REPORT OF THE JOINT NIH/DOE COMMITTEE TO EVALUATE THE ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS PROGRAM OF THE HUMAN GENOME PROJECT

Executive Summary

The Ethical, Legal, and Social Implications (ELSI) program is an integral part of the Human Genome Project, and it will continue to be essential as the focus of scientific research increasingly shifts to applied genetics. The responsibilities currently being undertaken by the Joint NIH-DOE ELSI Working Group (Working Group) are much too broad to be satisfied by any single body. Moreover, the placement of the Working Group, as a joint subcommittee of the National Advisory Council on Human Genome Research (NCHGR) at NIH and the Health and Environmental Research Advisory Committee (HERAC) at DOE is not commensurate with the more global role of some important policy formulation.

Accordingly, this Committee recommends dividing the Working Group's responsibilities among committees and at levels in the government better suited to the specific objectives assigned them. First, a newly established ELSI Research Evaluation Committee should have responsibility for oversight of the extramural ELSI grant portfolios at NCHGR and DOE. Second, an NIH-wide process should be used to coordinate the ELSI activities of the various institutes engaged in genetic research. Third, a federally-chartered Advisory Committee on Genetics and Public Policy should be established in the Office of the Secretary of HHS to undertake the formulation of public policy resulting from advances in genetics. The efforts of these committees must be coordinated so that there is two-way communication and facilitation of their common objectives.

Introduction

The Committee to Evaluate the Ethical, Legal, and Social Implications Program of the Human Genome Project (ELSI Evaluation Committee) was appointed on April 30, 1996, by Dr. Francis S. Collins, Director of the National Center for Human Genome Research (NCHGR), National Institutes of Health (NIH), and Dr. Ari Patrinos, Associate Director for Health and Environmental Research, Office of Health and Environmental Research, United States Department of Energy (DOE). The Committee was charged with taking a comprehensive look at the Joint NIH/DOE Working Group on the Ethical, Legal, and Social Implications of Human Genome Research (Working Group). According to the charge to the Committee (see Appendix A), "the main task of the committee will be to identify the functions that will need to be addressed in the future and to recommend an appropriate structure for effectively carrying these out."

The members of the Committee (see Appendix B for a roster of members) developed the following mission statement to guide their inquiries and deliberations.

> The Committee will evaluate the appropriate scope of ELSI activities and the role of external advisers in the

ELSI program. The Committee will assess how, in the near term, it would be best to structure input on ELSI issues raised by and as a consequence of the Human Genome Project. The Committee also will assess how, in the longer term, it would be best to structure input on ELSI issues raised more generally by research involving human genetics.

In its evaluations and recommendations the Committee will consider the organizational structure, staffing, and budgetary needs of an entity or program that has the responsibility of facilitating the free and open discussion by diverse groups and individuals of a wide range of ELSI issues. The Committee also will consider how the study of ELSI issues raised by genetics research can be coordinated with other related activities at NIH and DOE as well as with other governmental and private bodies that deal with similar issues of bioethics and health policy.

The Committee utilized various procedures in obtaining information relevant to this report. It obtained copies of documents from NIH and DOE related to their ELSI programs and the Working Group. It also conducted interviews with numerous individuals, including past and present officials of NIH and DOE, past and present members of the Working Group, and experts on ELSI issues. In addition, it solicited public input through written and electronic comments, as well as a public forum announced in the Federal Register.

Dr. Bettie Graham of the NCHGR served as Executive Secretary to the Committee. The members of the Committee are indebted to Dr. Graham and her staff for obtaining the necessary documents for the Committee and for logistical support. All interviewing, deliberating, and drafting were undertaken by the Committee members alone, within subcommittees, or in executive session.

Background

While the Human Genome Project is unquestionably an exciting and vitally important scientific research endeavor, it also presents formidable challenges to science policy and public affairs. From the outset, leaders of Congress and the Executive Branch recognized that as scientific research proceeded, it was essential to support parallel research on the ethical, legal, and social implications of human genome research. To this end, separate ELSI research programs were established at NIH and DOE. These unprecedented programs support important scholarly research on genetic counseling, privacy, discrimination, education, intellectual property, and numerous other issues.

