Program Announcement LAB 98-19
Human Genome Program
Ethical, Legal, and Social Implications

The Office of Biological and Environmental Research (OBER) of the Office of Energy Research (ER) of the U.S. Department of Energy (DOE), hereby announces its interest in receiving proposals from the National Laboratories in support of the Ethical, Legal, and Social Implications (ELSI) subprogram of the Human Genome Program (HGP). The Office of Biological and Environmental Research of the U. S. Department of Energy and the National Human Genome Research Institute of the National Institutes of Health are participating in a coordinated international program to "determine the complete sequence of the human genome, discover all the human genes and render them accessible for further biological study." This particular research notice invites research proposals that address ethical, legal, and social implications from the use of DNA sequence, genetic information, and functional knowledge resulting from the HGP.

A general discussion of the Human Genome Program, as well as past and ongoing activities in the ELSI area may be found in Primer on Molecular Genetics available on the Internet using the following web address:
http://www.ornl.gov/TechResources/Human_Genome/publicat/primer/intro.html
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Research proposals are invited that will address, analyze, or anticipate ELSI issues associated with human genome research. The DOE particularly encourages research in four broad areas:

I. The uses, impacts, implications of, and privacy of genetic information in the workplace, particularly screening and monitoring programs that involve the collection and evaluation of genetic information, and the use of the workplace as a research venue. Research is encouraged that would explore historical experiences, current practices, and lessons learned as they pertain to the collection and use of worker genetic information. This research can include issues arising from the creation, use, maintenance, privacy and disclosure of genetic information obtained in workplace settings that can include, but is not limited to, workplaces at which DOE activities are taking place or have in the past.

II. Access to, and protection of, genetic information particularly information stored in computerized databases, or obtained from stored human tissue or sample archives. Research is encouraged to explore confidentiality of genetic data in databanks and databases, the anonymization of genetic records and samples, and the intellectual

property protection of genetic information and genome research tools, technologies, and resources.

III. The preparation and dissemination of relevant educational materials in any appropriate medium that will enhance understanding of the ethical, legal, and social aspects of the HGP among the public or specified groups. An interest of this notice is the education of Institutional Review Boards (IRB) that review protocols involving the gathering of genetic information and genome investigators who work with human subjects or materials from which genetic information can be obtained. Additional groups of interest could include judges, the media, policy makers, and DOE employees and contractors.

IV. The ethical, legal, and societal implications of advances in the scientific understanding of complex or multi-genic characteristics and conditions, gene-environment interactions that result in diseases or disease susceptibilities, and human polymorphisms. In particular, the DOE is interested in studies identifying the responses of institutions (e.g., courts, employers, companies, schools, etc.) that must deal with "genetic uncertainty," e.g., lack of certainty of the results of screening for susceptibility genes, uncertain consequences of yet-undefined environmental influences, and highly polymorphic genes whose numerous alleles are not fully characterized.

All proposals should demonstrate knowledge of the relevant literature, any related completed activities, and should include detailed plans for the gathering and analysis of factual information and the associated ethical, legal, and social implications. All proposals should include, where appropriate, detailed discussion of human subjects protection issues, e.g., storage of, manipulation of, and access to data. Provisions to ensure the inclusion of women, minorities, and potentially disabled individuals must be described, unless specific exclusions are scientifically necessary and justified in detail. All proposed research should address the issue of efficient dissemination of results to the widest appropriate audience as well as a time line for their production and dissemination. In the absence of tangible products, rigorous assessments must be included to facilitate evaluation of progress. All proposals should include letters of agreement to collaborate from potential collaborators; these letters should specify the contributions the collaborators intend to make if the proposal is accepted and funded. If an educational effort for a specific group is proposed, the value to the Human Genome Program of that group or community should be explained in detail. In addition, the DOE encourages proposals for the support of novel and innovative conferences focusing on the concerns addressed in this notice, e.g., privacy and access to research materials, workplace uses of genetic information, education of targeted groups such as IRBs and investigators, and susceptibility/sensitivity genes, and polymorphisms.

