

Cooperative Institute for
Coastal & Estuarine Environmental Technology

Proposal Preparation Guide

Funding Opportunity:

Technologies to Assess Human Health Risks at Swimming Beaches



FY 2007 Environmental Technology Development Program

October 12, 2006

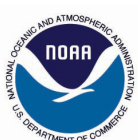


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Ask Us

Feel free to call CICEET with questions about any aspect of this RFP. Clarifying the requirements of each funding opportunity before you submit will improve your proposal's chance of success.

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The deadline for receipt of your proposal by CICEET is 1 p.m. (1300 hours), EST, on December 12, 2006.

1) About CICEET

The Cooperative Institute for Coastal and Estuarine Environmental Technology (CICEET) develops and applies tools for clean water and healthy coasts nationwide. CICEET is a partnership of the National Oceanic and Atmospheric Administration (NOAA) and the University of New Hampshire (UNH).

As a needs-based organization, CICEET works with coastal resource managers around the country to identify their priority environmental challenges. Then we analyze the obstacles—technical, social, political, and regulatory—that stand in the way of solutions.

If this analysis reveals that new or enhanced technology would help address a problem, CICEET designs a targeted competitive funding opportunity to meet this need. Investigators funded by CICEET must collaborate with the coastal management and regulatory communities to insure that their work stays focused on end user needs.

Tools created through CICEET funding opportunities are made available through training, outreach, and an evolving technology utilization program. CICEET has invested in more than 150 environmental technology development and demonstration projects since its inception in 1997. You can learn more about these projects on CICEET's Project Explorer: <http://ciceet.unh.edu>

While its administrative offices are located on the UNH campus in Durham, N.H., CICEET sponsors technology development in coastal states nationwide—primarily through its relationship with the National Estuarine Research Reserve System (NERRS). Many projects funded through CICEET are connected to one or more of the 27 NERRS sites or their watersheds.

Learn more at <http://ciceet.unh.edu>

2) About this RFP

The Cooperative Institute for Coastal and Estuarine Environmental Technology (CICEET) invites proposals to its Environmental Technology Development (ETD) Program for funding in FY 2007. Through this program, CICEET makes strategic investments in the development, demonstration, and application of tools to detect, prevent, and reverse the impacts of coastal pollution and habitat degradation to coastal ecosystems and communities.

This Request for Proposals (RFP) is open to U.S. scientists and innovators from academia, private industry, and the public sector who seek to develop tools that meet the priority needs of coastal management. Those familiar with CICEET's previous funding opportunities will note that research priorities presented here are more specific than those in the past. This reflects CICEET's new approach to RFP development, one that incorporates an analysis of the technical and non-technical factors that influence coastal management problems.

Research priorities for FY 2008 are under development, and we welcome your input! Please contact us with ideas for research priorities to consider for future RFPs:

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3) Funding Opportunity Description

CICEET invites proposals for one-year technology demonstration projects to participate in the Doheny Beach Epidemiology study planned by the Southern California Coastal Water Research Project (SCCWRP).

The goal of this effort is to improve our ability to protect public health at swimming beaches. To this end, the study will evaluate the effectiveness of fecal indicator-based methods that monitor beach water quality, and technologies that identify the sources of contamination. At the same time, it will examine how well results generated by these methods correlate with public health effects in swimmers.

This endeavor has significant management implications for the closing and reopening of beaches and the creation and revision of Total Maximum Daily Load (TMDL) standards. Further, it is an opportunity for researchers in the public sector, academia, or industry to better understand how well their technologies/methods correlate with observed health effects in swimmers.

Up to \$750,000 will be available for CICEET's funding opportunity related to this study. The number of projects funded will depend on available resources and the relative merit of proposals, as determined by a technical panel. Pending research project results, there may be "Phase 2" funding for selected projects to participate in SCCWRP's 2008 epidemiology activities.

4) Funding Priorities

CICEET's mission is to develop and apply effective, accessible technology that coastal resource managers nationwide can use to address their highest priority environmental challenges. Consequently, we will give preference to proposals that demonstrate the following:

- Focus on mature methods and technologies with documented performance characteristics;
- Demonstrate a reasonable expectation of linking results to health risk;
- Potential to address common logistical and budgetary constraints faced by managers around the country in the context of routine beach monitoring.

5) Research Priorities

CICEET will accept proposals that address one or more of the following three research priorities:

A. Demonstration of technologies or methods using "alternative" indicators of fecal pollution to predict health risks at swimming beaches. "Alternative indicators" are defined as those other than the U.S. EPA-recommended *Enterococcus spp.* for marine waters, and *Escherichia coli* for freshwater. Examples of alternative indicators, include but are not limited, to *Bacteroides*, various species within *Enterococcus spp.*; and viruses or other direct measures of pathogens.