In addition to establishing ELSI research programs, NIH and DOE established a Joint Working Group for the study of ELSI issues. The Working Group is currently structured as a subcommittee of the National Advisory Council on Human Genome Research of the NCHGR at NIH and as a subcommittee of the Health and Environmental Research Advisory Committee of the DOE. The Working Group is composed of experts in the fields of bioethics, law, the social sciences, and

basic and applied genetics, as well as representatives of professional societies and the public. The dedicated members of the Working Group have labored diligently to identify emerging issues, increase the level of public understanding, and help shape public policy. With the support of the leadership at NIH and DOE, the Working Group has made some important contributions to the analysis of ELSI issues, including the Report of the Task Force on Genetic Information and Insurance and the work of the ongoing Task Force on Genetic Testing.

As the Human Genome Project turns its attention to large-scale sequencing, it is appropriate to consider the mission and structure of future ELSI research. This assessment is particularly timely for four reasons. First, scientific developments are proceeding at an accelerating pace, thereby raising new ELSI issues calling for a rapid response. Second, the expanding potential of genomic technology will increasingly require research designed to anticipate, rather than simply respond to, emerging ELSI issues. Third, as large-scale sequencing projects are completed, a growing proportion of biomedical research will entail applied and clinical genetics, giving rise to a new set of substantive ELSI issues throughout the NIH. Finally, in the emerging era of applied genetics and molecular medicine, a variety of government agencies with regulatory responsibility for health issues will be involved to a much greater extent in implementing policies related to human genetics. For these reasons, new challenges will emerge in the coming years that can only be met by strengthening the ELSI program.

Essential Elements of an ELSI Program

The Committee carefully considered the input of the numerous individuals who shared their views on the ELSI program. From these views and the Committee's own analysis, we determined that the following are essential elements of an effective ELSI program.

1. The ELSI program is multi-faceted and must focus on and be responsive to a wide range of policy interests. This wide-ranging interest is reflected by the high interest in and support for ELSI activities by the public and Congress, who see this program as important to vital public concerns. The scope, complexity, and significance of ELSI issues have confirmed the wisdom of creating the ELSI program.

2. Oversight of the ELSI research program by external advisers is essential. This oversight should extend to both the NIH and DOE research portfolios and in helping to coordinate these two research efforts. Part of this effort is on the "front end" in identifying program goals and issues to be addressed. Part of the effort is on the "back end" in reviewing completed projects to assess the quality of work, identify gaps in research, and determine the appropriate areas for policy development. An additional element is to anticipate future issues in order to deal with them in a timely manner.

3. The ELSI program needs to generate public awareness on ELSI issues, many of which already have a direct and immediate

effect on numerous individuals. Closely related to generating public awareness is the need to provide a forum for the public, including consumers of genetic services, regarding ELSI issues. This fundamental part of the ELSI mission will ensure that the ELSI program has a practical as well as an academic orientation. The ELSI program also must maintain active liaison with professional groups working in human genetics.

4. As the focus of scientific research shifts from genomics to applied genetics, the number of government research institutions with an interest in genetics will continue to grow. At the NIH, several institutes already are deeply involved with research in clinical genetics, and these efforts are expected to increase substantially. Research at most of the institutes at NIH has important ethical, legal, and social implications and thus there is a clear need to coordinate ELSI activities on an NIH-wide basis.

5. As advances in genetics research lead to new initiatives in genetic testing, diagnosis, and therapy, federal regulatory agencies charged with oversight of health care will have an increased interest in genetics. The Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Care Financing Administration, and other agencies at the Department of Health and Human Services (HHS) all will need to consider ELSI issues related to their focus on genetics. Consequently, there is a need to coordinate the future ELSI activities of HHS.

6. A wide range of ELSI issues will demand regulatory or statutory intervention. There is a current and growing need to provide expert policy analysis to Congress, federal agencies, and state and local governments on ELSI issues. International cooperation on ELSI issues also will be necessary.

7. Finally, the importance to public accountability of providing an independent evaluation and review of ELSI issues cannot be overstated. The public views issues involving genetic research with a combined sense of excitement, awe, and trepidation. Part of the social bargain in undertaking the Human Genome Project was the assurance of an independent, critical assessment of the ethical, legal, and social implications of genomic and genetic research. The Committee is aware that it may not be possible to have a totally independent critique of federally-sponsored research housed within the federal government. Nevertheless, the recommendations included in this report are intended to assure so far as possible that there is an open and unfettered review of genetic research and the social consequences of that research.

