Program Announcement To DOE National Laboratories
LAB 01-14
Biomedical Engineering Program

SUMMARY

The Medical Sciences Division in the Office of Biological and Environmental Research (OBER) of the Office of Science (SC), U.S. Department of Energy (DOE), hereby announces its interest in receiving research proposals in support of the Biomedical Engineering (BME) Program. The goal of the BME Program is to support the development of innovative, high-risk technologies that will have a significant impact on future health care. Research proposals must be multidisciplinary in nature, utilize DOE National Laboratory resources and expertise, include an active medical research partner, and address major problems that have the potential to lead to the development of technology that will make a significant impact in biomedicine. Research proposals in the following areas of biomedical engineering research will be accepted: (1) components for artificial organs, (2) medical photonics, (3) *smart* medical instrumentation, and (4) biomedical imaging.

SUPPLEMENTARY INFORMATION

The DOE BME Program supports basic BME research projects that utilize the unique resources and expertise at DOE National Laboratories to develop new innovative medical technology. The goal of the BME Program is to support basic research and technology development that will ultimately lead to the development of technology that can be transferred to the National Institutes of Health for clinical testing or to industry for further commercial development. In this solicitation, OBER will support long-term, multi-disciplinary, multi-institutional research projects that address high-risk medical technology problems. OBER is especially interested in further developing basic technologies from other DOE Programs, such as defense, environmental, and physics into technologies that will have medical applications. Research projects must be technology based, cut across scientific disciplines, and result in the development of a technology that will have a medical impact. Special consideration will be given to those projects that utilize DOE National Laboratory resources and expertise. Due to the medical nature of the BME Program, each proposal is required to have at least one actively participating medical research center as a partner. At least 50% of the work must be completed at a DOE National Laboratory(s). To qualify for this announcement, a proposal "**must**" address a significant medical technology need. Collaborations among DOE National Laboratories are strongly encouraged and will be given special consideration. Researchers are encouraged to submit proposals in the following research areas:

(1) ***Components for Artificial Organs:*** The development of novel technologies that will aid in the overall development of "functional" artificial organs. This can include the use of micro/nano engineering techniques to develop innovative components for artificial organs.

(2) ***Medical Photonics:*** The development of advanced optical systems, including lasers, which will enhance the monitoring, detection, and treatment of disease.

(3) ***Smart Medical Instrumentation:*** The development and fabrication of "*smart*" medical instruments that can operate within the body either remotely or independently to monitor, detect, and treat various medical dysfunctions. This can include the development and fabrication of biological sensors that can be used to detect or monitor various physiological functions and disease *in situ* in real-time.

(4) ***Biomedical Imaging:*** The development of novel medical imaging systems. Research emphasis should be placed on combining optical imaging with other traditional medical imaging systems such as MRI, PET, and SPECT and on the development of small imaging systems that image in real-time in natural physiological conditions.

PREPROPOSALS

Potential proposers are strongly encouraged to submit a brief one-to-two page preproposal that describes the research objectives and technical approach(s) by January 18, 2001. Each preproposal will be evaluated on the following criteria: (1) relevance to the scope and research needs of the BME program, (2) medical impact, (3) strength of research collaborations, and (4) research and development plan. The preproposal **must** identify the following items on the cover sheet:

- DOE Program Announcement number
- Title of the project
- Lead institution
- Principal Investigator name
- Collaborating institutions with investigator's name
- Telephone, fax, and e-mail address

A response encouraging or discouraging the submission of a formal proposal will be communicated by *e-mail* to the Principal Investigator within 21 days of the due date. Preproposals should be sent to Sharon Betson, Office of Biological and Environmental Research, SC-73, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290. E-mail is acceptable for

submitting preproposals using the following address: sharon.betson@science.doe.gov. (E-mail submissions must adhere to the above format.)

PROGRAM FUNDING

Contingent on availability of appropriated funds in FY 2001 and the size of the awards, it is anticipated that up to 6 projects will be supported. Multiple year funding is also expected, contingent on availability of funds and research progress. Awards are expected to range from $500,000 to $2 million per year, total costs for all institutions participating in the project, with terms up to three years.

DATES

Preproposals referencing Program Announcement LAB 01-14 should be received by January 18, 2001.