Determining which viral pathogens are responsible for negative health effects in swimmers is beyond the scope of the SCCWRP study and this RFP. Rather, the goal is to consider viruses or other alternative measures as indicators of fecal pollution and health risk. Proposals addressing viruses should also include objectives related to improving the recovery of sufficient numbers of viruses (e.g., pre-concentration of samples), a historically challenging aspect of using viruses as indicator organisms.

B. Demonstrate technologies or methods, including those that are *in situ* or field-based, to quantify fecal indicators in a more timely manner than traditional methods. Projects should seek to enable, at a minimum, same-day management decisions.

C. Demonstrate practical, cost-effective microbial source identification tools that complement and add insight to the planned epidemiology study, CICEET research priorities A and B, as well as the SCCWRP activities outlined in the following section. These methods/technologies should have the potential for national application.

Fecal indicators can come from many different sources, and health risks associated with an indicator differ depending on the source. In this study, microbial source identification tools will be used to modify indicator measurements to further clarify the relationship between current indicator-based approaches, new indicator methods, and swimming-associated health effects. Applicants addressing this research priority must justify their approach given this overarching context.

6) What to Expect from SCCWRP

The epidemiology study will be conducted by SCCWRP in partnership with the University of California at Berkeley. The study will be a prospective cohort design in which approximately 35,000 swimmers will be monitored for water exposure while at the beach, and surveyed for 14 health symptoms over the following two weeks. The first year of the study will be conducted at Doheny Beach, located at the mouth of the San Juan Creek watershed in Dana Point, California. The primary contamination source at this site is nonpoint source runoff from the creek. Some portion of the beach failed state water quality standards 358 days in 2003.

While writing proposals for the CICEET RFP, applicants should keep in mind that SCCWRP will perform the following activities related to their projects:

- SCCWRP will begin sample collection in late May 2007. They will collect, filter, and send all water samples to CICEET investigators. Each investigator is expected to receive approximately 324 samples. Please do not include costs of collection, filtration, and shipping of samples in your proposed budget.
- SCCWRP will conduct traditional, U.S. EPA-recommended assays as a comparison with the alternative approaches being demonstrated. Do not include these activities in your proposals.
- At the study's completion, SCCWRP will produce a publishable epidemiological analysis. Any peer-reviewed articles that result from the analysis will include participating researchers as authors. The publication of articles outside the immediate scope of the epidemiological analysis will be at the discretion of the collaborating researchers.
- SCCWRP and CICEET will disseminate information regarding the study's results. While CICEET strongly encourages all of its proj-

ect investigators to conduct outreach related to project activities, we ask that you do not include dissemination or outreach as a funded activity in your proposal.

7) Eligibility

This RFP is open to investigators from United States academic institutions, state and local government agencies, non-governmental organizations (NGOs), and the private sector. Researchers from institutions outside the United States may be included as additional investigators, but cannot be principal investigators.

Federal agency personnel—including those from NOAA—are eligible if they can document statutory authority to supplement their appropriations with funds from other federal programs and entities. In some cases, obtaining this documentation can take time, so CICEET encourages such applicants to plan ahead. Federal applicants may not request salary compensation. Private-sector applicants may not include fee or profit in their budget requests.

Please note: CICEET will not accept proposals from CICEET investigators who have failed to submit final reports for completed projects, or progress reports for ongoing work.

8) Intellectual Property

In some instances, commercialization is the most efficient means of disseminating knowledge or technology. In others case, however, a non-commercial approach may be more appropriate.

Since the dissemination pathway is often not clear at the outset of a project, CICEET strongly suggests that you take the following steps to protect your technology's intellectual property at the proposal stage. By doing this, you will be able to talk freely about your invention and avoid the inadvertent loss of intellectual property rights.

Step 1: Take steps to protect your intellectual property as soon as possible so that you can discuss your research with colleagues in a manner that does not restrict your ability to choose the most appropriate dissemination path. If you receive funding, CICEET will ask you to discuss your research at a meeting with colleagues, coastal managers and industry representatives.

Step 2: Do not make assumptions about the commercialization value of your work. In our experience, researchers often make assumptions about the intellectual property process that are inaccurate.

Step 3: Talk to your institution's Office of Technology Transfer, or its Office of Intellectual Property. Determine the proper approach to intellectual property protection for your technology. This could include any of the following: prior-art research and determination of patentability; pursuit of "confidential and proprietary information"; pursuit of copyright; or no intellectual property protection steps whatsoever. (Note: The title page you download from this site comes with a confidentiality statement. Please review it and contact us with any questions.)