Conclusions Regarding the Current ELSI Mission and Structure

The charge of the ELSI Working Group is so broad and complex as to be confusing to various participants and observers. This confusion has led to uncertainty about its primary functions and reporting relationships. For example, while the Working Group has addressed broad policy issues, it has not provided in-depth advice regarding the extramural research program to the extent that it might. The inadequately defined mission of the Working Group also has led to inefficiencies in operation. Furthermore, serious

concerns have been raised about the Working Group's lack of resources and independence, as well as conflicts with the intramural policy making activities at NCHGR and the inadequate sharing of essential information by staff at NCHGR.

The Working Group is not positioned within the governmental scientific structure so as to fulfill the breadth of its charge. There is a fundamental discordance between a narrowly defined scientific research program and a much broader effort to formulate and implement policy regarding the social consequences of all genetic developments, both research and clinical. The NCHGR and the Office of Health and Environmental Research (OHER) at DOE are charged with genomic research. It is appropriate and essential for these agencies to fund research on a wide range of ELSI issues. It does not necessarily follow, however, that policy development on ELSI issues (such as clinical genetics, confidentiality of genetic data in medical records, health insurance coverage, and genetic discrimination in employment), is best achieved under the aegis of centers at NIH and DOE whose missions are limited to genome mapping and sequencing.

Several considerations -- the breadth of ELSI issues, the rapid pace of the science, the difference between running a research program and developing policy, and the variety of government agencies relevant to policies involving genetics -- converge to make it clear that effective research and policy development on ELSI issues cannot be accomplished by a single Working Group in its present location. Similarly, appropriate public and professional interactions in health policy development cannot be achieved under the current structure.

At the NIH, ELSI-type activities occur in multiple institutes and programs, some overlapping others to a significant extent. Research strategies, human subjects issues, and many other ELSI activities in the various institutes and programs require coordination and information sharing.

Addressing the ethical, legal, and social implications of developments in genetics will require strong support and continuing attention at NCHGR, throughout NIH and HHS, at DOE, and at all government agencies with responsibilities in related fields.

Recommendations

The Committee assessed the relative importance, interactions, and requirements for meeting the above enumerated essentials for the ELSI program. This assessment was carried out utilizing the available information and opinions from all forms of input and the Committee's own discussions. There is total agreement among the Committee and those we surveyed that the ethical, legal, and social implications raised by the Human Genome Project are of immense significance to all individuals, including the scientific community. Therefore, it is of the highest priority that an appropriate mechanism should be established to ensure that a rigorous, focused research program exists to build a foundation of knowledge about ELSI issues and to provide an open, independent forum for a full discussion of the issues. Extensive

interdisciplinary research on ELSI issues must be continued, and the current extramural funding mechanisms within NCHGR and DOE provide an appropriate means to carry forward this crucial mission.

The majority of research within the Human Genome Project has a very limited focus, that of producing the complete genome sequence on a tight time line. By contrast, the research goals of ELSI reach across all of genetics and beyond to clinical and social issues. In spite of the discordance between these two very different arenas, the location of the ELSI research program within the genome project is essential because it ensures a realistic connection between the research issues raised by the former and those addressed by the latter. As discussed above, however, the current NIH/DOE Joint Working Group on the Ethical, Legal, and Social Implications of Human Genome Research can no longer address the plethora of issues under the ELSI umbrella. A new structure is required to ensure that the public, government, and research community's interests in ELSI issues, as outlined above, are adequately met in a timely and informed fashion. Therefore, the Committee proposes the following three recommendations for restructuring the ELSI effort. These recommendations are given first in summary form and then in more detail.

1. The existing Working Group should be restructured and designated the ELSI Research Evaluation Committee, housed within NCHGR as an advisory committee to the Director and the Council and within DOE advisory to HERAC and the Genome Project. This new committee will focus on evaluating the quality, assessing the relevance, and planning and coordinating the scope of the ELSI grant portfolios for extramurally funded research at NCHGR and DOE. The ELSI Research Evaluation Committee also should anticipate new areas requiring investigation, evaluate the outcomes of funded research, and advise NCHGR and DOE about the distillation and dissemination of the results of the ELSI research portfolio.

2. The Director of NIH should consider establishing an ongoing process to coordinate the exchange among the institutes within NIH of information on the ethical, legal, and social implications of genetic research. This process should be directed to the reduction of duplication of effort within the NIH intramural and extramural research programs, the standardization of research protocols, and the promotion of active discussion of the issues that will lead to new research initiatives.