Formal proposals in response to Program Announcement LAB 01-14 should be received by 4:30 p.m., E.D.T., May 1, 2001, to be considered for merit review and funding in FY 2001.

EVALUATION CRITERIA

Proposals will be subjected to formal merit review (peer review) and will be evaluated against the following criteria:

- Scientific and/or technical merit of the project
- Appropriateness of the proposed method or approach
- Competency of the personnel and adequacy of the proposed resources
- Reasonableness and appropriateness of the proposed budget
- Utilization of DOE National Laboratory resources and expertise
- Impact proposed technology will have on health care
- Cohesiveness and strength of collaboration(s)

The evaluation will include program policy factors such as the relevance of the proposed research to the terms of the announcement and the uniqueness of the proposer's capabilities.

SUBMISSION INFORMATION

OBER will only accept ***Integrated Research Proposals*** from permanent full-time DOE National Laboratory employees (main affiliation must be a DOE National Laboratory). DOE proposers are strongly encouraged to collaborate with other National Laboratories and are required to collaborate with at least one major medical

research center. Each research proposal must have a DOE National Laboratory assuming the responsibility of the ***Lead Institution***. DOE is under no obligation to pay for any costs associated with the preparation or submission of proposals if an award is not made.

Guidelines for an Integrated Research Proposal:

To prepare an Integrated Research Proposal with either a private or academic institution, the lead DOE National Laboratory must prepare a proposal for their portion of the project and then combine each collaborating proposal into a single, *integrated research proposal*. Thus, each collaborating institution will prepare separate proposals, which will be compiled into a single integrated proposal, and submitted to OBER by the DOE National Laboratory lead institution. In each proposal, there must be a clear and distinct scope of work for each participant. Each non-DOE National Laboratory collaborating institution must submit a separate Face Page (Form DOE F 4650.2) and Budget Pages (Form DOE F 4620.1) for its portion of the project. DOE National Laboratories must submit a DOE Field Work Proposal format cover page (Reference DOE order 5700.7C) and separate Budgets Pages (Form DOE F 4620.1) for its portion of the project. A combined budget and project summary must also be included in the lead DOE National Laboratory proposal. Collaboration with other Federal Agencies must use proposal preparation instructions, which can be found at: http://www.sc.doe.gov/production/grants/fed_prop.html. The DOE lead National Laboratory must submit the components of the joint proposal to DOE in one package with a section that clearly describes the role to be played by each institution, the managerial arrangements for the project, and a description of the overall coordination of the project. If the project is approved for funding, OBER will fund the lead DOE National Laboratory and each collaborating institution separately. (*The lead DOE National Laboratory will retain the responsibility for the scientific management of the project*)

Proposal Format:

In response to this Solicitation, each proposal must follow the format outlined in the final section of this Announcement titled, **Guide for Preparation of Integrated Research Proposals**. In addition to these requirements, the *Lead DOE National Laboratory* must prepare a *proposal summary* which clearly describes: (1) the overall goals and scope of the project, (2) the role to be played by each institution, (3) the managerial arrangements for the project, (4) the overall coordination of the project, (5) a discussion of the use of DOE National Laboratory

resources and expertise, and (6) a discussion of the impact the research will have on health care. The Narrative section should be no more than 40 pages exclusive of attachments. Each collaborative project should be clearly marked and contain an abstract or project summary on a separate page with the name of the proposer, mailing address, phone, Fax, and e-mail listed. The proposal must include short curriculum vitaes that are consistent with NIH guidelines for all investigators.

For specific information for non-DOE National Laboratory collaborators concerning the development, submission of proposals, eligibility, limitations, evaluation, the selection process, and other policies and procedures can be found in 10CFR Part 605, and the Application Guide for the Office of Science Financial Assistance Program. Electronic access to the Guide and required forms is made available via the World Wide Web at: http://www.sc.doe.gov/production/grants/grants.html.

DOE policy requires that all potential proposers adhere to 10 CFR Part 745 "Protection of Human Subjects" or such later revision of those guidelines as may be published in the Federal Register. Any recipient of an award from SC performing research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules shall comply with NIH "Guidelines for Research Involving Recombinant DNA Molecules," which is available via the world wide web at: http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf, (59 FR 34496, July 5, 1994) or such later revision of those guidelines as may be published in the Federal Register.

