

**INDEX
TO REPORTS FROM THE
NATIONAL BIOETHICS ADVISORY COMMISSION**

October 2000

This is an Index of the published reports of the National Bioethics Advisory Commission (NBAC) as of October 2000. The reports contained in this Index are:

- *Cloning Human Beings (1997)*, referred to in the Index as “**CHB**”
- *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity (1998)*, referred to in the Index as “**DMC**”
- *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance (1999)*, referred to in the Index as “**HBM**”
- *Ethical Issues in Human Stem Cell Research (1999)*, referred to in the Index as “**HSC**”

All reports are available on the NBAC website at www.bioethics.gov, or can be requested by contacting the NBAC office: 6705 Rockledge Drive, Suite 700, Bethesda, MD 20892-7979. Fax: (301) 480-6900; Telephone: (301) 402-4242.

As other NBAC reports are published, this Index will be updated. If you find errors, please bring them to our attention using the above contact information.

Eric M. Meslin, Ph.D.
Executive Director

INDEX

A

Abortion

- embryonic germ cell research and, arguments against federal funding for, HSC-57
 - fetal tissue from, as source of embryonic germ cells, and causal responsibility for, HSC-46-47
 - fetal tissue from, as source of embryonic germ cells, and complicity with, religious disagreement on, HSC-103-104
 - fetal tissue from, as source of embryonic germ cells, and symbolic association with, HSC-47-48
 - fetal tissue from, as source of embryonic germ cells, consent and donation, HSC-48-49
 - fetal tissue from, as source of embryonic germ cells, ethical issues on, HSC-45-49
 - fetal tissue from, as source of embryonic germ cells, federal funding for research on, conclusions/recommendations, HSC-iii-iv, 68-69
 - fetal tissue from, donation for research, requirements for, conclusions/recommendations, HSC-vi-vii, 72-3
 - fetal tissue from, donors and general/consent considerations for, research evaluation, HSC-106
 - fetal tissue from, prohibition of sale of, conclusions/recommendations, HSC-vii, 74
 - fetuses from, as source of embryonic germ cells, related law, HSC-29-33
 - fetuses from, as source of stem cells, state law on, HSC-32-33
 - fetuses from, research using cells/tissues from, federal law on, HSC-29-31
- ACHRE. *See* Advisory Committee on Human Radiation Experiments (ACHRE)
- ACOG. *See* American College of Obstetricians and Gynecologists (ACOG)
- ACP. *See* American College of Physicians (ACP)
- AD. *See* Alzheimer's disease (AD)
- Adult stem (AS) cells, HSC-5
- clinical applications, potential, of research on, HSC-12-14
 - definition of, HSC-85
 - See also* Cells; Human stem cells; Mesenchymal stem cells; Neural stem cells; Stem cells
- Advance action
- informed consent, projected, for mentally disabled persons in research, decisionmaking role, DMC-29
 - personal values, projected, for mentally disabled persons in research, decisionmaking role, DMC-29
 - personal relationships, projected, for mentally disabled persons in research, decisionmaking role, DMC-29-30
 - planning and mentally disabled persons in research, enrollment role of, DMC-29-33
 - surrogate decision making and mentally disabled persons in research, enrollment role of, DMC-29-33
- Advanced Cell Technology, HSC-1, 7, 19
- Advisory Committee on Human Radiation Experiments (ACHRE), DMC-2-3, 71
- Affymetrix, HBM-15
- AFIP. *See* Armed Forces Institute of Pathology (AFIP)
- AFS. *See* American Society for Reproductive Medicine
- Age and aging
- cellular aging effects on nuclear transfer cloning, uncertainties, CHB-23-24
- AGS. *See* American Geriatric Society (AGS)
- Alabama
- cloning, human, legislation on, CHB-86
- Alaska
- mentally disabled persons in research, legislation on, DMC-71
- Allen, Anita, HBM-43
- Allocation of resources. *See* Resources, allocation of
- Alzheimer's Association, DMC-41
- Alzheimer's disease (AD)

nature of, DMC-7
See also Dementias; Mental diseases and disorders

AMA. *See* American Medical Association (AMA)

American Association of Medical Colleges
 human biological materials use in research, statement comparison, HBM-99

American College of Medical Genetics
 human biological materials use in research, statement comparison, HBM-99

American College of Obstetricians and Gynecologists (ACOG), CHB-85

American College of Physicians (ACP), DMC-30, 31, 46

American Fertility Society (AFS). *See* American Society for Reproductive Medicine

American Geriatric Society (AGS), DMC-22
 "Informed Consent for Research on Human Subjects with Dementia", DMC-22

American Medical Association (AMA), CHB-9, 95, 96

American Naturalist, CHB-2

American Psychiatric Association, DMC-19
Diagnostic and Statistical Manual of Mental Disorders, DMC-5

American Society for Reproductive Medicine, CHB-85

American Society of Human Genetics, HBM-33
 human biological materials use in research, statement comparison, HBM-99

Anglican Church, CHB-50
See also Christianity; Protestantism; Religion

Animals
 bovine embryonic stem cells, description and potential clinical applications of, HSC-15-16
 cell differentiation basic research, nuclear transfer cloning use for, CHB-28-29, 103
 cloning, nuclear transplantation, of, CHB-1, 15-16
 cloning of, for use in research, CHB-24-25
 cloning research, reasons for, CHB-24-29
 cow eggs fusion with human somatic cells, and creation of hybrid embryo, description, HSC-19
 frogs, nuclear transfer in, CHB-17, 18
 gene alterations, targeted, nuclear transfer cloning use for, CHB-26-28
 generation from embryonic stem cells, CHB-27, 28
 livestock breeding, nuclear transfer cloning advantages for, CHB-25
 livestock, transgenic, improved generation/propagation, nuclear transfer cloning use for, CHB-25-26
 mammalian stem cells isolated, list, HSC-14
 mammals, nuclear transfer cloning of, scientific uncertainties, CHB-22-24
 mammals, nuclear transfer in, experiments using, CHB-19-21
 mammals, preimplantation embryo development, CHB-15
 mice generation from embryonic stem cells, CHB-27, 28
 mouse embryonic stem cells, as models of early differentiation events in embryonic development, HSC-15
 mouse embryonic stem cells, description and potential clinical applications of, HSC-14-15
 primate embryonic stem cells, description and potential clinical applications of, HSC-16
 sheep cloning, science leading to, CHB-16-22
 sheep cloning, Scotland experiment, CHB-i, 1, 13, 103
 species differences in nuclear transfer cloning, CHB-22-23
 stem cell models of, description and potential clinical applications of, HSC-14-16
See also Transgenic animals

Appelbaum, Paul S., DMC-19, 58

Argentina
 cloning laws, CHB-3, 101

Argo, CHB-4

Arizona
 embryonic/fetal tissue use, legislation on, HSC-40
 family relationships, legislation on, CHB-87

Arkansas

- embryonic/fetal tissue use, legislation on, HSC-40
- Armed Forces
 - Korean War deaths, autopsies results, HBM-19
 - See also* Armed Forces Institute of Pathology (AFIP); U.S. Army
- Armed Forces Institute of Pathology (AFIP), HBM-14
 - See also* DNA Specimen Repository for Remains Identification; National Pathology Repository
- Army. *See* U.S. Army
- ART. *See* Assisted reproductive technology (ART)
- AS. *See* Adult stem (AS) cells
- Ascriptive identity. *See* Groups and group-based identity
- Assent. *See* Decisionmaking capacity
- Assisted reproductive technology (ART)
 - artificial insemination by donor, historical overview, CHB-5, 40
 - cloning by nuclear transfer, potential applications for, CHB-31-32
 - cloning, human, and control of nature, CHB-4-6
 - definition, HSC-85
 - federal legislation affecting, CHB-84
 - historical religious overview, CHB-38, 41
 - State legislation affecting, CHB-85
 - success rate, summary statistics, HSC-18
 - surrogacy, historical religious overview, CHB-40
 - See also* Infertility treatments; In vitro fertilization (IVF); Reproduction
- Assurance of Compliance, DMC-67
- Attorneys. *See* Durable power of attorney (DPA)
- Audits and auditors
 - independent, and mentally disabled research subjects, role of, DMC-28
 - research institutions and, guidance for, DMC-67
- Australia
 - assisted reproductive technologies, national standards for, HSC-81
 - cloning laws, CHB-3
 - fetal tissue use in research, HSC-81
- Autonomy
 - cloning, human, and, ethical/moral considerations, CHB-ii, 2, 3, 69, 72-77, 103
 - See also* Individual freedom of action
- Autopsies
 - human biological materials use in past research, summary, HBM-19
 - See also* Deaths; Medical tests and procedures

B

- Backlar, Patricia, DMC-11
- Baltimore, Maryland, HSC-7
 - See also* Maryland
- Bayer, HBM-15
- Beecher, Henry, DMC-15
- Behavioral research
 - prisoners as subjects, protections for, 45 CFR 46, Subpart C, in entirety, HBM-94-96
 - See also* Research
- Bein, Philip, DMC-22
- Benefits
 - embryonic germ/stem cell research, public/private support encouragement, and, HSC-59
 - human biological materials research use and, promotion of, ethical issues, HBM-42-43
 - human biological materials research use, and risks to relatives v., conclusions/ recommendations on,

HBM-vii, 72, 73
human stem cell research, and just distribution of, federal funding and, HSC-60-61
medical, direct, to mentally impaired research subjects, DMC-12, 44-45, 46
medical, indirect, to mentally impaired research subjects, DMC-45, 46-47
medical, not offered to mentally impaired research subjects by protocols with greater than minimal risk, recommendations, DMC-v, 61
medical, offered directly to mentally impaired research subjects by protocols with greater than minimal risk, recommendations, DMC-v, 60
medical, to other than impaired research subjects, DMC-45, 46-47
medical, v. greater than minimal risk to mentally impaired research subjects, DMC-46-47
risks v., for mentally impaired research subjects, balancing concerns, DMC-45-50
risks v., for mentally impaired research subjects, evaluation recommendations, DMC-iv, 56-57
risks v., for mentally impaired research subjects, independent research monitors and, DMC-49-50
risks v., for mentally impaired research subjects, Special Standing Panel and, DMC-47-48

Berg, Joseph M., DMC-31

Bible
Adam and Eve, CHB-44, 45
Garden of Eden, CHB-44, 45
Genesis, CHB-41, 45
humanity, characteristics inferred from, CHB-41-42
Tower of Babel, CHB-45
Tree of the Knowledge of Good and Evil, CHB-45
See also Christianity; Creation story; Religion

Biology. *See* Developmental biology

Biomedical research
prisoners as subjects, protections for, 45 CFR 46, Subpart C, in entirety, HBM-94-96
See also Research

Bioethics Commission. *See* National Bioethics Advisory Commission (NBAC)

Biological materials. *See* Human biological materials

Biotechnology Industry Organization
human biological materials use in research, statement comparison, HBM-99

Bipolar disorder
nature of, DMC-8
See also Mental diseases and disorders

Births
sheep cloning, technique changes leading to, CHB-21-22
See also Reproduction

Blastocysts
definition, HSC-85
human embryonic stem cells derived from, description, HSC-11, 16-17
See also Blastomere

Blastomere
definition, HSC-85
See also Blastocysts

Blood diseases and disorders
human embryonic stem cell research and, potential applications of, HSC-22-23
See also Diseases and disorders

Blumenthal, David, HSC-59

Bone diseases and disorders
human embryonic stem cell research and, potential applications of, HSC-22
See also Diseases and disorders

Bongso, A., HSC-16

Bonnie, Richard, DMC-22

Boston, Massachusetts, HBM-77, 78, 79

See also Massachusetts
Boys from Brazil, CHB-6
Brain
 research on, human tissue as singular resource for, HBM-20
Branzberg v. Hayes, CHB-75
Brave New World, CHB-6
Breeding
 livestock breeding, nuclear transfer cloning advantages for, CHB-25
 livestock, transgenic, generation/propagation, nuclear transfer cloning for, CHB-25-26
Briston-Myers Squibb, HBM-15
British Law Commission, DMC-37
Brown, Louise, CHB-5, 39; HSC-34
Burtchaell, James, HSC-47, 48
Bush, George, HSC-31

C

Cahill, Lisa, CHB-51, 72
Califano, Joseph, HSC-34
California
 cloning, human, legislation on, CHB-86
 medical records privacy and research use, laws on, HBM-36
 Supreme Court, HBM-50
 See also Menlo Park, California; San Francisco, California; University of California at Los Angeles (UCLA)
Calvinism, CHB-43
 See also Christianity; Protestantism; Religion
Canada
 “Ethical Conduct for Research Involving Humans”, DMC-42
 human biologic materials research use and, HBM-33, 34
 human embryo/fetal tissue use in research, HSC-3, 81
 dementia research, DMC-21, 28, 31, 48
 See also Canadian Royal Commission on New Reproductive Technologies
Canadian Royal Commission on New Reproductive Technologies, HSC-4, 49
 Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies, HSC-4
 See also Canada
Cancer
 human biological materials value to research on, HBM-19-20
 human embryonic stem cells research and, potential applications of, HSC-21
 See also Diseases and disorders; Prostate cancer
Capacity. *See* Decisionmaking capacity
Caplan, Arthur, HSC-61
Caregiver
 informal, for mentally impaired research subjects, issues overview, DMC-11
Carter, James E., CHB-39
Case law
 cloning, human, and Supreme Court cases, CHB-75
 cloning, human, procreation and fundamental liberties, CHB-90, 91, 92
 embryonic/fetal tissues use for research, case law, HSC-40-41
 medical records privacy and research use, protection of, HBM-38
 See also Akron v. Akron Center for Reproductive Health; *Branzberg v. Hayes*; *Curlender v. Bio-Science Laboratories*; *Doe v. Rampton*; *Eisenstadt V. Baird*; *Griswold v. Connecticut*; *Henley v. Wise*; *H.L. v. Matheson*; *Jane L. v. Bangert*; *Leigh v. Olson*; *Lifchez v. Hartigan*; *Margaret S. v.*

Edwards; Margaret S. v. Treen; Meyer v. Nebraska; Planned Parenthood Association v. City of Cincinnati; Planned Parenthood Association v. Fitzpatrick; Planned Parenthood of Minnesota v. Minnesota; Planned Parenthood of Southeastern Pennsylvania v. Casey; Scholberg v. Lifchez; T.D. v. New York State Office of Mental Health; Thornburg v. American College of Obstetrics and Gynecologists; U.S. Supreme Court; Webster v. Reproductive Health Services; Wolfe v. Schroering; Wynn v. Carey

Catholicism. *See* Roman Catholic Church

Causal responsibility

abortion and use of fetal tissue for embryonic germ cells and, ethical issues, HSC-46-47

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

Cells

aging of, nuclear transfer cloning effects, uncertainties, CHB-23-24

differentiation/development of, early studies, CHB-17-18

differentiation of, basic research on, animal cloning research use for, CHB-2, 28-29, 103

division cycle of, CHB-21-22

division cycle synchronization, CHB-21

Food and Drug Administration case-by-case regulation of materials/tissues, HSC-94-95

Food and Drug Administration proposed regulation of related products, implementation of, HSC-96

Food and Drug Administration regulation of related products, new approach to, HSC-95-96

Food and Drug Administration regulations on materials/tissues, application to human stem cells, HSC-94

Food and Drug Administration regulations on materials/tissues, overview, HSC-93-95

therapies, cell-based, nuclear transfer cloning potential applications in, CHB-30-31

See also Adult stem (AS) cells; Cellular cloning; Embryonal carcinoma (EC) cells; Embryonic germ (EG) cells; Embryonic stem (ES) cells; Human stem cells; Inner cell mass (ICM); Mesenchymal cells; Neural cells; Somatic cells; Stem cells

Cellular cloning

definition, CHB-14-15, A-1

See also Cells; Cloning

Center for Health Policy Studies (CHPS), HBM-77

Centers for Disease Control and Prevention (CDC), HBM-8, 20

National Center for Health Statistics, HBM-23

Workgroup for Community Engagement, HBM-8

45 CFR 46. *See* Code of Federal Regulations, Title 45, Part 46 (45 CFR 46)

Charo, R. Alta, HSC-51

Children

cloning of, consideration for exceptional cases, CHB-76-77

cloning of, ethical considerations, CHB-ii-iii, 7-8, 59-79, 103, 104

cloning of, eugenic concerns, CHB-ii, 6, 70-72, 103

cloning of, family integrity and, CHB-ii, 2, 3, 65-66, 103, 104

cloning of, federal funding moratorium for, CHB-i, iii, 3, 93-94, 105

cloning of, federal funding moratorium/private sector adherence, CHB-iii, 93, 94-96, 105

cloning of, freedom of scientific inquiry and, CHB-ii, 75-76, 103

cloning of, individuality and, CHB-ii, 2, 3, 63-65, 103

cloning of, individual liberty and, CHB-ii-iii, 72-73, 104

cloning of, legislative ban on, CHB-iv, 9, 93, 98-99, 105

cloning of, objectification concerns, CHB-ii, 3, 69-70, 103

cloning of, personal autonomy and, CHB-ii, 2, 3, 72-77, 103

cloning of, potential physical harms, CHB-ii, 3, 61-62, 103

cloning of, public policies and moral reasoning, CHB-ii-iii, 77-78, 104

cloning of, reproductive choice and, CHB-ii, 73-75, 103

cloning of, social values and, CHB-ii, iii, 67-68, 103-104

research use of, protections for, 45 CFR 46, Subpart D, in entirety, HBM-96-98

See also Families

China

cloning, human, position on, CHB-101

CHPS. *See* Center for Health Policy Studies (CHPS)

Christianity

- cloning, human, and, CHB-43, 46, 47, 51
- creation, biblical account, and humanity, CHB-41-42
- embryos, moral status of, HSC-50
- Nicene Creed, CHB-50
- See also* Anglican Church; Bible; Calvinism; Eastern Orthodox Church; Lutheran Church; Protestantism; Religion; Roman Catholic Church; Southern Baptist Church; United Church of Christ

Churches. *See* Anglican Church; Calvinism; Christianity; Eastern Orthodox Church; Islam; Judaism; Lutheran Church; Protestantism; Religion; Roman Catholic Church; Southern Baptist Church; United Church of Christ

Cibelli, Jose, HSC-19

Citizens for Responsible Care in Psychiatry and Research, DMC-22

Cleveland, Ohio, HBM-77, 78, 79

Clinton, William J., CHB-i, 3, 7, 10, 54, 85; HBM-44; HSC-i, ii, vii, 2, 3, 31, 34, 37, 61, 65, 69, 75

Cloning

- definition, CHB-14-16, A-1
- science and application of, CHB-13-33
- sheep, science leading to, CHB-16-22
- scientific uncertainties remaining, CHB-22-24
- See also* Cellular cloning; Human cloning; Molecular cloning; Nuclear transplantation cloning

Cloning Human Beings, HSC-2, 3, 37

Code of Federal Regulations, Title 45, Part 46 (45 CFR 46), DMC-iii, 1, 2, 17, 33, 39, 40, 41, 42, 46-48, 52, 53, 54, 57, 63; HBM-9, 27, 28, 29, 30, 36, 56, 62, 71; HSC-viii, 31, 34, 35, 61, 73, 78

- explanation/definition, DMC-24, 70-71
- interpretation of, HBM-ii-iii, 57-60
- human beings, including fetuses, as research subjects, general regulation of, HSC-30
- human biological materials, existing and publicly available samples, federal policy on, HBM-58-59
- human biological materials, identifiability of samples, federal policy on, HBM-57
- human biological materials, identifiable samples made unidentifiable, and informed consent, conclusions on, HBM-70-71
- human biological materials research results, policies on publication of, conclusions/recommendations on, HBM-vii, 73-74
- human biological materials research use, additional information requirements under, conclusions/recommendations, HBM-vi, 70
- human biological materials research use, and informed consent, issues overview, HBM-7
- human biological materials research use, and Institutional Review Board review exemption, regulations on, conclusions/recommendations, HBM-iii, 57-60
- human biological materials research use, federal regulations/policy interpretation for, conclusions/recommendations, HBM-iii, 57-60
- human biological materials research use, postmortem, regulations on, HBM-29, 73
- human biological materials research use, waiver of consent requirements, conclusions/recommendations, HBM-v-vi, 66-70
- mentally impaired persons in research, existing protections for, DMC-1, 2, 13
- Subpart A: Federal Policy for Protection of Human Subjects, in entirety, HBM-81-91
- Subpart B: Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization, in entirety, HBM-91-94
- Subpart C: Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, in entirety, HBM-94-96
- Subpart D: Additional DHHS Protections for Children Involved as Subjects in Research, in entirety, HBM-96-98

