

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)
OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH (NCER)
STANDARD INSTRUCTIONS FOR SUBMITTING A
2003-2004 STAR APPLICATION

under the Science To Achieve Results (STAR) Program

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)
OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
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Standard Form 424

Instructions for SF 424

Key Contacts Form (*NCER Form 1*)

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This document contains the standard instructions on how to apply for a STAR grant. Proposed projects must be specifically designed to advance the state of knowledge in the research areas described in the specific solicitation. Please see the NCER web site, <http://www.epa.gov/ncer>, for detailed information on research program areas by selecting “Research Opportunities.” Information on past grant awards may also be found on this site by selecting “Grants,” then making one of the selections under “Recipient’s Lists.”

1. Sorting Codes /Topic Areas

When applications for multiple research subjects are solicited by one Request for Applications (RFA), each distinct subject is referred to as a “topic area” and has a “sorting code” assigned to it to facilitate the review of applications. The sorting codes and application deadlines for each solicitation can be found at the end of the technical description of an RFA.

At various places within the application, applicants are asked to identify the sorting code corresponding to their proposed research topic area in the solicitation. It is the responsibility of the applicant to identify the proper sorting code, based on the nature of the proposed research. Failure to do so could result in an inappropriate peer review assignment. If your research seems to fit under more than one sorting code, choose the most appropriate one.

The sorting code must be placed at the top of the abstract (location is shown in the abstract format, see attachment, NCER Form 2), in Box 10 of Standard Form 424 (see description below in the section on SF424), and in the address on the package that is sent to the EPA (see Section 4. **How to Apply**, below). Each application submitted must fall under one topic area only, using a single sorting code. Applications submitted for more than one topic area will be assigned to the topic designated on the first version received, or to the first sorting code shown on the application.

2. The Application

The initial application is made through submission of the materials described below. ***It is essential that the application contain all information requested and be submitted in the formats described.*** Noncompliance with formatting instructions (page limits, font size, etc.) is grounds for administrative dismissal. Please note that If an application is being considered for an award (i.e., after external peer review and internal review), additional forms and other information will be requested by the EPA Project Officer. The application must contain the following:

A. Standard Form 424: The applicant must complete SF424 (see attached form and instructions). This form will be the ***first page*** of the application. Instructions for completion of the SF424 are included with the form. The form must contain the original signature of an authorized representative of the applying institution. Please note that both the Principal Investigator and an administrative contact are to be identified in Section 5 of the SF424.

Regarding Block 16 of the SF 424: research funded under this program may be eligible under E.O. 12372, "Intergovernmental Review of Federal Programs," if it affects public health or if an environmental impact statement is required. If applicable, an applicant should consult the office or official designated as the single point of contact in his or her State for more information on the process the State requires to be followed in applying for assistance, if the State has selected the program for review.

B. Key Contacts: The applicant must complete the Key Contacts Form (NCER Form 1, see attached) as the second page of the application. A copy of this form should also be completed for major subagreements (contacts at the institutions of primary co-investigators).

Please make certain that all contact information is accurate. An e-mail will be sent to the Principal Investigator (with a copy to the Administrative Contact) to acknowledge receipt of the application and to transmit other important information. If an e-mail acknowledgment has not been received within 30 days of the submission deadline, then immediately contact the project officer listed under "Contacts" in the solicitation.

C. Table of Contents: Provide a list of the major subdivisions of the application indicating the page number on which each section begins.

D. Abstract: *The abstract is a very important document.* All abstracts are provided to the peer review panelists, and some of the panelists may read only the abstract. Abstracts also play a critical role in programmatic review. Therefore, it is critical that the abstract accurately describes the research being proposed and convey all the essential elements of the research. Also, the abstracts of applications that receive funding will be posted on the NCER web site.

The abstract, **limited to one page**, should include the information indicated in the example format (NCER Form 2, see attached) and described below (1-8). Examples of abstracts for current grants may be found on the NCER web site.