ADDRESSES:

Preproposals referencing Program Announcement LAB 01-14 should be sent to Sharon Betson, Office of Biological and Environmental Research, SC-73, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290. E-mail is acceptable for submitting preproposals using the following address: sharon.betson@science.doe.gov.

Formal proposals referencing Program Announcement LAB 01-14, should be forwarded to Sharon Betson, Office of Biological and Environmental Research, SC-73, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, ATTN: Program Announcement LAB 01-14. This address must be used when submitting proposals by U.S. Postal Service Express Mail or any commercial mail delivery service, or when hand-carried by the proposer.

FOR FURTHER INFORMATION CONTACT:

Dr. Dean A. Cole, SC-73, Office of Biological and Environmental Research, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, telephone: (301) 903-3268, e-mail: dean.cole@science.doe.gov.

USEFUL BIOMEDICAL ENGINEERING WEB SITES:

- Biomedical Engineering Web Site: http://www.sc.doe.gov/production/ober/msd_bio_eng.html
- Biomedical Engineering Reports: http://www.sc.doe.gov/production/ober/msd_reports.html
- Laser Medicine Web Site: http://www.sc.doe.gov/production/ober/msd_laser.html
- Medical Imaging Web Site: http://www.sc.doe.gov/production/ober/msd_med_image.html

GUIDE FOR PREPARATION OF INTEGRATED RESEARCH PROPOSALS

Proposals submitted to the Office of Science (SC) as a result of this program announcement must follow the Department of Energy Field Work Proposal process with additional information requested to allow for scientific/technical merit review. The following guidelines for content and format are intended to facilitate an understanding of the requirements necessary for SC to conduct a merit review of a proposal. Please follow the guidelines carefully, as deviations could be cause for declination of a proposal without merit review.

1. Summary of Proposal Contents

- Field Work Proposal (FWP) Format (Reference DOE Order 5700.7C)
- FWP Proposal Cover Page (lead National Laboratory)
- Table of Contents
- List of all Participating Institutions and the total annual budget for each institutions
- Collaborating Institution Cover Pages (University and/or other National Laboratories)
- Budget and Budget Explanation for the lead institution and each collaborating institution
- Other support of investigators
- Abstract (one page)
- Narrative (includes proposal summary)
- Literature Cited
- Biographical Sketches

- Description of facilities and resources
- Appendix

2. Number of Copies to Submit

An original FWP with signatures plus seven copies of signed original FWP must be submitted.

3. Page Limits

The Narrative section of the proposal must be 40 pages or less exclusive of attachments.

4. Detailed Contents of the Proposal

Proposals must be readily legible, when photocopied, and must conform to the following three requirements: the height of the letters must be no smaller than 10 point with at least 2 points of spacing between lines (leading); the type density must average no more than 17 characters per inch; the margins must be at least one-half inch on all sides. Figures, charts, tables, figure legends, etc., may include type smaller than these requirements as long as they are fully legible.

5. Field Work Proposal Format (Reference DOE Order 5700.7C)

The Field Work Proposal (FWP) from DOE National Laboratories should be prepared and submitted consistent with policies of the investigator's laboratory and the local DOE Operations Office. Additional information is also requested to allow for scientific/technical merit review. Laboratories may submit proposals directly to the SC Program office listed above. A copy should also be provided to the appropriate DOE operations office.

6. FWP Proposal Cover Page

The following proposal cover page information may be placed on plain paper. No form is required.

- Title of proposed project
- SC Program Announcement title
- Name of laboratory
- Name of principal investigator (PI)
- Position title of PI
- Mailing address of PI
- Telephone number of PI
- Fax number of PI
- Electronic mail address of PI
- Name of official signing for laboratory*
- Title of official
- Fax number of official
- Telephone number of official
- Electronic mail address of official

- Requested funding for each year; total request
- Use of human subjects in proposed project:

    If activities involving human subjects **are not** planned at any time during the proposed project period, state **"No"** otherwise state **"Yes"**, and provide the IRB Approval date, Assurance of Compliance Number, and all other necessary information with the proposal.
- Use of vertebrate animals in proposed project:

    If activities involving vertebrate animals **are not** planned at any time during this project, state **"No"**; otherwise state **"Yes"**, and provide the IACUC Approval date, Animal Welfare Assurance number from NIH, and all necessary information with the proposal.
- Signature of PI, date of signature
- Signature of official, date of signature*
- List of all participating institutions, the Principal Investigator for each institution, and the total annual budget for each institution.