Step 4: Until talking with one of the specialists recommended in Step 3, do not disclose your idea in a public setting. "Disclosure" entails giving enough information—verbally or in written/graphic form—for a person "skilled in the art" to reproduce your invention.

9) Proposal Preparation

CICEET has prepared the following guide to submitting proposals for this funding opportunity. Please review the "What to expect from SC-CWRP" section of this RFP before you prepare this application. Each proposal must include the following:

- A) *Title page*
- B) *Abstract*
- C) *Narrative*
- D) *Investigator curriculum vitae*
- E) *Appendix of literature cited*
- F) *Budget forms*

A) *Title page*

CICEET requires all title pages to be in a standard format. Please use the form provided on the CICEET website: http://ciceet.unh.edu/rfp_2007/rfp_forms.html

B) *Abstract*

On a separate page, provide a one to two paragraph abstract summarizing the salient points of the proposal, including objectives, methods and expected outcomes.

C) Narrative

Narratives are not to exceed 15 single-spaced pages with one-inch margins. They must be formatted in "Times" 12-point font. Narratives must include the following elements:

1) Introduction: Clearly identify which Research Priorities (A through C) in this funding opportunity you plan to address with your project. Explain how your project addresses CICEET's "Funding Priorities" for this RFP. Briefly discuss how the methods you propose compare with other approaches to beach water quality monitoring.

2) Objectives: Outline your project's objectives and how they relate to one or more of the research priorities (A through C).

3) Methods: Describe the methods you will use to meet project objectives. You may use this section to expand on how the methods in this proposal compare with traditional and other alternative methods. You should include the following:

- Performance characteristics such as accuracy, precision, and specificity;
- Detailed information on sample analysis, including steps for quality assurance/control;
- Timeline for executing project;
- Demonstration of familiarity with the SCCWRP study and its location, Doheny Beach, CA;
- Identification of any cost-sharing activities, i.e., those related to the project, but not included in the CICEET budget request.

4) Usefulness to Management: Discuss the potential impacts of the proposed research, as it relates to beach water quality management. If successful, other scientists or managers may want to replicate your approach. Please discuss issues of practicality, such as cost per sample, level of technical ability required to implement the approach, and other logistical considerations. Applicability to other geographic regions should also be addressed.

5) Roles and Responsibilities: Describe the roles and responsibilities of the project participants.

6) Budget Justification: Please provide a detailed budget justification that explains the separate items in the budget file. Please note that funding for this RFP is limited. Therefore, methods that are less proven will need to demonstrate increased levels of cost-sharing.

7) Survey Question: CICEET would like to make its extramural research funding competition as user friendly as possible. Your answer will not impact the assessment of your proposal and will help us improve our RFP for future applicants.

On a scale of 1 to 5 (5 being the most favorable score), please rate this RFP document in terms of the following question: Did you have sufficient information and support to prepare your proposal?

Additional comments/suggestions are very welcome!

D) Investigator curriculum vitae

Please limit to two pages

E) Appendix of literature cited

F) Budget form

Please use the budget form provided for this funding opportunity. See http://ciceet.unh.edu/rfp_2007/rfp_forms.html

10) Submission

The deadline for receipt of your proposal by CICEET is 1 p.m. (1300 hours), EST, on December 12, 2006.

Your initial submission MUST be in electronic form, not a hard copy. After the deadline, applicants will be prevented from submitting proposals and will receive an automated reply that CICEET is no longer accepting submissions.

Please send your proposal as a single PDF attachment in an e-mail to submissions@ciceet.unh.edu

If you have questions about converting documents from common formats to PDF, please contact CICEET. Note that proposals sent in any other file format will NOT be accepted.

You must also send one signed hard copy of your proposal that includes documentation of your institution's federally negotiated indirect cost rate and contact information for the sponsored research office at your institution. The postmark must not be later than Tuesday, December 19, 2006. Please mail this to CICEET's Program Coordinator:

Cindy Tufts
Gregg Hall, Room 130
35 Colovos Road
University of New Hampshire
Durham, NH 03824-3534

You will receive notification of CICEET's proposal evaluations and decisions by early February 2007. Please note that the panel may elect to recommend that a proposal be awarded funds contingent on clarification or changes to the proposal. Due to the immovable deadline represented by the initiation of the epidemiology study, CICEET will require a very quick turnaround on these responses to the panel's questions. Please be prepared for this contingency during the first week of February.

