

3. Provide letter of support from the microbiology or infection control laboratory describing the laboratory capacity to perform the necessary functions listed in the eligibility criteria. Including capacity to change antimicrobial prescribing activity in the target population groups, and capacity to obtain and aggregate surveillance data (see application instructions).

In addition, documentation of relevant accomplishments, such as abstracts, manuscripts, or bibliographies may be included in appendices. Information that should be included in the narrative will not be accepted if placed in the appendices.

Budget Instructions: For each staff member listed under the Personnel line item, indicate their specific responsibilities. All other line-items should also be clearly justified.

F. Submission and Deadline

Letter of Intent (LOI)

All eligible parties intending to submit an application are requested to

inform CDC of their intention to do so by submitting a brief LOI no later than July 15, 1999. The purpose of the LOI is to assist CDC in timely planning and administration of the evaluation process. The LOI should be a brief notice that (1) identifies the applicant organization, and (2) provides the name, address, and telephone number of a contact person. LOI should be submitted to the technical assistant contact identified in ''where to obtain additional information'' section of this announcement.

Application

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189) Forms are in the application kit. On or before August 15, 1999 submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

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 by Grants Management office in time for scheduled review. (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.)

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

G. Evaluation Criteria

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

1. Understanding the objectives of the program (5 points) a. Demonstration of a clear understanding of the background and objectives of this cooperative agreement program.

b. Demonstration of a clear understanding of the requirements, responsibilities, and complexities that may be encountered in participating in this study network.

2. Description of target population groups involved in the program activities, including a medical intensive care unit and another population group. (5 points)

3. Description of existing capacity to perform enhanced surveillance during a period of changing antimicrobial prescribing activity in the target patient-populations. (40 points). a. Description of applicants past experience and documentation of accomplishments in conducting active surveillance, applied epidemiologic research, applied laboratory research, and prevention research on the incidence of nosocomial infections and/or antimicrobial resistant pathogens. (A list of relevant papers and abstracts should be included in the appendix, as well as the CV for all key professional personnel). (10 points)

b. Description of applicant's past experience and documentation of accomplishments in changing prescribing activity in an intensive care unit (e.g., previous experience with routine cycling or antimicrobial agents), and demonstrate the capacity to alter physician prescribing activity as a part of this study (see application content for suggested documentation criteria). (13 points)

c. Description of applicants past experience of collecting and aggregating surveillance data, including documentation (see application content) that susceptibility profiles of clinical isolates from medical intensive care unit patients include ≥2 of the following: (1) the proportion of Enterobacter cloacae resistant to ceftazidime or cefotaxime or ceftriaxone is >25%, (2) Pseudomonas aeurginosa isolates resistant to imipenem is >10%, (3) Klebsiella pneumoniae resistant to ceftazidime is >5%, and/or Acinetobacter baumanii resistant to ceftazidime is >20%. (10 points)

d. Demonstration of support from non-applicant participating departments, laboratories, individuals, or consultants, indicated in applicant's operational plan. Applicant should provide (in an appendix) letters of support which clearly indicate collaborators' willingness to be participants in the study network. Do not include letters of support from CDC personnel. (5 points)

e. Statements supporting applicant's ability to participate in a multi center collaborative network (2 points).

4. Operational plan (45 points). a. The extent to which the applicant's plan for establishing and maintaining the enhanced surveillance for antimicrobial resistant bacteria clearly describes the (1) proposed organizational and operative structure/procedures, (2) clearly identifies the roles and responsibilities of all participating departments or individuals, and (3) addresses each of the recipient activities. (15 points)

b. The extent to which the applicant describes plans for collaboration with CDC and the other members of this study network in the establishment and operation of the multi-center study described in this programs objectives, including project design/development, management and analysis of data, and synthesis and dissemination of findings. (10 points)

c. Description of consensus building process, which is ongoing or planned, to change prescribing practices in the target patient-population as a part of routine change in medical care (i.e., cycled availability of antimicrobial agents), and appropriateness of the described cycling program to alter the target pathogens as documented in that unit (see attachment I). (15 points)

d. 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 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; (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. (5 points)

5. Evaluation (5 points). Quality of a plan for monitoring and evaluating progress in achieving the purpose and overall objectives of this cooperative agreement program.

6. Budget (not scored). Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program. Extent to which applicant shows federal and non-Federal (e.g., State or Private Funding) shares of total cost for program.

7. Human Subjects (not scored). Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports. The first semiannual report is required with each year's continuation application and should cover program activities from beginning of the current budget period to the date of report/application preparation. The second semiannual report is due 90 days after the end of each budget period and should cover activities for the entire budget period recently completed. This second report

may simply be a ''cut/paste'' update of the first semiannual report to add information from date of first report to the end of the budget period.

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

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

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following other requirements are also applicable:

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

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Public Health Service Act, Section 301(a) [42 U.S.C. 241(a)], 317(k)(1) [42 U.S.C. 247b(k)(1)], and 317(k)(2) [42 U.S.C. section 247b(k)(2)], as amended. The catalog of federal domestic number is 93.283.

J. Where To Obtain Additional Information

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. See also the CDC home page on the Internet for information of programs and grants: http://www.cdc.gov

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Oppie Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99149, Centers for Disease Control and Prevention (CDC). 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone (770) 488–2748, Email address: oxb3@cdc.gov.

For program technical assistance, contact: Scott Fridkin, M.D., Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, MS E–55, Atlanta, GA 30333, Telephone number: (404) 639–6417, Email address: skf0@cdc.gov.

Dated: June 25, 1999.

John L. Williams,

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

[FR Doc. 99–16759 Filed 6–30–99; 8:45 am]

BILLING CODE 4163–18–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cancer Advisory Panel for Complementary and Alternative Medicine, Thursday, July 8, 1999, to Friday, July 9, 1999, Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814 which was published in the **Federal Register** on June 21, 1999, 64 FR 33105.

The public comments session is scheduled on July 9, 1999, from 11:00 am to 11:30 am.

Dated: June 24, 1999.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 99–16697 Filed 6–30–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel.

Date: July 22–23, 1999.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, One Metro Center, Bethesda, MD 20814.

Contact Person: Ken D. Nakamura, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301–402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: June 24, 1999.

Anna Snouffer,

Acting Committee Management Officer, NIH.

[FR Doc. 99–16698 Filed 6–30–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel.

Date: July 12–13, 1999.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ken D. Nakamura, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301 402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: June 24, 1999.

Anna Snouffer,

Acting Committee Management Officer, NIH.

[FR Doc. 99–16699 Filed 6–30–99; 8:45 am]

BILLING CODE 4140–01–M