

Intramural Research Project Proposal Instructions

Introduction

These instructions should be used for completion of full research project proposals for new intramural projects in the NIOSH Mining Program. Proposals in this format will normally be evaluated by external peer reviewers to help ensure the quality of the research done in the Program. The format of the proposals is based on the R01 research grant application format used by NIH and CDC, and is similar to the format used for NIOSH NORA proposals.

Specific Instructions for Completing the Project Proposal Form

Please observe the page limitations. A summary of these limitations is given in the following chart:

Page Limitations and Content Requirements

Section	Page Limit	Content
Part A		
Description	2	See instructions on page 2 in <i>Project Form.doc</i>
Biographical Sketches	2 (per sketch)	1 sketch for each senior investigator
Part B		
Project Plan*	20	Text plus all figures, charts, tables and diagrams
Literature Cited*		Complete citations including titles and all authors.
Appendix*		<ul style="list-style-type: none"> No more than 5 publications, including accepted or submitted manuscripts. Photographs (include an electronic copy in the Research Plan) Questionnaires Other materials that cannot be provided in electronic format.
Personnel Plan		Listing for all project personnel
Budget Spreadsheet		<i>Project Budget.xls</i>

*Not required for cooperative agreement projects

The form is to be prepared and submitted in electronic format, with the exception of Appendix items. The form should be prepared using the standard CDC Word Processing Package (Word). Please use Times New Roman Font, 12 point Normal, for all text (except for the form on the first page which uses 10 point type). Use the supplied margins of 0.75" left, 0.5" right, 1" top, 1" bottom. Please convert all diagrams, charts and photographs to electronic format. Most diagrams and charts can be inserted into the Word document using cut-and-paste from other Windows programs. Please scan photographs and insert them into the electronic document.

Appendix items that cannot be converted to electronic format may be submitted as hard copies. Submit 5 copies of each item and attach a copy of page 1 of the project form as a cover sheet.

Summary

1. Summary Form

- **Headers.** Enter name of project officer and project ID# in header A. (To edit header A, select Header/Footer from the Insert menu, select Header A and click on the edit button.) The project ID# must follow the format DIVID FY NORA XXXX, i.e. DSR 06 NORA SN01.
- **Title of Project.** Do not exceed 56 characters, including the spaces between words and punctuation. Choose a title that is specifically descriptive, rather than general.
- **Project Officer (Names of project officer).** Name the one person responsible for the scientific and technical direction of the project.
- **Degree(s).** Indicate up to three academic and professional degrees or other credentials, such as licenses.
- **Position Title.** Provide the professional or academic title of the principal investigator/co-principal investigators. If more than one title, indicate the one most relevant to the proposed project, such as Branch Chief, Team Leader, Staff Scientist.
- **Mailing Address.** Provide complete information (including room number, building and street address) necessary for postal delivery.
- **Branch/Division.** Provide Branch and Division names, please do not use acronyms.
- **Telephone, FAX, E-mail Address.** Provide a daytime telephone number, a FAX number, and an e-mail address.
- **Human Subjects.** If activities involving human subjects are not planned at anytime during the proposed work, indicate "No."

If activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, are planned at any time during the proposed project period, either at NIOSH or at any other performance site or collaborating institution, check "Yes."

If the planned activities involving human subjects are not exempt from Federal regulations, appropriate IRB approval is required and must be documented before any experimentation with human subjects can take place.

- **Vertebrate Animals.** If activities involving vertebrate animals are not planned at any time during the proposed project period, indicate "No."

If activities involving vertebrate animals are planned at any time during the proposed project period, either at NIOSH or at any other performance site or collaborating institution, indicate "Yes." An approved Institute Animal Care and Use Committee (IACUC) protocol is required and must be documented before any research using animals can be initiated.

- **Dates of Proposed Period of Support.** Identify start and end dates.
- **New Funds Required.** Provide an estimate of new funds being requested in FY2006 and an estimate of the total new funding for all years of the Project; do not include base

funding in this estimate. Extramural funding, for the summary page, should include only cooperative agreements. Research contracts should be listed under "Other Intramural."

- **FTEs.** Identify the number of new and current FTEs needed to carry out Program.

Note: Refer to FY 2005 Project Planning Guidance for complete information concerning the next 4 entries.

