

Office of Energy Research

Notice 97-11

Human Genome Program - Ethical, Legal, and Social Implications

**Department of Energy
Office of Energy Research**

Energy Research Financial Assistance Program Notice 97-11: Human Genome Program - Ethical, Legal, and Social Implications

AGENCY: U.S. Department of Energy

ACTION: Notice inviting grant applications

SUMMARY: The Office of Health and Environmental Research (OHER) 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, multi disciplinary, 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: Preapplications referencing Program Notice 97-11 should be received by April 17, 1997. Formal applications submitted in response to this notice must be received by 4:30 p.m., E.D.T., July 10, 1997, to permit timely consideration for awards in Fiscal Year 1998.

ADDRESSES: Preapplications referencing Program Notice 97-11 should be sent to Dr. Daniel W. Drell, Health Effects and Life Sciences Research Division, ER-72, Office of Health and Environmental Research, Office of Energy Research, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290. Formal applications referencing Program Notice 97-11 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 97-11. 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.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel W. Drell, Health Effects and Life Sciences Research Division, ER-72, Office of Health and Environmental Research, Office of Energy Research, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, phone: (301) 903-6488 or E-mail: daniel.drell@oer.doe.gov.

SUPPLEMENTARY INFORMATION: The DOE encourages the submission of applications that will address, analyze, or anticipate ELSI issues arising from advances in the scientific understanding of genetically influenced susceptibilities/sensitivities, complex or multi-genic characteristics and conditions, and human polymorphisms. This may include research on privacy and confidentiality issues (as well as ownership and commercialization issues) arising from the creation, use, maintenance, and disclosure of genetic information relevant to such complex or multi-genic conditions. This may also include research on the privacy implications of the development of HGP materials, resources, databases and technologies, as well as the privacy implications of the use of genetic information obtained in the workplace. Issues to be examined may also include (but are not limited to) implications of advances in the genetic characterization of complex traits and susceptibility/sensitivity genes and the impacts of advances in knowledge about polygenic conditions for individuals and communities potentially faced with these impacts (e.g. courts, schools, etc).

All applications should demonstrate knowledge of the relevant literature, 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. 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.

The DOE also solicits applications for the preparation and dissemination of 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; a particular interest of this notice is Institutional Review Boards (IRBs) and genome investigators who work with patients. This may include (but is not limited to) implications of disease predispositions, susceptibility genes, increased knowledge of polygenic conditions, informed consent issues or Human Genome Project materials- and resources-development and dissemination projects (e.g. the creation of a human DNA library, etc.). 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. susceptibility/sensitivity genes, polymorphisms, and education of IRBs and investigators).

Educational and conference applications should demonstrate awareness of the relevant literature, and include detailed plans for the accomplishment of project goals. In applications that propose the production of series for broadcast, audio-visuals or other 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 requests inclusion of a plan for assessment of the effectiveness of the proposed activities. For conference applications, a detailed and largely complete roster of speakers is necessary. At the completion of the conference, a summary or report is required. 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.

Possible outcomes of these research and/or educational efforts may include (but are not limited to): model guidelines for research practices for studies of polygenic conditions and susceptibility genes; consensus documents on implications or significance of the genetic bases for complex conditions; privacy and confidentiality studies of genetic information pertinent to complex conditions; model policies for genetic information about polygenic conditions for various settings (e.g. the workplace); exploration of worker/workplace issues; and materials for IRBs.

In all applications, a clear description of expected products or "deliverables" should be included, 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.

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. For applications which propose the development of college-level curricula, DOE requests both 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 towards the goals of the DOE Human Genome Program. The OHER 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 OHER 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 timelines projecting progress toward achieving proposed goals.

Potential applicants are strongly encouraged to submit a brief preapplication that consists of two to three pages of 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. Principal investigator address, telephone number, FAX number and E-mail address are required parts of the preapplication. A response to each preapplication discussing the potential program relevance of a formal application generally will be communicated within 20 days of receipt. ER's preapplication policy for submitting preapplications can be found on ER's Grants and Contracts Web Site at: <http://www.er.doe.gov/production/grants/preapp.html>.

It is anticipated that approximately \$1,500,000 will be available for grant awards in this area during FY 1998, contingent upon availability of appropriated funds. Multiple year funding of grant awards is expected, and is also contingent upon 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.

Applications will be subjected to formal merit review (peer review) and will be evaluated against the following evaluation criteria which are listed in descending order of importance 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 will often be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

To provide a consistent format for the submission, review and solicitation of grant applications submitted under this notice, the preparation and submission of grant applications must follow the guidelines given in the Application Guide for the Office of Energy Research Financial Assistance Program 10 CFR Part 605. Access to ER's Financial Assistance Application Guide is possible via the World Wide Web at: <http://www.er.doe.gov/production/grants/grants.html>.

DOE policy requires that potential applicants adhere to 10 CFR 745 "Protection of Human Subjects", 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.

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Published in the Federal Register March 3, 1997, Vol. 62, No. 41, pages 9419-9420.