1. **Research Category and Sorting Code:** Enter the full name of the solicitation under which your application is submitted and the code that corresponds to the appropriate RFA topic. (Be sure to substitute the appropriate letter and number for the "XX" in 2004-STAR-XX).
2. **Title:** Use the exact title of your project as it appears in the application. The title must be brief, yet represent the major thrust of the project. Because the title will be used by those not familiar with the project, strike a balance between highly technical words and phrases and more commonly understood terminology. Do not use phrases such as "research on."
3. **Investigators:** List the Principal Investigator, then the names and affiliations of each co-investigator who will significantly contribute to the project. Provide a web site URL or an E-Mail contact address for additional information.

4. **Institution:** In the same order as the list of investigators, list the name and city/state of each participating university or other applicant institution. The institution applying for assistance must be clearly identified.
5. **Project Period:** Show the proposed project beginning and ending dates.
6. **Project Cost:** Show the total dollar request, including direct and indirect costs, to the EPA for all grant years (the entire project period).
7. **Project Summary:** Provide three subsections addressing: (a) the objectives of the study (including any hypotheses that will be tested), (b) the experimental approach to be used (a description of the project proposed), and (c) the expected results of the project and how it addresses the research needs identified in the solicitation, including the estimated improvement in risk assessment or risk management that will result from successful completion of the proposed work.
8. **Supplemental Keywords:** Supply keywords to assist database searchers in finding your research, without duplicating terms already used in the text of the abstract. A complete set of keywords is very important. A list of suggested keywords is attached for your use (NCER form 3).

E. Research Plan: This description must not exceed fifteen (15) consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins. The description must provide the following information:

1. **Objectives:** List the objectives of the proposed research and the hypotheses being tested during the project, and briefly state why the intended research is important. This section should also include any background or introductory information that would help explain the objectives of the study. If this application is for continuation of research supported by an existing or former grant awarded under the STAR program, indicate the number of the grant and provide a brief report of progress and results achieved under that grant (one to two pages recommended).
2. **Approach:** Outline the research design, methods, and techniques that you intend to use in meeting the objectives stated above (five to 10 pages recommended).
3. **Expected Results or Benefits:** Describe the results you expect to achieve during the project and their benefits. This section should also discuss how the research results will lead to solutions to environmental problems (one to two pages recommended) and improve the public's ability to protect the environment and human health. A clear, concise description will help NCER understand the merits of the research.
4. **General Project Information:** Discuss other information relevant to the potential success of the project. This should include facilities, personnel, project schedules, proposed management, interactions with other institutions, etc. Applications for multi-investigator projects must identify project management and the functions of each investigator within a team, and describe plans for communication and sharing of data (one to two pages recommended).

5. Important Attachments: Appendices and/or other information may be included but must remain within the 15-page limit. Letters of intention to support the research plan are only appropriate to assure the commitment of a resource (e.g., commitment of a person's time or use of equipment) not under the control of the proposing institution. Such letters, limited to one brief paragraph, should be included as an addendum to the budget justification section. Letters describing the substance of the support for the research plan must be included within the 15-page limit for that section of the proposal. References cited are in addition to the 15 pages.

The following sections must be included in addition to the 15-page Research Plan.

F. Resumes: Provide the resumes of all principal investigators and important co-workers. The resume for each individual must not exceed two consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

G. Current and Pending Support: Identify any current and pending financial resources that are intended to support research related to the proposal or which would consume the time of principal investigators. Complete the Current and Pending Support form (NCER form 5, see attached) for each investigator and other important co-workers.

H. Budget: The applicant must present a detailed, itemized budget for the entire project. This budget must be in the format provided in the example (NCER Form 4, see attachment) and must not exceed two consecutively numbered (bottom center), 8.5x11-inch pages with 1-inch margins.