3. The Secretary of Health and Human Services should establish, in the Office of the Secretary, a federally chartered Advisory Committee on Genetics and Public Policy. This committee will assume the role of identifying issues and formulating policy to ensure integration of new genetic knowledge into health care standards.

<u>Details of Recommendations</u>:

Recommendation 1: ELSI Research Evaluation Committee

a. The duties of the new committee should include:

(1) Conducting a systematic and regular evaluation of the NCHGR and DOE ELSI research portfolios.

(2) Making an active attempt to identify new questions and concerns of sufficient merit to warrant the initiation of research to provide the knowledge necessary for addressing the ethical legal, and social concerns and development of appropriately informed policy.

(3) Conducting a review of and assisting in the preparation of RFAs calling for research within the ELSI arena.

(4) Developing a means to provide sufficiently thorough and appropriate input to ensure accountability to the public and other government agencies.

b. The committee will be advisory to the Director and the Council of NCHGR as well as the genome project director at DOE and HERAC.

c. The membership will be selected from the areas of bioethics, education, epidemiology, genome science, health policy, history, human genetics, law, research methodology, public health, and the social sciences, as well as public membership. The committee's membership should not exceed 12, and members should be appointed for their expertise rather than as representatives of particular constituencies. A small committee is essential for efficiency and effectiveness, but it must be large enough to ensure that appropriate expertise in the relevant disciplines is available and that an adequate number of people will attend each meeting. The members should have rotating terms not to exceed four years, comparable to Study Section and NCHGR Council service.

d. A deficiency noted by many during the review of the Working Group was the failure to provide adequate orientation and instruction to those members not familiar with the NIH and DOE systems. Because much of the expertise required for the committee will continue to include a broad group of ethicists, lawyers, philosophers, social scientists, and others who may be unfamiliar with NIH and DOE procedures, and because the major role of the committee is the design and evaluation of the NCHGR and DOE research portfolios, it is essential that new committee members receive a thorough orientation to the procedures within NIH and DOE. The orientation should include discussion of the two-tier review system, priority scores, program relevance, the development of RFAs, contracts versus grants, and other matters.

e. The committee must meet often enough to ensure a consistent oversight function. Three meetings per year, perhaps contiguous with NCHGR Council sessions, should be sufficient. Coordination with DOE also should be a consideration.

f. The committee must have adequate staff support to carry out its functions. Because the committee will not be responsible for the larger, more arduous duty of policy development, including staffing task forces, a single dedicated staff person should suffice to arrange meetings and provide the committee with necessary information. Strong differences of opinion surround the issue of whether the NCHGR staff provided adequate information on the ELSI portfolio to the Working Group. It is not necessary to

resolve that issue, but merely to note that an open, unfiltered flow of information in both directions is essential for the new committee to succeed in its mission of providing the necessary guidance and public assurances.

g. In recommending research priorities, the committee should be sensitive to any appearance of a conflict of interest by discipline or area of inquiry.

Recommendation 2: Communication and Coordination within NIH

a. Many ELSI concerns have implications for the design, methodology, and conduct of NIH research. Genetic research raises a wide range of ELSI issues, including informed consent, testing of minors, confidentiality, and duty to warn. Therefore, it is important that all of the institutes at NIH become familiar with, participate in the discussion of, and oversee research quality in accordance with recognized ELSI principles and concerns.

b. There is a real possibility for the evolution of different standards in the conduct of research across the NIH (intramural and extramural), which could lead to an undermining of public trust and inadvertent harm to the public.

c. The Evaluation Committee would encourage NIH to coordinate the ELSI activities on research ethics in genetic studies within the institutes. To avoid duplication of effort and possible inconsistent policies, the Director of NIH should consider implementing an ongoing process for communication and coordination that would build upon the ELSI efforts at NCHGR and elsewhere and provide the information, guidance, and oversight required for the intramural and extramural research of all of the institutes.