Educational and conference proposals should demonstrate awareness of the relevant literature, include detailed plans for the accomplishment of project goals, and clearly describe the outcomes or "deliverables" from the activity. For conference proposals, a detailed and largely complete roster of speakers is necessary. Educational and conference proposals must also demonstrate awareness of the need to reach the widest appropriate audience, and not be focused exclusively on a local community or group. For all conferences supported under this notice, a summary report is required following the conference. In proposals that would support the production of educational materials, the DOE requests that samples of previous similar work by the producers and writers be submitted along with the proposal. In proposals for the support of educational activities, the DOE requires inclusion of a plan for assessment of the effectiveness of the proposed activities.

DOE does not encourage proposals dealing with issues consequent to the initiation or implementation of genetic testing protocols. Also, DOE does not encourage survey-based research, unless a compelling case is made that this methodology is critical to address an issue of uncommon significance. DOE generally discourages proposals for local efforts (e.g., college or school curricula that will not be disseminated) and requests detailed justification of the need for external support, beyond normal departmental and college resources, evidence of commitment from the parent department or college, and a dissemination plan. Proposals for the writing of scholarly publications or books should include justifications for the relevance of the publications or book to the goals of the Human Genome Project as well as discussion of the estimated readership and impact. DOE ordinarily will not provide unlimited support for a funded program and thus strongly encourages the inclusion of plans for transition to self-sustaining status.

The dissemination of materials and research data in a timely manner is essential for progress toward the goals of the DOE Human Genome Program. The OBER requires the timely sharing of resources and data. Proposers should, in their proposals, discuss their plans for disseminating research results and materials that may include, where appropriate, publication in the open literature, wide-scale mailings, etc. Once OBER and the proposer have agreed upon a distribution plan, it will become part of the award conditions. Funds to defray the costs of disseminating results and materials are allowable; however, such requests must be sufficiently detailed and adequately justified. Proposers should also provide time lines projecting progress toward achieving proposed goals.

DATES: Potential proposers are strongly encouraged to submit a brief preproposal. All preproposals should be received by DOE by 4:30 P.M., E.D.T., July 30, 1998. Early submissions are encouraged. A response encouraging or discouraging a formal proposal will be communicated to the proposer within 20 days of receipt.

Formal proposals, in response to this program announcement, must be received by 4:30 p.m., E.D.T., September 17, 1998, in order to be accepted for merit review and to permit timely consideration for award in Fiscal Year 1999.

ADDRESS: Preproposals, referencing Program Announcement LAB98-19, should be forwarded to: Dr. Daniel W. Drell, Office of Biological and Environmental Research, ER-72, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, Attn: Program Announcement LAB98-19.

Formal proposals, referencing Program Announcement LAB98-19, should be forwarded to: U.S. Department of Energy, Office of Energy Research, Office of Biological and Environmental Research, ER-72, 19901 Germantown Road, Germantown, MD 20874-1290, Attn: Program Announcement LAB98-19. This address also 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. An original and seven copies of the proposal must be submitted.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel W. Drell, Office of Biological and Environmental Research, ER-72, 19901 Germantown Road, Germantown, MD 20874-1290; telephone: (301) 903-6488; E-mail: daniel.drell@oer.doe.gov..

Program Funding

It is anticipated that up to a total of $500,000 will be available for awards to the National Laboratories to be made in Fiscal Year 1999 for the Human Genome Ethical Legal and Social Implications Research Program, contingent on the availability of appropriated funds. Award sizes are expected to be on the order of $100,000-200,000 per year. Collaborative projects involving several research groups or more than one institution may receive larger awards if merited.

Preproposals

A brief preproposal is strongly encouraged. The preproposal should identify, on the cover sheet, the Laboratory, the Laboratory Division, Principal Investigator name, address, telephone, fax and E-mail address, title of the project, and the field of scientific research. The preproposal should consist of a two to three page narrative describing the research project objectives and methods of accomplishment. These will be reviewed relative to the scope and research needs described in this Announcement.

Preproposals are strongly encouraged but not required prior to submission of a full proposal. Please note that notification of a successful preproposal is not an indication that an award will be made in response to the formal proposal.

