

# APPENDIX K

## BIBLIOGRAPHY AND INTERNET RESOURCES

### Bibliography

*Access Handbook: Conducting Health Studies at Department of Energy Sites*, U. S. Department of Energy, Office of Epidemiologic Studies, Washington, DC, May .

*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

10 CFR Part 1008, “Records Maintained on Individuals.”

“Common Rule,” or “The Federal Policy for the Protection of Human Subjects,” adopted June 18, 1991, and codified for the U. S. Department of Energy in the Code of Federal Regulations as 10 CFR Part 745.

Defense Reauthorization Act of 1993, P. L. 102-484, Section 3162, authorizing the DOE to “... establish and carry out a program for the identification of an ongoing medical evaluation of current and former DOE employees who are subject to significant health risks as a result of exposure of such employees to hazardous or radioactive substances during employment.”

DOE Policy DOE P 443.1, “Protection of Human Subjects,” May 15, 2000 (see Appendix L).

DOE Order DOE O 443.1, “Protection of Human Subjects,” May 15, 2000 (see Appendix M).

DOE Order 481.1, “Work for Others (Non-Department of Energy Funded Work)”, September 30, 1996.

“Department of Energy/Department of Health and Human Services Memorandum of Understanding,” 1990 (renewed 1996), for the IRB review of health research and related studies at DOE facilities when the study is managed by the Department of Health and Human Services.

Freedom of Information Act, 5 U.S.C. 552.

*Human Subjects Research Handbook*, 2<sup>nd</sup> edition, U. S. Department of Energy, Office of Health and Environmental Research, Washington, DC, January 1996.

Privacy Act of 1974, P. L. 93-579, 5 U.S.C. 552a

*Protecting Human Research Subjects, Institutional Review Board Guidebook*, U. S. Department of Health and Human Services, National Institutes of Health, Office for the

Protection from Research Risks, Washington, DC, 1993.

*The Report to the Secretary.* (SPERA Report). The Secretarial Panel for the Evaluation of Epidemiologic Research Activities for the U.S. Department of Energy. March 1990.

## Internet Resources

### 1. Department of Energy, Protecting Human Subjects Program

<http://www.science.doe.gov/ober/humsubj/>

The goal of the Human Subjects Research program at DOE is to ensure that the rights and welfare of human research subjects are protected while advances in biomedical, environmental, nuclear, and other research continue to lead to discoveries that benefit humanity. In addition to the primary information for this program, two areas of resources related to **Protecting Human Subjects** have been added: **DOE Worker Health-Related Studies** and **Scientific Integrity**.

### 2. The DOE Human Radiation Experiments

<http://www.ohre.doe.gov>

The Office of Human Radiation Experiments, established in March 1994, leads the Department of Energy's efforts to tell the agency's Cold War story of radiation research using human subjects. This site includes an intensive effort to identify and catalog relevant historical documents from DOE's 3.2 million cubic feet of records scattered across the country. Internet access to these resources is a key part of making DOE more open and responsive to the American public.

### 3. Department of Energy Human Genome Program

[http://www.science.doe.gov/ober/hug\\_top.html](http://www.science.doe.gov/ober/hug_top.html)

The U.S. Human Genome Project (HGP), composed of the DOE and NIH Human Genome Programs, is the national coordinated effort to characterize all human genetic material by determining the complete sequence of the DNA in the human genome. The HGP's ultimate goal is to discover all the more than 80,000 human genes and render them accessible for further biological study. To facilitate the future interpretation of human gene function, parallel studies are being carried out on selected model organisms. View [timeline](#) and [history](#) for background information on the project.

### 4. National Institute for Occupational Safety and Health (NIOSH)

<http://www.cdc.gov/niosh/about.html>

The National Institute for Occupational Safety and Health (NIOSH) was established by the Occupational Safety and Health Act of 1970. NIOSH is part of the Centers for Disease Control and Prevention (CDC) and is the only federal Institute responsible for conducting research and making recommendations for the prevention of work-related illnesses and injuries.

#### **5. The National Institutes of Health, Office of Human Subjects Research**

<http://helix.nih.gov:8001/ohsr/whatohsr.php3>

The Office of Human Subject Research (OHSR) was established to help Intramural Research Program (IRP) investigators understand and comply with the ethical guidelines and regulatory requirements for research involving human subjects. OHSR's overall goal is to promote and support the IRP's efforts to conduct innovative research that protects the rights and promotes the welfare of human subjects.