If a sub-agreement, such as a sub-contract, is included in the application, provide a separate budget for the sub-contract in the same format. Include the total amount for the sub-agreement under "Contracts" in the master budget. A project which contains a sub-agreement constituting more than 40% of the total direct cost of the grant will be subject to special review. Additional justification for use of such a sub-contract must be provided, discussing the need for this agreement to accomplish the objectives of the research project.

Please note that institutional cost-sharing is not required and, therefore, does not have to be included in the budget table. However, if you intend to cost-share, a brief statement concerning cost-sharing should be added to the budget justification, and estimated dollar amounts must be included in the appropriate categories in the budget table.

I. Budget Justification: Describe the basis for calculating the personnel, fringe benefits, travel, equipment, supplies, contractual support, and other costs identified in the itemized budget and explain the basis for their calculation. (Special attention should be given to explaining the "travel," "equipment," and "other" categories.) The budget justification should not exceed two consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

Budget information should be supported at the level of detail described below.

1. Personnel - List all staff positions by title. Give annual salary, percentage of time assigned to the project, and total cost for the budget period.
2. Fringe Benefits - Identify the percentage used and the basis for its computation.
3. Travel - Specify the estimated number of trips and locations, and other costs for each type of travel. Explain the need for any travel outside the United States. Include travel funds for annual STAR program progress reviews and a final workshop to report on results .
4. Equipment - Identify computers, and each item to be purchased which has an estimated cost of \$5,000 or more per unit and a useful life of more than one year. (Items with a unit cost of less than \$5,000 are considered supplies, per regulation.)
5. Supplies - "Supplies" means all tangible property other than "equipment." Identify categories of supplies to be procured (e.g., laboratory supplies or office supplies).
6. Contractual - Identify each proposed subagreement (grant or contract) and specify its purpose and estimated cost. Subagreements more than \$25K should have a separate itemized budget included as part of the application.
8. Other - List each item in sufficient detail for the EPA to determine the reasonableness of its cost relative to the research to be undertaken.
9. Indirect Charges - If indirect charges are included in the budget, indicate the approved rate and base with an explanation of how indirect costs were calculated.

J. Quality Assurance Statement: For any project involving data collection or processing, conducting surveys, environmental measurements, modeling, or the development of environmental technology (whether hardware-based or via new techniques) for pollution control, provide a Statement on processes that will be used to assure that results of the research satisfy the intended project objectives. EPA is particularly interested in the quality controls for data generation and acquisition, and how data validation and usability will be verified. The Statement must describe a system that complies with ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, and must not exceed two consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

For each item below, either present the required information, reference the specific location of the information in the Research Plan, or provide a justification of why the item does not apply to the proposed research.

1. Identify the individual who will be responsible for the quality assurance and quality control aspects of the research. (Quality assurance (QA) is an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, or item is of the type and quality needed for the project. Quality control (QC) is the

system of technical activities that measures the attributes and performance of a process or item against defined standards, to verify that they meet the stated requirements.)

2. Discuss the activities to be performed or the hypothesis to be tested and criteria for determining acceptable data quality. (Note: Such criteria may be expressed in terms of precision, accuracy, representativeness, completeness, and comparability or in terms of data quality objectives or acceptance and evaluation criteria.) Also, these criteria must be applied to determine the acceptability of existing, or “secondary,” data to be used in the project. (In this context, secondary data may be defined as data previously collected for other purposes or from other sources.)
3. Describe the study design. Include sample type(s) and location requirements, all statistical analyses that were or will be used to estimate the types and numbers of physical samples required, or equivalent information for studies using survey and interview techniques, or describe how new technology will be benchmarked to improve existing processes, such as those used by industry.
4. Describe the procedures that will be used in the calibration and performance evaluation of all analytical instrumentation and all methods of analysis to be used during the project. Explain how the effectiveness of any new technology will be measured.
5. Describe the procedures for the handling and custody of samples, including sample collection, identification, preservation, transportation, and storage, or how the accuracy of test measurements will be verified.
6. Discuss the procedures for data reduction and reporting, including a description of all statistical methods to make inferences and conclusions, with identification of any statistical software to be used; discuss any computer models to be designed or utilized and describe the associated verification and validation techniques.
7. Describe the quantitative and/or qualitative procedures that will be used to evaluate the success of the project, including any plans for peer or other reviews of the study design or analytical methods prior to data collection.

