

TITLE: Develop Written OHRP Guidance Documents

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PROPOSED PERIOD OF PERFORMANCE: July 15, 2004 through July 14, 2005.

PRICING METHOD: Cost Plus Fixed Fee

Include the 1% NIH Admin fee in your budget.

Proposals should be submitted by email to pscacquisitions@psc.gov attention Chris Ganey. The subject line should read "Develop Written OHRP Guidance Documents", Proposal from {Insert your firm's name}. **Page limit 15.**

Proposals may be submitted in Microsoft Word, Wordperfect and Excel Formats. Please submit documents in a format where the documents may be viewed but not altered (write protected, read-only or PDF) by the viewer.

This task order may be awarded without negotiations; therefore, all Offerors are urged to submit their most favorable proposal at this time.

PROPOSAL DUE DATE: June 21, 2004, by 3:00 PM Eastern Standard Time.

STATEMENT OF WORK

Develop Written OHRP Guidance Documents

BACKGROUND

The Office for Human Research Protections (OHRP) is one of 12 components of the Office of Public Health and Science (OPHS) of the Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS). OHRP is responsible for providing departmental level leadership and oversight on all matters related to the protection of human subjects participating in research conducted or supported by HHS. OHRP's responsibilities include promoting and coordinating appropriate HHS regulations, policies and procedures both within HHS and in coordination with other Departments and Agencies in the Federal Government. The OHRP Division of Policy and Assurances, among other things, has responsibility for maintaining, developing, promulgating and updating policy and guidance documents regarding regulatory requirements and ethical issues for biomedical and behavioral research involving human subjects.

In January 2002, OHRP created the inter-divisional policy coordinating committee (IPCC) to, among other functions, develop and update guidance documents on the HHS regulations for the protection of human subjects. The guidance documents provide information for institutional review boards (IRBs), research institutions, researchers, and sponsors regarding the HHS human subject protection regulations, the application of those regulations, and related policy issues. The IPCC is an internal OHRP committee that is chaired by the Director, Division of Policy and Assurances, and is composed of representatives from OHRP's Office of the Director, the Division of Policy and Assurances, the Division of Education and Development and the Division of Compliance Oversight, and the HHS Office of General Counsel.

OHRP's guidance documents on various aspects of HHS' regulations for the protection of human subjects (45 CFR part 46), are available on its website at <http://ohrp.osophs.dhhs.gov/g-topics.htm>. Many of these documents need to be updated and OHRP has received numerous requests from the research community to develop guidance beyond the documents currently available. The overall goal of this contract is to increase OHRP's capacity to write guidance documents.

PURPOSE

The purpose of this acquisition is to update, revise, and develop guidance documents on various aspects of HHS' regulations for the protection of human subjects (45 CFR part 46). The Contractor shall prepare written documents based on and incorporating input from the IPCC.

TASKS

The Contractor shall perform the following tasks:

Task 1: Prepare written guidance documents. These documents shall explain and interpret the requirements of the HHS regulations for the protection of human subjects, offer guidance on the implementation of the HHS regulations, and address related policies as appropriate.

- ô 1.1 prepare guidance document on the development, operation, and use of human specimen repositories and databases; up to 15 pages; due date to be determined.
- ô 1.2 prepare guidance document(s) on research involving children, including the 45 CFR 46.407 process for the HHS Secretary's review of certain research involving children; up to 15 pages per document; due date to be determined.
- ô 1.3 prepare guidance document(s) on requirements for informed consent in HHS conducted or supported research involving human subjects; up to 15 pages per document; due date to be determined.
- ô 1.4 prepare additional guidance documents; topics to be determined; due date to be determined.

Ten days from the date of the award, OHRP staff and the awardee will meet to discuss time frame and commitments.

Task 2: Attend weekly meetings of the IPCC as appropriate. At these meetings, the documents that are being planned or being written, will be discussed.

Task 3: Prepare draft Federal Register Notices. When public comment is needed on new or revised guidance documents, the Contractor shall draft Federal Register Notices.

Task 4: Analyze public comments. The Contractor shall analyze public comments received in response to the Federal Register Notices. Based on these comments, the Contractor shall prepare further revisions to draft guidance documents.

Task 5: Prepare bimonthly (twice a month) progress reports.

TECHNICAL EVALUATION FACTORS

The following criteria will be used in the proposal evaluation with each criterion weighted as indicated. The Government reserves the right to give technical merit of the proposals precedence over cost. However, as a result of technical evaluation, where proposals are determined to essentially equal, then price shall become the determining factor. Award will be made to the Offeror whose proposal provide the best value to the Government as evaluated under the criteria described below.

UNDERSTANDING THE PROBLEM

The offeror must provide a comprehensive statement of the scope and purpose of the intent and requirements. This understanding should provide a clear awareness of the task order objectives and their significance. Offeror should demonstrate particular knowledge of human subject protection regulations, 45 CFR part 46, including requirements surrounding informed consent, research involving children, and the use of human specimen repositories and databases. 30 Points

TECHNICAL APPROACH

The Offeror must provide documentation of the capability to perform all tasks required by the Statement of Work. The Offeror must provide a detailed plan for each task that demonstrates thoughtful planning and creative problem-solving, and that results in the development and creation of accurate, timely, and audience appropriate guidance documents. The Offeror must provide specific plans for quality assurance against the requirements for the task order, and evaluation of services provided under this task order. The Offeror must demonstrate the adequacy of plans for ensuring the hiring and retention of highly qualified staff. It should provide a detailed plan for ensuring performance of the services in the event of staff shortages due to illness, attrition, etc. 30 Points

QUALIFICATIONS OF THE ORGANIZATION AND PROPOSED STAFF

Corporate capability

The offeror must demonstrate evidence of corporate experience relevant to the proposed procurement. The offeror shall list all Government and commercial contracts, grants, and other awards of a nature, complexity, and magnitude similar to the proposed procurement that were awarded to or performed by the offeror within the past four (4) years. Such a list should include:

1. Contract/grant number
2. Monetary value and type of contract/grant
3. Description of services furnished
4. Name of Government agency and/or commercial company
5. Current address and telephone number of the cognizant Government contracting/grant officer and cognizant project officer, if applicable.

Personnel requirements

The personnel to be used under this contract will be evaluated on the basis of experience, qualifications, and availability of proposed staff to provide management, creative, and technical skills necessary to the successful performance of each task.

1. The Project Director must be designated, and shall be a senior staff member of the company. He/she shall be evaluated on prior performance and demonstrated understanding of HHS regulations, guidance and policy. Supporting materials shall include a resume showing extensive education, training, and experience with human subject protections issues, HHS regulations, guidance and policy. If the Offeror's proposal includes subcontracting relationships, evidence must be provided of the ability of the Project Director to ensure timely completion of quality work from a subcontractor.

2. The writing staff must have specialized training or education in science writing or editing as well as demonstrated ability to develop or edit written materials that effectively "translate" scientific and/or technical information for various target audiences, using plain language or easy-to-read standards.

3. The writing staff must demonstrate the ability to work collaboratively with a federal office (the Interdivisional Policy Coordinating Committee of the Office for Human Research Protections) in order to write and edit effective written guidance documents. 30 Points.

SAMPLES

Materials should include written guidance or procedures interpreting technical requirements and/or regulations for multiple audiences. These samples should indicate the level of editing needed to produce the final product and an explanation of the purpose of the product. 10 Points

COMPETITIVE RFTOP