#### **6. The National Institutes of Health, Office of Protection from Research Risks**

<http://helix.nih.gov:8001/ohsr/whatoprr.php3>

Office for Protection from Research Risks (OPRR) is charged with interpreting and overseeing implementation of the regulations regarding the Protection of Human Subjects codified at Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) promulgated by the Department of Health and Human Services (DHHS). Also, OPRR is responsible for providing guidance on ethical issues in biomedical and behavioral research. A major difference between OHSR and the OPRR is that the OHSR's activities are limited to the Intramural Research Program (IRP), NIH, while the OPRR has oversight and educational responsibilities wherever DHHS funds are used to conduct or support research involving human subjects.

#### **7. Ethical, Legal, and Social Implications of Human Genetics Research - National Genome Research Institute**

<http://www.nhgri.nih.gov/ELSI/>

The ELSI Program was established in 1990 by the architects of the Human Genome Project to anticipate and address the ethical, legal and social issues that arise as the result of human genetic research. The links included in this site provide current information on the history of ELSI, the kinds of issues and activities in which ELSI is involved, ELSI research and training opportunities at the NHGRI and related resources, publications and web pages.

#### **8. The National Institutes of Health, Human Genome Project**

<http://www.nhgri.nih.gov/>

The Human Genome Project (HGP) is an international research effort to characterize the genomes of human and selected model organisms through complete mapping and sequencing of their DNA, to develop technologies for genomic analysis, to examine the ethical, legal, and social implications of human genetics research, and to train scientists who will be able to use the tools and resources developed through the HGP to pursue biological studies that will improve human health.

**9. The National Institutes of Health, Bioethics Resources on the Web**

<http://www.nih.gov/sigs/bioethics/index.html>

This Web site contains a broad collage of annotated web links, and while this list is comprehensive, it is not totally inclusive. The listed resources and organizations provide background information and various positions on issues in bioethics. Where possible, NIH has linked directly to those positions.

**10. Interagency HREX (Interagency Working group)**

<http://hrex.dis.anl.gov/>

The Human Radiation Experiments (HREX) Information Management System was originally commissioned by the Department of Energy. It was designed to allow users to search for imaged historical radiation documents. The Department of Energy created a simple, accessible collection of historical records on radiation experiment research. HREX currently contains over 250,000 pages of historical documents from the following agencies: Department of Defense (DOD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Veterans' Affairs (VA), and Central Intelligence Agency (CIA). HREX users can customize their search using the Advanced Features to find the records they need.

**11. National Bioethics Advisory Commission Web Site**

[http://bioethics.gov/cgi-bin/bioeth\\_counter.pl](http://bioethics.gov/cgi-bin/bioeth_counter.pl)

The National Bioethics Advisory Commission (NBAC) was created in 1995 by Executive Order. The NBAC provides advice and makes recommendations to the National Science and Technology Council chaired by the President, other appropriate government entities, and the public on bioethical issues arising from research on human biology and behavior, and the applications, including the clinical applications, of that research.

**12. Centers for Disease Control and Prevention (CDC)**

<http://www.cdc.gov/>

The CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability.

**13. Department of Labor, Department of Health and Human Services - Genetic Information and the Workplace**

[http://www.dol.gov/dol/\\_sec/public/media/reports/genetics.htm](http://www.dol.gov/dol/_sec/public/media/reports/genetics.htm)

Advances in genetics hold much promise for improving health. However, genetic information can also be used unfairly to discriminate against or stigmatize individuals on the job. For example, people may be denied jobs or benefits because they possess particular genetic traits--even if that trait has no bearing on their ability to do the job.

**14. Occupational Safety and Health Administration (OSHA)**

<http://www.osha.gov/about.html>

The mission of the Occupational Safety and Health Administration (OSHA) is to save lives, prevent injuries and protect the health of America's workers. To accomplish this, federal and state governments must work in partnership with the more than 100 million working men and women and their six and a half million employers who are covered by the Occupational Safety and Health Act of 1970.

**15. White House Publications**

<http://www.pub.whitehouse.gov/retrieve-documents.html>

Links to President Clinton's Executive Order prohibiting discrimination on the basis of genetic information is accessible at this site. This site also contains links to related presidential statements and press briefings. The official text of the Executive Order is provided in Appendix E of this document.

**16. University of California, Los Angeles--Protection of Human Subjects Web Site**

<http://www.oprs.ucla.edu/>

The Office for Protection of Research Subjects (OPRS) serves as the administrative arm for federally mandated compliance committees responsible for reviewing all research protocols that involve the use of human and animal subjects. Charged with implementing University policies that are based on federal regulations and State laws, the committees are composed of faculty, community representatives and consultants representing special subject populations. The committees work in partnership with the OPRS to maintain the federal assurances that govern the use of human and animal subjects in research conducted by UCLA investigators and students, handle special problems, and participate in audits.