Recommendation 3: Advisory Committee on Genetics and Public Policy.

a. There is no doubt that policy issues must be considered at a level that not only permits but encourages full participation by all interested parties, including concerned members of the public, professional societies, government regulatory agencies, and the research community. In other words, policy development must occur at a level that provides a public forum for discussion of these critical issues and not only permits but encourages the active participation of all of the stakeholders to formulate and implement policy.

b. A forum at the HHS-wide level is needed to promote public awareness of ELSI issues, and the high profile of a federally chartered committee would go a long way towards ensuring the independent review of the issues as sought by Congress and the public. This location at the Secretary level provides the greatest independence that can be achieved within government for a body that is to be reviewing what government is doing in a complex policy arena involving multiple federal agencies. Private foundations and interested lay groups should be actively encouraged to continue their high level of interest, participation, and independent study of ELSI issues and policy.

c. Such an advisory committee reporting to the Secretary of HHS would be ideally placed to coordinate information, activity, planning, and policy development among the HHS agencies with an interest in these issues, such as the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Health Care Financing Administration. It also could interact more effectively with the National Bioethics Advisory Commission and other federal agencies, such as the Department of Energy, the Department of Justice, and the Environmental Protection Agency, as well as the Congress.

d. Among the responsibilities of this committee will be to advise the Secretary of HHS and other government officials on matters concerning: genetic policies and practice, legislative and regulatory policy, professional education, public education, access to and quality of genetic services, privacy and confidentiality, and discrimination based on genetic information. The committee should consist of 15-18 members with expertise in these and related issues.

e. The committee should be independent and look to the future. It should identify emerging ELSI issues and, as necessary, form task forces to address them. The task force approach already has been effectively used, as illustrated by the current Task Force on Genetic Testing. However, the experience of this Task Force has also clearly shown the problems that arise for a group situated in an inappropriate governmental location. (The Task Force is technically a subcommittee of a subcommittee of an advisory council within a center at NIH and a subcommittee of a subcommittee of an advisory committee of an office at DOE.) Professional societies and government agencies whose participation is vital to successful policy development also will find working with a group at the level of the Secretary much simpler and more effective.

f. The Advisory Committee on Genetics and Public Policy will be well situated to seek and actively solicit expert input from a wide variety of individuals, organized groups, researchers, and private industry as new issues emerge rapidly over the next two decades.

g. The committee must be supported by a budget and staffing level commensurate with the magnitude of its responsibility and in providing assurances to the public that policy issues raised by new genetic discoveries will be explored critically, in detail, in a timely fashion, and at the highest levels of government.

Mark A. Rothstein, J. D.

Bartha Maria Knoppers, LL.D.

M. Anne Spence, Ph.D.

Jayne Mackta

Patricia A. Buffler, Ph.D., M.P.H.

Marynard V. Olson, Ph.D.

James F. Childress, Ph.D.

Kenneth I. Shine, M. D.

Charles J. Epstein, M. D.

Bailus Walker, Jr., Ph.D., M.P.H.

Stephen Hilgartner, Ph.D.

CHARGE TO THE ELSI EVALUATION COMMITTEE

BACKGROUND

The DOE and the NCHGR rely on the scientific community to provide advice and guidance in defining, refining and advancing the goals and disseminating the results of the Human Genome Project. In 1989, the NIH Program Advisory Committee (PAC) on the Human Genome established several working groups to help the agencies refine the research agenda of the Human Genome Program. In addition to establishing working groups to focus on mapping and informatics issues and mouse research, a working group was also established to develop a plan to deal with the ethical, legal and social consequences of the Human Genome Program. The DOE subsequently agreed to make these working groups a joint effort. All working groups, except the NIH-DOE ELSI Working Group (hereafter called the Working Group), have completed their tasks even though the goals have not been completed. Except in the area of ELSI, subsequent advice has been provided through ad hoc committees.

Many changes have occurred since the Working Group was established, thus making this a propitious time for its evaluation. With the official start of the Human Genome Project in fiscal year 1990, NCHGR established a chartered National Advisory Council for Human Genome Research to advise it on its programs. The Council has one-third lay members, most of whom are chosen for their ELSI expertise. In 1993, the PAC was merged into the Council and the Working Group became a sub-committee of the Council. While PAC was active, advice to DOE on ELSI issues was channeled through the Health and Environmental Research Advisory Committee. With the elimination of the PAC, advice from the Working Group was provided directly to the Chair of the Human Genome Task Group at DOE headquarters. More recently, the Executive Branch is in the process of establishing a National Bioethics Advisory Commission whose responsibility it will be to consider issues of bioethics arising from research on human biology and behavior and the application of that research.

