

Office of Energy Research

Notice 98-19

Human Genome Program - Ethical, Legal, and Social Implications

Department of Energy
Office of Energy Research

Energy Research Financial Assistance Program Notice 98-19; Human Genome Program - Ethical, Legal, and Social Implications

Agency: U.S. Department of Energy

Action: Notice inviting grant applications.

SUMMARY: The Office of Biological and Environmental Research (OBER) of the Office of Energy Research (ER), U.S. Department of Energy (DOE), hereby announces its interest in receiving applications in support of the Ethical, Legal, and Social Implications (ELSI) subprogram of the Human Genome Program (HGP). The HGP is a coordinated, multidisciplinary, directed research effort aimed at obtaining a detailed understanding of the human genome at the molecular level. This particular research notice invites research grants that address ethical, legal, and social implications from the use of information and knowledge resulting from the HGP.

DATES: Potential applicants are strongly encouraged to submit a brief preapplication. All preapplications, referencing Program Notice 98-19, should be received by 4:30 p.m., E.D.T., July 30, 1998. Early submissions are encouraged. A response discussing the potential program relevance and encouraging or discouraging a formal application generally will be communicated within 20 days of receipt.

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

ADDRESSES: Preapplications, referencing Program Notice 98-19, should be sent to: Dr. Daniel W. Drell, Office of Biological and Environmental Research, ER-72, 19901 Germantown Road, Germantown, MD 20874-1290.

Formal applications, referencing Program Notice 98-19, should be forwarded to: U.S. Department of Energy, Office of Energy Research, Grants and Contracts Division, ER-64, 19901 Germantown Road, Germantown, MD 20874-1290, ATTN: Program Notice 98-19. This address also must be used when submitting applications by U.S.

Postal Service Express Mail, or any commercial mail delivery service, or when hand carried by the applicant. An original and seven copies of the application must be submitted.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel W. Drell, Office of Biological and Environmental Research, ER-72, Office of Energy Research, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, telephone: (301) 903-6488 or E-mail: daniel.drell@oer.doe.gov. The full text of Program Notice 98-19 is available via the Internet using the following web site address: <http://www.er.doe.gov/production/grants/grants.html>.

SUPPLEMENTARY INFORMATION: The DOE encourages the submission of applications 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 applications 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 applications 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 applications 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 applications should include letters of agreement to collaborate from potential collaborators; these letters should specify the contributions the collaborators intend to make if the application 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 applications 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 applications 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 applications, a detailed and largely complete roster of speakers is necessary. Educational and conference applications 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 applications that propose the production of educational materials, the DOE requests that samples of previous similar work by the producers and writers be submitted along with the application. In applications 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 applications 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 applications 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. Applications 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. Applicants should, in their applications, 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 applicant 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. Applicants should also provide time lines projecting progress toward achieving proposed goals.

Program Funding

It is anticipated that approximately \$1,500,000 will be available for multiple grant awards to be made during Fiscal Year 1999, contingent upon the availability of appropriated funds. Multiple year funding of grant awards is expected, and is also contingent upon the availability of funds. Previous awards have ranged from \$50,000 per year up to \$500,000 per year with terms from one to three years; most awards average about \$200,000 per year for two or three years. Similar award sizes are anticipated for new grants. Generally, conference awards do not exceed \$25,000 and indirect costs are not allowed as part of conference grant awards.

Collaboration

Applicants are encouraged to collaborate with researchers in other institutions, such as universities, industry, non-profit organizations, federal laboratories and federally funded research and development centers (FFRDCs), including the DOE National Laboratories, where appropriate, and to incorporate cost sharing and/or consortia wherever feasible.

Collaborative research applications may be submitted in several ways:

(1) When multiple private sector or academic organizations intend to propose collaborative or joint research projects, the lead organization may submit a single application which includes another organization as a lower-tier participant (subaward) who will be responsible for a smaller portion of the overall project. If approved for funding, DOE may provide the total project funds to the lead organization who will provide funding to the other participant via a subcontract arrangement. The application should clearly describe the role to be played by each organization, specify the managerial arrangements and explain the advantages of the multi-organizational effort.

(2) Alternatively, multiple private sector or academic organizations who intend to propose collaborative or joint research projects may each prepare a portion of the application, then combine each portion into a single, integrated scientific application. A separate Face Page and Budget Pages must be included for each organization participating in the collaborative project. The joint application must be submitted to DOE as one package. If approved for funding, DOE will award a separate grant to each collaborating organization.

(3) Private sector or academic organizations who wish to form a collaborative project with a DOE FFRDC may not include the DOE FFRDC in their application as a lower-tier participant (subaward). Rather, each collaborator may prepare a portion of the proposal, then combine each portion into a single, integrated scientific proposal. The private sector or academic organization must include a Face Page and Budget Pages for its portion of the project. The FFRDC must include separate Budget Pages for its portion of the project. The joint proposal must be submitted to DOE as one package. If approved for funding, DOE will award a grant to the private sector or academic organization. The FFRDC will be funded, through existing DOE contracts, from funds specifically designated for new FFRDC projects. DOE FFRDCs will not compete for funding already designated for private sector or academic organizations. Other Federal laboratories who wish to form collaborative projects may also follow guidelines outlined in this section.

Preapplications

A brief preapplication should be submitted. The preapplication should identify, on the cover sheet, the institution, Principal Investigator name, address, telephone, fax and E-mail address, title of the project, and the field of scientific research. The preapplication 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 of the DOE's Human Genome Program.

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

Applications will be subjected to a scientific merit review (peer review) and will be evaluated against the following evaluation criteria listed in descending order of importance as codified at 10 CFR 605.10(d):

1. Scientific and/or Technical Merit of the Project,
2. Appropriateness of the Proposed Method or Approach,
3. Competency of Applicant's Personnel and Adequacy of Proposed Resources,
4. 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 and an agency's programmatic needs. Note, external peer reviewers are selected with regard to both their scientific expertise and the absence of conflict-of-interest issues. Non-federal reviewers may be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

Information about development and submission of applications, eligibility, limitations, evaluation, selection process, and other policies and procedures may be found in 10 CFR Part 605 and in the Application Guide for the Office of Energy Research Financial Assistance Program. Electronic access to the Guide and required forms is made available via the World Wide Web at:

<http://www.er.doe.gov/production/grants/grants.html>.

Energy Research, as part of its grant regulations, requires at 10 CFR 605.11(b) that a recipient receiving a grant 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 Catalog of Federal Domestic Assistance number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR Part 605.

John Rodney Clark
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for Resource Management
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Published in the Federal Register June 15, 1998, Volume 63, Number 114, Pages 32649-32651.