ANSI/ASQC E4, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, is available for purchase from the American Society for Quality, phone 1-800-248-1946, item T55. Only in exceptional circumstances should it be necessary to consult this document. An EPA guidance document, Guidance on Satisfying EPA Quality System Requirements for STAR Grants (EPA QA/G-1STAR) is available for potential applicants and addresses in detail how to comply with ANSI/ASQC E4 for STAR grants. This may be found on the Internet at <http://www.epa.gov/ncer> under “Guidance and FAQs.”

3. Confidentiality

By submitting an application in response to this solicitation, the applicant grants EPA permission to make limited disclosures of the application to technical reviewers both

within and outside the Agency for the express purpose of assisting the Agency with evaluating the application. Information from a pending or unsuccessful application will be kept confidential to the fullest extent allowed under law; information from a successful application may be publicly disclosed.

4. How to Apply

The original and eight (8) copies of the complete application (9 in all) and one (1) additional copy of the abstract, **must be received by NCER no later than 4:00 P.M. Eastern Time** on the closing date assigned to the topic area (see solicitation for date).

The application and abstract must be prepared in accordance with these instructions. Informal, incomplete, or unsigned applications will be returned without review. The original, signed copy of the application must not be bound or stapled in any way. The other eight (8) required copies of the application should be secured with paper or binder clips or secure staples.

Because of security concerns, applications cannot be personally delivered. They must be sent through regular mail, express mail, or a major courier.

The following address must be used for regular mail:

U.S. Environmental Protection Agency

Peer Review Division (8725F)

Sorting Code: 2004-STAR-XX (replace the "XX" with the appropriate code)

1200 Pennsylvania Avenue, NW

Washington, D.C. 20460

Please note: Due to uncertainties associated with timely delivery of regular mail, it is especially important to follow the procedures described in the second paragraph of section 2.B if this method of delivery is used.

The following address must be used for express mail and couriers:

U. S. Environmental Protection Agency

Peer Review Division (8725F)

Sorting Code: 2004-STAR-XX (replace the "XX" with the appropriate code)

1025 F. Street, NW (Room 3500)

Washington, DC 20004

Phone: (202) 233-0686

5. Guidelines, Limitations, and Additional Requirements

Applications should be focused on a limited number of research objectives that can be adequately and clearly demonstrated to meet the RFA requirements. Explicitly state the main hypotheses that you will investigate, the data you will create or use, the analytical tools you will use to investigate these hypotheses or analyze these data, and the results you expect to achieve. Research methods must be clearly stated so that the reviewers can evaluate the appropriateness of your approach and the tools you intend to use. The statement: "we will evaluate the data using the usual statistical methods" is not specific enough for peer reviewers.

If you wish to submit applications for more than one STAR RFA, you must ensure that the research proposed in each is significantly different from any other that has been submitted to the EPA or from any other grant you are currently receiving from the EPA or another federal government agency.

To be considered timely, applications and initial proposals must be received by the Agency on or before the deadline date published in the RFA. Applications received after the published deadline or applications that deviate from the prescribed format will be returned to the sender without further consideration. Also, applications exceeding the funding limits described in the RFA will be returned without review.

After evaluation and selection for award, applicants recommended for funding will be required to submit additional certifications and an electronic version of the revised project abstract, and may be requested to provide responses to comments or suggestions offered by the peer reviewers, a revised budget, and/or to resubmit their proposal. EPA Project Officers will contact Principal Investigators to obtain these materials. Before or after an award, certain applicants will be expected to provide additional quality assurance documentation.