- **% Project Category.** Assign weights to each of the following categories as they represent this project: Administration, Information, Research, Service, Surveillance or Training. Percentages should equal 100% and no attribution should be less than 10%.
- **% NORA Priority Area.** List NORA priority areas addressed in this Project and assign percentages to each area. No attribution should be less than 20%, total attribution may be less than 100%. To meet the NORA Quality Assurance Committee (QAC) criteria, 80% of the NORA research must be coded in a single NORA priority area.
- **% Special Interest Area.** Identify percentage of Project that applies to Special Interest Areas. Information entered in this section should be coordinated with the Program Analyst in your Division or Laboratory. NIOSH special Interest Areas include: Agriculture, Asthma, Cancer, Construction, Child Ag, Ergonomics, Energy, Firefighters, Genetics, Healthcare Workers, HIV, Latex, Mining, NORA 98, NORA 99, NORA 00, Service Sector, Silicosis, Small business, TB, Violence and transportation.
- **% GPRA.** Assign weights to the following GPRA Goals as they represent this project: 1) Research, 2) Surveillance, 3) Evaluation, Intervention and Recommendations, 4) Information, Training and Capacity, and 5) Other Administrative Costs. Percentages should equal 100%.

2. Description, Performance Sites, and Key Personnel

- **Description.** Note the instructions on the form page 2.
- **Performance Site(s).** Indicate where the work described in the Description will be conducted. If there is more than one performance site, list all the sites.
- **Key Personnel. Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project.** Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. External collaborators and partners should be included if they meet the definition of key personnel. Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel and are not to be described here, but if they are NIOSH employees, they should be listed in the Detailed Personnel Plan. For each individual, provide: name, organization, and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, principal investigator, co-investigator, laboratory technician, etc. Use additional pages as necessary.

3. Biographical Sketch

- This section must contain the biographical sketches of all key personnel. Each biographical sketch is limited to two pages maximum.

Research Proposal, Personnel Plan, and Budget

1. Resources

- Provide requested information on facilities and major equipment required to conduct the proposed project.

2. Research Plan (not required for cooperative agreement projects)

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies. The scientific peer review will focus primarily on this section.

- **Project Plan.** Organize Items a-d, to answer these questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are you going to do the work? **Do not exceed 10 pages for Items a-d.** All tables, graphs, figures, diagrams, and charts must be included within the 10 page limit. Full-sized glossy photographs of material such as electron micrographs or gels may be included in an Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan.

The total for items a-d may not exceed 10 pages, including all tables and figures; recommended number of pages for specific sub sections is listed.

- a. Specific Aims.** List the broad, long-term objectives and what the specific work proposed is intended to accomplish. For research projects, state the hypotheses to be tested.
- b. Background and Significance.** Briefly sketch the background leading to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance and occupational safety and health relevance of the research described in this proposal by relating the specific aims to the broad, long-term objectives.
- c. Preliminary Studies/Progress Report.** Use this section to provide an account of the project officer's/program director's preliminary studies pertinent to the proposal and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project. The complete references to appropriate publications and manuscripts **submitted or accepted** for publication may be listed, and are not part of the page limitations. Five collated sets of no more than 5 such items of background material may be submitted in the appendix.
- d. Design and Methods.** Carefully describe the project design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the

aims. As part of this section, provide a tentative sequence or time-table for the project. List annual accomplishments that can be tracked. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Note on Gender and Minority Inclusion for Research Involving Human Subjects.

The NIOSH policy is that women and members of minority groups and their subpopulations must be included in all NIOSH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

Address the inclusion of women and members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of proposed outreach programs for recruiting women and minorities as participants. Provide a compelling rationale and justification for requesting any exclusions noted above.

- e. **Literature Cited.** List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. While there is no page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.
- f. **Consultants.** Attach appropriate letters here from all individuals confirming their roles in the project.

Sections g-i are identical to items needed for the IRIS system, which will be used for NIOSH project and program planning. The length of sections g-i is not to exceed one and one half pages. It is not necessary to enter information into IRIS at this time.