See also Federal regulations

Colchis, CHB-4

Collaboration

- genetics databases and, universities/private industry creation of, HBM-15
- Collections
 - human biological materials, overview of, HBM-13-15
- College of American Pathologists
 - human biological materials use in research, statement comparison, HBM-100
- Collins, Francis, HBM-4
- Comments. *See* Public comments
- Commerce
 - embryonic/fetal material and, prohibition of, conclusions/recommendations, HSC-vii, 74
 - embryonic germ/stem cell research, compensation/reimbursement of donors for, issues for, HSC-106
 - See also* Commodification
- Commissioned papers. *See* Papers commissioned
- Commissioner statements. *See* Statements
- Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *See* Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research
- Commodification
 - human biological materials use and, ethical issues, HBM-50-51
 - See also* Commerce; Objectification
- Common Rule. *See* Code of Federal Regulations, Title 45, Part 46 (45 CFR 46)
- Compensation. *See* Commerce
- Computers. *See* Databases
- Conclusions and recommendations
 - cadaveric fetal tissue, as source of embryonic germ cells, federal funding for research on, HSC-iii-iv, 68-69
 - cadaveric fetal tissue/embryos from infertility treatments, donation for research, requirements for, HSC-vii, 72-73
 - cloning, children, federal agencies/departments continued deliberation on, CHB-v, 106
 - cloning, children, federal funding moratorium for, CHB-iii, 105
 - cloning, children, federal funding moratorium/private sector adherence, CHB-iii, 105
 - cloning, children, legislative ban on, CHB-iv, 105
 - cloning, human, conclusions/recommendations, CHB-iii-v, 103-106
 - cloning, human, cooperation with foreign nations, CHB-iv, 106
 - cloning, human, morality of, CHB-iii-iv, 106
 - cloning, human, religious views, CHB-iv-v, 106
 - embryonic/fetal material, prohibition of sale of, HSC-vii, 74
 - embryonic germ/stem cell research, federal funding, ethics of, HSC-iii-vi, 68-72
 - embryonic germ/stem cell research, institutional review of derivation protocols, HSC-viii, 77-78
 - embryonic germ/stem cell research, national oversight/review of, need for, HSC-vii-viii, 74-77
 - embryonic germ/stem cell research, national oversight/review panel creation/duties, HSC-vii-viii, 76-77
 - embryonic germ/stem cell research, privately funded, issues for, HSC-ix-x, 78-80
 - embryonic germ/stem cell research, sponsoring federal agencies review of protocols, HSC-viii-ix, 78
 - embryos created by in vitro fertilization solely for research, as source of embryonic stem cells, federal funding for research on, HSC-v, 71-72
 - embryos from infertility treatments, as source of embryonic stem cells, federal funding for research on, HSC-iv-v, 60-71
 - embryos from somatic cell nuclear transfer cloning, as source of embryonic stem cells, federal funding for research on, HSC-v-vi, 72
 - human biological materials, identifiable samples rendered unidentifiable, and informed consent, HBM-70-71
 - human biological materials research results, and reporting to subjects, HBM-vi-vii, 71-72
 - human biological materials research results, publication/dissemination of, HBM-vii, 73-74
 - human biological materials research use, and Institutional Review Board exemption, regulations on, HBM-iii, 57-60
 - human biological materials research use, and Institutional Review Board expedited review, regulations on,

HBM-iii, 60

human biological materials research use, and potential harms to others, HBM-vii, 72-73
human biological materials research use, and professional education/responsibilities, HBM-vii-viii, 74
human biological materials research use, and risks to groups, HBM-vii, 72, 73
human biological materials research use, and risks v. potential benefits to relatives, HBM-vii, 73
human biological materials research use, and waiver of consent, regulations on, HBM-v-vi, 66-70
human biological materials research use, federal regulations/policy on, interpretation of, HBM-iii, 57-60
human biological materials research use, informed consent requirements for, HBM-iv, 62-66
human biological materials research use of coded/identified samples, requirements for, HBM-iii-iv, 62
human biological materials research use of medical records, HBM-viii, 74-75
human biological materials, unlinked samples made from coded/identified samples, special concerns on, HBM-iii, 60-62
human stem cell research, ethical and policy considerations, HSC-ii-iii, 66-67
human stem cell research, federal support/oversight of, HSC-i-xi, 65-81
human stem cell research, scientific/medical considerations and ethical concerns, HSC-i-ii, 65-66
mentally impaired research subjects, and, DMC-iii-vii, 51-67
mentally impaired research subjects, decisionmaking capacity assessment, DMC-iv, 58-59
mentally impaired research subjects, durable power of attorney powers for decision making, DMC-vi, 62-63
mentally impaired research subjects, educational materials review/development, DMC-vi, 63-64
mentally impaired research subjects, family/friends involvement in decision making, DMC-vi, 63
mentally impaired research subjects, funding increases to support protections, DMC-vii, 64-65
mentally impaired research subjects, incapacity determinations/research enrollment, notification of, DMC-v, 59
mentally impaired research subjects, informed consent and capacity assessment, knowledge of, DMC-vi-vii, 64
mentally impaired research subjects, informed consent to research, DMC-iv, 57-58
mentally impaired research subjects, Institute of Medicine review of studies, DMC-vii, 64
mentally impaired research subjects, Institutional Review Board membership, DMC-iii, 53-54
mentally impaired research subjects, legally authorized representatives for decision making, DMC-vi, 62-63
mentally impaired research subjects, objection to participation, DMC-iv, 58
mentally impaired research subjects, Prospective Authorization for decision making, DMC-v, 61
mentally impaired research subjects, protections for, recommendations, DMC-iii-vii, 53-65
mentally impaired research subjects, protocols with greater than minimal risk, but direct medical benefit, DMC-v, 60
mentally impaired research subjects, protocols with greater than minimal risk, not offering direct medical benefit, DMC-v, 61
mentally impaired research subjects, protocols with minimal risk, DMC-v, 60
mentally impaired research subjects, regulatory recommendations for, DMC-iii-vii, 52-65
mentally impaired research subjects, research design, DMC-iv, 55-57
mentally impaired research subjects, risk categories for, DMC-v, 60-61
mentally impaired research subjects, risks v. benefits evaluation, DMC-iv, 56-57
mentally impaired research subjects, Special Standing Panel creation, DMC-iii-iv, 54-55
mentally impaired research subjects, surrogate decision making for, DMC-v-vi, 61-63
National Stem Cell Oversight and Review Panel, ongoing review/assessment for, HSC-x-xi, 80-81
research protocols, human subjects extended protections for, CHB-iv, 105

Confidentiality

human biological materials information and employment discrimination, ethical issues, HBM-44-45
human biological materials information and familial/psychosocial harm, ethical issues, HBM-46
human biological materials information and group-related harms, ethical issues, HBM-46-47
human biological materials information and, harms from breaches of, ethical issues, HBM-43-46
human biological materials information and health insurance discrimination, ethical issues,

HBM-44-45

human biological materials information and stigmatization, ethical issues, HBM-45-46

human biological materials research use and, public beliefs on, forum findings, HBM-78

See also Privacy rights

Congress, U.S. *See* U.S. Congress

Consent

cadaveric fetal tissue, as source of embryonic germ cells, consent/general considerations for donors, research evaluation, HSC-106

cadaveric fetal tissue, as source of embryonic germ cells, ethical issues, HSC-48-49

embryos from infertility treatments, as source of embryonic stem cells, considerations for donors, research evaluation, HSC-106-107

human biological materials research use and, public beliefs on, forum findings, HBM-78

voluntary, mentally disabled persons in research and, centrality of, DMC-17-18

See also Informed consent; Objection

Consent forms. *See* Informed consent

Consent process. *See* Informed consent

Constitution, U.S. *See* Constitutional law; U.S. Constitution

Constitutional law

cloning, human, liberties and limitations, CHB-ii-iii, 8-9, 88-90, 104

First Amendment, CHB-75, 90

Fourteenth Amendment, CHB-75

See also Fundamental liberties; Individual freedom of action; U.S. Constitution

Cornell University, CHB-95

Council for Responsible Genetics, CHB-95

Council of Europe, CHB-3, 100

See also Europe

Council of International Organizations of Medical Sciences, DMC-51

Creation story

biblical account and human cloning, CHB-41-42

cloning, human, position and, CHB-41-42

humanity, characteristics inferred from, CHB-41-42

See also Bible

Curlender v. Bio-Science Laboratories, CHB-90

Curran, Charles, CHB-38

Currie, W. Bruce, CHB-95

D

Data and Safety Monitoring Boards (DSMBs), DMC-49

Databases

embryonic germ/stem cell research, oversight/review panel creation/duties, conclusions/recommendations, HSC-vii, 76

genetics, collaboration between universities/private industry in creating, HBM-15

Iceland central health records database, overview of, HBM-22

Davis, Bernard, CHB-6

Davis, Dena, HSC-55

DC. *See* District of Columbia (DC)

Deaths

cloning, human, exceptional cases considered for, CHB-76-77

human biological materials research use, postmortem, ethical perspectives, HBM-49

human biological materials research use, postmortem, regulations on, HBM-29, 73

See also Autopsies

Decisionmaking capacity

capacity assessment and information disclosure, procedures for, DMC-21-23
 impairments, decisional, and incapacity, DMC-18-19
 impairments, decisional, persistent, and capacity, DMC-19-21
 mental disorders that may affect, nature of, DMC-7-8
 mentally impaired research subjects and, advance planning role, DMC-29-33
 mentally impaired research subjects and, assent/objection role, DMC-27-29
 mentally impaired research subjects and, assessment of, recommendations, DMC-iv, vi-vii, 58-59, 64
 mentally impaired research subjects, and decisional impairment, issues overview, DMC-9-10
 mentally impaired research subjects and, durable power of attorney powers for, recommendations, DMC-
 vi, 62-63
 mentally impaired research subjects and, family/friends involvement in, recommendations, DMC-vi, 63
 mentally impaired research subjects and, guidance for Institutional Review Boards, DMC-73-76
 mentally impaired research subjects and, incapacity determinations, notification of, recommendations,
 DMC-v, 59
 mentally impaired research subjects and, informed consent and limitations on, DMC-17-25
 mentally impaired research subjects and, legally authorized representatives role, DMC-vi, 33-37, 62-63
 mentally impaired research subjects and, conclusions and recommendations, DMC-iii-vii, 53-65
 mentally impaired research subjects and, papers commissioned, DMC-83
 mentally impaired research subjects and, participation objections, recommendations, DMC-iv, 58
 mentally impaired research subjects and, Prospective Authorization for, recommendations, DMC-v, 61
 mentally impaired research subjects and, public comments, DMC-77-80
 mentally impaired research subjects and, regulatory history, DMC-69-72
 mentally impaired research subjects and, risk v. benefit assessment, enhancement opportunities,
 Institutional Review Boards and, DMC-48-49
 mentally impaired research subjects and, substantive requirements for, DMC-23-25
 mentally impaired research subjects and, surrogacy role, DMC-v-vi, 29-37, 61-63
 mentally impaired research subjects and surrogates, independent professional support for, DMC-37
 mentally impaired research subjects and, statements of commissioners, DMC-85-88
 mentally impaired research subjects and, testimony, DMC-81-82
 mentally impaired research subjects in protocols with greater than minimal risk and not offering direct
 medical benefit, guidance for Institutional Review Boards, DMC-76
 mentally impaired research subjects in protocols with greater than minimal risk but offering direct
 medical benefit, guidance for Institutional Review Boards, DMC-75
 mentally impaired research subjects in protocols with minimal risk, guidance for Institutional Review
 Boards, DMC-74
 Declaration of Helsinki, CHB-75; DMC-23, 47, 51, 69
 Decode Genetics, HBM-22
 Defense Department. *See* Department of Defense (DoD)
 Delaware
 mentally disabled persons with affected decisionmaking capacity in research, legislation on, DMC-71
 Delirium
 nature of, DMC-7
 See also Mental diseases and disorders
 Dementias
 Canada research on, DMC-21, 28, 31
 nature of, DMC-7
 See also Alzheimer's disease (AD); Mental diseases and disorders
Democracy and Disagreement, CHB-73
 Demopulos, Demetrios, HSC-54
 Denmark
 cloning, human, laws on, CHB-3, 95
 Denominations. *See* Anglican Church; Calvinism; Eastern Orthodox Church; Lutheran Church; Protestantism;
 Roman Catholic Church; Southern Baptist Church; United Church of Christ

Deoxyribonucleic acid (DNA), CHB-iv, 14, 17, 18, 21, 24, 25, 26, 28, 32, 39, 74, 83, 85, 87, 94, 105; HBM-3, 4, 13, 14, 18, 19, 21, 34
definition, CHB-A-1

Department of Agriculture. *See* U.S. Department of Agriculture (USDA)

Department of Defense (DoD), DMC-31, 32; HBM-15
See also DNA Specimen Repository

Department of Education, CHB-85; DMC-57
See also Department of Health, Education and Welfare (DHEW); National Institute for Disability and Rehabilitative Research (NIDRR)

Department of Energy
human biological materials use in research, statement comparison, HBM-100

Department of Health and Human Services (DHHS), CHB-84, 85, 93; DMC-vii, 2, 40, 42, 53, 54, 57, 64, 70; HBM-5, 36; HSC-iv, 29, 34, 37, 38, 55, 73, 78
Assistant Secretary, HSC-30
children as research subjects, protections for, 45 CFR 46, Subpart D, in entirety, HBM-96-98
embryonic germ/stem cell research, and national oversight/review panel creation/duties, conclusions/ recommendations, HSC-vii-viii, 76-77
General Counsel, HSC-35, 59, 70
human biological materials use in research, statement comparison, HBM-100
human research subjects protection, 45 CFR 46, Subpart A, in entirety, HBM-81-91
Office of the Inspector General, DMC-7, 71
National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/ recommendations, HSC-x-xi, 80-81
pregnant women, fetuses, and in vitro fertilization in research, protections for, 45 CFR 46, Subpart B, in entirety, HBM-91-94
prisoners in biomedical/behavioral research, protections for, 45 CFR 46, Subpart C, in entirety, HBM-94-96
Secretary, DMC-iii, 47, 48, 49, 55; HBM-8, 35, 86, 91, 92, 94, 95, 97; HSC-viii, 31, 35, 75, 76
See also Department of Health, Education and Welfare (DHEW)

Department of Health, Education and Welfare (DHEW), DMC-1, 21, 70; HSC-49
Secretary, HSC-29, 34
See also Department of Education; Department of Health and Human Services (DHHS)

Department of Labor, CHB-85; HBM-5, 83

Depression
nature of, DMC-8
See also Mental diseases and disorders

DES. *See* Diethylstilbestrol (DES)

Design
research involving human embryonic germ/stem cells, considerations for, HSC-105-107
research involving mentally impaired subjects and, considerations in, guidance for Institutional Review Boards, DMC-65
research involving mentally impaired subjects and, recommendations, DMC-iv, 55-57
research involving mentally impaired subjects, ethics of study design, issues overview, DMC-12-14

Destiny. *See* Human destiny

Developmental biology
human embryonic stem cell research and, potential applications of, HSC-21

DHEW. *See* Department of Health, Education and Welfare (DHEW)

DHHS. *See* Department of Health and Human Services (DHHS)

Diagnostic tests and procedures. *See* Electroencephalography; Functional magnetic resonance imaging (fMRI); Magnetic resonance imaging (MRI); Medical tests and procedures; Positron emission tomography (PET); Venipuncture

Diethylstilbestrol (DES), HBM-19

Differentiation
cellular, basic research on, animal cloning research use for, CHB-2, 28-29, 103

cellular, early studies, CHB-17-18
definition, CHB-A-1
early studies, CHB-17-18
mouse embryonic stem cells, as models of early events in embryonic development, HSC-15

Dignity. *See* Human dignity

Disclosure of information
decisionmaking capacity assessment and, procedures for, DMC-21-23
human biological materials and, employment discrimination from, ethical issues, HBM-44-45
human biological materials and, familial/psychosocial harm from, ethical issues, HBM-46
human biological materials and, group-related harms from, ethical issues, HBM-46-47
human biological materials and, health insurance discrimination from, ethical issues, HBM-44-45
human biological materials and, privacy/confidentiality of, harms from breaches of, ethical issues, HBM-43-46
human biological materials and, stigmatization from, ethical issues, HBM-45-46
human biological materials research results publication, conclusions/recommendations on, HBM-vii, 73-74
human biological materials research results, reporting to subjects, conclusions/recommendations on, HBM-vi-vii, 71-72
human biological materials research use, additional disclosure requirements, conclusions/recommendations, HBM-vi, 70
mentally impaired research subjects and, guidance for institutions, DMC-67
research institutions and mentally impaired subjects, guidance for, DMC-67
See also Information

Discrimination
employment, and human biological materials information, ethical issues, HBM-5, 44-45
health insurance, and human biological materials information, ethical issues, HBM-5, 44-45
See also Stigmatization

Diseases and disorders
fatally ill person, human cloning for biological material, public policy proposals, CHB-53
See also Blood diseases and disorders; Bone diseases and disorders; Cancer; Mental diseases and disorders; Nervous system diseases and disorders; Parkinson's disease; Prostate cancer; Systemic lupus erythematosus (SLE); Viruses

District of Columbia (DC), DMC-63; HSC-32, 36, 73
District Court for, HSC-96
fetal/embryonic tissue use, legislation on, HSC-43

DNA. *See* Deoxyribonucleic acid (DNA)

DNA Specimen Repository, HBM-15
See also Department of Defense (DoD)

DNA Specimen Repository for Remains Identification, HBM-14, 15
See also Armed Forces Institute of Pathology (AFIP)

Doctors. *See* Health care professionals

DoD. *See* Department of Defense (DoD)

Doerflinger, Richard, HSC-52-53

Dolly, CHB-i, 1, 2, 3, 8, 9, 13, 16, 26, 28, 29, 31, 32, 33, 40, 60, 61, 83; HSC-10, 12, 37
science leading to, CHB-16-22

Dominion. *See* Human dominion over nature

Donations
cadaveric fetal tissue and embryos from infertility treatments for research and, requirements for, conclusions/recommendations, HSC-vi-vii, 72-73
cadaveric fetal tissue as source of embryonic germ cells, ethical issues, HSC-48-49
cadaveric fetal tissue as source of embryonic germ cells, general/consent considerations for donors, research evaluation, HSC-106
embryos from infertility treatments for, general/consent considerations for donors, research evaluation, HSC-106-107

human embryonic germ/stem cell research, identification/recruitment of donors for, issues for, HSC-106
Dorff, Elliot, CHB-44, 47, 53, 54; HSC-50
DPA. *See* Durable power of attorney (DPA)
Drugs and drug testing
 development limitations for mentally impaired research subjects, issues for, DMC-10
 toxicity/efficacy of, testing for, potential applications of human embryonic stem cell research, HSC-23
 See also Erythropoietin (EPO); Investigational new drug (IND); Tissue plasminogen activator (tPA)
DSMBs. *See* Data and Safety Monitoring Boards (DSMBs)
Duff, Nancy, CHB-52, 68
Durable power of attorney (DPA), DMC-vi, 30, 34, 35, 36, 46, 66
 mentally impaired research subjects, advance planning/surrogate role in enrollment, DMC-29
 mentally impaired research subjects, decision making powers of, recommendations, DMC-vi, 62-63
Dworkin, Ronald, HSC-52