If you have questions regarding the format and guidelines for proposal preparation, please contact CICEET.

11) Evaluation

CICEET will conduct an initial compliance review of all proposals. Any deemed "non-compliant" will be eliminated from the competition, and CICEET will notify the applicants. Non-compliant proposals are so deemed for failure to do one or more of the following:

- Follow the narrative structure as noted above;
- Adequately address the questions posed within each narrative component;
- Adequately address the Research Priorities noted above;
- Follow directions with regard to formatting and submission procedures.

Compliant proposals will be reviewed by an expert panel composed of scientists, program managers, and public health / natural resource managers from institutions and agencies throughout the United States.

Please note that projects recommended for funding are subject to a National Environmental Policy Act (NEPA) review regarding the environmental impacts of the proposed research. Funding is contingent upon compliance with NEPA guidelines. You can learn more about NEPA at <http://www.epa.gov/compliance/nepa/>.

Proposals will be evaluated according to the following criteria:

1) Appropriateness: To what degree do the objectives, methods, and overall approach of the proposal support the goals of CICEET as stated in this RFP? Did the proposal clearly delineate which of the three research priorities (A through C) is being addressed? How well did the proposal address the following questions?

- Is there a reasonable expectation that the proposed measurement will improve our ability to predict water-quality related health risk for swimmers?

- Are the proposed methods to measure the indicator mature? Have they been demonstrated to be repeatable and sensitive? CICEET seeks methods ready for inclusion in an epidemiology studies in 2007, not those that require development.

- Should the indicator be demonstrated to have a relationship to health risk, are the cost and logistics associated with the measurement such that they would likely be adopted by local beach monitoring programs?

2) Technical Approach: To what extent does the proposal demonstrate excellence in technical capability and familiarity with the scientific subject matter? How well have the applicants demonstrated with documented performance characteristics that their methods are appropriately mature? How well did the applicant make the case that the methods are well-coordinated with the goals of the epidemiology study?

3) Management Impact: To what extent has the applicant demonstrated an understanding of the factors that ultimately impact beach water quality managers and made a case for the utility of the technology or methods presented in the proposal? Is it transferable to other geographic areas? What are the costs and skill levels required to implement this technology should it be used on an ongoing basis?

4) Personnel: Are the identified personnel qualified for the proposed work? Is the team sufficient for the work described, or are there critical skill sets not represented in the project team?

5) Budget: Is the budget appropriate?

12) Why CICEET is partnering with SCCWRP

In the summer of 2006, CICEET implemented a technology/research gap analysis related to public health and the monitoring of water quality at swimming beaches. This analysis included more than 20 one-on-one interviews with key stakeholders, including beach managers, regulators, researchers, and citizen groups.

Several key issues emerged. A recurring concern among the interviewees was the need to better understand how various water quality indicators—and the technologies that measure them—actually relate to swimming-associated health effects.

Due to the analysis, CICEET engaged in discussions with SCCWRP about the potential benefits of partnering on SCCWRP's upcoming epidemiology study that will begin in the spring of 2007. As designed, the study has the potential to form the basis of California's future Total Maximum Daily Load (TMDL) standards related to beach water quality monitoring. It could influence TMDLs in other states, as well. Further, it is an opportunity for researchers in the public sector, academia, or industry to better understand how well their technologies/methods correlate with observed health effects in swimmers.

CICEET, therefore, decided to collaborate with SCCWRP in order to leverage resources around this critical issue. CICEET's overall focus remains national, and preference in this RFP will be given to proposals that reflect the needs of beach managers across the country.

13) Appendix: SCCWRP Study

Title: Epidemiology Study of Swimming-Related Illnesses at Nonpoint Source Polluted Beaches

Project Leader: Southern California Coastal Water Research Project: <http://www.sccwrp.org>

Contact: Dr. Ken Schiff, Deputy Director of SCCWRP, kens@sccwrp.org

Introduction

Fecal indicator bacteria (FIB) have been measured for decades to help public health managers evaluate marine recreational water quality, but the epidemiology studies used to select the present FIB and their associated health risk thresholds have been conducted primarily at sites where human sewage is the dominant fecal source.

Improvements in point source control have led to nonpoint—and in many cases nonhuman—fecal sources becoming the dominant beach contamination problem in many areas of the country. For example, 225 waterbodies in California have been classified as impaired due to fecal pollution, with 83% of these due to nonpoint, and perhaps nonhuman, sources. It is unclear how well the epidemiological relationships that support the presently used FIB apply to these locations where nonpoint fecal sources are dominant.