The Working Group has provided invaluable advice to the NCHGR and DOE. It initially helped to define the parameters of the research grants program, sponsored regional town meetings to educate the public about the Human Genome Program and the ELSI issues arising from the research, oversaw the Task Force on Genetic Information and Insurance and is playing a similar role with the Task Force on Genetics Testing. The Working Group has also commented or provided advice on a number of issues, such as, informed consent, privacy, discrimination, and genetic testing for cystic fibrosis and breast cancer.

CHARGE

As the products of the Human Genome Program move from the laboratory to practical applications, the ethical, legal and social implications of Human Genome Research will present issues and dilemmas that NCHGR and DOE will need to address. Therefore, it is envisioned that outside, objective advice on such matters will continue to be important. As we begin to plan for the next five years of the Human Genome Program, it will be essential to determine how best this can be accomplished. Therefore, DOE and NCHGR have established the ELSI Evaluation Committee (hereafter called the Committee) to take a comprehensive look at the function and structure of the Working Group and its

relationship to other federal advisory committees. Whereas a review of the Working Group's past activities may be useful, the main task of the committee will be to identify the functions that will need to be addressed in the future and to recommend an appropriate structure for effectively carrying these out. It should not be assumed that the current structure is optimal and the Committee should be free to recommend alternative solutions. In examining the recommended function/structure, the Committee should assess the degree of autonomy, the reporting structure, and the relationship to other national commissions, advisory boards and federal staff functions. It is anticipated that the Committee will need to interview not only staff within NCHGR and DOE, but also members of the Working Group, the extramural community and other organizations that might have an interest in the outcomes of the Working Group.

It is anticipated that the Committee will complete its work and deliver its report to the NCHGR and DOE national advisory bodies by December 1996.

April 29, 1996

Appendix B

ROSTER
ELSI EVALUATION COMMITTEE

Mark A. Rothstein, J.D., Co-Chair
Hugh Roy and Lillie Cranz
Cullen Distinguished
Professor of Law
Director, Health Law and Policy
Institute
University of Houston Law Center
Room 104-TU2
4800 Calhoun Rd.
Houston, TX 77204-6381
([redacted])

M. Anne Spence, Ph.D., Co-Chair
Professor
Department of Pediatrics
Division of Human Genetics
Building 27, Room 104
University of California
Medical Center
101 The City Drive South
Orange, CA 92668
([redacted])

Patricia A. Buffler, Ph.D., M.P.H.
Dean, School of Public Health
University of California, Berkeley
140 Warren Hall
Berkeley, CA 94720
([redacted])

James F. Childress, Ph.D.
Edwin B. Kyle Professor of
Religion and
Professor of Medical Education
Cocke Hall, Basement Room 10
University of Virginia
Charlottesville, VA 22903
([redacted])

Charles J. Epstein, M.D.
Professor of Pediatrics
Chief, Division of Medical
Genetics
Room U-585L
University of California, San
Francisco
San Francisco, CA 94143-0748
([redacted])

Stephen Hilgartner, Ph.D.
Assistant Professor of Science
and Technology Studies
632 Clark Hall
Cornell University
Ithaca, NY 14853
([redacted])

Bartha Maria Knoppers, LL.D.
Professor
Senior Researcher (CRDP)
Faculty of Law
University of Montreal
C.P. 6128, Succ. Centre-ville
Montreal (Quebec),
Canada, H3C 3J7
([redacted])

Jayne Mackta
Executive Director
New Jersey Association
for Biomedical Research
507 Westminister Avenue
Elizabeth, NJ 07208
([redacted])

Marynard V. Olson, Ph.D.
Professor
Department of Molecular
Biotechnology
University of Washington
School of Medicine
Mail Stop FJ-20
Fluke Hall on Mason Rd.
Seattle, WA 98195
([redacted])

Kenneth I. Shine, M.D.
President, Institute of Medicine
National Academy of Sciences
2101 Connecticut Ave., N.W.
Washington, DC 20418
([redacted])

Bailus Walker, Jr., Ph.D., M.P.H.
Professor, Environmental and
Occupational Medicine
Associate Director
Howard University Cancer Center
2041 Georgia Avenue, N.W.
Washington, DC 20001
([redacted])

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ELSI EVALUATION COMMITTEE

Mark A. Rothstein, J.D., Co-Chair
Hugh Roy and Lillie Cranz
Cullen Distinguished
Professor of Law
Director, Health Law and Policy
Institute
University of Houston Law Center
Room 104-TU2
4800 Calhoun Rd.
Houston, TX 77204-6381
([redacted])