E

EAB. *See* Ethics Advisory Board (EAB)
Eastern Orthodox Church, HSC-54, 67
 human stem cell research, perspectives on, presentation summary, HSC-102
 See also Christianity; Religion
EC. *See* Embryonal carcinoma (EC) cells
Education
 human biological materials research use, ethical issues in, and opportunities for, conclusions/
 recommendations, HBM-vii-viii, 74
 mentally impaired research subjects and risk v. benefit assessment, Institutional Review Boards and
 enhancement opportunities, DMC-48-49
 mentally impaired research subjects, materials review/development, recommendations, DMC-vi, 63-64
 See also Graduate Medical Education (GME)
Education Department. *See* Department of Education
EG. *See* Embryonic germ (EG) cells
EGE. *See* European Group of Ethics (EGE)
Egozcue, J., CHB-101
Einstein, Albert, CHB-33
Eisenstadt v. Baird, CHB-91-92
Electroencephalography, DMC-42
Electrofusion
 nuclear transfer in mammals via, CHB-20
Elliott, Carl, DMC-23
ELSI Working Group
 human biological materials use in research, statement comparison, HBM-100
Embryonal carcinoma (EC) cells, HSC-5, 8
 See also Cells; Stem cells
Embryonic germ (EG) cells
 abortion association with, arguments against federal funding for research, HSC-57
 blood disorders, potential applications of research on, HSC-22-23
 bone/cartilage diseases, potential applications of research on, HSC-22
 cadaveric fetal tissue, as source of, and causal responsibility for abortion, HSC-46-47
 cadaveric fetal tissue, as source of, and perceived complicity with abortion, religious disagreement on,
 HSC-103-104
 cadaveric fetal tissue, as source of, and symbolic association with abortion, HSC-47-48
 cadaveric fetal tissue, as source of, consent and donation issues, HSC-48-49
 cadaveric fetal tissue, as source of, ethical issues on, HSC-45-49
 cadaveric fetal tissue, as source of, federal funding for research on, conclusions/ recommendations, HSC-

iii-iv, 68-69

cadaveric fetal tissue, donation for research, requirements for, conclusions/recommendations, HSC-vi-vii, 72-73

cadaveric fetuses, as sources of, related law, HSC-29-33

cadaveric fetuses, research using cells/tissue from, federal law on, HSC-29-31

cancer therapy, potential applications of research on, HSC-21

definition of, HSC-85

derivation/use in research, synergy from combined federal effort, HSC-59

description of, HSC-8-9

drug testing for efficacy/toxicity, potential applications of research on, HSC-23

federal funding for research on derivation/use of, related arguments, HSC-57-61

federal funding for research on, moral objections to, HSC-57

federal oversight/review policies adoption for research, ethical issues, HSC-61

fetal material donation for research on, state laws on, HSC-32-33

fetal tissue transplantation, conditions for federal support of, HSC-30-31

human cells from fetal primordial germ cells, description, HSC-17, 19

human, research on, potential medical applications of, HSC-20-23

isolation and culture of, introduction, HSC-1-2

National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/recommendations, HSC-x-xi, 80-81

nervous system diseases, potential applications of research on, HSC-21-22

organs for transplantation, potential applications of research on, HSC-23

research on, and institutional review of derivation protocols, conclusions/recommendations, HSC-viii, 77-78

research on, compensation/reimbursement of donors for, issues for, HSC-106

research on, donor identification/recruitment for, issues for, HSC-106

research on, federal funding, ethics of, conclusions/recommendations, HSC-iii-vi, 68-72

research on, national oversight/review of, need for, conclusions/recommendations, HSC-vii-viii, 74-77

research on, national oversight/review panel creation/duties, conclusions/recommendations, HSC-vii-viii, 76-77

research on, oversight/review of, considerations for evaluating, HSC-107

research on, privately funded and eligible for federal funding, issues for, conclusions/recommendations, HSC-ix-x, 78-79

research on, public/private support, benefits of, HSC-59

research on, sponsoring federal agencies review of protocols, conclusions/recommendations, HSC-viii-ix, 78

research/scientific design considerations for studies involving, HSC-105

reproduction, human, and developmental biology, potential applications of research on, HSC-21

sources of, ethical issues on, HSC-45-57

sources of, legal issues raised by research involving, HSC-29-38

transplantation, potential applications of research on, HSC-20-21

See also Cells; Embryos and embryonic materials; Human stem cells; Stem cells

Embryonic stem (ES) cells

animal models of, description and potential clinical applications of, HSC-14-16

blood disorders, potential applications of research on, HSC-22-23

bone/cartilage diseases, potential applications of research on, HSC-22

bovine embryonic stem cells, description and potential clinical applications of, HSC-15-16

cancer therapy, potential applications of research on, HSC-21

cloning by somatic cell nuclear transfer, and isolation/culture of, HSC-12

cloning by somatic cell nuclear transfer, as source of, ethical issues, HSC-56-57

cloning by somatic cell nuclear transfer, as source of, related law, HSC-36-37

definition, CHB-26, A-2; HSC-85

derivation of, scientific progress and federal support of, issues, HSC-58-59

derivation/use research, synergy from combined federal effort, HSC-59

description of, HSC-9-12
drug testing for efficacy/toxicity, potential applications of research on, HSC-23
embryo destruction association with, arguments against federal funding for research, HSC-57
embryos created by in vitro fertilization, as source of for research, importance of intentions and
“discarded-created” distinction, HSC-55-56
embryos created by in vitro fertilization, as source of, related law, HSC-33-36
embryos created by in vitro fertilization, research using cells/tissues from, related law, HSC-34-36
embryos created by in vitro fertilization, solely for research, as source of, federal funding for research on,
conclusions/ recommendations, HSC-v, 71-72
embryos created by in vitro fertilization, solely for research, ethical issues, HSC-55
embryos created solely for research, ethical issues, HSC-55-56
embryos from cloning, as source of, federal funding for research on, conclusions/ recommendations, HSC-
v-vi, 72
embryos from infertility treatments, and derivation/use of, ethical distinctions and relationships, HSC-54-
55
embryos from infertility treatments, and research use for, ethical issues, HSC-49-55
embryos from infertility treatments, as source of, federal funding for research on, conclusions/
recommendations, HSC-iv-v, 60-71
embryos from infertility treatments, donation requirements for research use, conclusions/
recommendations, HSC-vi-vii, 72-73
federal funding for research on derivation/use of, related arguments, HSC-57-61
federal funding for research on, moral objections to, HSC-57
federal oversight/review policies adoption for research, ethical issues, HSC-61
fetal/embryonic tissues, and isolation/culture of, HSC-9
human, growth and derivation of, repeated necessity for, HSC-19-20
human, lines derived from blastocysts, description, HSC-11, 16-17
human, research on, potential medical applications of, HSC-20-23
human, sources of, HSC-9, 10-12
hybrid, created from fusion of human somatic cells with cow eggs, description, HSC-19
isolation and culture of, introduction, HSC-1-2
mammalian, list, HSC-14
mice generation from, CHB-27, 28
mouse, as models of early differentiation events in embryonic development, HSC-15
mouse, description and potential clinical applications of, HSC-14-15
National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/
recommendations, HSC-x-xi, 80-81
nervous system diseases, potential applications of research on, HSC-21-22
organs for transplantation, potential applications of research on, HSC-23
primate, description and potential clinical applications of, HSC-16
public/private support for, benefits of, HSC-59
reproduction, human, and developmental biology, potential applications of research on, HSC-21
research on, donor compensation/reimbursement, issues for, HSC-106
research on, donor identification/recruitment, issues for, HSC-106
research on, federal funding, ethics of, conclusions/recommendations, HSC-iii-vi, 68-72
research on, institutional review of derivation protocols, conclusions/ recommendations, HSC-viii, 77-78
research on, national oversight/review of, need for, conclusions/ recommendations, HSC-vii-viii, 74-77
research on, national oversight/review panel creation/duties, conclusions/ recommendations, HSC-vii-viii,
76-77
research on, oversight/review of, considerations for evaluating, HSC-107
research on, privately funded, issues for, conclusions/ recommendations, HSC-ix-x, 78-80
research on, sponsoring federal agencies review of protocols, conclusions/ recommendations, HSC-viii-ix,
78
research/scientific design considerations for studies involving, HSC-105
sources of, ethical issues on, HSC-45-57

sources of, legal issues raised by research involving, HSC-29-38
therapies, cell-based, nuclear transfer cloning potential applications for, CHB-30
transplantation, potential applications of research on, HSC-20-21
See also Cells; Embryos and embryonic materials; Human stem cells; Stem cells

Embryos and embryonic materials

cadaveric fetal tissue for, general/consent considerations for donors, research evaluation, HSC-106
cloning, nuclear transfer, creation of, as source of embryonic stem cells, federal funding for research,
HSC-v-vi, 72
definition, CHB-A-2; HSC-5, 85
destruction of, association with embryonic stem cell research, arguments against federal funding for,
HSC-57
embryonic germ/stem cells, sources of, HSC-9, 10-12
embryonic stem cell isolation/culture from, HSC-9
embryonic stem cell research and, creation solely for, ethical issues, HSC-55-56
human, early development of, summary, HSC-10, 11
hybrid, created from fusion of human somatic cells with cow eggs, description, HSC-19
infertility treatments and, derivation of embryonic stem cells from, federal funding for research,
conclusions/ recommendations, HSC-iv-v, 60-71
infertility treatments and, derivation/use of embryonic stem cells from, ethical distinctions and
relationships, HSC-54-55
infertility treatments and, donation requirements for research, conclusions/recommendations, HSC-vi-vii,
72-73
infertility treatments and, donors general/consent considerations, research evaluation, HSC-106-107
infertility treatments and, moral status of, ethical issues, HSC-49-51
infertility treatments and, research use for embryonic stem cells, ethical issues, HSC-49-55
infertility treatments and, research use for embryonic stem cells, importance of shared views, HSC-
51-53
in vitro fertilization creation of, and use for embryonic stem cell research, intentions and “discarded-
created” distinction, HSC-55-56
in vitro fertilization creation of, as source of embryonic stem cells, related laws, HSC-33-36
in vitro fertilization creation of, research using cells/tissues from, related laws, HSC-34-36
in vitro fertilization creation of solely for embryonic stem cell research, ethical issues, HSC-55
in vitro fertilization creation of solely for embryonic stem cell research, federal funding for, conclusions/
recommendations, HSC-v, 71-72
mammal preimplantation development, CHB-15
moral status of, disagreement among religious traditions, HSC-103
mouse embryonic stem cells, as models of early differentiation events in development of, HSC-15
research using, ethical concerns, CHB-i-ii, 3, 5, 60
sale of, prohibition of, conclusions/recommendations, HSC-vii, 74
transfer of, definition, CHB-A-2
See also Embryonic germ (EG) cells; Embryonic stem (ES) cells; Fetus and fetal tissue; Human biological
materials; Pregnancy; Reproduction

Employment

discrimination in, and human biological materials information, ethical issues, HBM-5, 44-45
Energy Department. *See* Department of Energy
Environmental Protection Agency (EPA), HBM-82
EPA. *See* Environmental Protection Agency (EPA)
EPO. *See* Erythropoietin (EPO)
Equal Employment Opportunity Commission, HBM-5
Erythropoietin (EPO), CHB-14
ES cells. *See* Embryonic stem (ES) cells
Ethical Advisory Board, HBM-94; HSC-34
research involving pregnant women, fetuses, and in vitro fertilization, requirements for, 45 CFR 46,
Subpart B, HBM-92

Ethics

- cadaveric fetal tissue and embryos from infertility treatments, donation for research, requirements for, conclusions/ recommendations, HSC-vi-vii, 72-73
- cadaveric fetal tissue, as source of embryonic germ cells, causal responsibility for abortion, HSC-46-47
- cadaveric fetal tissue, as source of embryonic germ cells, consent and donation issues, HSC-48-49
- cadaveric fetal tissue, as source of embryonic germ cells, federal funding for research on, conclusions/ recommendations, HSC-iii-iv, 68-69
- cadaveric fetal tissue, as source of embryonic germ cells, issues on, HSC-45-49
- cadaveric fetal tissue, as source of embryonic germ cells, symbolic association with abortion, HSC-47-48
- cadaveric association with embryonic germ cell research, arguments against federal funding for, HSC-57
- cloning by somatic cell nuclear transfer, as source of embryonic stem cells for research, issues, HSC-56-57
- cloning, children, eugenic concerns, CHB-ii, 6, 70-72, 103
- cloning, children, exceptional cases considered, CHB-76-77
- cloning, children, family integrity and, concerns, CHB-ii, 2,3, 65-66, 103
- cloning, children, freedom of scientific inquiry and, CHB-ii, 75-76, 103
- cloning, children, individuality and, morality of, CHB-ii, 2, 3, 63-65, 103
- cloning, children, individual liberty and, CHB-72-73
- cloning, children, objectification of, concerns, CHB-ii, 3, 69-70, 103
- cloning, children, personal autonomy and, CHB-ii, 2, 3, 72-77, 103
- cloning, children, potential physical harms, CHB-ii, 3, 61-62, 103
- cloning, children, public policies and moral reasoning, CHB-ii-iii, 77-78, 104
- cloning, children, reproductive choice and, CHB-ii, 73-75, 103
- cloning, children, social values and, potential harms, CHB-ii, iii, 67-68, 103-104
- cloning, human, considerations, CHB-ii-iii, 7-8, 59-79, 104
- cloning, human, Western faith themes concerning, CHB-ii, iii, 2, 41-52, 103-104
- embryo destruction association with embryonic stem cell research, arguments against federal funding for, HSC-57
- embryo moral status, disagreement among religious traditions, HSC-103
- embryonic/fetal material, prohibition of sale of, conclusions/recommendations, HSC-vii, 74
- embryonic germ/stem cell research, federal funding and, conclusions/recommendations, HSC-iii-vi, 68-72
- embryonic germ/stem cell research, federal oversight/review policies adoption, issues, HSC-61
- embryonic germ/stem cell research, institutional review of derivation protocols, conclusions/ recommendations, HSC-viii, 77-78
- embryonic germ/stem cell research, national oversight/review of, need for, conclusions/ recommendations, HSC-vii-viii, 74-77
- embryonic germ/stem cell research, national oversight/review panel creation/duties, conclusions/ recommendations, HSC-vii-viii, 76-77
- embryonic germ/stem cell research, on derivation/use, synergy from combined federal effort, HSC-59
- embryonic germ/stem cell research, privately funded, issues for, conclusions/ recommendations, HSC-ix-x, 78-80
- embryonic germ/stem cell research, public/private support encouragement, benefits of, HSC-59
- embryonic germ/stem cell research, sponsoring federal agencies review of protocols, conclusions/ recommendations, HSC-viii-ix, 78
- embryonic germ/stem cells derivation/use, federal funding for research on, related arguments, HSC-57-61
- embryonic germ/stem cells, federal funding for research on, moral objections to, HSC-57
- embryonic germ/stem cells, sources of, issues on, HSC-45-57
- embryonic stem cells derivation, scientific progress and federal support of, issues, HSC-58-59
- embryos created by in vitro fertilization and used for embryonic stem cell research, importance of intentions and “discarded-created” distinction, HSC-55-56
- embryos created by in vitro fertilization, solely for embryonic stem cell research, federal funding for, conclusions/ recommendations, HSC-v, 71-72
- embryos created by in vitro fertilization, solely for embryonic stem cell research, issues, HSC-55
- embryos created by somatic cell nuclear transfer cloning, as source of embryonic stem cells, federal funding for research on, conclusions/recommendations, HSC-v-vi, 72

embryos created solely for embryonic stem cell research, issues, HSC-55-56
 embryos from infertility treatments, as source of embryonic stem cells for research, federal funding for, conclusions/ recommendations, HSC-iv-v, 60-71
 embryos from infertility treatments, as source of embryonic stem cells for research, importance of shared views, HSC-51-53
 embryos from infertility treatments, as source of embryonic stem cells for research, issues on, HSC-49-55
 embryos from infertility treatments, derivation/use of embryonic stem cells from, distinctions and relationships, HSC-54-55
 embryos from infertility treatments, moral status of, HSC-49-51
 human biological materials information and privacy/confidentiality, harms from breaches of, issues, HBM-43-46
 human biological materials information disclosure, employment discrimination from, issues, HBM-44-45
 human biological materials information disclosure, familial/psychosocial harm from, issues, HBM-46
 human biological materials information disclosure, group-based harms from, issues, HBM-46-47
 human biological materials information disclosure, health insurance discrimination from, issues, HBM-44-45
 human biological materials information disclosure, stigmatization from, issues, HBM-45-46
 human biological materials research results publication and, conclusions/recommendations on, HBM-vii, 73-74
 human biological materials research use and informed consent, perspectives on, HBM-47-49
 human biological materials research use and, issues overview, HBM-8-9
 human biological materials research use and just institutions/policies/practices, perspectives on, HBM-49-50
 human biological materials research use and, perspectives on, HBM-10, 41-52
 human biological materials research use and, professional education/responsibilities for, conclusions/recommendations on, HBM-vii-viii, 74
 human biological materials research use, benefits v. harms/wrongs of, perspectives, HBM-42-43
 human biological materials research use, postmortem, perspectives, HBM-49
 human biological materials use and commodification, ethical issues, HBM-50-51
 human biological materials use in objectionable research, ethical perspectives on, HBM-49
 human biological materials use, respect for human sources of, perspectives, HBM-47-49
 human biological materials use, subjects treatment as moral agent, HBM-47
 human stem cell research and, glossary, HSC-85-86
 human stem cell research and, papers commissioned on, HSC-111
 human stem cell research and, testimony, public/expert, on, HSC-109
 human stem cell research, ethical issues overview, HSC-2-3
 human stem cell research, federal funding for alternative sources of, related arguments, HSC-57-60
 human stem cell research, federal funding recipients and federal regulations, HSC-60
 human stem cell research, federal support/oversight of, conclusions/recommendations, HSC- i-xi, 65-81
 human stem cell research, issues in, HSC-45-62
 human stem cell research, just distribution of potential benefits from, federal funding and, HSC-60-61
 human stem cell research, policy considerations and, HSC-ii-iii, 66-67
 human stem cell research, scientific/medical considerations and, HSC-i-ii, 65-66
 legally authorized representatives for research decision making, protections for validity of, DMC-36
 mentally impaired research subjects, protections for, issues overview, DMC-i-iii, 1-7
 mentally impaired research subjects, study design and, issues overview, DMC-12-14
 research findings publication and, guidelines for, HBM-34-35
See also Harms; Social values; Wrongs
 Ethics Advisory Board (EAB), HSC-34, 35, 49, 75
 Ethnic groups and ethnicity
 stigmatization by research use of human biological materials, public beliefs on, findings, HBM-78-79
 See also Hispanic Americans
 See also Native Americans
 Etzioni, Amitai, CHB-73

Eugenics

cloning of children, concerns about, CHB-ii, 6, 70-72, 103

definition, CHB-70

See also Genes and genetics

Euripides, CHB-4

Europe

cloning, human, position on, CHB-100

laws and standards, and Iceland health records database, issues, HBM-22

molecular scientists and DNA sequence, HBM-3

See also Council of Europe; European Commission; European Group of Ethics (EGE); European Union

European Commission

human biologic materials research use, perspectives of, HBM-33

See also Europe

European Group of Ethics (EGE)

human biologic materials research use, perspectives of, HBM-33

Opinion on Human Tissue Banking, HBM-33

See also Europe

European Union

fetal tissue use in research, HSC-81

human biologic materials research use, perspectives of, HBM-33

See also Europe

Evaluation

cadaveric fetal tissue for, general/consent considerations for donors, research and, HSC-106

embryos from infertility treatments for, general/consent considerations for donors, research and, HSC-106-107

human embryonic germ/stem cell research, identification/recruitment of donors for, issues for, HSC-106

human embryonic germ/stem cell research, compensation/reimbursement of donors for, issues for, HSC-106

human embryonic germ/stem cell research, review/oversight of, considerations for, HSC-107

human embryonic germ/stem cells, scientific/research design considerations for studies involving, HSC-105

legally authorized representatives and mentally impaired research subjects, and, DMC-36-37

National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/recommendations, HSC-x-xi, 80-81

research protocol risks v. benefits for mentally impaired research subjects, recommendations for, DMC-iv, 56-57

self-, voluntary, for research involving mentally impaired subjects, guidance for Institutional Review Boards, DMC-67

Executive Office of the President

Statement of the Administration on Policy, HSC-37

Executive orders, HSC-37

Expert testimony. *See* Testimony and speakers

F

Fadlallah, S.M.H., CHB-43

Families

cloning, children, family integrity and, concerns, CHB-ii, 2, 3, 65-66, 103

cloning, human, and, religious concerns, CHB-2-3, 51-52, 104

human biological materials information disclosure and, conflicts from, ethical issues, HBM-46

human biological materials research use, and risk v. potential benefit to relatives, conclusions/recommendations on, HBM-vii, 72, 73

mentally impaired research subjects, decision making involvement of, recommendations, DMC-vi, 63

state legislation on relationships, CHB-87
See also Children

Farley, Margaret, HSC-50

FDA. *See* Food and Drug Administration (FDA)

FD&C Act. *See* Federal Food, Drug, and Cosmetic Act (FD&C Act)

Federal departments and agencies

- cloning, human, continued collaboration on, CHB-v, 106
- embryonic germ/stem cell research, review of protocols by, conclusions/ recommendations, HSC-viii-ix, 78

See also Federal government

Federal Food, Drug, and Cosmetic Act (FD&C Act), HSC-93, 94, 95

Federal funding for research

- abortion association with embryonic germ cells, arguments against, HSC-57
- cloning, children, moratorium, CHB-i, iii, 3, 93-94, 105; HSC-37
- cloning, children, moratorium on and private sector adherence, CHB-iii, 93, 94-96, 105
- cloning, human, limitations for, CHB-83-84, 85
- embryo destruction association with embryonic stem cell research, arguments against, HSC-57
- embryonic germ cells derived from cadaveric fetal tissue, research on and, conclusions/ recommendations, HSC-iii-iv, 68-69
- embryonic germ/stem cell research and, benefits of, HSC-59
- embryonic germ/stem cell research and, ethics of, conclusions/recommendations, HSC-iii-vi, 68-72
- embryonic germ/stem cell research, and institutional review of derivation protocols, conclusions/ recommendations, HSC-viii, 77-78
- embryonic germ/stem cell research and, moral objections to, HSC-57
- embryonic germ/stem cell research, and national oversight/review panel creation/duties, conclusions/ recommendations, HSC-vii-viii, 76-77
- embryonic germ/stem cell research, national oversight/review of, need for, conclusions/ recommendations, HSC-vii-viii, 74-77
- embryonic germ/stem cell research, privately funded and eligible for, issues for, conclusions/ recommendations, HSC-ix-x, 78-79
- embryonic germ/stem cell research, sponsoring federal agencies review of protocols, conclusions/ recommendations, HSC-viii-ix, 78
- embryonic germ/stem cells derivation/use of, research on, related arguments on, HSC-57-61
- embryonic germ/stem cells derivation/use research, synergy from combined federal effort, HSC-59
- embryonic stem cell research, privately funded and not eligible for, issues for, conclusions/ recommendations, HSC-x, 79-80
- embryonic stem cells derivation, scientific progress and, issues, HSC-58-59
- embryonic stem cells derived from embryos created by in vitro fertilization solely for research, and, conclusions/ recommendations, HSC-v, 71-72
- embryonic stem cells derived from embryos from infertility treatments, research on and, conclusions/ recommendations, HSC-iv-v, 60-71
- embryonic stem cells derived from embryos from somatic cell nuclear transfer cloning, research on and, conclusions/recommendations, HSC-v-vi, 72
- embryos created for research use, ban on, HSC-34-35, 38
- human biological materials research use, current regulations on, HBM-28
- human stem cell research and alternative sources, arguments for, HSC-57-58
- human stem cell research and, conclusions/recommendations, HSC- i-xi, 65-81
- human stem cell research and, disagreement among religious traditions, HSC-104
- human stem cell research and, regulatory requirements, HSC-60
- human stem cell research and, just distribution of potential benefits from, HSC-60-61
- human stem cell research and, sustaining science/technology leadership and, HSC-60
- human stem cell research, arguments against certain types, HSC-57-58
- human stem cell research, arguments for certain types, HSC-58-60
- mentally impaired research subjects, increases for protections, recommendations, DMC-vii, 64-65

See also Federal government; Research; Research funding

Federal government

cloning, human, limited powers over individual freedom of action, CHB-ii-iii, 8-9, 89-90, 104

See also Federal departments and agencies; Federal funding for research; Federal legislation; Federal regulation; Public policy; Regulation; U.S. Congress