- g. **Mission Relevance.** This section should be brief (not to exceed 20 lines) but should describe the public health **impact** of the study. Describe the **need** for the project. Some elements that might be included in this section include:
 - o A statement of the problem(s) being addressed.
 - o Statistics that describe the number of people affected, extent of exposure, etc.
 - o How the project relates to the NORA and Mining/Ag or Construction research priorities, other NIOSH research priorities, Healthy People 2010, and/or surveillance.
 - o How the results might be used by a regulatory agency such as the OSHA, EPA, or MSHA.
 - o How the project might be used to improve the health and safety of working men and women.
- h. **Project Description.** (not to exceed 20 lines) Elements in the project might include:

- Hypotheses, goals, objectives and methodology
- Unique strength of project staff and partners (interdivisional + external).
- Results or public health accomplishments or products (publications, CRADA, Alerts, etc.), to be anticipated.
- Why project is being done as proposed, e.g., intramural, a support contract, extramural.
- Time frame for project.

- i. Short Project Summary.** (3-4 sentences, not to exceed 10 lines) Provide a short, succinct description of the project that can be understood by both technical and nontechnical audiences. A focused description of the project should be provided.

The following format should be used for each short summary:

- Select 3 keywords/phrases from the attachment in the latest version of the NIOSH Project Planning Guidance that best categorize your project
- Keywords/phrases should appear exactly as they appear in the attachment.
- A statement of purpose (no more than 1-2 sentences) should appear at the beginning of the abstract. Avoid beginning abstracts with statements that quote statistics, since there are many sources and methods for determining these numbers and it would be difficult to provide citations for every project.
- Provide a brief abstract of no more than 100-130 words (inclusive of the purpose statement) provide one or two sentences at the close of the abstract that addresses expected outcomes.

Sections j-l are items needed for the r2p component. Do not exceed two pages.

- j. Involvement of Stakeholders.** Stakeholders are internal and external partners, who are involved in the research, will use the research, or who will be impacted by the research findings.

- Characterize the role of each stakeholder in each project phase selecting from these potential roles:
 - Project conception - stakeholder was involved in the identification of the problem the project is addressing; helped to demonstrate need for project; or other pre-project role.
 - Planner - stakeholder was involved in the planning for the project.
 - Research collaborator - stakeholder is a research collaborator, either formally or informally.
 - Funding Source - stakeholder is providing funds (either direct or in-kind) for conducting the project.
 - Translator - stakeholder will translate research findings to end user. Examples of translators are regulatory agencies, unions, professional associations, trade magazines.
 - Evaluator - stakeholders who will assist in the evaluation of the project.

- k. Technology Transfer.** Identify if the work will likely result in a Cooperative Research and Development Agreement (CRADA), Employee Invention Report (EIR), or a Memorandum of Understanding (MOU) that will directly affect the problem addressed.

- l. Marketing/ Dissemination.** Each project should describe a preliminary plan for transmitting the knowledge or products to the end user. End users may be other researchers who will forward or expand the research concept, regulatory agencies who will use the findings in standard setting, translators who will interpret the findings for others, or workers and employers who will put the information to use. The

marketing plan should be developed to ensure the information is delivered through channels and in media appropriate to the target audience. The information or product must be relevant and practical.

Be sure to address the following:

- A description of who will use the findings, technologies, or information;
- How the findings, technologies, or information will be transmitted to the stakeholders;
- Stakeholder involvement in the development of the marketing plan.

3. Detailed Personnel Plan

- **Name and Degrees.** Starting with the project officer, list the names and degrees of all employees who are involved with the project during the budget period.
- **Role on Project.** Identify the role of each individual listed on the project. Describe their specific functions.
- **Percent of Effort on Project.** For each FTE position, list the percent effort to be spent on this project.

4. Detailed Budget Plan

- **Complete the Excel form *ProjectBudget.xls* as follows:** New and existing funding should be broken out separately. On a separate page, provide detailed justification for all projected expenditures.
- **Personnel Salaries and Benefits** include onboard PS&B costs under contribution from current allocation.

Use actual PS&B to project costs for each employee.

Use 5% when projecting cost of living increases in out year projections.

- **Travel.** Itemize travel requests. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.
- **Contractual.** Enter estimate of contractual costs, excluding Research and Development Contracts (R&D Contracts), R&D Contractual information should be entered in the Extramural section of this form.
- **Supplies.** Estimate overall cost of supplies.
- **Other.** Itemize any other expenses by category and unit cost. These might include, patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, and service contracts. Justify costs on the next page where necessary.
- **Cooperative Agreement.** Provide cost.
- **Research and Development Contract.** Provide Cost