

**Office of Science
Notice 02-14**

***Human Genome Program -
Ethical, Legal, and Social Implications***

Department of Energy (DOE)

Office of Science Financial Assistance Program Notice 02-14; 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 (BER) of the Office of Science (SC), 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). Applications should focus on issues of (1) genetics and the workplace, (2) storage of genetic information and tissue samples, (3) education, or (4) complex or multigenic traits. 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 applications that address ethical, legal, and social implications resulting 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 02-14, should be received by 4:30 p.m., E.S.T., January 24, 2002. 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.S.T., March 28, 2002, to be accepted for merit review and to permit timely consideration for award in Fiscal Year 2002.

ADDRESSES: Preapplications, referencing Program Notice 02-14, should be sent by email to Joanne.Corcoran@science.doe.gov or by mail to Dr. Daniel W. Drell, Office of Biological and Environmental Research, SC-72, 19901 Germantown Road, Germantown, MD 20874-1290.

Formal applications, referencing Program Notice 02-14, should be forwarded to: U.S. Department of Energy, Office of Science, Grants and Contracts Division, SC-64, 19901 Germantown Road, Germantown, MD 20874-1290, ATTN: Program Notice 02-14. 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, SC-72, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, telephone: (301) 903-4742 or email: daniel.drell@science.doe.gov. The full text of Program Notice 02-14 is available via the Internet using the following web site address: <http://www.sc.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 in four broad areas:

I. Genetics and the Workplace

Research is encouraged on the uses, impacts, implications of, and privacy of genetic information in the workplace. A particular emphasis of this solicitation is screening and monitoring programs that involve the collection and evaluation of worker genetic information. Research is also encouraged on the use of the workplace as a research venue and the resulting challenges for Institutional Review Boards (IRBs) that are responsible for the oversight of such activities. Research could explore historical experiences, current practices, international practices, the economics of, and lessons learned as they pertain to the collection and use of worker genetic information. Research can include issues arising from the creation, use, maintenance, privacy, and disclosure of genetic information obtained in workplace settings that can include, but are not limited to, workplaces at which DOE activities are taking place or have in the past.

II. Storage of Information and Samples

Research is encouraged on access to, and protection of genetic information stored in databases (especially computerized databases), or obtained from stored human tissue or sample archives. Research can explore threats to, issues surrounding, and protection of the confidentiality of genetic data in databanks and databases, approaches to anonymizing existing or new genetic records and samples, approaches to assessing the economics of genetic data collection, and explorations of the intellectual property protection of genetic information and genome research tools, technologies, and resources. Research can also explore the privacy and ownership issues associated with genetic data in records collected as part of occupational medical surveillance, as well as in academic genetics research.

III. Education

Research is encouraged to create and disseminate 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. A particular interest of this solicitation is the creation of innovative and novel materials for Institutional Review Boards (IRB) and Ethics Boards that review protocols involving the gathering of genetic information from genome investigators who work with human subjects, materials from which human genetic information

can be obtained, or genetics research involving the workplace. Educational efforts should not target specific groups that have already been the subject of past ELSI awards (for further information about past awards under previous ELSI solicitations, see <http://www.ornl.gov/hgmis/elsi/elsi.html>). Applications for new mass media projects (e.g., TV documentaries) are not encouraged, nor are new high school- or college-level curricula, under this notice.

IV. Complex or Multigenic Traits

Research is encouraged that addresses the ethical, legal, and societal implications of advances in the scientific understanding of complex or multi-genic characteristics and conditions. Conditions may include, but are not limited to, behavioral conditions, diseases of aging, vulnerability to substance abuse, susceptibility to workplace exposure hazards (such as chemicals or radiation), or other common conditions with a partial genetic basis. This research may address:

- 1) Gene - environment interactions that result in diseases or disease susceptibilities.
- 2) Studies that explore the novel issues raised by research on complex conditions.
- 3) The responses of institutions (e.g., courts, employers, companies or company health officers, schools, etc., including Federal Agencies) that must deal with "genetic uncertainty," e.g., uncertainty about the significance of results of screening for susceptibility genes, uncertainty about the role of yet-undefined environmental influences, and uncertainty about the implications of different alleles at highly polymorphic genes when those 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 personal genetic 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 provide a plan to disseminate 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 evaluate progress or outcomes. 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 and measures for assessment of effectiveness described. 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 outcome 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 geographically limited 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 BER 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 BER 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.

Additional Request for Small Grants

The DOE also encourages small grant applications, to a maximum of \$33,000 total costs, for innovative and exploratory activities within the previously described areas. Such exploratory grants could be used to carry out pilot or investigative research on an issue consistent with any of the above areas of ELSI research, support a sabbatical leave to organize and hold a conference, or to initiate start-up studies that could generate preliminary data for a subsequent grant application. This program could be appropriate for a research scientist interested in exploring a related area of ELSI research, or a scholar conducting ELSI research of one type to explore an ELSI research topic of a different type. Such applications must use the standard DOE application forms that can be found on the Internet at: <http://www.sc.doe.gov/production/grants/grants.html>. The description of research activities should not be more than five pages and curriculum vitae should not exceed two pages. These small grants, which will be peer reviewed, will not extend beyond one year from the award date. It is expected that up to seven of these awards might be made in FY 2002. As with larger applications to this notice, applications should be sent to the address given above.

Program Funding

It is anticipated that approximately \$800,000 will be available for multiple grant awards (including any small grants) to be made during Fiscal Year 2002, 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 (not applicable for any small grants as stated above). 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, DOE National Laboratories, industry, non-profit organizations, other federal laboratories and federally funded research and development centers (FFRDCs), where appropriate, and to incorporate cost sharing and/or consortia wherever feasible. Additional information on collaboration is available in the Application Guide for the Office of Science Financial Assistance Program that is available via the Internet at: <http://www.sc.doe.gov/production/grants/Colab.html>.

Preapplications

A brief preapplication should be submitted. The preapplication should identify, on the cover sheet, the institution, Principal Investigator name, address, telephone, fax and email 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 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 is under no obligation to pay for any costs associated with the preparation or submission of applications if an award is not made.

DOE policy requires that potential applicants 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.

The Office of Science, as part of its grant regulations, requires at 10 CFR 605.11(b) that a recipient receiving a grant and performing 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/rdna-apr98.pdf>, (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
Associate Director of Science
for Resource Management

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