Federal legislation

cloning, human, laws affecting, CHB-iv, 8-9, 84-85, 86, 105

embryonic germ cells from cadaveric fetuses, research using and, HSC-29-31

embryos created by in vitro fertilization, research using cells/tissues from, and, HSC-34-35

fetal tissue transplantation, conditions for support of, HSC-30-31

human stem cells, application of FDA regulations on human cellular materials/tissues, HSC-94

human stem cells, FDA authority over, overview, HSC-93-97

human cellular materials/tissues, FDA case-by-case regulation of, HSC-94-95

human cellular materials/tissues, FDA regulations on, overview, HSC-93-95

human cellular/tissue-based products, new approach to FDA regulation of, HSC-95-96

human stem cell research, ethical and policy considerations, HSC-ii-iii, 66-67

medical records privacy and research use, regulations governing, HBM-35-36

S. 1601, Human Cloning Prohibition Act, HSC-37

See also Federal Food, Drug, and Cosmetic Act (FD&C Act); Federal government; Federal regulation; Fertility Clinic Success Rate and Certification Act of 1992; Health Insurance Portability and Accountability Act (HIPAA) of 1996; National Organ Transplant Act of 1984 (NOTA); NIH Revitalization Act of 1993; Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA); Public Health Service Act (PHS Act); Public Law 104-91; Public Law 104-208; Uniform Anatomical Gift Act (UAGA); U.S. Congress

Federal oversight. *See* Federal regulation

Federal policies. *See* Federal government; Federal regulation; Public policy

Federal Policy for the Protection of Human Subjects. *See* Code of Federal Regulations, Title 45, Part 46 (45 CFR 46)

Federal Register, HBM-82, 86, 91, 94, 95, 96

Federal regulation

cloning used as source for embryonic stem cells, related law, HSC-36-37

embryonic germ/stem cell research, and adoption of policies for, ethical issues, HSC-61

embryonic germ/stem cell research and, national panel creation/duties, conclusions/ recommendations, HSC-vii-viii, 76-77

embryonic germ/stem cell research and, need for, conclusions/ recommendations, HSC-vii-viii, 74-77

fetal tissue transplantation, conditions for support of, HSC-30-31

human biological materials, existing and publicly available samples, HBM-58-59

human biological materials, identifiability of samples, HBM-57

human biological materials research use and, discussion of, HBM-i-iii, 10, 55-56

human biological materials research use and informed consent, HBM-7, 30-31

human biological materials research use, and Institutional Review Board concern for third-party interests, HBM-31

human biological materials research use, and Institutional Review Board expedited review, HBM-iii, 30, 60

human biological materials research use, and Institutional Review Board review exemption, HBM-iii, 29-30, 57-60

human biological materials research use, and Institutional Review Board review requirements, HBM-30-32, 105-109

human biological materials research use and, interpretation of, conclusions/recommendations, HBM-iii, 57-60

human biological materials research use and, justice in, ethical issues, HBM-49-50

human biological materials research use, and waiver of consent, conclusions/recommendations, HBM-v-vi, 66-70

human biological materials research use, current scope of, HBM-27-32

human biological materials use in prostate cancer research protocol, regulatory issues, HBM-31-32

human cellular materials/tissues, FDA regulations on, HSC-93-95
human cellular/tissue-based products, new approach to FDA regulation of, HSC-95-96
human stem cell research and, conclusions/recommendations, HSC- i-xi, 65-81
human stem cell research, ethical and policy considerations, HSC-ii-iii, 66-67
human stem cells, application of FDA regulations on human cellular materials/tissues, HSC-94
human stem cells, FDA authority over, overview, HSC-93-97
medical records privacy and research use, and, HBM-35-36
mentally impaired research subjects, advance decision making for, regulations/policy on, DMC-31-32, 34
National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/
recommendations, HSC-x-xi, 80-81
research governed by, definition of, HBM-56
research involving human beings, including fetuses, and, HSC-30
research involving human subjects, HBM-28-29, 57-58
science, control over, considerations, CHB-6-7
See also Code of Federal Regulations, Title 45, Part 46 (45 CFR 46); Federal government; Federal
legislation; Public policy; Regulation

Feinberg, Joel, CHB-63, 64
Fertility Clinic Success Rate and Certification Act of 1992, CHB-84, 96
Fertilization. *See* In vitro fertilization (IVF); Reproduction
Fetus and fetal tissue
cadaveric, as source of embryonic germ cells, and causal responsibility for abortion, HSC-46-47
cadaveric, as source of embryonic germ cells, and perceived complicity with abortion, religious
disagreement on, HSC-103-104
cadaveric, as source of embryonic germ cells, and symbolic association with abortion, HSC-47-48
cadaveric, as source of embryonic germ cells, consent and donation issues, HSC-48-49
cadaveric, as source of embryonic germ cells, ethical issues on, HSC-45-49
cadaveric, as source of embryonic germ cells, federal funding for research on, conclusions/
recommendations, HSC-iii-iv, 68-69
cadaveric, as source of embryonic germ cells, related law, HSC-29-33
cadaveric, as source of stem cells, state law on, HSC-32-33
cadaveric, donation for research, requirements for, conclusions/recommendations, HSC-vi-vii, 72-73
cadaveric fetal tissue, general/consent considerations for donors, research evaluation, HSC-106
cadaveric, research using cells/tissue from, federal law on, HSC-29-31
definition, HSC-5
development stages of, HSC-11
donation of, for embryonic germ cell research, state laws on, HSC-32-33
embryonic stem cell isolation/culture from, HSC-9
embryonic germ cells from primordial germ cells of, description, HSC-17, 19
research activities on, protections for, 45 CFR 46, Subpart B, in entirety, HBM-91-94
research involving human beings, including fetuses, general regulation of, HSC-30
sale of, prohibition of, conclusions/recommendations, HSC-vii, 74
transplantation of, conditions for federal support of, HSC-30-31
See also Embryos and embryonic materials; Human biological materials; Pregnancy

Finances, personal
mentally impaired research subjects and adequacy of, issues for, DMC-11
Finland. *See* Declaration of Helsinki
Fletcher, Joseph, CHB-38-39
Florida
cloning, human, legislation on, CHB-85, 86
family relationships, legislation on, CHB-87
medical records privacy and research use, laws on, HBM-36-37
See also Miami, Florida
fMRI. *See* Functional magnetic resonance imaging (fMRI)
Food and Drug Administration (FDA), CHB-97; DMC-19, 32; HBM-8, 27, 28, 56, 82, 83; HSC-iii, 61, 67, 75

discretion of, and special deference for, HSC-3
Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, HSC-96
human cellular materials/tissues, FDA regulations on, HSC-93-95
human cellular/tissue-based products, new approach to FDA regulation of, overview of, HSC-95-96
human stem cells, application of regulations on human cellular materials/tissues, HSC-94
human stem cells, statutory/regulatory authority over, overview, HSC-93-97
mentally impaired persons in research, existing protections for, DMC-2
Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products, HSC-96

Foreign countries
cloning, human, reaction to, CHB-3
human biological materials research use, opinions on, HBM-33-34
See also Foreign laws; U.S.-foreign relations

Foreign laws
cloning, human, and, CHB-3, 95, 100, 101
See also Foreign countries; U.S.-foreign relations

Foreign relations. *See* U.S.-foreign relations

Forums
human biological materials research use and ethnic stigmatization, public beliefs on, HBM-78-79
human biological materials research use and ownership/consent, public beliefs on, HBM-78
human biological materials research use and privacy/confidentiality, public beliefs on, HBM-78
human biological materials research use and safeguards, public beliefs on, HBM-79
human biological materials research use and sponsorship, public beliefs on, HBM-79
human biological materials research use and third-party concerns, public beliefs on, HBM-79
human biological materials research use, public beliefs on, findings, HBM-77-79
human biological materials storage, public knowledge on, findings, HBM-77

Four Corners, HBM-20
Framington Heart Study, HBM-21
France
cloning, human, laws on, CHB-100
Freedman, Benjamin, HSC-48
Friends
mentally impaired research subjects, decision making involvement of, recommendations, DMC-vi, 63
Functional magnetic resonance imaging (fMRI), DMC-4
See also Magnetic resonance imaging (MRI)

Fundamental liberties
cloning, human, procreation, and, CHB-ii, 91-93, 103
See also Constitutional law; Individual freedom of action

Funding. *See* Federal funding for research; Research funding

G

Gearhart, John D., HSC-1, 7, 19, 31
Genes and genetics
databases of, collaboration between universities/private industry, HBM-15
definition, CHB-A-2
determinism, cloning and, CHB-2, 32-33
determinism, definition, CHB-32
expression of, regulation of, research on, CHB-18-19
imprinting of, definition, CHB-A-2
imprinting of, nuclear transfer cloning effects of, CHB-2
information on, comparison with other medical information, concerns overview, HBM-3-4

- intervention in, religious considerations, CHB-39, 41
- locating, value of stored human biological materials for, HBM-21, 23
- targeting of, animal cloning research for, CHB-26-28
- targeting of, definition, CHB-A-2
- See also* Eugenics
- Georgetown University, HSC-49
- George Washington University, CHB-40
- Germany
 - cloning laws, CHB-3, 95, 100
 - fetal tissue use in research, HSC-81
 - Nazi doctors trial, DMC-17
 - Nazi Germany, eugenic practices in, CHB-71
 - Nuremberg, DMC-17
 - See also* Nuremberg Code, 1946-49
- Germ cells
 - definition, HSC-85
 - See also* Research on human stem cells
- Geron Corporation, HSC-7
- Glaxo Wellcome, HBM-15
- Glendon, Mary Ann, CHB-73, 89
- Glossaries
 - cloning human beings, ethical concerns, CHB-A-1-3
 - human stem cell research, ethical issues, HSC-85-86
- GME. *See* Graduate Medical Education (GME)
- God
 - cloning, human, and, CHB-4, 46, 47, 48, 49, 50, 68
 - cloning, human, and human partnership with, CHB-44-45
 - cloning, human, and humans as created co-creators, CHB-45
 - cloning, human, and warnings not to play, CHB-42-43
 - image of, moral meaning, interpretations of, CHB-41-42
- Gordon, J.B., CHB-17, 18
- Gostin, L.O., HBM-4
- Government departments and agencies. *See* Federal departments and agencies
- Government funding. *See* Federal funding for research
- Government. *See* Federal departments and agencies; Federal funding for research; Federal government; Federal legislation; Federal regulation; Laws and legislation; Public policy; State legislation
- Government regulation. *See* Federal regulation
- Graduate Medical Education (GME)
 - teaching institutions, HBM-14
- Great Britain. *See* United Kingdom
- Greece
 - classical culture, CHB-4
 - mythology, CHB-47, 68
- Grisso, Thomas, DMC-19
- Griswold v. Connecticut*, CHB-91
- Groups and group-based identity
 - harms from human biological materials information disclosure, ethical issues, HBM-7-8, 46-47
 - harms from human biological materials research use, conclusions/recommendations on, HBM-vii, 72, 73
- Guthrie cards, HBM-1, 14
- Gutmann, Amy, CHB-73, 78; HSC-51

H

Häring, Bernard, CHB-38, 49

Harms

- employment discrimination from human biological materials information, ethical issues, HBM-44-45
 - familial/psychosocial conflicts from human biological materials information, ethical issues, HBM-46
 - group-related, from human biological materials information, HBM-vii, 46-47, 72, 73
 - health insurance discrimination from human biological materials information, ethical issues, HBM-44-45
 - human biological materials research use and, potential for others, conclusions/recommendations on, HBM-vii, 72-73
 - minimization of, from human biological materials research use, ethical issues, HBM-42-43
 - privacy/confidentiality of human biological materials information and, ethical issues, HBM-43-46
 - relatives risks v. potential benefits, from human biological materials research use, conclusions/recommendations on, HBM-vii, 73
 - stigmatization from human biological materials information, ethical issues, HBM-45-46
- See also* Wrongs

Harris polls, HBM-5, 45

Harvard Medical School, CHB-6

Hawaii. *See* Honolulu, Hawaii; Mililani, Hawaii

Health and Human Services Department. *See* Department of Health and Human Services (DHHS)

Health care. *See* Health care professionals; Medicine

Health care professionals

- independent advisors for mentally impaired research subjects, guidance for Institutional Review Boards, DMC-67
 - independent support for mentally impaired research subjects and surrogacy in decision making, DMC-37
- See also* Medicine

Health, Education and Welfare Department. *See* Department of Health, Education and Welfare (DHEW)

Health insurance

- discrimination in, and human biological materials information, ethical issues, HBM-5, 44-45
- See also* Medical information; Medical records; Medicine

"Health Insurance in the Age of Genetics", HBM-44

Health Insurance Portability and Accountability Act (HIPAA) of 1996, HBM-35

Health records. *See* Medical records

Hefner, Philip, CHB-47

Helsinki, Finland. *See* Declaration of Helsinki

Hemings, Eston, HBM-3

Hemings, Sally, HBM-3

Henley v. Wise, CHB-75

HHANES. *See* Hispanic Health and Nutrition Examination Survey (HHANES)

Himmeler, Heinrich, HSC-47

HIPAA. *See* Health Insurance Portability and Accountability Act (HIPAA) of 1996

Hippocratic oath, CHB-61

Hispanic Health and Nutrition Examination Survey (HHANES), HBM-23

Hispanic Americans, HBM-23

See also Ethnic groups and ethnicity

History

- mentally impaired persons in research, regulation of, CHB-69-72
- religion and human cloning, overview, CHB-38-41

Hoechst Marion Roussel, HBM-15

Honolulu, Hawaii, HBM-77, 78, 79

HUGO. *See* Human Genome Organization (HUGO)

Human biological materials

- bodies/body parts and self-identity and, issues overview, HBM-6
- bodies/body parts, commodification of, ethical issues, HBM-50-51
- brain research use of human tissue, HBM-20
- cancer research and, value of, HBM-19-20

categories of, National Bioethics Advisory Commission definitions, HBM-i, 16-18, 57-58
 cellular materials/tissues, FDA regulations on, application to human stem cells, HSC-94
 cellular materials/tissues, FDA regulations on, HSC-93-95
 cellular/tissue-based products, new approach to FDA regulation of, overview of, HSC-95-96
 collections of, overview of, HBM-13-15, 57-58
 embryos created by in vitro fertilization, research using cells/tissues from, federal law on, HSC-34-35
 embryos created by in vitro fertilization, research using cells/tissues from, state law on, HSC-35-36
 existing and publicly available, federal policy on, HBM-58-59
 fatally ill person, human cloning for, and public policy proposals, CHB-53
 federal regulations governing, discussion of, HBM-i-iii, 55-56
 gene location, value of stored materials for, HBM-21, 23
 identifiability of, HBM-15-18, 57-58
 identifiable samples rendered unidentifiable, and informed consent, conclusions on, HBM-70-71
 information disclosure and, employment discrimination from, ethical issues, HBM-5, 44-45
 information disclosure and, familial/psychosocial harm from, ethical issues, HBM-46
 information disclosure and, group-related harms from, ethical issues, HBM-7-8, 46-47
 information disclosure and, health insurance discrimination from, ethical issues, HBM-5, 44-45
 information disclosure and, stigmatization from, ethical issues, HBM-5, 45-46
 information privacy/confidentiality of, harms from breaches of, ethical issues, HBM-5-6, 43-46
 just institutions/policies/practices for use of, ethical issues, HBM-49-50
 longitudinal studies and, value of, HBM-20-21
 records privacy and, concerns overview, HBM-5-6
 repository collections of, definition of, HBM-i, 16, 18, 58
 research appropriate use of, issues overview, HBM-4-9
 research samples of, definition of, HBM-i, 16-18, 58
 research value of, overview, HBM-1-3
 respect for human sources of, ethical perspectives on, HBM-47-49
 samples, coded, definition, HBM-i, 17-18, 58
 samples, coded/identified, requirements for research use of, conclusions/recommendations, HBM-iii-iv, 62
 samples, identified, definition, HBM-i, 17, 18, 58
 sample source identification, necessity for research/clinical purposes, HBM-18-19
 samples, unidentified, definition, HBM-i, 16-17, 18, 58
 samples, unlinked, creation from coded/identified samples, special concerns on, conclusions/
 recommendations, HBM-iii, 60-62
 samples, unlinked, definition, HBM-i, 16-17, 18, 58
 specimens, identified, definition, HBM-i, 16, 18, 58
 specimens, unidentified, definition, HBM-i, 16, 18, 58
 storage of, public knowledge on, forum findings, HBM-77
 stored specimens in U.S., statistics on, HBM-14
 unique human tissue collections, requirements for, HBM-23
 viruses, tracking of, and, HBM-20
See also Embryos and embryonic materials; Fetus and fetal tissue; Humans; Research involving human
 biological materials

Human cloning

autonomy, personal, and, CHB-ii, 2, 3, 72-77, 103
 cases, assessments of, and related public policy proposals, CHB-52-55
 cases, exceptional, consideration/arguments for, CHB-76-77
 children, ethical considerations, CHB-59-79
 children, eugenic concerns, CHB-ii, 6, 70-72, 103
 children, family integrity and, concerns, CHB-ii, 2, 3, 65-66, 103, 104
 children, federal funding moratorium for, CHB-i, iii, 3, 93-94, 105
 children, federal funding moratorium/private sector adherence, CHB-i, iii, 3, 93, 94-96, 105
 children, individuality and, morality of, CHB-ii, 2, 3, 63-65, 103
 children, legislative ban on, CHB-iv, 9, 93, 98-99, 105

children, objectification of, concerns, CHB-ii, 3, 69-70, 103
 children, physical harms to, CHB-ii, 3, 61-62, 103
 children, public policies and moral reasoning, CHB-ii-iii, 77-78, 104
 children, social values and, potential harms, CHB-ii, iii, 67-68, 103-104
 constitutional limitations on policy formulation for, CHB-8-9, 88-90
 creation of humans, biblical story of, and, CHB-41-42
 destiny, human, and, CHB-45-47, 104
 dignity, human, and, CHB-47-49, 104
 embryonic stem cells derived from products of, related law, HSC-36-37
 embryonic stem cells produced by somatic cell nuclear transfer cloning, ethical issues, HSC-56-57
 ethical considerations for, CHB-ii-iii, 59-79, 104
 family, concerns about, and, CHB-ii, 2, 3, 51-52, 103, 104
 federal legislation affecting, CHB-84-85, 86
 foreign nations, cooperation with, CHB-v, 93, 99-101, 106
 glossary on, CHB-A-1-3
 God, warnings not to play, and, CHB-42-43
 knowledge, quest for, and, CHB-43-44
 laws affecting efforts, CHB-84-86
 liberties, fundamental, and procreation and, CHB-ii, 8-9, 91-93, 103
 liberty, individual, and, CHB-ii-iii, 72-73, 104
 morality and public policy formulation for, CHB-90-93
 nature and responsible dominion over, CHB-4-6, 42-47, 104
 papers commissioned on, CHB-C-1
 policy options developed for, CHB-93-101
 procreation/reproduction and, CHB-, ii, 49-50, 103, 104
 religious perspectives on, CHB-ii, iii, iv-v, 2, 7-8, 37-55, 103-104, 106
 reproductive choice and, CHB-ii, 73-75, 103
 scientific inquiry, freedom of, and, CHB-ii, 75-76, 103
 State legislation affecting, CHB-85-87
 testimony and public speakers on, CHB-B-1
See also Cloning; Humans; Nuclear transplantation cloning

Human destiny
 cloning, human, and continuing creation, CHB-46-47
 cloning, human, and divine mandate of mastery, CHB-46
 cloning, human, and genetic apocalypse, CHB-45-46
 cloning, human, and, religious views, CHB-45-47, 104
See also Human dignity; Humans

Human dignity
 cloning, human, and commodification, CHB-49
 cloning, human, and objectification, CHB-ii, 3, 48-49, 103
 cloning, human, and religious views, CHB-47-49, 104
 cloning, human, and sanctity of life, CHB-48
See also Human destiny; Humans

Human dominion over nature
 cloning, human, and, CHB-4-6, 42-47, 104
See also Humans

Human Embryo Research Panel, CHB-5; HSC-v, 3, 34, 49, 54, 55, 71, 75
See also National Institutes of Health (NIH)

Human Fetal Tissue Transplantation Research Panel, HSC-vii, 30, 45, 46, 48, 74
See also National Institutes of Health (NIH)

Human Genome Diversity Project, CHB-100
See also Human Genome Organization (HUGO)

Human Genome Organization (HUGO), CHB-100; HBM-33, 34
 Ethics Committee, HBM-33

human biological materials use in research, statement comparison, HBM-100
 International Ethics Committee, CHB-100
Statement on DNA Sampling: Control and Access, HBM-33
Statement on the Principled Conduct of Genetic Research, CHB-100
See also Human Genome Diversity Project; Human Genome Project

Human Genome Project, CHB-32, 100; HBM-3, 9, 21, 47
See also Human Genome Organization (HUGO)

Humanity
 characteristics of, inferred from biblical story of creation, CHB-41-42
See also Humans

Human reproduction. *See* Humans; Reproduction; Assisted reproductive technology (ART)

Humans
 co-creators created with God, and human cloning, CHB-45
 definition of human subject for research, HBM-57, 107
 God and, partnership, and human cloning, CHB-44-45
 research and human beings, including fetuses, general regulation of, HSC-30
 research and human subjects, current federal regulations governing, HBM-28-29
 stewardship over nature, and human cloning, CHB-44
See also Human biological materials; Human cloning; Human destiny; Human dignity; Human dominion
 over nature; Human stem cells; Humanity; Protections for human subjects; Research involving
 human biological materials; Research involving human stem cells