*(*This signature certifies that personnel and facilities are available as stated in the proposal, if the project is funded.)*

7. Table of Contents

Provide the initial page number for each of the sections of the proposal. Number pages consecutively at the bottom of each page throughout the proposal. Start each major section at the top of a new page. Do not use unnumbered pages and do not use suffices, such as 5a, 5b.

8. List of Participating Institutions

A list of all participating institutions should include: (1) the name, address, phone number, and e-mail address of the principal investigator, (2) academic affiliation, and (3) the total annual budget for each institution.

9. Collaborating Institution Cover Page(s)

Each non-DOE National Laboratory collaborating institution should submit a separate Face Page (Form DOE F 4650.2). Instructions can be found in the Application Guide for the Office of Science Financial Assistance Program, 10 CFR Part 605. Access to SC's Financial Assistance Application Guide is possible via the World Wide Web at: http://www.sc.doe.gov/production/grants/grants.html. Block 15 of the SC grant face page (form DOE F4650.2) should list the PI's phone number, fax number, and e-mail address.

10. Budget and Budget Explanation

A detailed budget is required for the overall project and for each collaborative project for the entire project period (up to three years), and for each fiscal year. It is preferred that DOE's budget page, *Form 4620.1* be used for providing budget information. Collaborating Universities should use *DOE Form 4620.1*. Modifications of categories are permissible to comply with institutional practices, for example with regard to overhead costs. A written justification of each budget item is to follow the budget pages. For personnel this should take the form of a one-sentence statement of the role of the person in the project. Provide a detailed justification of the need for each item of permanent equipment. Explain each of the other direct costs in sufficient detail for reviewers to be able to judge the appropriateness of the amount requested. Further instructions regarding the budget submission can be found at Office of Sciences Financial Assistance web site: http://www.sc.doe.gov/production/grants/forms.html.

Salaries and Wages: List the name of the principal investigator and other key personnel and the estimated number of person-months for which DOE funding is requested. Proposers should list the number of postdoctoral associates and other professional positions included in the proposal and indicate the number of full-time- equivalent (FTE) person-months and rate of pay (hourly, monthly or annually). For graduate and undergraduate students and all other personnel categories such as secretarial, clerical, technical, etc., show the total number of people needed in each job title and total salaries needed. Salaries requested must be consistent with the institution's regular practices. The budget explanation should define concisely the role of each position in the overall project.

Equipment: DOE defines equipment as "an item of tangible personal property that has a useful life of more than two years and an acquisition cost of $25,000 or more." Special purpose equipment means equipment which is used only for research, scientific, or other technical activities. Items of needed equipment should be individually listed by description and estimated cost, including tax, and adequately justified. Allowable items ordinarily will be limited to scientific equipment that is not already available for the conduct of the work. General-purpose office equipment normally will not be considered eligible for support.

Domestic Travel The type and extent of travel and its relation to the research should be specified. Funds may be requested for attendance at

meetings and conferences, travel associated with the proposed work, and subsistence. In order to qualify for support, attendance at meetings or conferences must enhance the investigator's capability to perform the research, plan extensions of it, or disseminate its results. Consultant's travel costs also may be requested. *(Funds should be included for participation in an annual BME workshop for the lead investigator from each institution involved in the project.)*

Foreign Travel Foreign travel is any travel outside Canada and the United States and its territories and possessions. Foreign travel may be approved only if it is directly related to project objectives.

Other Direct Costs The budget should itemize other anticipated direct costs not included under the headings above, including materials and supplies, publication costs, computer services, and consultant services (which are discussed below). Other examples are: aircraft rental, space rental at research establishments away from the institution, minor building alterations, service charges, and fabrication of equipment or systems not available off-the-shelf. Reference books and periodicals may be charged to the project only if they are specifically related to the research.

