Instructions for Applying for Administrative Supplements to Funded R01, P01, P50 Grants and U01 and U19 Cooperative Agreements

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Supplement Title:	Dissemination of Surveillance Research Findings
Available Funds:	$300,000
Request Receipt Deadline:	May 30, 2006
First Possible Award Date:	September 1, 2006

Eligibility Requirements

Requests for administrative supplemental funding may be submitted by National Cancer Institute (NCI)-funded cancer control intervention research RO1, P01, P50, U01, and U19 grantees (domestic applicant institutions only), as long as the following conditions are met:

1. The focus of the parent award grant is related to the focus of the dissemination of surveillance research supplement that is being proposed;
2. There are no funds in the parent award related to the proposed dissemination of surveillance research findings effort;
3. There must be an active parent grant during the entire funding period of this supplement; and
4. The Principal Investigator (PI) for the supplement must be the PI of the parent grant.

Foreign institutions and organizations are not eligible under this supplemental funding initiative.

Investigators who have contracts in surveillance research are encouraged to identify and collaborate with investigators with active grants in this area. Contracts are not eligible for supplements under this mechanism. The following links may be helpful:

1. Active Cancer Control Research Grants: http://cancercontrol.cancer.gov/grants/query.asp
2. Identify Research Partners through Cancer Control PLANET: http://cancercontrolplanet.cancer.gov/

Research Objective

The purpose of these administrative supplements is to fund the dissemination of promising surveillance research findings that have been developed and/or tested in the original R01, P01, P50, U01, or U19 (Type 1) project. These supplements have been designed to provide 1-year funding to cancer control investigators who are conducting peer-reviewed research (with an active NCI grant award) related to the surveillance of cancer throughout the cancer control continuum, including, but not limited to: risk factors, screening, cancer rates, treatment, and outcomes. Areas of surveillance research across the cancer control continuum that may be eligible for these supplements, include but not limited to: tobacco use; diet and physical activity patterns; sun exposure and ultraviolet (UV) radiation exposure; use of chemopreventive agents; use of genetic testing for cancer susceptibility; use of screening for breast, cervix, and colorectal cancers; cancer rates, morbidity and mortality; cancer treatment and patterns of care; and cancer outcomes.

Examples of research objectives for the surveillance supplements may include:

- Testing strategies for applying surveillance data to problems in cancer-related policy, programs, and practice across the cancer continuum.
- Communications research to test different ways to "tell compelling stories" with surveillance research data.
- Improving strategies for the dissemination of surveillance research tools and data, including:
    - The development and evaluation of tools for communication and education to new audiences who may benefit from the knowledge of surveillance research tools and data;
    - The development of new methods for analyzing surveillance data to be directly applicable to developing policy, programs, and practice in specific communities, practice areas, or populations;
    - The development of data use tools or training venues for increasing the use of surveillance tools and data;
    - Developing and/or testing methods for educating communities on the use of surveillance research to improve cancer-related policy, programs, and practice in their communities

Funds Available

The NCI intends to commit approximately $300,000 in FY 2006 to fund from 2-3 administrative supplements in response to this initiative. An applicant may request a project period of one year and a budget for total costs of up to $100,000 per year. Applications specifically designed to provide data for larger, future investigator initiated grants are also encouraged. Although the financial plans of the NCI provide support for this program, administrative supplement awards pursuant to this initiative are contingent upon the availability of funds and the receipt of a sufficient number of meritorious requests.

Application Procedure

P01 and U19 grantees must identify the individual project for which they are seeking supplemental funds. Multiple requests from P01 and U19 grantees are acceptable. However, separate supplement requests must be submitted for individual components of the parent P01 or U19 grant.

All requests must include the following:

a. Cover letter:
   Request the supplement and identify this program.
   - If applicable, state intent to submit a request for a no-cost extension.
   - Include the following statement: "Per supplement instructions, a detailed budget request is enclosed."

b. PHS 398 Cover page:
   - Item 1: The request must have the same title as the parent grant. Please include the number of the parent grant.
   - Item 2: Identify as "Administrative Supplement."
   - Item 3: The request must have the same PI as the parent grant.
   - Item 4: Request a single year of support. There must be an active parent grant during the entire funding period.

c. Detailed Budget of Initial Budget Period (PHS 398, Form 4)
   - All applicants can request up to $100,000 in total costs per year and must provide a detailed budget.

d. Research Plan
   Provide a description of the pilot work or proposed dissemination and evaluation plan and how it relates to the surveillance research findings in the parent grant. This description should include an introduction, surveillance research findings justifying dissemination, relevance to target populations and settings for dissemination, proposed dissemination theory, strategies and methodology (all of the preceding incorporating new findings in the field since the intervention study was completed), procedures to assess dissemination program effectiveness, and plans to sustain effective dissemination approaches once the supplement funding period has ended (not to exceed 12 pages).
   - Dissemination and evaluation plan needs to be informed by dissemination theories and include process measures tracking dissemination plan components.

- If the parent grant is a U01 or U19 cooperative agreement award, explain how the project will fit within the U01/U19 cooperative agreement terms and conditions of award.

The following materials should also accompany the request:

1. Surveillance research findings and/or manuscripts must be provided.
2. Include individual biosketches for key personnel.
3. Include relevant letters of support from key partner organizations, which plan to use the surveillance research findings specify how the surveillance data may be used.

Requests should contain enough detail to allow assessment of the scientific merit of the proposed surveillance research dissemination and dissemination evaluation plans and the appropriateness of the request for supplemental funding. Budgets should not exceed $100,000 in total costs for a time period not exceeding 12 months. All requests require an itemized budget and must be signed by the grantee institution's business office. Requests for administrative supplements under this program must comply with NIH policies for inclusion of women, minorities, and children in research involving human subjects. (See later section for information regarding new policies.)