Human stem cells
 adult, types and potential clinical applications of, HSC-12-14
 cadaveric fetal tissue, as source of embryonic germ cells, causal responsibility for abortion, HSC-46-47
 cadaveric fetal tissue, as source of embryonic germ cells, consent and donation issues, HSC-48-49
 cadaveric fetal tissue, as source of embryonic germ cells, ethical issues on, HSC-45-49
 cadaveric fetal tissue, as source of embryonic germ cells, symbolic association with abortion, HSC-47-48
 cadaveric fetuses, as sources of embryonic germ cells, related law, HSC-29-33
 cadaveric fetuses, as sources of stem cells, state law on, HSC-32-33
 cloning by somatic cell nuclear transfer, as source of embryonic stem cells, related law, HSC-36-37
 definitions, HSC-4-5
 embryonic germ cells from fetal primordial germ cells, description, HSC-17, 19
 embryonic germ/stem cells, sources of, ethical issues on, HSC-45-57
 embryonic stem cells derivation, scientific progress and federal support of, issues, HSC-58-59
 embryos created by in vitro fertilization, as sources of embryonic stem cells, related law, HSC-33-36
 embryos from infertility treatments, derivation/use of embryonic stem cells from, ethical distinctions and
 relationships, HSC-54-55
 embryos from infertility treatments, moral status of, ethical issues, HSC-49-51
 embryonic stem cell lines derived from blastocysts, description, HSC-16-17
 embryonic stem cells, sources of, HSC-9, 10-12
 ethical issues on, overview, HSC-2-3
 Food and Drug Administration regulations on human cellular materials/tissues, application to, HSC-94
 Food and Drug Administration statutory/regulatory authority over human stem cells, overview, HSC-93-
 97
 hybrid embryo, from fusion of human somatic cells and cow eggs, description, HSC-19
 isolation/culture of, from blastocysts, HSC-11
 isolation/culture of, from embryonic/fetal tissues, HSC-9
 isolation/culture of, overview, HSC-1-2
 mesenchymal stem cells, description and potential clinical applications of, HSC-13-14
 models of, description, HSC-16-17, 19
 neural stem cells, description and potential clinical applications of, HSC-12-13
 report framework, HSC-3-4
See also Adult stem (AS) cells; Cells; Embryonic germ (EG) cells; Embryonic stem (ES) cells; Humans;
 Mesenchymal stem cells; Neural stem cells; Research on human stem cells; Stem cells

Human subjects, protections for. *See* Protections for human subjects
Huxley, Aldous, CHB-6

I

Iceland

Director General of Public Health, HBM-22
health records central database, overview of, HBM-22
Ministry of Health and Social Security, HBM-22
Parliament, HBM-22

ICM. *See* Inner cell mass (ICM)

IDEs. *See* Investigational device exemption applications (IDEs)

Identification

human biological materials, sample source for, necessity for, HBM-15-18

Identity. *See* Individuality

Illinois

cloning, human, legislation on, CHB-86
mentally disabled persons in research, legislation on, DMC-71

IND. *See* Investigational new drug (IND)

Independent advisors

health care professional advisors for mentally impaired research subjects, guidance for Institutional Review Boards, DMC-67
professional support for subjects and surrogates in research decision making, DMC-37
research monitors, and risk v. benefit assessment for mentally impaired subjects, DMC-49-50

Indiana

fetal/embryonic tissue use, legislation on, HSC-40

Indian Health Service, HBM-8

See also Native Americans

Individuality

cloning, children, and, morality of, CHB-ii, 2, 3, 63-65, 103
personhood and human cloning, Kantian moral philosophy, CHB-69-70
separateness, quality of, CHB-63

Individual freedom of action

cloning, human, and, constitutional considerations, CHB-ii-iii, 8-9, 89-90, 104
cloning, human, and, ethical arguments, CHB-ii, 72-73, 103
See also Autonomy; Constitutional law; Fundamental liberties

Infertility treatments

embryonic stem cells derived from embryos from, federal funding for research on, conclusions/recommendations, HSC-iv-v, 60-71
embryos from, derivation/use of embryonic stem cells from, ethical distinctions and relationships, HSC-54-55
embryos from, donation for research, requirements for, conclusions/recommendations, HSC-vi-vii, 72-73
embryos from, general/consent considerations for donors, research evaluation, HSC-106-107
embryos from, moral status of, ethical issues, HSC-49-51
embryos from, research use for embryonic stem cells, ethical issues, HSC-49-55
embryos from, research use for embryonic stem cells, importance of shared views, HSC-51-53
See also Assisted reproductive technology (ART); Reproduction

Informal caregiver. *See* Caregiver

Information

genetic v. other medical, comparison of, and concerns overview, HBM-3-4
See also Disclosure of information; Medical information

Informed consent

human biological materials, identifiable samples made unidentifiable and, conclusions on, HBM-70-71

human biological materials research results publication and, conclusions/recommendations on, HBM-vii, 73-74

human biological materials research use and, additional information requirements, conclusions/recommendations, HBM-vi, 70

human biological materials research use and choice, ethical issues, HBM-48

human biological materials research use and competence of subject, ethical issues, HBM-48-49

human biological materials research use and comprehension of risks/benefits, ethical issues, HBM-48-49

human biological materials research use and disclosure of risks/benefits, ethical issues, HBM-48

human biological materials research use and, ethical perspectives on, HBM-47-49

human biological materials research use and, minimal risk regulations, conclusions/recommendations, HBM-vi, 66-68

human biological materials research use and, nature of, overview, HBM-6-7

human biological materials research use and, obtaining new consent, conclusions/recommendations, HBM-iv, 63-66

human biological materials research use and, practicability regulations, conclusions/recommendations, HBM-vi, 69-70

human biological materials research use and, previously obtained, conclusions/recommendations, HBM-iv, 62-63, 64-66

human biological materials research use and, regulations on, HBM-30-31

human biological materials research use and, subjects rights/welfare regulations, conclusions/recommendations, HBM-v-vi, 68

human biological materials research use and voluntariness, ethical issues, HBM-48

human biological materials research use and waiver of, “opt out” protection, HBM-63, 70

human biological materials research use and waiver of, regulations on, conclusions/recommendations, HBM-v-vi, 66-70

human biological materials research use, requirements proposed by National Bioethics Advisory Commission for, HBM-109

human research subjects, process for, guidance for Institutional Review Boards, DMC-65-66

human research subjects protection, requirements for, 45 CFR 46, Subpart A, HBM-88-90

mentally impaired research subjects and advance planning of, decision making role, DMC-29

mentally impaired research subjects and, centrality of, DMC-17-18

mentally impaired research subjects, and decisional impairment and, DMC-9-10

mentally impaired research subjects and, expanding knowledge of, recommendations, DMC-vi-vii, 64

mentally impaired research subjects and, limitations on decisionmaking capacity and, DMC-17-25

mentally impaired research subjects and, recommendations, DMC-iv, 57-58

voluntary, mentally disabled persons in research and, centrality of, DMC-17-18

See also Consent

In His Image, CHB-6, 39

Inner cell mass (ICM), CHB-20

definition, CHB-A-2

See also Cells

Institute of Medicine (IOM), DMC-vii, 64

mentally impaired research subjects, review of studies by, recommendations, DMC-vii, 64

Resource Sharing in Biomedical Research, HSC-60

Institutional Review Boards (IRBs), CHB-61, 84, 97, 98; DMC-i, ii, iii, vi, 17, 18, 20-21, 22, 25, 28, 32, 33, 34, 35, 36, 37, 39, 45, 46, 46, 50, 52, 64, 70, 71, 86, 87; HBM-ii, 8, 9, 29, 32, 35, 36, 38, 39, 41, 42, 46, 79; HSC-ix, 5, 16, 35, 61, 74, 75, 76

children as research subjects, protections for, requirements for, 45 CFR 46, Subpart D, HBM-96

embryonic germ/stem cell research, and institutional review of derivation protocols, conclusions/recommendations, HSC-viii, 77-78

human beings, including fetuses, as research subjects, general regulation of, HSC-30

human biological materials, identifiability of, and review by, HBM-15-18

human biological materials, identifiable samples made unidentifiable, and informed consent, conclusions on, HBM-70-71

human biological materials research results, reporting to subjects, conclusions/recommendations on, HBM-vi-vii, 71-72

human biological materials research use, additional information requirements for, conclusions/recommendations, HBM-vi, 70

human biological materials research use and informed consent, issues overview, HBM-7

human biological materials research use, and risk to groups, conclusions/recommendations on, HBM-vii, 72, 73

human biological materials research use, concern for third-party interests, HBM-31

human biological materials research use, expedited review for, HBM-iii, 30, 60

human biological materials research use, federal regulations on, interpretation of, conclusions/recommendations, HBM-iii, 57-60

human biological materials research use, guidance for review by, HBM-105-109

human biological materials research use, informed consent requirements, HBM-iv, 30-31, 62-66, 109

human biological materials research use, minimal risk guidelines for, conclusions/recommendations, HBM-v-vi, 66-68

human biological materials research use of coded/identified samples, requirements for, conclusions/recommendations, HBM-iii-iv, 62

human biological materials research use, potential harms to others, conclusions/recommendations on, HBM-vii, 72-73

human biological materials research use, practicability regulations for, conclusions/recommendations, HBM-vi, 69-70

human biological materials research use, process proposed by National Bioethics Advisory Commission, HBM-106

human biological materials research use, review exemption, regulations on, HBM-iii, 29-30, 57-60

human biological materials research use, review for, regulations on, HBM-30-32, 105-109

human biological materials research use, subjects rights/welfare regulations for, conclusions/recommendations, HBM-v-vi, 68

human biological materials research use, waiver of consent requirements, conclusions/recommendations, HBM-v-vi, 66-70

human biological materials, unlinked samples made from coded/identified samples, special concerns on, conclusions/recommendations, HBM-iii, 60-62

human biological materials use in prostate cancer research protocol, regulatory issues for, HBM-31-32

human research subjects protection, requirements for, 45 CFR 46, Subpart A, HBM-85-88

human research subject, current definition of Office for Protection from Research Risks, HBM-107

mentally impaired research subjects, and audit and disclosure by institutions, guidance for, DMC-67

mentally impaired research subjects, and decision making by family/friends, recommendations for, DMC-vi, 63

mentally impaired research subjects, and decisionmaking capacity assessment of, recommendations, DMC-iv, 58-59

mentally impaired research subjects, and membership of, recommendations, DMC-iii, 53-54

mentally impaired research subjects, and protocols posing minimal/greater than minimal risk, definition of, DMC-40-43

mentally impaired research subjects, appropriate selection by, recommendations for, DMC-v, 55-56

mentally impaired research subjects, education/decision making and risk v. benefit assessment by, DMC-48-49

mentally impaired research subjects, guidance for, DMC-65-67, 73-76

mentally impaired research subjects, protections for, review by, DMC-1, 3, 4, 6, 13, 14, 15

mentally impaired research subjects, risk assessment by, DMC-43-44

mentally impaired research subjects, risk categories for, recommendations for, DMC-v, 60-61

mentally impaired research subjects, risks v. benefits evaluation by, recommendations for, DMC-iv, 56-57

pregnant women, fetuses, and in vitro fertilization, research protections for, requirements for, 45 CFR 46, Subpart B, HBM-92

prisoners in biomedical/behavioral research, protections for, requirements for, 45 CFR 46, Subpart C, HBM-94-95

Institutions

- Graduate Medical Education teaching institutions, HBM-14
- justice of, for human biological materials research use, ethical issues, HBM-49-50
- medical/scientific, and human biological materials research use, policies of, HBM-32-33
- mentally impaired research subjects and, responsibilities of, issues overview, DMC-14-15
- mentally impaired research subjects, audit and disclosure by, guidance for, DMC-67

Insurance. *See* Health insurance

International Committee of Medical Journal Editors, HBM-35, 44

Uniform Requirements for Manuscripts Submitted to Biomedical Journals, HBM-35, 44

International opinions. *See* Foreign countries

Investigational device exemption applications (IDEs)

Investigational new drug (IND), HSC-94, 95, 96

See also Drugs and drug testing

In vitro fertilization (IVF), CHB-38

definition, CHB-A-2; HSC-86

embryos created by, as sources of embryonic stem cell research, importance of intentions and “discarded-created” distinction, HSC-55-56

embryos created by, as sources of embryonic stem cells, related law, HSC-33-36

embryos created by, as sources of embryonic stem cells solely for research, and federal funding for, conclusions/ recommendations, HSC-v, 71-72

embryos created by, research using cells/tissues from, federal law on, HSC-34-35

embryos created by, research using cells/tissues from, state law on, HSC-35-36

embryos created by, solely for embryonic stem cell research, ethical issues, HSC-55

Great Britain, first in vitro birth, CHB-39

human embryonic stem cells from, HSC-9, 10

procedure summary, HSC-17

research activities involving, protections for, 45 CFR 46, Subpart B, in entirety, HBM-91-94

See also Assisted reproductive technology (ART); Reproduction

IOM. *See* Institute of Medicine (IOM)

IRBs. *See* Institutional Review Boards (IRBs)

Islam

cloning, human, positions on, CHB-37, 38, 40, 43, 44-45, 51, 52, 104

embryo/fetus, moral status of, HSC-50, 67

human stem cell research, perspectives on, presentation summary, HSC-102

See also Religion

Italy

Milan, neural stem cell study, HSC-13

IVF. *See* In vitro fertilization (IVF)

J

Japan

cloning, human, position on, CHB-101

Jefferson, Thomas, HBM-3

Jesus, CHB-50

Jewish faith. *See* Judaism

Johns Hopkins University, HSC-31

School of Medicine, HSC-1, 7

Jonas, Hans, CHB-63-64

Jordan, Michael, CHB-33

Judaism

cloning, human, positions on, CHB-37, 38, 39-40, 43, 44, 46, 51, 52, 53, 54, 104

Conservative, perspectives on human stem cell research, HSC-101

creation, biblical account, and humanity, CHB-41-42
embryo/fetus, moral status of, HSC-50, 67
human stem cell research, perspectives on, presentation summary, HSC-100-102
Orthodox, perspectives on human stem cell research, HSC-101
Talmud, CHB-46
See also Religion

Jurassic Park, CHB-6

Justice

human biological materials research use and, for institutions/policies/practices, ethical issues, HBM-49-50
human biological materials use and commodification, ethical issues, HBM-50-51

K

Kant, Immanuel, CHB-69-70

Kass, Leon, CHB-65, 67

King, Patricia, HSC-51-52

Knowledge, scientific. *See* Science and technology

Kopelman, Loretta, DMC-41-42

Korean War

American soldiers killed, autopsies results, HBM-19

L

Labor Department. *See* Department of Labor

LAR. *See* Legally authorized representative (LAR)

Laws and legislation

cadaveric fetuses as sources of embryonic germ cells, and, HSC-29-33

cloning, children, legislative ban on, CHB-iv, 9, 93, 98-99, 105

cloning, human, considerations, CHB-8-9, 83-101

cloning used as source for embryonic stem cells, and, HSC-36-37

embryonic stem cells, research involving sources of, issues raised by, HSC-29-38

embryos created by in vitro fertilization, as sources of embryonic stem cells, and, HSC-33-36

See also Case law; Constitutional law; Federal legislation; Foreign laws; Malpractice law; State legislation

Lederberg, Joshua, CHB-2

Legally authorized representative (LAR), DMC-32, 54, 58, 60, 74, 75, 76

authority of, role in medical decision making for mentally disabled persons, DMC-36

decisionmaking role for mentally impaired research subjects, DMC-v-vi, 33-37, 61-63

ethical validity of for research decision making, protections to ensure, DMC-36

evaluation, ongoing, of, for research decision making role of, DMC-36-37

incapacity determinations/research enrollment, notification of mentally impaired subjects, recommendations, DMC-v, 59

mentally impaired research subjects and decisionmaking surrogacy for, independent professional support for, DMC-37

mentally impaired research subjects and, further considerations for, guidance for Institutional Review Boards, DMC-66-67

Levine, Robert, DMC-30

Liberties. *See* Constitutional law; Fundamental liberties; Individual freedom of action

Lifchez v. Hartigan, CHB-92

Livestock. *See* Animals

Living will

mentally disabled persons in research, advance planning role in enrollment, DMC-29

Loma Linda University

Institutional Review Board, DMC-21-22, 49
Longitudinal studies
 human biological materials and, value of, HBM-20-21
 See also Research
Louisiana
 cloning, human, legislation on, CHB-85
 fetus, human, experimentation with, legislation, HSC-33, 41, 43
Lutheran Church, CHB-47, 50
 See also Christianity; Protestantism; Religion

M

MacIntyre, Alistair, HSC-51
MacKay, C.R., HBM-71
Macklin, Ruth, CHB-67, 77
Magnetic resonance imaging (MRI), DMC-42, 48
 See also Functional magnetic resonance imaging (fMRI)
Major histocompatibility complex (MHC), HSC-20-21
 transplantation and, potential applications of human embryonic stem cell research, HSC-20-21
Maine
 cloning, human, legislation on, CHB-85
Malpractice law
 State legislation affecting assisted reproduction techniques, CHB-85, 86
 See also Laws and legislation
Maryland
 Attorney General, DMC-72
 cloning, human, legislation on, CHB-86
 mentally disabled persons in research, legislation on, DMC-31, 32-33, 42, 43, 46, 49, 71, 72
 See also Baltimore, Maryland
Massachusetts
 mentally disabled persons in research, legislation on, DMC-71
 See also Boston, Massachusetts; Worcester, Massachusetts
Maternity. *See* Pregnancy
McCormick, Richard, CHB-38, 49
McLaren, Anne, CHB-101
Medea, CHB-4
Medicaid
 cloning, human, and, CHB-93
Medical education. *See* Graduate Medical Education (GME); Health care professions
Medical information
 genetic v. other medical information, comparison of, and concerns overview, HBM-3-4
 human biological materials and, disclosure of, group-related harms from, ethical issues, HBM-7-8, 46-47
 human biological materials and, employment discrimination from, ethical issues, HBM-5, 44-45
 human biological materials and, familial/psychosocial harm from, ethical issues, HBM-46
 human biological materials and, health insurance discrimination from, ethical issues, HBM-5, 44-45
 human biological materials and, stigmatization from, ethical issues, HBM-5, 45-46
 human biological materials and, privacy/confidentiality of, harms from breaches of, ethical issues, HBM-43-46
 human biological materials research results, reporting to subjects, conclusions/recommendations on, HBM-vi-vii, 71-72
 See also Information; Medical records; Medicine
Medical insurance. *See* Health insurance
Medical professions. *See* Health care professions

Medical records

- human biological materials research use and privacy issues, overview, HBM-5-6
- human biological materials research use, conclusions/recommendations on, HBM-viii, 74-75
- Iceland central health records database, overview of, HBM-22
- privacy of, and research use, regulations governing, HBM-35-38
- privacy of, and research use, state laws on, HBM-36-38
- See also* Medical information; Medicine

Medical tests and procedures

- cloning by nuclear transfer, potential therapeutic applications, CHB-29-32
- See also* Autopsies; Medical transplantation; Medicine

Medical transplantation

- fetal tissue and, conditions for federal support of, HSC-30-31
- human embryonic stem cell research and, potential applications of, HSC-20-21
- organs for, potential applications of human embryonic stem cell research for, HSC-23
- organ/tissue, nuclear transfer cloning potential applications for, CHB-29-30
- See also* Medical tests and procedures; Medicine

Medicare

- cloning, human, and, CHB-93, 94

Medicine

- adult stem cells, types and potential clinical applications of, HSC-12-14
- animal stem cell models, description and potential clinical applications of, HSC-14-16
- benefits, direct, to mentally impaired research subjects, DMC-12, 44-45, 46, 75
- benefits, indirect, to mentally impaired research subjects, DMC-45, 46-47
- benefits, in research protocols with greater than minimal risk, not offered to mentally impaired subjects, recommendations, DMC-v, 61
- benefits, in research protocols with greater than minimal risk, offered directly to mentally impaired subjects, recommendations, DMC-v, 60
- benefits to mentally impaired research subjects, definition of, DMC-44-45
- benefits to other than mentally impaired research subjects, DMC-45, 46-47
- benefits v. greater than minimal risk to mentally impaired research subjects, DMC-v, 46-47, 60, 61
- benefits v. risks for mentally impaired research subjects, balancing concerns, DMC-45-50
- benefits v. risks for mentally impaired research subjects, independent research monitors and, DMC-49-50
- benefits v. risks for mentally impaired research subjects, Institutional Review Boards education/decisionmaking enhancement, DMC-48-49
- benefits v. risks for mentally impaired research subjects, Special Standing Panel and, DMC-47-48
- bovine embryonic stem cells, description and potential clinical applications of, HSC-15-16
- human biological materials, sample source identification for clinical purposes, HBM-18-19
- human embryonic stem cells and, potential applications of, HSC-20-23
- human stem cell research, considerations for, and ethical concerns, HSC-i-ii, 65-66
- human stem cell research, potential clinical applications of, HSC-7-23
- mammalian stem cells isolated, list, HSC-14
- mesenchymal stem cells, description and potential clinical applications of, HSC-13-14
- mouse embryonic stem cells, description and potential clinical applications of, HSC-14-15
- neural stem cells, description and potential clinical applications of, HSC-12-13
- organizations, medical, and human biological materials research use, policies of, HBM-32-33
- primate embryonic stem cells, description and potential clinical applications of, HSC-16
- See also* Health care professionals; Health insurance; Medical information; Medical records; Medical tests and procedures; Medical transplantation