- **Materials and Supplies:** The budget should indicate in general terms the type of required expendable materials and supplies with their estimated costs. The breakdown should be more detailed when the cost is substantial.
- **Publication Costs/Page Charges:** The budget may request funds for the costs of preparing and publishing the results of research, including costs of reports, reprints page charges, or other journal costs (except costs for prior or early publication), and necessary illustrations.
- **Consultant Services:** Anticipated consultant services should be justified and information furnished on each individual's expertise, primary institutional affiliation, daily compensation rate, and number of days expected service. Consultant's travel costs should be listed separately under travel in the budget.
- **Computer Services:** The cost of computer services, including computer-based retrieval of scientific and technical information, may be requested. A justification based on the established computer service rates should be included.
- **Subcontracts:** Subcontracts should be listed so that they can be properly evaluated. There should be an anticipated cost and an

explanation of that cost for each subcontract. The total amount of each subcontract should also appear as a budget item. *(The budget for collaborating institutions should be submitted separately and not included in this item.)*

- **Indirect Costs:** Explain the basis for each overhead and indirect cost. Include the current rates.

11. Other Support of Investigators

Other support is defined as all financial resources, whether Federal, non-Federal, commercial, or institutional, available in direct support of an individual's research endeavors. Information on active and pending other support is required for all senior personnel, including investigators at collaborating institutions to be funded by a subcontract. For each item of other support, give the institution or agency, inclusive dates of the project or proposed project, annual funding, and level of effort devoted to the project.

12. Abstract

Provide an abstract of no more than 400 words. Give the broad, long-term objectives and what the specific research proposed is intended to accomplish. The abstract must clearly discuss; (1) how the proposed research addresses the scientific/technical area specifically described in this announcement, (2) the collaborative nature of the project, and (3) the medical impact of the proposed research.

13. Narrative

The narrative comprises the research plan for the project and is limited to 40 pages. It must contain the following subsections:

Proposal Summary: The *Lead National Laboratory* must include a section which clearly describes: (1) the overall goals and scope of the project, (2) the role to be played by each institution, (3) the managerial arrangements for the project, (4) the overall coordination of the project, (5) a discussion of use of National Laboratory resources and expertise, and (6) a discussion of the impact the research will have on health care.

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 of the research described in the proposal. Explain the relevance of the project to the research needs identified by the Office of Science. Include

references to relevant published literature, both to work of the investigators and to work done by other researchers.

Preliminary Studies: Use this section to provide an account of any preliminary studies that may be pertinent to the proposal. Include any other information that will help to establish the experience and competence of the investigators to pursue the proposed project. References to appropriate publications and manuscripts submitted or accepted for publication may be included.

Research Design and Methods: Describe the research design and the procedures to be used to accomplish the specific aims of the project. Describe new techniques and methodologies and explain the advantages over existing techniques and methodologies. As part of this section, provide a tentative sequence or timetable for the project.

Consortium Arrangements: If any portion of the project described under "Research Design and Methods" is to be done as a consortium with another institution, provide information on the institution and why it is to do the specific component of the project. Further information on any such arrangements is to be given in the sections "Budget and Budget Explanation," "Biographical Sketches," and "Description of Facilities and Resources".

14. Literature Cited

List all references cited in the narrative. Limit citations to current literature relevant to the proposed research. Information about each reference should be sufficient for it to be located by a reviewer of the proposal.

15. Biographical Sketches

This information is required for senior personnel at the laboratory submitting the proposal and at all collaborating institutions. The biographical sketch is limited to a maximum of two pages for each investigator.

16. Description of Facilities and Resources

Describe briefly the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe pertinent capabilities, including support facilities (such as machine shops) that will be used during the project. List the most important equipment items already available for the project and their pertinent capabilities. Include this information for each collaborating institution, if any.

17. Appendix

Include collated sets of all appendix materials with each copy of the proposal. Do not use the appendix to circumvent the page limitations of the proposal. Information should be included that may not be easily accessible to a reviewer. Reviewers are not required to consider information in the Appendix, only information in the body of the proposal. *(Please Note: Reviewers may not have time to read the appendix materials with the same care as they would read the main proposal)*. The appendix may contain the following items: up to five publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to this project, but not generally available to the scientific community; and letters from investigators at other institutions stating their agreement to participate in the project (do not include letters of endorsement of the project).

18. Human Subjects

DOE policy requires that potential proposers adhere to 10 CFR Part 745 "Protection of Human Subjects," or such later revision of those guidelines as may be published in the Federal Register

19. Recombinant DNA Research.

Any recipient of an award from SC performing research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules shall comply with the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules," which is available via the world wide web at: http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf, (59 FR 34496, July 5, 1994,) or such later revision of those guidelines as may be published in the Federal Register.