**17. Oak Ridge National Laboratory–Protecting Human Subjects Web Site**

<http://www.ornl.gov/oshp/hshome.html>

The Oak Ridge National Laboratory (ORNL) site provides both legal ethical guidance for researchers working in the Oak Ridge DOE environment. A flow diagram for the ORNL IRB approvals is a useful model for understanding IRB approval process approvals. There are also listings of current research projects at ORNL.

**18. Advisory Committee on Human Radiation Experiments (National Security Archive)**

<http://www.gwu.edu/~nsarchiv/radiation/>

The Advisory Committee on Human Radiation Experiments (ACHRE), was created by President Clinton on January 15, 1994 to investigate and report on the use of human beings as subjects of federally funded research using ionizing radiation. ACHRE constructed a gopher site to provide public electronic access to information about its activities. Created by Executive Order and subject to the Federal Advisory Committee Act (FACA), the Advisory Committee was obligated to provide public access to its activities, processes and papers. The Advisory Committee believed, however, that the nature of the subject it investigated and the human stories that comprise it placed on it a special responsibility to disseminate as broadly as possible the results of its investigations, the implications of that history for our own time, and its best judgment concerning the rights and responsibilities of those involved.

**19. Clinical Trials and Human Subject Protection, U.S. Food and Drug Administration**

<http://www.fda.gov/oc/health/hsp.html>

This site presents the Food and Drug Administration's (FDA's) current guidance on protection of human subjects of research. It is published as Level 2 guidance in accordance with the FDA "Good Guidance Practices." However, in many places throughout this document, a specific regulation is cited and the requirements of the regulation are reiterated. The regulations are enforceable. This site also has many useful links to related sites.

**20. HealthPathfinder, Health Law and Policy Institute, University of Houston**

<http://www.law.uh.edu/healthpathfinder/>

HealthPathfinder contains hundreds of annotated links from the Health Law and Policy Institute's Web site to informative Web sites pertaining to health law, health policy, and general health. The Health Law and Policy Institute accepts no advertising and receives

no income or benefit of any kind from referral Web sites. The Health Law and Policy Institute is not responsible for the content or availability of any linked Web sites. The linked Web sites are divided into easily identified categories.

## **21. American Society for Bioethics and Humanities**

<http://www.asbh.org/>

The American Society for Bioethics and Humanities (ASBH) is a professional society of more than 1,200 individuals, organizations, and institutions interested in bioethics and humanities. This Web site, established in January 1998, is intended initially to serve as a source of information about ASBH for members and prospective members. It also will serve as a resource for anyone interested in bioethics and humanities by providing a group of further on-line resources and links to aid in finding other related information through the Internet.

## **22. The Genome Action Coalition**

<http://www.tgac.org/legislation.html>

The Genome Action Coalition (TGAC) site provides access to links on genetic discrimination relating to insurance, employment, and medical records privacy. TGAC, begun in 1995, is comprised of patient advocacy organizations, professional organizations in the field of genetics and genomics, consumer organizations, university-based research facilities, pharmaceutical research companies and biotechnology companies. The Coalition exists to promote an environment in government and in the private sector in which genome research can continue to flourish.

## **23. Public Responsibility in Medicine and Research (PRIM&R)**

<http://www.aamc.org/research/primr/descriptn.htm>

Public Responsibility in Medicine and Research (PRIM&R) was founded in 1974 by a group of research scientists and clinicians from eastern Massachusetts. They were concerned that, due to the combination of a complex regulatory climate and a lack of public confidence in the research process, clinical investigations were being misunderstood and unreasonably criticized. While mindful of the need for responsible regulation, PRIM&R founders felt that both the regulators and the public should be made more aware of the scientist's perspective, and that ongoing dialogue regarding bioethical and research-related issues would foster increased understanding and mutual respect. PRIM&R, therefore, is a national nonprofit organization dedicated to educating the medical and legal professions, industry and the public about the ethical, legal, and policy dimensions of appropriate and ethical research. It is committed to the advancement of strong research programs and believes in the importance of increased sensitivity to patient concerns and ethical precepts.

## **24. Applied Research Ethics National Association**

<http://www.aamc.org/research/primr/arena/>

ARENA is a national service organization for professionals concerned with issues relating to the protection of human subjects, the humane care and treatment of animals, scientific misconduct, ethical decision-making in healthcare, and other ethical issues pertaining to biomedical and behavioral research. ARENA's mission is the promotion of networking among its members, the development of educational activities, the resolution and/or amelioration of mutual problems, and the professional advancement of its members in order to enhance the ethical conduct of research and medicine.