Medline, DMC-13

Meilaender, Gilbert, CHB-50, 51, 63, 66; HSC-55

Menlo Park, California, HSC-7

See also California

Mental diseases and disorders

- nature of some disorders affecting decisionmaking capacity, DMC-7-8

research on, promise of, issues overview, DMC-4-5
See also Alzheimer's disease (AD); Bipolar disorder; Delirium; Dementias; Depression; Diseases and disorders; Mental health care; Mental retardation; Psychotic disorders; Research involving mentally impaired subjects; Schizophrenia; Substance abuse disorders

Mental health care
 problems for mentally impaired research subjects, issues in, DMC-10-11
See also Medicine; Mental diseases and disorders

Mental retardation
 nature of, DMC-8
See also Mental diseases and disorders

Mesenchymal stem cells
 clinical applications, potential, and description of, HSC-13-14
See also Adult stem (AS) cells; Cells; Human stem cells; Stem cells

Meyer v. Nebraska, CHB-75

MHC. *See* Major histocompatibility complex (MHC)

Miami, Florida, HBM-77, 78, 79
See also Florida

Michigan
 cloning, human, legislation on, CHB-85

Mililani, Hawaii, HBM-77, 78, 79

Military personnel. *See* Armed forces

Millennium Pharmaceuticals, HBM-15

Minnesota
 cloning, human, legislation on, CHB-85
 fetus, human, commercialization, legislation on, HSC-33, 43
 medical records use in research, laws on, HBM-36, 37

Missouri
 cloning, human, legislation on, CHB-86
 mentally disabled persons in research, legislation on, DMC-71

Molecular cloning
 definition, CHB-14, A-2
See also Cloning

Monitors
 independent, and risk v. benefit assessment for mentally impaired research subjects, DMC-49-50

Monticello, HBM-3

Moore, John, HBM-50

Moorhouse, Anne, DMC-31

Moral agent
 human biological materials use, subjects treatment as, ethical issues, HBM-47

Morality. *See* Ethics; Moral agent; Social values

Mount Pelion, CHB-4

MRI. *See* Magnetic resonance imaging (MRI)

Muller, H.J., CHB-71

Multiple assurance agreement, CHB-84

Multiple Project Assurance, HBM-28

Mutation
 definition, CHB-A-3
 somatic cells and, nuclear transfer cloning effects of, uncertainties, CHB-24

N

Nagel, Thomas, HSC-51
National Action Plan for Breast Cancer, HBM-64, 66

National Bioethics Advisory Commission (NBAC), CHB-3-4, 7, 8, 37, 38, 50, 59, 60, 61-62, 63, 66, 67, 72, 77, 79, 83, 91; DMC-i, ii, 18, 20, 21, 22, 23, 24, 25, 27, 28, 29, 30, 31, 33, 34, 35, 36, 37, 39, 40, 41, 43, 44, 45, 46, 47, 48, 49, 50, 71; HBM-ii, 2, 7, 10, 13, 27, 32, 35, 38, 39, 41, 42, 43, 44, 46, 48, 49, 50, 51, 56, 75, 77; HSC-2, 3, 4, 5, 35, 37, 49, 50, 51, 53, 54, 55, 59

cadaveric fetal tissue and embryos from infertility treatments, donation for research, requirements for, conclusions/recommendations, HSC-vi-vii, 72-73

cadaveric fetal tissue, as source of embryonic germ cells, federal funding for research on, conclusions/recommendations, HSC-iii-iv, 68-69

cloning, children, federal agencies/departments continued deliberation on, conclusions/recommendations, CHB-v, 106

cloning, children, federal funding moratorium for, conclusions/recommendations, CHB-iii, 105

cloning, children, legislative ban on, conclusions/recommendations, CHB-iv, 105

cloning, human, conclusions/recommendations, CHB-iii-v, 103-106

cloning, human, cooperation with foreign nations, conclusions/recommendations; CHB-iv, 106

cloning, human, morality of, conclusions/recommendations; CHB-iii-iv, 106

cloning, human, policy options developed, CHB-93-101

cloning, human, religious views, conclusions/recommendations, CHB-iv-v, 106

embryonic/fetal material, prohibition of sale of, conclusions/recommendations, HSC-vii, 74

embryonic germ/stem cell research, and federal funding, ethics of, conclusions/recommendations, HSC-iii-vi, 68-72

embryonic germ/stem cell research, and institutional review of derivation protocols, conclusions/recommendations, HSC-viii, 77-78

embryonic germ/stem cell research, national oversight/review of, need for, conclusions/recommendations, HSC-vii-viii, 74-77

embryonic germ/stem cell research, privately funded, issues for, conclusions/recommendations, HSC-ix-x, 78-80

embryonic germ/stem cell research, sponsoring federal agencies review of protocols, conclusions/recommendations, HSC-viii-ix, 78

embryos created by in vitro fertilization solely for research, as source of embryonic stem cells, federal funding for research on, conclusions/recommendations, HSC-v, 71-72

embryos from infertility treatments, as source of embryonic stem cells, federal funding for research on, conclusions/recommendations, HSC-iv-v, 60-71

embryos from somatic cell nuclear transfer cloning, as source of embryonic stem cells, federal funding for research on, conclusions/recommendations, HSC-v-vi, 72

human stem cell research, ethical and policy considerations, HSC-ii-iii, 66-67

human stem cell research, federal support/oversight of, conclusions/recommendations, HSC-i-xi, 65-81

human stem cell research, scientific/medical considerations and ethical concerns, HSC-i-ii, 65-66

National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/recommendations, HSC-x-xi, 80-81

human biological materials, categories definition by, HBM-i, 16-18, 58

human biological materials, identifiable samples rendered unidentifiable, and informed consent, conclusions on, HBM-70-71

human biological materials research results publication, conclusions/recommendations on, HBM-vii, 73-74

human biological materials research results, reporting to subjects, conclusions/recommendations on, HBM-vi-vii, 71-72

human biological materials research use, and Institutional Review Board expedited review, conclusions/recommendations, HBM-iii, 60

human biological materials research use, and Institutional Review Board review exemption, regulations on, conclusions/recommendations, HBM-iii, 57-60

human biological materials research use, and professional education/responsibilities, conclusions/recommendations on, HBM-vii-viii, 74

human biological materials research use, and waiver of consent, regulations on, conclusions/recommendations, HBM-v-vi, 66-70

human biological materials research use, appropriate, issues identified by, HBM-4-5

human biological materials research use, federal regulations on, interpretation of, conclusions/recommendations, HBM-iii, 57-60

human biological materials research use, informed consent requirements, HBM-iv, 62-66, 109

human biological materials research use of coded/identified samples, requirements for, conclusions/recommendations, HBM-iii-iv, 62

human biological materials research use of medical records, conclusions/recommendations on, HBM-viii, 74-75

human biological materials research use, potential harms to others, conclusions/recommendations on, HBM-vii, 72-73

human biological materials research use, process proposed by, HBM-106

human biological materials research use, risks to groups, conclusions/recommendations on, HBM-vii, 72, 73

human biological materials research use, risks v. potential benefits to relatives, conclusions/recommendations on, HBM-vii, 73

human biological materials research use, underlying premises/considerations of analysis by, HBM-9

human biological materials, unlinked samples made from coded/identified samples, special concerns on, conclusions/recommendations, HBM-iii, 60-62

human research subjects, extended protections for, conclusions/recommendations, CHB-iv, 105

mentally impaired research subjects, conclusions/recommendations, DMC-iii-vii, 51-67

mentally impaired research subjects, decisionmaking capacity of, conclusions/recommendations, DMC-iii-vii, 58-59

mentally impaired research subjects, durable power of attorney powers for decision making, conclusions/recommendations, DMC-vi, 62-63

mentally impaired research subjects, educational materials review/development, conclusions/recommendations, DMC-vi, 63-64

mentally impaired research subjects, family/friends involvement in decision making, conclusions/recommendations, DMC-vi, 63

mentally impaired research subjects, funding increases to support protections for, conclusions/recommendations, DMC-vii, 64-65

mentally impaired research subjects, incapacity determinations/research enrollment, notification of, conclusions/recommendations, DMC-v, 59

mentally impaired research subjects, informed consent and capacity assessment, knowledge of, conclusions/recommendations, DMC-vi-vii, 64

mentally impaired research subjects, informed consent to research, conclusions/recommendations, DMC-iv, 57-58

mentally impaired research subjects, Institute of Medicine review of studies, conclusions/recommendations, DMC-vii, 64

mentally impaired research subjects, Institutional Review Board membership, conclusions/recommendations, DMC-iii, 53-54

mentally impaired research subjects, legally authorized representatives for decision making, conclusions/recommendations, DMC-vi, 62-63

mentally impaired research subjects, objection to participation, conclusions/recommendations, DMC-iv, 58

mentally impaired research subjects, Prospective Authorization for decision making, conclusions/recommendations, DMC-v, 61

mentally impaired research subjects, protections review by, issues overview, DMC-1-5, 9, 11, 12, 13, 15

mentally impaired research subjects, protocols with greater than minimal risk, but direct medical benefit, conclusions/recommendations, DMC-v, 60

mentally impaired research subjects, protocols with greater than minimal risk, not offering direct medical benefit, conclusions/recommendations, DMC-v, 61

mentally impaired research subjects, protocols with minimal risk, conclusions/recommendations, DMC-v, 60

mentally impaired research subjects, regulatory recommendations for, DMC-iii-vii, 52-65

mentally impaired research subjects, research design, conclusions/recommendations, DMC-iv, 55-57

mentally impaired research subjects, risk categories for, conclusions/recommendations, DMC-v, 60-61

mentally impaired research subjects, risks v. benefits evaluation, conclusions/recommendations, DMC-iv, 56-57

mentally impaired research subjects, Special Standing Panel creation, conclusions/recommendations, DMC-iii-iv, 54-55

mentally impaired research subjects, surrogate decision making for, conclusions/recommendations, DMC-v-vi, 61-63

process of, CHB-9-10

Protocol Project, DMC-13

National Center for Human Genome Research. *See* U.S. National Center for Human Genome Research

National Commission. *See* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DMC-i, 6, 21, 28, 42, 44, 45, 47, 51, 70, 85, 86, 87, 88; HBM-41, 42; HSC-29, 30

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research, DMC-9, 24, 27, 40, 49; HBM-41-42, 49

Report on Research Involving Children, DMC-41, 43

Research Involving Those Institutionalized as Mentally Infirm, 1978, DMC-6, 69

National Committee on Vital and Health Statistics, HBM-35

National Conference of Catholic Bishops, HSC-52-53

National Council of Churches of Christ, CHB-39

National Health and Nutrition Examination Surveys (NHANES), HBM-23

National Health Examination Surveys Cycles 1, 3, and 3; HBM-23

National Heart, Lung and Blood Institute (NHLBI), HBM-33

human biological materials use in research, statement comparison, HBM-101

National Human Genome Research Institute

Director, HBM-4

National Institute for Disability and Rehabilitative Research (NIDRR), DMC-53

See also Department of Education

National Institute of Allergy and Infectious Diseases (NIAID), HBM-7-8

AIDS clinical trials, HBM-8

National Institute of Mental Health (NIMH)

Genetics Initiative, HBM-23

National Institute on Aging, DMC-66

National Institutes of Health (NIH), CHB-85; DMC-iii, vi-vii, 15, 33, 37, 41, 48, 53, 64; HBM-viii, 14, 27, 66, 74, 82, 84, 86; HSC-iv, v, viii, 3, 30, 31, 34, 35, 37, 38, 45, 59, 70, 71, 73, 75, 76, 77, 78

Ad Hoc Working Group, HSC-35

Advisory Committee to the Director (ACD), HSC-34, 35

Clinical Center, DMC-30, 35, 46

Director, HSC-30, 34, 70, 75, 94

human biological materials research use, and professional education promotion by, conclusions/recommendations, HBM-vii-viii, 74

mentally impaired research subjects, capacity assessment/informed consent, knowledge of, recommendations for, DMC-vi-vii, 64

Policies for Protection of Human Subjects, DMC-1

“Research Involving Individuals with Questionable Capacity to Consent”, DMC-24, 33

See also Human Embryo Research Panel; Human Fetal Tissue Transplantation Research Panel; Office for Protection from Research Risks (OPRR); Recombinant DNA Advisory Committee (RAC); Trans-NIH Bioethics Subcommittee; Women’s Health Initiative (WHI)

National Neurological Institute Carlo Besta, HSC-13

National Organ Transplant Act of 1984 (NOTA), HSC-33, 36, 74

National Pathology Repository, HBM-14

See also Armed Forces Institute of Pathology (AFIP)

National Science and Technology Council, DMC-3

National Society of Genetic Counselors, CHB-96

National Stem Cell Oversight and Review Panel, HSC-ix, 78, 79
embryonic germ/stem cell research, and creation/duties of, conclusions/ recommendations, HSC-vii-viii, 76-77
review/assessment for, ongoing, conclusions/ recommendations, HSC-x-xi, 80-81

Native Americans
human biological materials used in objectionable research, ethical perspectives, HBM-49
Navajos, HBM-20
Tribal Governments, HBM-8
See also Ethnic groups and ethnicity; Indian Health Service

Nature
human dominion, responsible, over, and human cloning, CHB-4-6, 42-47, 104
human partnership with God, and human cloning, CHB-44-45
humans as created co-creators, and human cloning, CHB-45
human stewardship over, and human cloning, CHB-44

Navajos. *See* Native Americans

Nazis, CHB-55
doctors trial, DMC-17
eugenic ideas practiced by, CHB-71
experimentation by, HSC-47, 48

NBAC. *See* National Bioethics Advisory Commission (NBAC)

Nervous system diseases and disorders
human embryonic stem cell research and, potential applications of, HSC-21-22
See also Diseases and disorders; Parkinson's disease

Neural stem cells
clinical applications, potential, and description of, HSC-12-13
See also Adult stem (AS) cells; Cells; Human stem cells; Stem cells

New Hampshire
cloning, human, legislation on, CHB-85
embryo, human, use of material from for research, legislation on, HSC-36, 43
family relationships, legislation on, CHB-87

New Jersey
cloning, human, legislation on, CHB-86

New Mexico
embryonic/fetal tissue use, legislation on, HSC-40

New York State
cloning, human, legislation on, CHB-86
medical records privacy and research use, case law on, HBM-38
mentally disabled persons in research, legislation on, DMC-71-72
Office of Mental Health, DMC-71

New York Times, HSC-1, 2, 7

NHANES. *See* National Health and Nutrition Examination Surveys (NHANES)

NHLBI. *See* National Heart, Lung and Blood Institute (NHLBI)

NIAID. *See* National Institute of Allergy and Infectious Diseases (NIAID)

NIDRR. *See* National Institute for Disability and Rehabilitative Research (NIDRR)

Niemann, H., HSC-15

NIH. *See* National Institutes of Health (NIH)

NIH Revitalization Act of 1993, HSC-31, 32, 33, 34, 73

NIMH. *See* National Institute of Mental Health (NIMH)

Nobel Prize for Medicine, 1954, HSC-29

North Carolina
cloning, human, legislation on, CHB-86

North Dakota
cloning, human, legislation on, CHB-85

family relationships, legislation on, CHB-87

NOTA. *See* National Organ Transplant Act of 1984 (NOTA)

Novartis, HBM-15

Nuclear power plant accidents

Chernobyl nuclear accident site, HBM-4

Nuclear transfer. *See* Nuclear transplantation cloning

Nuclear transplantation cloning

- animals and, CHB-15-16, 17
- animals and, reasons for, CHB-24-29
- animals research use, cloning for, CHB-24-25
- autonomy, personal, and, CHB-ii, 2, 3, 72-77, 103
- cases, exceptional, consideration/arguments for, CHB-76-77
- cell-based therapies, potential applications of, CHB-30-31
- cell differentiation basic research, use for, CHB-2, 28-29, 103
- cellular aging effects, uncertainties, CHB-23-24
- children, ethical considerations, CHB-ii-iii, 7-8, 59-79, 104
- children, eugenic concerns, CHB-ii, 6, 70-72, 103
- children, family integrity and, concerns, CHB-ii, 2, 3, 65-66, 103, 104
- children, federal funding moratorium for, CHB-iii, 9, 93-94, 105
- children, federal funding moratorium/private sector adherence, CHB-iii, 93, 94-96, 105
- children, individuality and, morality of, CHB-ii, 2, 3, 63-65, 103
- children, legislative ban on, CHB-iv, 9, 93, 98-99, 105
- children, objectification of, concerns, CHB-ii, 3, 69-70, 103
- children, physical harms, CHB-ii, 3, 61-62, 103
- children, public policies and moral reasoning, CHB-ii-iii, 77-78, 104
- children, social values and, potential harms, CHB-, ii, iii, 67-68, 103-104
- definition, CHB-15-16, A-3
- gene alterations, targeted, use for, CHB-26-28
- genetic determinism and, CHB-2, 32-33
- genetic imprinting phenomenon effects on, uncertainties, CHB-23
- human, constitutional limitations on policy formulation for, CHB-8-9, 88-90
- human, cooperation with foreign nations to enforce policies, CHB-iv, 9, 93, 99-101, 106
- human embryonic stem cells, derived from, HSC-3, 10-12
- human embryonic stem cells derived from, ethical issues, HSC-56-57
- human embryonic stem cells derived from, federal funding for research, conclusions/
recommendations, HSC-v-vi, 72
- human embryonic stem cells derived from, related law, HSC-36-37
- human, ethical considerations for, CHB-ii-iii, 7-8, 59-79, 104
- human, federal legislation affecting, CHB-84-85, 86
- human, fundamental liberties and procreation and, CHB-ii-iii, 91-93, 104
- human, laws affecting efforts, CHB-84-87
- human, morality and public policy formulation for, CHB-ii-iii, 90-93, 104
- human, policy options developed, CHB-93-101
- human, religious perspectives on, CHB-ii, iii, iv-v, 2, 7-8, 37-55, 103-104, 106
- human, State legislation affecting, CHB-85-87
- human stem cell research, sources for, HSC-10, 11, 20
- liberty, individual, and, CHB-ii-iii, 72-73, 104
- livestock breeding, advantages of use for, CHB-25
- livestock, transgenic, generation/propagation use of, CHB-25-26
- mammals and, experiments using, CHB-19-21
- organ/tissue transplantation, potential applications of, CHB-29-30
- reproduction, assisted, and, CHB-4-5, 31-32
- reproductive choice and, CHB-ii, 73-75, 104
- science and application of, CHB-13-33

scientific inquiry, freedom of, and, CHB-ii, 75-76, 103
scientific uncertainties remaining on, CHB-22-24
sheep cloning by somatic cell nuclear transfer, CHB-i, 1, 103
somatic cell mutations effects, uncertainties, CHB-24
species differences in, uncertainties, CHB-22-23
technique changes allowing for Dolly's birth, CHB-21-22
technique reproducibility, CHB-22
therapeutic applications, potential, of, CHB-29-32
See also Cloning; Human cloning

Nucleus

definition, CHB-A-3
reprogramming of, CHB-21

Nuffield Council on Bioethics, DMC-5

Nuremberg Code, 1946-49, CHB-61, 75; DMC-12, 18, 24, 29, 47, 51, 69

See also Germany

Nurses' Health Study, HBM-21

Nussbaum, Martha, CHB-63

O

Objectification

cloning of children and, concerns about, CHB-ii, 3, 69-70, 103

See also Commodification

Objection

mentally impaired persons in research protocols and, recommendations, DMC-iv, 58

mentally impaired persons in research protocols, enrollment role of, DMC-27-29

See also Consent

Observer, The, CHB-i, 1

OCESAA. *See* Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA)

O'Donovan, Oliver, CHB-50

Office for Protection from Research Risks (OPRR), CHB-97; DMC-3, 49, 54, 57, 67; HBM-27, 28, 39, 82, 84, 86
Guidebook, HBM-35; HSC-30, 35, 75

human biological materials, existing and publicly available samples, federal policy on, HBM-58-59

human biological materials, identifiability of samples, federal policy on, HBM-57

human biological materials research use, additional information requirements for, conclusions/
recommendations, HBM-vi, 70

human biological materials research use, and coded/identified samples, requirements for, conclusions/
recommendations, HBM-iii-iv, 62

human biological materials research use, and Institutional Review Board expedited review,
conclusions/recommendations, HBM-iii, 60

human biological materials research use, and Institutional Review Board review exemption, regulations
on, conclusions/ recommendations, HBM-iii, 57-60

human biological materials research use, and risk to groups, conclusions/recommendations on, HBM-vii,
72, 73

human biological materials research use, federal regulations on, interpretation of, conclusions/
recommendations, HBM-iii, 57-60

human biological materials research use, statement comparison, HBM-101

human subject for research, current definition of, HBM-107

mentally impaired research subjects, capacity assessment/informed consent, knowledge of,
recommendations for, DMC-vi-vii, 64

See also National Institutes of Health (NIH)

Office of Technology Assessment (OTA)

Research Funding as an Investment, HSC-60
Office of the White House Press Secretary
“Memorandum for the Heads of Executive Departments and Agencies”, HSC-37
Ohio. *See* Cleveland, Ohio
Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), HSC-34, 35
Oocyte
definition, HSC-86
embryonic stem cells derived through somatic cell nuclear transfer cloning, federal funding for research on, conclusions/recommendations, HSC-v-vi, 72
OPRR. *See* Office for Protection from Research Risks (OPRR)
Oregon
cloning, human, legislation on, CHB-86
Organs, human
transplantable, potential applications of human embryonic stem cell research for, HSC-23
Organ transplantation. *See* Medical transplantation; Organs, human
OTA. *See* Office of Technology Assessment (OTA)
Oversight. *See* Federal regulation; Regulation
Ownership
human biological materials research use and, public beliefs on, forum findings, HBM-78
Oxford English Reference Dictionary, HBM-46, 69