Exciting new technology is bringing a new breed of potential nontraditional measurement strategies for assessing health risk in bathing waters. These new methods include rapid quantification of traditional FIB, identifying specific hosts of fecal pollution (microbial source identification), new fecal indicator bacteria, and human specific pathogens.

While the laboratory techniques necessary to measure these new potential indicators have been developed, these technologies have not been evaluated in an epidemiological study that documents the relationship of these measurements to the incidence of swimming-related illness. Until such relationships are established, and in some cases new standards promulgated, these methods will not be adopted for use by beach managers such as public health agencies, regulatory personnel, or beach owners/operators.

Objectives

The objective of this project is to conduct an epidemiology study that will quantify the risk of swimming associated illnesses, and test indicators of that risk, at beaches polluted by nonpoint sources of fecal contamination. The project will address three primary questions:

- 1) Is there a risk of swimming-related illnesses at nonpoint source polluted beaches compared to nonswimmers?
- 2) Are these illnesses correlated to the traditional FIB measurements used by existing beach monitoring programs?
- 3) Are there new, alternative assessment tools that are more predictive of health risk than traditional monitoring methods?

Methods

This study will be conducted over three years at several beaches. The first year of sampling will be conducted at Doheny State Beach in Dana Point, California. This beach, located at the mouth of the San Juan Creek watershed, has three characteristics that make it ideal for the proposed project. First, it has a high swimmer density, with 10,000 visitors on a typical summer weekend. Second, it has sufficiently poor water quality to ensure swimmer exposure. For example, some portion of the beach failed state water quality standards 358 days in 2003. Third, millions of dollars have been spent on infrastructure improvements so that remaining fecal pollution is believed to emanate primarily from nonpoint sources. Sampling in the second year will take place at Surfrider Beach in Malibu, with sampling locations in the third year dependent on results from the first two years.

The study will be conducted using a prospective cohort design, in which swimmers (and nonswimmers) are monitored for water exposure while at the beach and surveyed for illness that occurs in the two weeks subsequent to their beach visit. They will be queried with respect to nearly 20 symptoms, including specific symptoms of gastrointestinal (nausea, vomiting, HCGI, etc.), respiratory (coughing, phlegm, significant respiratory disease), dermatological illnesses (skin rash, infected scrapes, etc.), and non-specific symptoms (fever, chills, eye irritation, earache, ear discharge, eye irritation). Multivariate analyses (adjusted for covariates such as gender, race, and age) will assess relationships between water contact and levels of water quality indicators.

During the first year, an estimated 9,000 swimmers will be monitored for water exposure on 27 days comprising the weekends and holidays between Memorial and Labor Day. Water quality will be assessed three times per day at four beach locations, selected to represent a gradient of historical water quality conditions (with water quality improving at distance from the mouth of San Juan Creek). In addition to sites along the beach, two sites will be measured within San Juan Creek. One of these will be in the lagoon at the creek terminus, where birds are plentiful. The other will be in the creek upstream of the lagoon, which drains several upstream municipalities. Both of creek sampling locations will be sampled once daily.

Measurements at all sites will include both traditional and non-traditional indicators. Traditional FIB methods will quantify total coliform, fecal coliform, and enterococcus using membrane filtration. *Enterococcus* will also be measured using the Enterolert chromogenic substrate method.

Nontraditional measurements will include *Bacteroides*, adenovirus, Norwalk virus, coliphage (Somatic and F+), and rapid methods for quantifying *Enterococcus* and *E. coli*. The rapid indicator methods will include the QPCR technique being developed by Dr. Rachel Noble of University of North Carolina and Dr. Richard Haugland of EPA. It will also include the NASBA based method of GenProbe, Inc. Details of these methods can be found at: ftp://ftp.sccwrp.org/pub/download/PDFs/485_rapid_methods_II.pdf.

The virus and coliphage methods will be performed by Dr. Mark Sobsey of University of North Carolina, the methods for which can be found at: ftp://ftp.sccwrp.org/pub/download/PDFs/449_mb_epi.pdf.

The *Bacteroides* measurements will be conducted by Dr. Katherine Field of Oregon State University using primers intended to quantify human-specific and bird-specific host gene sequences.

SCCWRP recognizes that epidemiological studies are expensive and are conducted infrequently, providing limited opportunities for investigators to evaluate alternate indicators in a health risk context. SCCWRP is seeking to add to the mix of alternative exposure measurements that are included in the study through partnerships with other researchers, such as those partnerships that are being facilitated by CICEET. It is anticipated that several new indicators, or variances on methods for measuring these indicators, will be added as study planning matures.