

Office of Energy Research

Notice 96-09
Human Genome Program -
Ethical, Legal, and Social Implications

DEPARTMENT OF ENERGY
OFFICE OF ENERGY RESEARCH

Energy Research Financial Assistance Program Notice 96-09: Human Genome Program - Ethical, Legal, and Social Implications

AGENCY: U.S. Department of Energy (DOE)

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, hereby announces its interest in receiving applications in support of the Ethical, Legal, and Social Implications (ELSI) subprogram of the Human Genome Program (HGP). This program 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 encompasses research grants that address ethical, legal, and social issues that may arise 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 96-09, should be received by DOE by 4:30 P.M. E.S.T., March 28, 1996. A response discussing the potential program relevance of a formal application generally will be communicated to the applicant within 30 days of receipt. The deadline for receipt of formal applications submitted in response to this notice must be received by 4:30 p.m., E.D.T., July 11, 1996, to be accepted for merit review in September 1996 and to permit timely consideration for award in fiscal year 1997.

ADDRESSES: Preapplications referencing Program Notice 96-09 should be sent to Dr. Daniel W. Drell, U.S. Department of Energy, Office of Health and Environmental Research, ER-72, 19901 Germantown Road, Germantown, MD 20874-1290.

After receiving notification from DOE concerning successful preapplications, applicants may prepare formal applications and send them 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 96-09. The above address for formal applications also must be used when submitting formal applications by U.S. Postal Service Express Mail, and commercial mail delivery service, or when handcarried by the applicant.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel W. Drell, U.S. Department of Energy, Office of Health and Environmental Research, ER-72, 19901 Germantown Road, Germantown, MD 20874-1290, by telephone (301) 903-6488, by FAX (301) 903-8521, or preferably by E-mail, joanne.corcoran@oer.doe.gov.

SUPPLEMENTARY INFORMATION: The DOE encourages the submission of applications to conduct research on privacy and confidentiality issues from the creation, use, maintenance, and disclosure of genetic information. This may include (but is not limited to) issues of ownership, commercialization, and control of genetic information, and the protection of the privacy of genetic information in various settings, including the workplace. 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 involving collaborations should include letters of support from the potential collaborators; these letters should specify the contributions the collaborator intends 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 scientific, as well as the ethical, legal, and social aspects of the HGP among public or specified groups. If an educational effort for a specific group is proposed, the value to the HGP of that group or community should be explained in detail. In addition, the DOE encourages applications for the support of conferences focusing on the ethical, legal, and social implications of the HGP. Issues to be examined may include (but are not limited to) implications of advances in the genetic characterization of complex traits (e.g., disease predisposition or susceptibility genes) and the impacts of advances in knowledge about polygenic conditions for various communities potentially faced with these impacts (e.g., courts, schools, etc.).

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.

Ordinarily, DOE does not encourage applications dealing with issues consequent to genetic testing protocols. Additionally, 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 that 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 HGP 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 brief preapplication, in accordance with 10 CFR 600.10(d)(2), should consist of two to three pages of narrative describing the research project objectives and methods of accomplishment. The preapplications will be reviewed for relevance to the notice, and further instructions will be provided with the response. Preapplications determined by staff of the Office of Health and Environmental Research to be insufficiently directed at the goals of the notice will be returned without further review to the applicant. Telephone and facsimile numbers are required parts of the preapplication, and electronic mail addresses are desirable.

It is anticipated that approximately \$1,300,000 will be available for grant awards in this area during FY 1997, 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 1 to 3 years; most awards average about \$200,000 per year for 2 or 3 years. Similar award sizes are anticipated for new grants.

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. The Application Guide is available from the U.S. Department of Energy, Office of Health and Environmental Research, Health Effects and Life Sciences Research Division, ER-72, 19901 Germantown Road, Germantown, MD 20874-1290. Telephone requests may be made by calling (301) 903-6488. Internet requests can be made to: joanne.corcoran@oer.doe.gov. Electronic access to ER's Financial Assistance Guide is possible via the Internet using the following E- mail address: <http://www.er.doe.gov>

The Office of Energy Research, as part of its grant regulations, requires at 10 CFR 605.11(b) that a grantee funded by ER 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" (59 FR 34496, July 5, 1994), or such later revision of those guidelines as may be published in the Federal Register.

The dissemination of materials and research data in a timely manner is essential for progress towards the goals of the DOE HGP. 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.

The Catalog of Federal Domestic Assistance Number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR part 605.

Issued in Washington, D.C.

John Rodney Clark
Associate Director
for Resource Management
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Published in the Federal Register February 7, 1996, Vol. 61, No. 26,
pages 4631-4633.