P

Papers commissioned
cloning human beings, ethical concerns, CHB-C-1
human biological materials used in research, HBM-115
human stem cell research, ethical issues, HSC-111
mentally disabled persons in research protocols, DMC-83
Parfit, Derek, CHB-62
Parkinson’s disease
potential treatment for, summary, HSC-22
See also Diseases and disorders; Nervous system diseases and disorders
Pathologists Consensus, HBM-32, 33
human biological materials use in research, statement comparison, HBM-101
Pavarotti, Luciano, CHB-33
Pelias, CHB-4
Pellegrino, Edmund D., HSC-49
Pennsylvania
cloning, human, legislation on, CHB-85
Department of Health, CHB-85
fetal tissue, human, use for research, legislation on, HSC-32, 40
See also University of Pennsylvania
Personal autonomy. *See* Autonomy
Personal finances. *See* Finances, personal
Personhood. *See* Individuality
PET. *See* Positron emission tomography (PET)
Peters, Ted, CHB-43
Pfizer, HBM-15
PHS Act. *See* Public Health Service Act (PHS Act)
Physical safety
cloning of children, potential physical harms, CHB-ii, 3, 61-62, 103
Physicians. *See* Health care professionals

Physicians' Health Study, HBM-21
Pittenger, M.F., HSC-13
P.L. 104-91. *See* Public Law 104-91
P.L. 104-208. *See* Public Law 104-208
Planned Parenthood of Southeastern Pennsylvania v. Casey, CHB-90, 92
Planning
 advance, and mentally impaired research subjects, enrollment role of, DMC-29-33
Pluripotency
 definition, HSC-1, 5, 86
Pope, the. *See* Vatican
Positron emission tomography (PET), DMC-4, 42, 48, 86
Power of attorney. *See* Durable power of attorney (DPA)
Practicability
 human biological materials research use and, regulations on, conclusions/recommendations, HBM-vi, 69-70
Pregnancy
 research activities on, protections for, 45 CFR 46, Subpart B, in entirety, HBM-91-94
 See also Embryo; Fetus and fetal tissue; Reproduction
President. *See* Executive Office of the President; Executive orders; Presidential directives; White House
Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, CHB-39; DMC-70
Presidential commissions. *See* Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research
Presidential directives, HSC-37
Press Secretary. *See* Office of the White House Press Secretary
PRIM&R/ARENA Tissue Banking Working Group
 human biological materials use in research, statement comparison, HBM-101
Prisoners
 biomedical/behavioral research subjects, protections for, 45 CFR 46, Subpart C, in entirety, HBM-94-96
Privacy rights
 human biological materials information and employment discrimination, ethical issues, HBM-44-45
 human biological materials information and familial/psychosocial harm, ethical issues, HBM-46
 human biological materials information and group-related harms, ethical issues, HBM-46-47
 human biological materials information and, harms from breaches of, ethical issues, HBM-43-46
 human biological materials information and health insurance discrimination, ethical issues, HBM-44-45
 human biological materials information and stigmatization, ethical issues, HBM-45-46
 human biological materials research results, publication of and, conclusions/recommendations on, HBM-vii, 73-74
 human biological materials research use and, public beliefs on, forum findings, HBM-78
 medical records and research use of human biological materials, concerns overview, HBM-5-6
 medical records and, research use of, regulations governing, HBM-35-38
 medical records and, research use of, State laws protecting, HBM-36-38
 See also Confidentiality
Private sector
 cloning, children, federal funding moratorium/private sector adherence, CHB-iv, 9, 93, 94-96, 105
 embryonic germ/stem cell research, privately funded and eligible for federal funding, issues for, conclusions/ recommendations, HSC-ix-x, 78-79
 embryonic germ/stem cell research, privately funded, benefits of support for, HSC-59
 embryonic stem cell research, privately funded and not eligible for federal funding, issues for, conclusions/ recommendations, HSC-x, 79-80
 genetics databases creation, collaboration with universities, HBM-15
Procreation
 cloning, human, and fundamental liberties and, CHB-ii, 91-93, 103
 cloning, human, and, religious views on, CHB-49-50, 104

See also Reproduction

Professional societies
embryonic stem cell research, privately funded and not eligible for federal funding, issues for, conclusions/ recommendations, HSC-x, 79-80

Professional statements. *See* Statements

Prometheus, CHB-43, 47

Prospective Authorization, DMC-76; HBM-49
human biological materials research use, ethical perspectives on, HBM-49
mentally impaired research subjects, risk categories for, recommendations, DMC-v, 60-61
mentally impaired research subjects, surrogate decision making for, recommendations, DMC-v-vi, 61-63

Prostate cancer
human biological materials use in research protocol, regulatory issues for Institutional Review Board, HBM-31-32
See also Cancer; Diseases and disorders

Protections for human subjects
children as research subjects and, 45 CFR 46, Subpart D, in entirety, HBM-96-98
consent process for research participation, additional protections possible, guidance for Institutional Review Boards, DMC-65-67
federal regulations on, 45 CFR 46, Subpart A, in entirety, HBM-81-91
human biological materials research use and rights/welfare of, conclusions/recommendations, HBM-v-vi, 68
human biological materials research use and waiver of, “opt out” protection, HBM-63, 70
human biological materials research use, safeguards for, public beliefs on, forum findings, HBM-79
mentally impaired research subjects and, ethical standards, issues overview, DMC-i-iii, 1-7
mentally impaired research subjects and, conclusions on, DMC-ii
mentally impaired research subjects and, recommendations, DMC-iii-vii, 53-65
mentally impaired research subjects, funding increases for, recommendations, DMC-vii, 64-65
pregnant women, fetuses, and in vitro fertilization in research and, 45 CFR 46, Subpart B, in entirety, HBM-91-94
prisoners in biomedical/behavioral research and, 45 CFR 46, Subpart C, in entirety, HBM-94-96
See also Humans; Research

Protestantism
cloning, human, positions on, CHB-37, 38-41, 43, 45, 46-47, 49, 51, 52, 53, 55, 104
embryo/fetus, moral status of, HSC-50, 67
human stem cell research, perspectives on, presentation summary, HSC-102-103
See also Anglican Church; Calvinism; Christianity; Lutheran Church; Religion; Southern Baptist Church; United Church of Christ

Psychosocial harms
human biological materials information disclosure and, conflicts from, ethical issues, HBM-46

Psychotic disorders
nature of, DMC-8
See also Mental diseases and disorders

Public beliefs
human biological materials research use and ethnic stigmatization, forum findings, HBM-78-79
human biological materials research use and, forum findings, HBM-77-79
human biological materials research use and ownership/consent, forum findings, HBM-78
human biological materials research use and privacy/confidentiality, forum findings, HBM-78
human biological materials research use and safeguards, forum findings, HBM-79
human biological materials research use and sponsorship, forum findings, HBM-79
human biological materials research use and third-party concerns, forum findings, HBM-79
human biological materials storage and, forum findings, HBM-77

Public comments
human biological materials used in research, HBM-111-112
mentally disabled persons in research protocols, DMC-77-80

See also Testimony and speakers

Public Health Service Act (PHS Act), HSC-35, 93, 94, 95-96

Public Law 104-91; CHB-85

Public Law 104-208; CHB-85

Public policy

- cloning, children and, moral reasoning, CHB-77-78
- cloning, children, federal funding moratorium for, CHB-iii, 9, 93-94, 105
- cloning, children, federal funding moratorium/private sector adherence, CHB-iii, 9, 93, 94-96, 105
- cloning, children, legislative ban on, CHB-i, iv, 3, 9, 93, 98-99, 105
- cloning, human, assessments of various cases of, and related proposals, CHB-52-55
- cloning, human, considerations, CHB-ii-iii, 8-9, 83-101, 104
- cloning, human, constitutional limitations on formulation of, CHB-ii-iii, 8-9, 88-90, 104
- cloning, human, cooperation with foreign nations to enforce policies, CHB-iv, 9, 93, 99-101, 106
- cloning, human, morality and formulation of, CHB-ii-iii, 90-93, 104
- cloning, human, options developed, CHB-93-101
- research protocols, human subjects extended protections for, CHB-iv, 9, 93, 97, 105

See also Federal government; Federal regulation

Public testimony. *See* Testimony and speakers

Publishing and publications

- human biological materials information and, privacy/confidentiality of, ethical issues, HBM-43-46
- human biological materials research results and, conclusions/recommendations on, HBM-vii, 73-74
- research findings dissemination, ethical guidelines for, HBM-34-35

R

Rabb, Harriet, HSC-35

RAC. *See* Recombinant DNA Advisory Committee (RAC)

Radin, Margaret, CHB-69

Rahner, Karl, CHB-38

Ramsey, Paul, CHB-38, 39, 40, 43, 45-46, 49, 51

RAND

- Critical Technologies Institute, CHB-95

Ratizinger, Joseph Cardinal, CHB-48

Reagan, Ronald, HSC-31

Recommendations. *See* Conclusions and recommendations

Recombinant DNA Advisory Committee (RAC), CHB-94, 95; HSC-ix, 79

See also National Institutes of Health (NIH)

Records. *See* Medical records

Registry, public

- embryonic germ/stem cell research, oversight/review panel creation/duties, conclusions/recommendations, HSC-vii, 76

Regulation

- embryonic germ/stem cell research and, considerations for evaluating, HSC-107
- embryonic germ/stem cell research, and institutional review of derivation protocols, conclusions/recommendations, HSC-viii, 77-78
- embryonic germ/stem cell research, and national panel creation/duties for, conclusions/recommendations, HSC-vii-viii, 76-77
- embryonic germ/stem cell research, and need for, conclusions/recommendations, HSC-vii-viii, 74-77
- embryonic germ/stem cell research, sponsoring federal agencies review of protocols, conclusions/recommendations, HSC-viii-ix, 78
- stem cell research and, conclusions/recommendations, HSC- i-xi, 65-81
- mentally impaired persons in research protocols, history of, CHB-69-72
- mentally impaired persons in research protocols, recommendations for, DMC-iii-vii, 52-65

National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/
recommendations, HSC-x-xi, 80-81

See also Federal government; Federal regulation

Reilly, P., HBM-72

Relationships

personal, projection of, decisionmaking role for mentally disabled persons in research, DMC-29-30

See also Families; Friends

Relatives. *See* Families

Religion

cadaveric fetal tissue use for embryonic germ cells, disagreement among religious traditions, HSC-103-104

cloning, human, and biblical story of creation, CHB-41-42

cloning, human, and, conclusions/recommendations on, iv-v, 106

cloning, human, and family, concerns, CHB-2, 3, 51-52, 104

cloning, human, and human destiny, CHB-45-47, 104

cloning, human, and human dignity, CHB-47-49, 104

cloning, human, and human dominion over nature, CHB-4-6, 42-47, 104

cloning, human, and procreation/reproduction, CHB-49-50, 104

cloning, human, and scientific knowledge, CHB-43-44

cloning, human, and warnings not to play God, CHB-42-43

cloning, human, assessments of various scenarios and related public policy proposals, CHB-52-55

cloning, human, historical overview of considerations, CHB-38-41

cloning, human, perspectives on, CHB-ii, iii, 2, 7-8, 37-55, 103-104

cloning, human, themes in Western faith traditions concerning, CHB-41-52, 103-104

embryo moral status, disagreement among religious traditions, HSC-103

human stem cell research and federal funding, disagreement among religious traditions, HSC-104

human stem cell research, broad areas of agreement/disagreement among, presentations summary, HSC-103-104

human stem cell research, perspectives on, summary of presentations, HSC-99-104

See also Anglican Church; Bible; Calvinism; Christianity; Creation story; Eastern Orthodox Church; Islam; Judaism; Lutheran Church; Protestantism; Roman Catholic Church; Southern Baptist Church; United Church of Christ

Repositories

human biological materials, collections of, definition, HBM-i, 16, 18, 58

human biological materials, identified specimens, definition, HBM-i, 16, 18, 58

human biological materials research use of coded/identified samples, requirements for, conclusions/
recommendations, HBM-iii-iv, 62

human biological materials, unidentified specimens, definition, HBM-i, 16, 18, 58

Reproducibility

nuclear transfer cloning and, CHB-22

Reproduction CHB-16

cloning, human, and control over, arguments for, CHB-ii, 4-5, 73-75, 103

cloning, human, and, religious views on, CHB-49-50

human embryonic stem cell research and, potential applications of, HSC-21

preimplantation embryo development in mammals, and cloning, CHB-15

See also Assisted reproductive technology (ART); Infertility treatments; In vitro fertilization (IVF);
Procreation; Sterility

Research

animal cloning research, reasons for, CHB-24-29

animal use for, cloning animals for, CHB-24-25

biomedical/behavioral, prisoners in, protections for, 45 CFR 46, Subpart C, in entirety, HBM-94-96

brain, human tissue as singular resource, HBM-20

cancer, value of human biological materials to, HBM-19-20

cell differentiation, cloning for, CHB-28-29

children as subjects, protections for, 45 CFR 46, Subpart D, in entirety, HBM-96-98
embryo, human, using, ethical concerns, CHB-i-ii, 3, 5, 60
federal regulation of, definition of, HBM-56
gene alterations, targeted, cloning for, CHB-26-28
gene location, value of stored human biological materials for, HBM-21, 23
human beings, including fetuses, as subjects, general regulation of, HSC-30
human subject, current definition of Office for Protection from Research Risks, HBM-107
human subjects protection, 45 CFR 46, Subpart A, in entirety, HBM-81-91
human subjects in research protocols, extended protections for, CHB-iv, 9, 93, 97, 105
livestock breeding, cloning advantages for, CHB-25
livestock, transgenic, generation/propagation, cloning for, CHB-25-26
longitudinal studies, value of human biological materials to, HBM-20-21
medical records privacy and use for, regulations governing, HBM-35-38
medical records privacy and use for, state laws on, HBM-36-38
mental disorders and, promise of, issues for, DMC-4-5
pregnant women, fetuses, and in vitro fertilization in, protections for, 45 CFR 46, Subpart B, in entirety, HBM-91-94
publication of findings, ethical guidelines for, HBM-34-35
unique human tissue collections, requirements for, HBM-23
viruses, tracking of using human biological materials archives, HBM-20
See also Behavioral research; Biomedical research; Federal funding for research; Longitudinal studies; Nuclear transplantation cloning; Protections for human subjects; Research agencies; Research funding; Research involving human biological materials; Research involving human stem cells; Research involving mentally impaired subjects; Science and technology

Research agencies

embryonic germ/stem cell research, review of protocols by, conclusions/ recommendations, HSC-viii-ix, 78
See also Federal departments and agencies; Research

Research funding

embryonic germ/stem cell research, privately funded and eligible for federal funding, issues for, conclusions/ recommendations, HSC-ix-x, 78-79
embryonic stem cell research, privately funded and not eligible for federal funding, issues for, conclusions/ recommendations, HSC-x, 79-80
human biological materials research use and, public beliefs on sponsorship, forum findings, HBM-79
See also Federal funding for research; Research

Research involving human biological materials

appropriate use of, increasing discussion on, overview, HBM-4-9
beliefs, public, on, forum findings, HBM-77-79
benefits v. harms/wrongs of, ethical issues, HBM-42-43
comments, public, on, HBM-111-112
commodification of body/parts and, ethical issues, HBM-50-51
consent, waiver of, for, regulations on, conclusions/recommendations, HBM-v-vi, 66-70
discrimination potential of information from, overview, HBM-5
employment discrimination from information disclosure, ethical issues, HBM-44-45
education/responsibilities, professional, for, conclusions/recommendations on, HBM-vii-viii, 74
ethical perspectives on, HBM-10, 41-52
ethical use of, differing opinions on, overview of, HBM-8-9
ethnic groups stigmatization and, public beliefs on, forum findings, HBM-78-79
familial/psychosocial harm from information disclosure, ethical issues, HBM-46
federal regulations governing, current, HBM-10, 28-32
federal regulations governing, discussion of, HBM-i-iii, 55-56
federal regulations governing, interpretation of, conclusions/recommendations, HBM-iii, 57-60
group-related harms from information disclosure, ethical issues, HBM-46-47
group-related risks of, conclusions/recommendations on, HBM-vii, 72, 73

harms to others, potential, of, conclusions/recommendations on, HBM-vii, 72-73
health insurance discrimination from information disclosure, ethical issues, HBM-44-45
human subjects, current definition of Office for Protection from Research Risks, HBM-107
human subjects, current federal regulations governing, HBM-28-29, 57-58
information from and group-related concerns, overview, HBM-7-8
informed consent and, ethical perspectives on, HBM-47-49
informed consent and, nature of, issues overview, HBM-6-7
informed consent requirements for, conclusions/recommendations, HBM-iv, 62-66
informed consent requirements for, regulations on, HBM-30-31
informed consent requirements proposed by National Bioethics Advisory Commission for, HBM-109
Institutional Review Board concern for third-party interests, regulations on, HBM-31
Institutional Review Board expedited review for, regulations on, HBM-iii, 30, 60
Institutional Review Board review exemption, regulations on, HBM-iii, 29-30, 57-60
Institutional Review Board review for, regulations on, HBM-30-32, 105-109
international perspectives on, HBM-33-34
issues on, overview, HBM-1
just institutions/policies/practices for, ethical issues, HBM-49-50
medical records privacy and, concerns on, overview, HBM-5-6
medical records use in, conclusions/recommendations on, HBM-viii, 74-75
medical/scientific organization policies for, HBM-32-33
National Bioethics Advisory Commission underlying premises/considerations, HBM-9
objectionable, ethical perspectives, HBM-49
ownership and consent for, public beliefs on, forum findings, HBM-78
papers commissioned on, HBM-115
past, summary, HBM-19
postmortem use of samples, ethical perspectives, HBM-49
postmortem use of samples, regulations on, HBM-29
privacy/confidentiality for information on, harms from breaches of, ethical issues, HBM-43-46
privacy/confidentiality for, public beliefs on, forum findings, HBM-78
process proposed by National Bioethics Advisory Commission for, HBM-106
prostate cancer research protocol, regulatory issues for Institutional Review Boards, HBM-31-32
publication/dissemination of results, ethical issues, conclusions/recommendations on, HBM-vii,
73-74
relatives and risks v. potential benefits of, conclusions/recommendations on, HBM-vii, 73
research value of materials, overview, HBM-1-3
results from, reporting to subjects, conclusions/recommendations on, HBM-vi-vii, 71-72
safeguards for, public beliefs on, forum findings, HBM-79
samples, coded, definition, HBM-i, 17-18, 58
samples, coded/identified, requirements for use of, conclusions/recommendations, HBM-iii-iv, 62
samples, definition, HBM-i, 16-18, 58
samples, identifiable, rendered unidentifiable, and informed consent, conclusions on, HBM-70-71
samples, identified, definition, HBM-i, 17, 18, 58
sample source identification, necessity for, HBM-18-19
samples, unidentified, definition, HBM-i, 16-17, 18, 58
samples, unlinked, creation from coded/identified samples, special concerns on, conclusions/
recommendations, HBM-iii, 60-62
samples, unlinked, definition, HBM-i, 16-17, 18, 58
self-identity relationship with body/body parts and, issues overview, HBM-6
sponsorship of, public beliefs on, forum findings, HBM-79
statements, professional, on, comparison of, HBM-99-103
stigmatization from information disclosure, ethical issues, HBM-5, 45-46
subjects, respect for, ethical issues, HBM-47-49
subjects treatment as moral agents, ethical issues, HBM-47
testimony, public/expert, on, HBM-113

third-party concerns for, public beliefs on, forum findings, HBM-79
value of, current research, HBM-19-21, 23