M. Anne Spence, Ph.D., Co-Chair
Professor
Department of Pediatrics
Division of Human Genetics
Building 27, Room 104
University of California
Medical Center
101 The City Drive South
Orange, CA 92668
(714) 456-8385

Patricia A. Buffler, Ph.D., M.P.H.
Dean, School of Public Health
University of California, Berkeley
140 Warren Hall
Berkeley, CA 94720
([redacted])

James F. Childress, Ph.D.
Edwin B. Kyle Professor of
Religion and
Professor of Medical Education
Cocke Hall, Basement Room 10
University of Virginia
Charlottesville, VA 22903
([redacted])

Charles J. Epstein, M.D.
Professor of Pediatrics
Chief, Division of Medical
Genetics
Room U-585L
University of California, San
Francisco
San Francisco, CA 94143-0748
([redacted])

Stephen Hilgartner, Ph.D.
Assistant Professor of Science
and Technology Studies
632 Clark Hall
Cornell University
Ithaca, NY [redacted]
([redacted])

Bartha Maria Knoppers, LL.D.
Professor
Senior Researcher (CRDP)
Faculty of Law
University of Montreal
C.P. 6128, Succ. Centre-ville
Montreal (Quebec),
Canada, H3C 3J7
([redacted])

Jayne Mackta
Executive Director
New Jersey Association
for Biomedical Research
507 Westminister Avenue
Elizabeth, NJ 07208
([redacted])

Marynard V. Olson, Ph.D.
Professor
Department of Molecular
Biotechnology
University of Washington
School of Medicine
Mail Stop FJ-20
Fluke Hall on Mason Rd.
Seattle, WA [redacted]
([redacted])

Kenneth I. Shine, M.D.
President, Institute of Medicine
National Academy of Sciences
2101 Connecticut Ave., N.W.
Washington, DC 20418
([redacted])

Bailus Walker, Jr., Ph.D., M.P.H.
Professor, Environmental and
Occupational Medicine
Associate Director
Howard University Cancer Center
2041 Georgia Avenue, N.W.
Washington, DC 20001
([redacted])

NIH-DOE ELSI Working Group

Member Roster

ActingChair:
Troy Duster, PhD, Director
Institute for the Study of Social Change
2420 Bowditch Avenue
University of California
Berkeley, CA 94720

Betsy Anderson, Director
CAPP National Parent Resource Center
Federation for Children with Special Needs
95 Berkely Street
Suite 104
Boston, MA 02116

James Bowman, MD
Professor Emeritus,
Depts. of Pathology, Medicine,
Committee on Genetics
University of Chicago
5841 South Maryland Avenue
Chicago, IL 60637

David Cox, MD, PhD
Dept. of Genetics M-322
School of Medicine
Stanford University
Stanford, CA 94305

Rebecca Eisenberg, JD
University of Michigan Law School
439 Hutchins Hall
625 South State Street
Ann Arbor, MI 48109

Beth Fine, MS, CGC
Asst. Prof. of Obstetrics & Gynecology
Coordinator,Graduate Program Genetic Counseling
Northwestern Univeristy Medical School
18-171 Ward Bldg. (W143)
303 East Chicago Avenue
Chicago, IL 60611

Neil Holtzman, MD, MPH
Genetics & Public Policy Studies
The Johns Hopkins Medical Inst
550 North Broadway
Suite 511
Baltimore, MD 21205

Philip Kitcher, PhD
Department of Philosophy
Univ of California-San Diego
MSC 0302
La Jolla, CA 92093

Joseph McInerney
Biological Sciences Curriculum Studies
5415 Mark Dabling Boulevard
Colorado Springs, CO 80918-3842

Jeffrey Murray, MD
Department of Pediatrics
2613 J.C.P.
University of Iowa
Iowa City, IA 52242

Dorothy Nelkin
Department of Sociology
New York University
269 Mercer Street, 4th Floor
New York, NY 10003

Rayna Rapp, PhD
Department of Anthropology
New School for Social Research
65 Fifth Avenue
New York, NY 10003

Marsha Saxton, MS
The Project on Women and Disability
One Ashburton Place
Room 1305
Boston, MA 02108