Applications are selected for an award subject to the availability of funding.

Collaborative applications involving more than one institution must be submitted as a single administrative package from one of the institutions involved.

Research funded under this program may be eligible under E.O. 12372, "Intergovernmental Review of Federal Programs," if it affects public health or if an environmental impact statement is required. If applicable, an applicant should consult the office or official designated as the single point of contact in his or her State for more information on the process the State requires to be followed in applying for assistance, if the State has selected the program for review.

Congress, through OMB, has instructed each agency to implement Information Quality Guidelines designed to "provide policy and procedural guidance . . . for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies." EPA's implementation may be found at <http://www.epa.gov/oeiinter/qualityguidelines/index.html> . These procedures may apply to data generated by grant recipients if those data are disseminated as described in the Guidelines.

6. Review and Selection

A. Review and Selection Process. All grant applications are reviewed by an appropriate technical peer review panel. This review is designed to evaluate each proposal according to its scientific merit. Applications that receive scores of excellent and very good from the peer reviewers are subjected to a programmatic review within the EPA to assure a balanced research portfolio for the Agency. Applications are then recommended for funding to the NCER Director who makes funding decisions. Applications are selected for an award based on consideration of the scientific quality of proposals and relevance to EPA program research priorities, program balance, budget and available funds. Selected applicants will be required to provide additional information (see above) and the application will be forwarded to the grants administration office for award in accordance with the EPA's procedures.

Customarily, applicants are notified about award decisions within six months of the application deadline. A summary statement of the scientific review by the peer panel will be provided to each applicant with the award or declination letter.

B. Peer Review and Criteria. In general, each peer review group is composed of non-EPA scientists, engineers, social scientists, and/or economists who are experts in their respective disciplines and are proficient in the technical subjects they are reviewing. Reviewers are asked to assign a summary score to the application of either excellent, very good, good, fair, or poor, and use the criteria below to help them in their evaluations. These criteria are listed in descending order of importance.

1. The originality and creativity of the proposed research, the appropriateness and adequacy of the research methods proposed, and of the Quality Assurance Statement. Is the research approach practical and technically defensible, and can the project be performed within the proposed time period? Will the research contribute to scientific knowledge in the topic area? Will the results be disseminated broadly to enhance scientific and technological understanding? What may be the benefits of the proposed activity to society? Is the proposal well-prepared with supportive information that is self-explanatory or understandable?
2. The qualifications of the principal investigator(s) and other key personnel, including research training, demonstrated knowledge of pertinent literature, experience, and publication records. Will all key personnel make a significant time commitment to the project?
3. The responsiveness of the proposal to the research needs identified for the topic area. Does the proposal adequately address the objectives specified by the EPA for this topic area?
4. The availability and/or adequacy of the facilities and equipment proposed for the project. Are there any deficiencies that may interfere with the successful completion of the research?
5. Although budget information does not reflect on the application's scientific merit, the reviewers are asked to provide their view on the appropriateness and/or

adequacy of the proposed budget and its implications for the potential success of the proposed research. Input on requested equipment is of particular interest.

7. Funding Mechanism

The funding mechanism for all awards issued under STAR solicitations will consist of assistance agreements from the EPA. All award decisions are subject to the availability of funds. In accordance with Public Law 95-224, the primary purpose of a grant is to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition for the direct benefit or use of the Agency. In issuing a grant agreement, the EPA anticipates that there will be no substantial EPA involvement in the design, implementation, or conduct of the research. However, the EPA will monitor research progress through annual reports provided by grantees and other contacts, including site visits, with the Principal Investigator.

8. Expectations and Responsibilities of STAR Grantees

Expectations and responsibilities of NCER grantees are summarized in this section; see www.epa.gov/ncer/guidance for full terms and conditions associated with an award, including what activities require prior approval of the EPA.