The earliest anticipated award date for this program will be September 1, 2006. Inquiries related to this notice should be addressed to the NCI Program Director for the particular R01, P01, P50, U01, or U19 for which the supplement is being requested. Applicants are ENCOURAGED to discuss the efficacy data (e.g., effect sizes, consistency with prior research, relevance to target populations) supporting their administrative supplement request from the original project with their respective NCI research project Program Director prior to submission.

Submission of Administrative Supplement Request

Submit a signed, typewritten original of the request, as well as five copies of the request and five copies of all required accompanying program materials, publications, biosketches, and letters of support, in one package to:

Emily Dowling
Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Blvd., EPN Room 4111
Bethesda, MD 20892
Rockville, MD 20852 (for express/courier service)

REQUESTS HAND-DELIVERED BY INDIVIDUALS TO THE NATIONAL CANCER INSTITUTE WILL NOT BE ACCEPTED. This policy does not apply to courier deliveries (i.e., FEDEX, UPS, DHL, etc.)
(http://grants.nih.gov/grants/guide/notice-files/NOT-CA-02-002.html).

Review Considerations

Upon receipt, requests will be reviewed for completeness and for responsiveness by the NCI. Incomplete and/or non-responsive requests will not be considered.

Administrative supplement requests that are complete and responsive to the supplement announcement will be evaluated for scientific and technical merit by NCI program staff (and other appropriate persons and selected outside consultants) who have expertise in the cancer control surveillance area and/or dissemination and diffusion research) in accordance with the review criteria stated below. Only those requests that describe research deemed to have the highest scientific merit will be considered for funding.

Review Criteria

The goal of NCI-supported dissemination (administrative) supplements is to advance our understanding of effective strategies to encourage dissemination and utilization of surveillance research findings for program and policy decisions. The purpose is to improve the control of disease and enhance health. The staff and consultants will evaluate the following aspects of the administrative supplement requests in order to judge the likelihood that the proposed project will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered by the reviewers, weighting them as appropriate for each request. The administrative supplement request does not need to be strong in all categories in order for it to receive a favorable evaluation. For example, an investigator may propose to carry out important work that, by its nature, is not innovative, but is essential to move a field forward.

The five categories of review criteria to be used in the evaluation of these administrative supplement requests are listed below.

1. Significance. Do the surveillance research findings justify dissemination? Does the dissemination of the proposed surveillance findings address an important cancer control problem? If the aims of the proposed project are achieved, how will dissemination and the use of surveillance findings be advanced? What will be the effect on the concepts or methods that drive this field? Does the pilot work show promise for dissemination?
2. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the surveillance data that are proposed for dissemination? Has the applicant made appropriate updates of the surveillance research findings based on the most current data? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the applicant demonstrate an understanding of dissemination principles? Is the dissemination approach appropriate to the problem and population? Are the procedures to assess the dissemination of surveillance research findings appropriate? Is the evaluation plan linked to the dissemination plan and does the evaluation incorporate the best available data to track dissemination process and impact (within the limits of temporal and

budgetary constraints)? How appropriate are the plans to sustain effective dissemination approaches once the supplemental funding period has ended? Is the pilot work likely to result in a subsequent proposal?

3. Innovation. Does the proposed dissemination of surveillance research findings employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the intervention that is proposed for dissemination challenge existing paradigms or develop new methodologies or technologies? Is the pilot likely to develop an innovative line of research?
4. Investigator. Is the investigator appropriately trained and qualified to carry out this work? Does the investigator team include specific dissemination expertise? Relevant letters of support from key partner organizations, which may plan to use the surveillance research findings, are required.
5. Environment. Does the environment in which the dissemination work will be done contribute to the probability of success? Do the proposed approaches take advantage of unique features of the information delivery environment or employ useful, collaborative arrangements? Is there evidence of institutional support?

To assess the potential for sustainable use of the surveillance research findings by the target population, the initial review also will examine the administrative supplement requests for demonstration of the following items: the appropriateness of proposed project budget and duration; and the adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the goals of the dissemination plans. Finally, the provisions for the protection of human subjects and the safety of the intervention environment will be examined.

Award Criteria

Requests for administrative supplements submitted to the Division of Cancer Control and Population Sciences, NCI, will be considered for award based upon the following considerations: (a) scientific and technical merit; (b) program relevance; (c) dissemination potential; (d) balance of cancer control surveillance topics; and (e) availability of funds. Special consideration will be given to requests that involve plans plan to disseminate surveillance research information concerning low income and ethnically diverse populations.

Required Federal Citations

ALL REQUIRED FEDERAL CITATIONS for PHS grants apply to this administrative supplement including the following:

Human Subjects Protection:
Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); and efficacy, effectiveness, and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State, and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be

included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Public Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are: (1) first produced in a project that is supported in whole or in part with Federal funds; and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations:

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Inquiries

Direct inquiries concerning the dissemination supplements and administrative review matters to:
Jon F. Kerner, Ph.D.
Deputy Director for Research Dissemination and Diffusion
Division of Cancer Control and Population Sciences
6130 Executive Boulevard, EPN Room 6144
Bethesda, MD 20892-0001 (for U.S. Postal Service express or regular mail)
Rockville, MD 20852 (for express/courier delivery)
Telephone: 301-594-7294
E-mail: jon.kerner@nih.gov

Direct inquiries regarding fiscal matters to:
Ms. Crystal Wolfrey
Office of Grants Administration
6120 Executive Boulevard, EPS Room 243
Bethesda, MD 20892-7150 (for U.S. Postal Service express or regular mail)
Rockville, MD 20852 (for express/courier delivery)
Telephone: 301-496-8634
E-mail: crystal.wolfrey@nih.gov