Liaison from the American Society of Human Genetics:
Laird G. Jackson, MD
Department of Medicine
Division of Medical Genetics
Thomas Jefferson University
1100 Walnut Street
Philadelphia, PA 19107-5502

Liaison from the American College of Medical Genetics:
Michael Kaback, MD
Children's Hospital-San Diego
Genetics Laboratory
8110 Birmingham Way
San Diego, CA 92123

Representative from the Health and Environmental Research Advisory Committee:
John Mulvihill, MD
Prof of Human Genetics
Co-Director
Pittsburgh Genetic Institute
University of Pittsburgh
Crabtree Hall, Rm. A300
130 DeSoto Street
Pittsburgh, PA 15261

Liaison from the National Society of Genetic Counselors:
Vivian J. Weinblatt, MS, CGC
Thomas Jefferson Univ Hospital
Division of Genetics
1100 Walnut Street
400 MOB
Philadelphia, PA 19107

Liaison for the Alliance of Genetic Support Groups:
Joan O. Weiss, MSW, LCSW
Executive Director
35 Wisconsin Avenue
Suite 440
Chevy Chase, MD 20815

National Advisory Council for Human Genome Research

Member Roster

Lennette J. Benjamin, M.D.
Associate Professor of Medicine
Albert Einstein College of Medicine
Co-Director
Bronx Comprehensive Sickle Cell Center
Montefiore Medical Hospital Center
111 East 210th Street
Bronx, NY 10467

R. Daniel Camerini-Otero, M.D., Ph.D.
Chief, Genetics and Biochemistry Branch
National Institute of Diabetes and
Digestive and Kidney Diseases
National Institutes of Health
Building 10, Room 9D15
9000 Rockville Pike
Bethesda, MD 20892

Ellen W. Clayton, M.D.
Associate Professor of Law, and
Assistant Professor of Pediatrics
Vanderbilt University
Medical Center East 5028
1215 21st Avenue South
Nashville, TN 37232-8555

David R. Cox, M.D., Ph.D.
Professor of Genetics and Pediatrics
Department of Genetics M-336
Stanford University School of Medicine
300 Pasteur Drive
Stanford, CA 94305

Troy Duster, Ph.D.
Professor of Sociology, and
Director
Institute for the Study of Social Change
University of California
2420 Bowditch Avenue
Berkeley, CA 94720

Leroy E. Hood, M.D., Ph.D.
Department of Molecular Biotechnology
University of Washington, Box 357730
Room K357
Seattle, WA 98195-7730

Richard A. Mathies, Ph.D.
Professor of Chenistry
Department of Chemistry
310 Hildebrand Hall
University of California
Berkeley, CA 94720

Rodney Rothstein, Ph.D.
Associate Professor
Department of Genetics & Development
Columbia University
College of Physicians & Surgeons
701 W. 168th Street
New York, NY 10032

Diane C. Smith, Ph.D.
Xerox Corporation
Xerox Production Systems
100 Willowbrook
Fairport, NY 14450

M. Anne Spence, Ph.D.
Professor
Department of Pediatrics
Division of Human Genetics
University of California Medical Center
Building 27, Room 104
101 The City Drive South
Orange, CA 92668

David Valle, M.D.
Professor of Pediatrics
Johns Hopkins University School of Medicine
725 N. Wolfe Street
PCTB, Room 802
Baltimore, MD 21206

Barbara J. Wold, Ph.D.
Associate Professor of Biology
Division of Biology 156-29
California Institute of Technology
1201 E. California Boulevard
Pasadena, CA 91125

Executive Secretary
Elke Jordan, Ph.D.
Deputy Director
National Center for Human Genome Research
National Institutes of Health
Bethesda, MD 20892

Chairperson
Francis S. Collins, M.D., Ph.D.
Director
National Center for Human Genome Research
National Institutes of Health
Bethesda, MD 20892

Liaison Members

Beverly S. Emanuel, Ph.D.
American Society of Human Genetics
9650 Rockville Pike
Bethesda, MD 20814

Director
Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Wood Building
5th Floor, Room 5033B
Philadelphia, PA 19104

Rosalie Goldberg, MS, CGC
National Society of Genetic Counselors, Inc.
Montefiore Medical Center
111 East 210th Street
Bronx, NY 10467

Kurt Hirschhorn, M.D.
American College of Medical Genetics
Chairman
Department of Pediatrics
Mt. Sinai School of Medicine
One Gustave Levy Place
New York, NY 10029