A. Meetings. Principal Investigators will be expected to budget for, and participate in, periodic All-Investigators Meetings (also known as progress reviews) approximately once per year with EPA scientists and other grantees to report on research activities and to discuss issues of mutual interest.

B. Approval of Changes after Award. Prior written approval is required from the EPA if there is to be significant change in the research that deviates markedly from work described in the application. Examples of these changes are contained in 40 C.F.R. 30.25. Prior written approval is also required from the EPA for incurring costs greater than 90 calendar days prior to award.

C. Human Subjects. A grant recipient must agree to meet all EPA requirements for studies using human subjects prior to implementing any work with these subjects. These requirements are given in 40 C.F.R. 26, referred to as the “Common Rule.” No work involving human subjects, including recruiting, may be initiated before the EPA has received a copy of the Institutional Review Board’s (IRB) approval of the project and the EPA has also provided approval. Where human subjects are involved in the research, the recipient must provide evidence of subsequent IRB reviews, including amendments or minor changes of protocol, as part of annual reports.

D. Animal Welfare. A grant recipient must agree to comply with the Animal Welfare Act of 1966 (P.L. 89-554), as amended. All projects involving vertebrate animals must have approval from the applying organization’s Institutional Animal Care and Use Committee before issuance of an EPA grant.

E. Data Access and Information Release. 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. All data sets, models, and databases developed under STAR grants may become accessible to the public and therefore freely available to all researchers. If such data are requested by the public, the EPA must ask for it, and the grantee must submit it, in accordance with A-110 and EPA regulations at 40 C.F.R. 30.36.

F. Reports. A grant recipient must agree to provide annual progress reports with associated summaries for posting on NCER's web site, and a final report with an executive summary for web posting.

G. Acknowledgement of EPA Support. A grant recipient must agree to provide copies of any peer reviewed journal article(s) resulting from the research during the project period. In addition, the recipient should notify the EPA Project Officer of any papers published after completion of the grant which were based on research supported by the grant. NCER intends to post references to all publications resulting from the grant on the NCER web site.

EPA's full or partial support should be acknowledged in journal articles, oral or poster presentations, news releases, interviews with reporters and other communications. Any documents developed under the agreement for distribution to the public or inclusion in a scientific, technical, or other journal shall include the following statement:

This publication [article] was developed under a STAR Research Assistance Agreement No. _____ awarded by the U.S. Environmental Protection Agency. It has not been formally reviewed by the EPA. The views expressed in this document are solely those of [name of recipient] and the EPA does not endorse any products or commercial services mentioned in this publication.

A graphic that can be converted to a slide or used in other ways, such as on a poster, is located at http://es.epa.gov/ncer/guidance/star_images.html. Use of this graphic in oral and poster presentations is expected.

9. Contacts

Additional general information on the STAR grants program, forms used for applications, etc., may be obtained by exploring our Web page at <http://www.epa.gov/ncer>. Specific technical questions should be directed to the EPA contact person whose name is provided in each solicitation.

10. Privacy Act and Public Burden Statements

This RFA requests information for proposal forms and in project reports. The information on proposal forms, including quality-related data, will be used in connection with the selection of qualified proposals. Project reports submitted by awardees will be

used for program evaluation. The information requested may be disclosed to qualified reviewers as part of the proposal review process, and to other government agencies needing information as part of the review process or in order to coordinate programs. Submission of the information is voluntary. However, failure to provide full and complete information may reduce the possibility of receiving an award. The OMB control number for this collection (General Administrative Requirements for Assistance Programs) is 2030-0020 (expires 2005). EPA regulations, as stated in 40 C.F.R. 30.54, require the inclusion of data quality planning documents, which are covered by Quality Assurance Specification and Requirements, OMB # 2080-0033.

11. Applicable Federal Citations

See the specific RFA for applicable Catalog of Federal Domestic Assistance (CFDA) citations. Awards by the EPA are made and administered under the authority of 40 C.F.R. Part 30 and 40, and applicable statutes.