Any recipient of an award from ER to perform research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules shall comply with the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules," which is available via the world wide web at: **http://www.niehs.nih.gov/odhsb/biosafe/nih/nih97-1.html**, (59 FR 34496, July 5, 1994), or such later revision of those guidelines as may be published in the Federal Register.

The instructions and format described below should be followed. Reference announcement LAB 98-19 on all submissions and inquiries about this program.

OFFICE OF ENERGY RESEARCH
GUIDE FOR PREPARATION OF SCIENTIFIC/TECHNICAL PROPOSALS TO BE SUBMITTED BY NATIONAL LABORATORIES

Proposals from National Laboratories submitted to the Office of Energy Research (ER) as a result of this program announcement will 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 ER 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. Evaluation Criteria

Proposals will be subjected to formal merit review (peer review) and will be evaluated against the following criteria which are listed in descending order of importance:

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

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

capabilities, and demonstrated usefulness of the research for proposals in other DOE Program Offices as evidenced by a history of programmatic support directly related to the proposed work.

2. Summary of Proposal Contents

Field Work Proposal Format (Reference DOE Order 5700.7C) (DOE ONLY)
Proposal Cover Page
Table of Contents
Abstract
Narrative
Literature Cited
Budget and Budget Explanation
Other support of investigators
Biographical Sketches
Description of facilities and resources
Appendix

2.1 Number of Copies to Submit

An original and seven copies of the formal proposal/FWP must be submitted.

3. 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 12 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 so long as they are still fully legible.

3.1 Field Work Proposal Format (Reference DOE Order 5700.7C)
(DOE ONLY)

The Field Work Proposal (FWP) is to 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 ER Program office listed above. A copy should also be provided to the appropriate DOE operations office.

3.2 Proposal Cover Page

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

Title of proposed project
ER Program announcement title
Name of laboratory
Name of principal investigator (PI)
Position title of PI
Mailing address of PI
Telephone 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 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", provide the IRB Approval date and Assurance of Compliance Number and include all necessary information with the proposal should human subjects be involved.
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 and Animal Welfare Assurance number from NIH and include all necessary information with the proposal.
Signature of PI, date of signature
Signature of official, date of signature*

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

3.4 Abstract

Provide an abstract of no more than 250 words. Give the broad, long-term objectives and what the specific research proposed is intended to accomplish. State the hypotheses to be tested. Indicate how the proposed research addresses the ER scientific/technical area specifically described in this announcement.

3.5 Narrative

The narrative comprises the research plan for the project and is limited to 25 pages. It should contain the following subsections:

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 Energy Research. 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.

Subcontract or Consortium Arrangements: If any portion of the project described under "Research Design and Methods" is to be done in collaboration 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".

3.6 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.

3.7 Budget and Budget Explanation

A detailed budget is required for the entire project period, which normally will be three years, and for each fiscal year. It is preferred that DOE's budget page, Form 4620.1 be used for providing budget information*. 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 are given in section 4 of this guide.

* Form 4620.1 is available at web site:
http://www.er.doe.gov/production/grants/forms.html

3.8 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 organization or agency, inclusive dates of the project or proposed project, annual funding, and level of effort devoted to the project.

3.9 Biographical Sketches

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

3.10 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 subcontracting institution, if any.

3.11 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 that in the body of the proposal. Reviewers may not have time to read extensive appendix materials with the same care as they will read the proposal proper.

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).

4. Detailed Instructions for the Budget
(DOE Form 4620.1 "Budget Page" may be used)

4.1 Salaries and Wages

List the names 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.

4.2 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 $5000 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.

4.3 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, other travel associated with the 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.

4.4 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.

4.5 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.

a. 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.

b. 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.

c. Consultant Services

Anticipated consultant services should be justified and information furnished on each individual's expertise, primary organizational affiliation, daily compensation rate and number of days expected service. Consultant's travel costs should be listed separately under travel in the budget.

d. 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.

e. 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.

4.6 Indirect Costs

Explain the basis for each overhead and indirect cost. Include the current rates.