Office of Science
Notice 03-06

Human Genome Program -
Ethical, Legal, and Social Implications

Department of Energy

Office of Science Financial Assistance Program Notice 03-06: 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 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, and (2) complex or multigenic traits. 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. This notice is part of a transition towards a wider societal implications activity in OBER, linked to the Genomes to Life program and no longer focusing principally on human genomics.

DATES: Potential applicants are strongly encouraged to submit a brief preapplication. All preapplications, referencing Program Notice 03-06, should be received by 4:30 p.m., E.S.T., November 25, 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., February 13, 2003, to be accepted for merit review and to permit timely consideration for award in Fiscal Year 2003.

ADDRESSES: Preapplications, referencing Program Notice 03-06, should be sent to: Dr. Daniel W. Drell, Office of Biological and Environmental Research, SC-72/Germantown Building, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585-1290.

Formal applications in response to this solicitation are to be electronically submitted by an authorized institutional business official through DOE's Industry Interactive Procurement System (IIPS) at: http://e-center.doe.gov/. IIPS provides for the posting of solicitations and receipt of applications in a paperless environment via the Internet. In order to submit applications through IIPS your business official will need to register at the IIPS website. The Office of Science will

include attachments as part of this notice that provide the appropriate forms in PDF fillable format that are to be submitted through IIPS. Color images should be submitted in IIPS as a separate file in PDF format and identified as such. These images should be kept to a minimum due to the limitations of reproducing them. They should be numbered and referred to in the body of the technical scientific application as Color image 1, Color image 2, etc. Questions regarding the operation of IIPS may be e-mailed to the IIPS Help Desk at: HelpDesk@pr.doe.gov or you may call the help desk at: (800) 683-0751. Further information on the use of IIPS by the Office of Science is available at: http://www.sc.doe.gov/production/grants/grants.html. The full text of Program Notice 03-06 is available via the Internet using the following web site address: http://www.sc.doe.gov/production/grants/grants.html.

If you are unable to submit an application through IIPS please contact the Grants and Contracts Division, Office of Science at (301) 903-5212 in order to gain assistance for submission through IIPS or to receive special approval and instructions on how to submit printed applications.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel W. Drell, Office of Biological and Environmental Research, SC-72/Germantown Building, Office of Science, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585-1290, telephone: (301) 903-6488 or E-mail: daniel.drell@science.doe.gov.

SUPPLEMENTARY INFORMATION: The DOE encourages the submission of applications that will address, analyze, or anticipate ELSI issues associated with human genome research in two broad areas:

I. Genetics and the Workplace
Research is encouraged on the uses, impacts, implications of, and privacy of genetic and other disease-related 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. Examples might include surveillance programs (involving asymptomatic screening or testing) for exposure to workplace hazards (e.g., beryllium or other metals), or how testing results might influence policy formulation in the absence of definitive associations between test results and health outcomes. 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 screening test information. Research can include issues arising from the creation, use, maintenance, privacy, and disclosure of genetic and/or medical 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. The final product should lead to best practices guidance or suggestions for policy relevant recommendations.

II. Complex or Multigenic Traits ,BR> 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, (e.g., gene- environment interactions), that result in diseases or disease susceptibilities. Conditions may include, but are not limited to, behavioral conditions, diseases of aging, vulnerability to substance abuse, susceptibility to workplace exposure hazards

(chemicals or radiation), or other common conditions with a partial genetic basis. This research may address:

1) Studies that explore the novel ethical, legal, and social issues raised by research on, and new insights into, complex conditions.

2) The responses of institutions (e.g., courts, employers, financial institutions, 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 for rigorous assessments to evaluate progress or outcomes. Where a product (guidelines, recommendations, documents, etc.) is the result, dissemination plans including timelines must be discussed. 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.

In previous solicitations in this program, a focus on educational efforts for specific groups was included. Here, applications for the development and dissemination of educational materials will not be considered in order that OBER can encourage as high priorities those projects that address the explicitly stated goals of this solicitation.

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. Applications for the writing of scholarly publications or books should include justifications for the relevance of the publications or books, to the goals of this notice, 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.

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 which can be found on the Internet at: http://www.sc.doe.gov/production/grants/grants.html, but 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 five of these awards might be made in Fiscal Year 2003. As with larger applications to this notice, applications are required to be submitted electronically through the IIPS.

Program Funding

It is anticipated that approximately $600,000 will be available for multiple grant awards (including any small grants) to be made during Fiscal Year 2003, 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 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 for responsiveness to the scope and research needs described in this notice. 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.

Merit Review

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 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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