See also Human biological materials; Research

Research involving human stem cells

adult, types and potential clinical applications of, HSC-12-14
alternative sources of stem cells, federal funding for, related arguments, HSC-57-58
benefits, potential, from, just distribution of, and federal funding, HSC-60-61
blood disorders, potential applications of embryonic stem cells and, HSC-22-23
bone/cartilage diseases, potential applications for embryonic stem cells and, HSC-22
cadaveric association with embryonic germ cell research, arguments against federal funding for, HSC-57
cadaveric fetal tissue, as source of embryonic germ cells, causal responsibility for abortion, HSC-46-47
cadaveric fetal tissue, as source of embryonic germ cells, consent and donation issues, HSC-48-49
cadaveric fetal tissue, as source of embryonic germ cells, ethical issues on, HSC-45-49
cadaveric fetal tissue, as source of embryonic germ cells, federal funding for, conclusions/
recommendations, HSC-iii-iv, 68-69
cadaveric fetal tissue, as source of embryonic germ cells, symbolic association with abortion, HSC-47-
48
cadaveric fetal tissue and embryos from infertility treatments, donation requirements for,
conclusions/recommendations, HSC-vi-vii, 72-73
cadaveric fetal tissue for, donors general/consent considerations, research evaluation, HSC-106
cadaveric fetuses as sources of embryonic germ cells, related law, HSC-29-33
cadaveric fetuses as sources of stem cells, state law on, HSC-32-33
cadaveric fetuses, use of cells/tissues from, federal law on, HSC-29-31
cancer therapy, potential applications for embryonic stem cells and, HSC-21
clinical applications, potential, of, HSC-7-23
cloning by somatic cell nuclear transfer, as source of embryonic stem cells, ethical issues, HSC-56-57
cloning by somatic cell nuclear transfer, as source of embryonic stem cells, federal funding for,
conclusions/ recommendations, HSC-v-vi, 72
cloning by somatic cell nuclear transfer, as source of embryonic stem cells, related law, HSC-36-37
definitions, HSC-4-5
drug testing for efficacy/toxicity, potential applications of embryonic stem cells and, HSC-23
Eastern Orthodox perspectives on, presentation summary, HSC-102
embryo destruction association with embryonic stem cells, arguments against federal funding for, HSC-57
embryonic/fetal material for, prohibition of sale of, conclusions/recommendations, HSC-vii, 74
embryonic germ cells and, donated fetal material use for, state laws on, HSC-32-33
embryonic germ cells, description of, HSC-8-9
embryonic germ cells from fetal primordial germ cells, description, HSC-17, 19
embryonic germ/stem cells and, compensation/reimbursement of donors for, issues for, HSC-106
embryonic germ/stem cells and, design considerations for studies involving, HSC-105
embryonic germ/stem cells and, federal funding, ethics of, conclusions/recommendations, HSC-
iii-vi, 68-72
embryonic germ/stem cells and, federal funding for, moral objections to, HSC-57
embryonic germ/stem cells, and federal oversight/review policies adoption, ethical issues, HSC-61
embryonic germ/stem cells and, identification/recruitment of donors for, issues for, HSC-106
embryonic germ/stem cells and, institutional review of derivation protocols, conclusions/
recommendations, HSC-viii, 77-78
embryonic germ/stem cells and, national oversight/review of, need for, conclusions/ recommendations,
HSC-vii-viii, 74-77
embryonic germ/stem cells and, national oversight/review panel creation/duties, conclusions/
recommendations, HSC-vii-viii, 76-77
embryonic germ/stem cells and, privately funded, issues for, conclusions/ recommendations, HSC-ix-x,
78-80
embryonic germ/stem cells and, public/private support encouragement, benefits of, HSC-59
embryonic germ/stem cells and, review/oversight of, considerations for evaluating, HSC-107

embryonic germ/stem cells and, sponsoring federal agencies review of protocols, conclusions/
recommendations, HSC-viii-ix, 78

embryonic germ/stem cells derivation/use, federal funding for, related arguments, HSC-57-61

embryonic germ/stem cells derivation/use, synergy from combined federal effort, HSC-59

embryonic germ/stem cells, sources of, ethical issues on, HSC-45-57

embryonic stem cells, and sources of, legal issues raised by, HSC-29-38

embryonic stem cells derivation, scientific progress and federal support of, issues, HSC-58-59

embryonic stem cells, description of, HSC-9-12

embryonic stem cells, research involving sources of, legal issues raised by, HSC-29-38

embryos created by in vitro fertilization, as sources of embryonic stem cells, related law, HSC-33-36

embryos created by in vitro fertilization and used for research, importance of intentions and “discarded-
created” distinction, HSC-55-56

embryos created by in vitro fertilization solely for, ethical issues, HSC-55

embryos created by in vitro fertilization solely for, federal funding for, conclusions/ recommendations,
HSC-v, 71-72

embryos created by in vitro fertilization, use of cells/tissues from, related laws, HSC-34-36

embryos created solely for, ethical issues, HSC-55-56

embryos from infertility treatments, as source of embryonic stem cells; federal funding for, conclusions/
recommendations, HSC-iv-v, 60-71

embryos from infertility treatments, derivation/use of embryonic stem cells from, ethical distinctions and
relationships, HSC-54-55

embryos from infertility treatments for, donor considerations, research evaluation, HSC-106-107

embryos from infertility treatments, moral status of, ethical issues, HSC-49-51

embryos from infertility treatments, use for embryonic stem cells, ethical issues, HSC-49-55

embryos from infertility treatments, use for embryonic stem cells, importance of shared views, HSC-51-53

ethical issues for, HSC-ii-iii, 2-3, 45-62, 66-67

ethical issues for, glossary, HSC-85-86

ethical issues for, papers commissioned, HSC-111

ethical issues for, testimony, public/expert, on, HSC-109

federal funding for, disagreement among religious traditions, HSC-104

federal funding for, and sustaining science/technology leadership, HSC-60

federal funding of certain types of, arguments against, HSC-57-58

federal funding of certain types of, arguments for, HSC-58-60

federal funding recipients and federal regulations for, HSC-60

federal support for and oversight of, conclusions/recommendations, HSC- i-xi, 65-81

fetal tissue transplantation, conditions for federal support of, HSC-30-31

Food and Drug Administration statutory/regulatory authority over human stem cells, overview, HSC-93-
97

Food and Drug Administration regulations on human cellular materials/tissues, application to human
stem cells, HSC-94

human beings, including fetuses, as subjects, general regulation of, HSC-30

Islamic perspectives on, presentation summary, HSC-102

Jewish perspectives on, presentation summary, HSC-100-102

medical applications, potential, of embryonic stem cells and, HSC-20-23

mesenchymal, description and potential clinical applications of, HSC-13-14

National Stem Cell Oversight and Review Panel, ongoing review/assessment for, conclusions/
recommendations, HSC-x-xi, 80-81

nervous system diseases, potential applications of embryonic stem cells and, HSC-21-22

neural, description and potential clinical applications of, HSC-12-13

organs, transplantable, potential applications of embryonic stem cells and, HSC-23

Protestant perspectives on, presentation summary, HSC-102-103

religious perspectives on, broad areas of agreement/disagreement, presentations summary, HSC-103-104

religious perspectives on, summary of presentations, HSC-99-104

report framework, HSC-3-4

reproduction, human, and developmental biology, potential applications of embryonic stem cells and, HSC-21

Roman Catholic perspectives on, presentation summary, HSC-99-100

scientific/medical considerations and ethical concerns for, HSC-i-ii, 65-66

transplantation, potential applications of embryonic stem cells and, HSC-20-21

See also Human stem cells; Research

Research involving mentally impaired subjects

- access model for, DMC-17, 18
- advance planning role in enrollment, DMC-29-33
- assent/objection role in enrollment, DMC-27-29
- audit and disclosure by institutions, guidance for, DMC-67
- benefits, medical, direct, to subjects, DMC-44-45, 46
- benefits, medical, indirect, to subjects, DMC-45, 46-47
- benefits, medical, to other than subjects, DMC-45, 46-47
- benefits to subjects, definition of, DMC-44-45
- benefits v. risks for, balancing concerns, DMC-45-50
- benefits v. risks for, evaluation of, recommendations, DMC-iv, 56-57
- benefits v. risks for, Institutional Review Boards education/decisionmaking enhancement, DMC-48-49
- benefits v. risks for, Special Standing Panel and, DMC-47-48
- capacity assessment and informed consent, knowledge of, recommendations, DMC-vi-vii, 64
- consent process for, additional protections possible, guidance for Institutional Review Boards, DMC-65-66
- context of, guidance for Institutional Review Boards, DMC-65
- decisionmaking capacity assessment for, recommendations, DMC-iii-vii, 58-59
- decisionmaking for, substantive requirements for, DMC-23-25
- design considerations in, guidance for Institutional Review Boards, DMC-65
- design for, recommendations, DMC-iv, 55-57
- design of study, ethics of, issues overview, DMC-12-14
- drug development, limitations on, issues for, DMC-10
- durable power of attorney powers for decision making, recommendations, DMC-vi, 62-63
- educational materials review/development, recommendations, DMC-vi, 63-64
- family/friends involvement in decision making, recommendations, DMC-vi, 63
- financial resources adequacy of, issues for, DMC-11
- funding increases to support protections, recommendations, DMC-vii, 64-65
- health care problems for, issues for, DMC-10-11
- incapacity determinations/research enrollment, notification of, recommendations, DMC-v, 59
- independent health care professional advisors for, guidance for Institutional Review Boards, DMC-67
- independent monitors, and risk v. benefit assessment for, DMC-49-50
- independent professional support, for subjects and surrogates in decision making, DMC-37
- informal caregiver for, issues overview, DMC-11
- informed consent for, and decisional impairment, issues overview, DMC-9-10
- informed consent for, and limitations on decisionmaking capacity, DMC-17-25
- informed consent for, centrality of, DMC-17-18
- informed consent, recommendations, DMC-iv, 57-58
- Institute of Medicine review of studies, recommendations, DMC-vii, 64
- Institutional Review Boards, guidance for, DMC-73-76
- Institutional Review Boards membership, recommendations, DMC-iii, 53-54
- institutions and researchers, responsibilities of, issues overview, DMC-14-15
- legally authorized representatives for decision making, DMC-vi, 33-37, 62-63, 66-67
- medical benefit, direct, possibility of, issues overview, DMC-12
- National Bioethics Advisory Commission conclusions/recommendations, DMC-iii-vii, 51-67
- National Bioethics Advisory Commission review of selected protocols and consent forms, DMC-13
- objection to participation, recommendations, DMC-iv, 58
- papers commissioned on, DMC-83
- Prospective Authorization for decision making, recommendations, DMC-v, 61

- protection model for, DMC-18
- protections for, additional guidance for Institutional Review Boards, DMC-65-67
- protections for, conclusions on, DMC-ii
- protections for, ethical standards, issues overview, DMC-i-iii, 1-7
- public comments on, DMC-77-80
- regulatory history of, DMC-69-72
- regulatory recommendations for, DMC-iii-vii, 52-65
- risk assessment for, Institutional Review Boards and, DMC-43-44
- risk categories for, recommendations, DMC-v, 60-61
- risk definition/assessment for, problems in, DMC-39-44
- risk, minimal/greater than minimal for, Institutional Review Boards and, DMC-v, 40-43, 60, 61, 74, 75, 76
- self-evaluation, voluntary, for, guidance for Institutional Review Boards, DMC-67
- Special Standing Panel creation, recommendations, DMC-iii-iv, 54-55
- statements of commissioners on, DMC-85-88
- substantive experience of disorders for, issues for, DMC-10
- surrogate decision making for, DMC-v-vi, 29-37, 61-63
- testimony on, DMC-81-82
- values to guide, issues overview, DMC-8-9
- See also* Mental diseases and disorders; Research
- “Research on Embryos in Vitro: The Various Types of Research”, CHB-101
- “Research on Human Conceptuses”, CHB-101
- Resources, allocation of
 - cloning, human, and, ethical considerations, CHB-68
- Respect for persons
 - human biological materials use and commodification of body, ethical issues, HBM-50-51
 - human biological materials use and, ethical issues, HBM-47-49
- Review bodies. *See* Institutional Review Boards (IRBs); Special Standing Panel (SSP)
- Rhode Island
 - cloning, human, legislation on, CHB-85
 - embryo/fetus/human commercialization, legislation on, HSC-33
- Richmond, Virginia, HBM-77, 79
 - See also* Virginia
- Right to privacy. *See* Privacy rights
- Risk
 - a priori* assessments of benefits v., for research, recommendations, DMC-57
 - assessment of, for mentally impaired research subjects, Institutional Review Boards and, DMC-43-44
 - benefits v., for mentally impaired research subjects, evaluation recommendations, DMC-iv, 56-57
 - categories for research protocols with mentally impaired subjects, recommendations, DMC-v, 60-61
 - definition/assessment of, for mentally impaired research subjects, problems in, DMC-39-44
 - greater than minimal, for research not offering direct medical benefit to mentally impaired subjects, DMC-v, 46-47, 61, 76
 - greater than minimal, for research protocols offering direct medical benefit for mentally impaired subjects, DMC-v, 46, 60, 75
 - human biological materials research use and, for groups, conclusions/recommendations on, HBM-vii, 72-73
 - human biological materials research use and, for relatives, conclusions/recommendations on, HBM-vii, 72, 73
 - medical benefits v. for mentally impaired research subjects, balancing concerns, DMC-45-50, 75
 - medical benefits v. for mentally impaired research subjects, Institutional Review Boards education/decisionmaking enhancement, DMC-48-49
 - medical benefits v. for mentally impaired research subjects, Special Standing Panel and, DMC-47-48
 - minimal, analysis for human biological materials research use, conclusions/recommendations, HBM-v-vi, 66-68

minimal, for research protocols using mentally impaired subjects, DMC-v, 46, 60, 74
minimal/greater than minimal, for mentally impaired research subjects, DMC-40-43, 46-47, 74, 75, 76
minimizing for research protocols with mentally impaired subjects, recommendations, DMC-iv, 56
monitors, independent, and assessment for mentally impaired research subjects, DMC-49-50
per se assessments of benefits v., for research, recommendations, DMC-57
Robertson, John, CHB-61-62, 68; HSC-48, 54
Roche Holding, HBM-15
Roman Catholic Church
 cloning, human, and, CHB-37, 38-41, 43, 44, 47, 49, 51, 52, 54, 104
 embryo/fetus, moral status of, HSC-50, 67
 human stem cell research, perspectives on, presentation summary, HSC-99-100
 See also Christianity; Religion
Rorvik, David, CHB-6, 39
Roslin Institute, CHB-i, ii, 1; HSC-37
Rosner, Fred, CHB-39

S

Sachedina, Abdulaziz, CHB-43, 52
Sachs, Greg, DMC-33
Safeguards. *See* Protections for human subjects
Saito, S., HSC-15
Samples
 coded, of human biological materials, definition, HBM-i, 17-18, 58
 coded, of human biological materials, rendered unlinked, special concerns for, conclusions/
 recommendations, HBM-iii, 60-62
 coded, of human biological materials, requirements for research use, conclusions/recommendations,
 HBM-iii-iv, 62
 human biological materials, definition, HBM-i, 16-18
 human biological materials, source identification, necessity for, HBM-18-19
 identifiable, of human biological materials, rendered unidentifiable, and informed consent, conclusions
 on, HBM-70-71
 identified, of human biological materials, definition, HBM-i, 17, 18, 58
 identified, of human biological materials, rendered unlinked, special concerns for, conclusions/
 recommendations, HBM-iii, 60-62
 identified, of human biological materials, requirements for research use, conclusions/recommendations,
 HBM-iii-iv, 62
 unidentified, of human biological materials, definition, HBM-i, 16-17, 18, 58
 unlinked, of human biological materials, created from coded/identified samples, special concerns on,
 conclusions/recommendations, HBM-iii, 60-62
 unlinked, of human biological materials, definition, HBM-i, 16-17, 18, 58
San Francisco, California, HBM-77, 78, 79
 See also California
Sanger Centre, HBM-15
Schizophrenia
 nature of, DMC-8
 See also Mental diseases and disorders
Scholberg v. Lifchez, CHB-92
Science and technology
 cloning, science and application of, CHB-13-33
 cloning, scientific uncertainties remaining, CHB-22-24
 embryonic stem cells derivation, federal support of, and progress in, issues, HSC-58-59
 freedom of scientific inquiry, and human cloning, CHB-ii, 75-76, 103

- human embryonic germ/stem cells, considerations for studies involving, HSC-105
- human stem cell research, considerations for, and, ethical concerns, HSC-i-ii, 65-66
- knowledge, quest for, and religious views on human cloning, CHB-43-44
- organizations, scientific, and human biological materials research use, policies of, HBM-32-33
- regulation of, considerations, CHB-6-7
- sheep cloning, science leading to, CHB-16-22
- technological imperative, religious views on human cloning, CHB-44
- US leadership sustenance in, and federal funding for human stem cell research, HSC-60
- See also* Research
- SCNT. *See* Nuclear transplantation cloning
- Scotland. *See* United Kingdom
- Searle, HBM-15
- Seidelman, William, HSC-47
- Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies, HSC-61
- Sexual reproduction. *See* Assisted reproductive technology (ART); Reproduction
- Shalala, Donna, HSC-31
- Sheep. *See* Animals
- Siegel, Seymour, CHB-39
- SLE. *See* Systemic lupus erythematosus (SLE)
- SmithKline Beecham, HBM-15
- Social values
 - cloning of children and, potential harms to, CHB-ii, iii, 67-68, 103-104
 - See also* Ethics
- Somatic cells, CHB-16-21
 - definition, CHB-1, A-3; HSC-86
 - human, fusion with cow eggs to create hybrid embryo, description, HSC-19
 - mutations in, nuclear transfer cloning effects, uncertainties, CHB-24
 - See also* Cells; Nuclear transplantation cloning
- Somatic cell nuclear transfer (SCNT) cloning. *See* Nuclear transplantation cloning
- South Carolina
 - cloning, human, legislation on, CHB-86
- Southern Baptist Church
 - “Against Human Cloning”, CHB-54
 - Christian Life Commission, CHB-54
 - Convention, CHB-54
 - See also* Christianity; Protestantism; Religion
- Soviet Union
 - Chernobyl nuclear accident site, HBM-4
- Spain
 - cloning laws, CHB-3, 101
- Speakers. *See* Testimony and speakers
- Special review panel. *See* Special Standing Panel (SSP)
- Special Standing Panel (SSP), DMC-iii-iv, 54, 55, 61, 64, 86
 - mentally impaired research subjects, creation of, recommendations, DMC-iii-iv, 54-55
 - mentally impaired research subjects, risks v. medical benefits for, review by, DMC-47-48, 76
- Specimens
 - identified, of human biological materials, definition, HBM-i, 16, 18, 58
 - unidentified, of human biological materials, definition, HBM-i, 16, 18, 58
- SSP. *See* Special Standing Panel (SSP)
- State legislation
 - cadaveric fetuses as sources of stem cells, and, HSC-32-33
 - cloning, human, CHB-85-87
 - embryos created by in vitro fertilization, research using cells/tissues from, and, HSC-35-36
 - family relationships, CHB-87

fetal material donation for research on embryonic germ cells, laws facilitating, HSC-32
 fetal material donation for research on embryonic germ cells, laws restricting, HSC-32-33
 medical records privacy and research use, protection of, HBM-36-38
 mentally disabled persons in research, decisionmaking concerns, DMC-31, 32-33, 34, 35, 42, 43, 71, 72
See also Federal legislation; Laws and legislation; Uniform Anatomical Gift Act (UAGA)

Statements
 Commissioner, mentally disabled persons in research protocols, DMC-85-88
 professional, human biological materials used in research, comparison of, HBM-99-103

Stem cells
 definition, HSC-86
 types of, description of, HSC-8-9, 10-14
See also Adult stem (AS) cells; Cells; Embryonal carcinoma (EC) cells; Embryonic germ (EG) cells;
 Embryonic stem (ES) cells; Human stem cells; Mesenchymal stem cells; Neural stem cells

Sterility
 cloning, human, assessment of scenarios, and public policy proposals, CHB-53
See also Reproduction

Stewardship
 human, over nature, and human cloning, CHB-44

Stigmatization
 human biological materials information and, ethical issues, HBM-5, 45-46
See also Discrimination

Storage
 human biological materials and, public knowledge on, forum findings, HBM-77
 human biological materials, collections of, overview of, HBM-13-15
 human biological materials in U.S., statistics, HBM-14

Strelchenko, N.S., HSC-15

Subcommittee on Labor, Health and Human Services, Education and Related Agencies. *See* Senate Subcommittee on
 Labor, Health and Human Services, Education and Related Agencies

Substance abuse disorders
 nature of, DMC-8
See also Mental disease and disorders

Sullivan, Louis, HSC-31

Summary and recommendations. *See* Conclusions and recommendations

Supreme Court. *See* U.S. Supreme Court

Surrogacy
 mentally impaired research subjects and decision making, recommendations, DMC-v-vi, 61-63
 mentally impaired research subjects and, decisionmaking role of, DMC-29-37
 professional support, independent, for subjects and surrogates in research decision making, DMC-37

Symbolism
 abortion and, association with fetal tissue as source of embryonic germ cells, ethical issues, HSC-47-48

Synergy
 embryonic germ/stem cell derivation/use research, and combined federal effort, HSC-59

Systemic lupus erythematosus (SLE), HBM-17-18
See also Diseases and disorders

T

T.D. v. New York State Office of Mental Health, DMC-28, 71
 Court of Appeals, DMC-29

Technically assisted reproduction. *See* Assisted reproductive technology (ART)

Technology. *See* Science and technology

Tandler, R.M., CHB-46, 52, 53

Tennessee

fetal/embryonic tissue use, legislation on, HSC-40

Testament. *See* Living will

Testimony and speakers

- cloning human beings, CHB-B-1
- human biological materials used in research, HBM-113
- human stem cell research, ethical issues, HSC-109
- mentally disabled persons in research protocols, DMC-81-82

See also Public comments

Tompson, Dennis, CHB-73, 78; HSC-51

Thomson, James A., HSC-1, 7, 16

Third parties

- human biological materials research use and, Institutional Review Board concern, HBM-31
- human biological materials research use and, public beliefs on, forum findings, HBM-79

Thoreau, Henry David, CHB-6

Thornburg v. American College of Obstetrics and Gynecologists, CHB-90

Tissue plasminogen activator (tPA), CHB-14

Tissue transplantation. *See* Medical transplantation

Totipotency

- definition, CHB-A-3; HSC-1, 4, 5, 86

tPA. *See* Tissue plasminogen activator (tPA)

Trade associations

- embryonic germ/stem cell research, privately funded and eligible for federal funding, issues for, conclusions/ recommendations, HSC-ix-x, 78-79
- embryonic stem cell research, privately funded and not eligible for federal funding, issues for, conclusions/ recommendations, HSC-x, 79-80

Transgenic animals

- livestock, improved generation/propagation, nuclear transfer cloning use for, CHB-25-26

See also Animals

Trans-NIH Bioethics Subcommittee

- human biological materials use in research, statement comparison, HBM-101

See also National Institutes of Health (NIH)

Transplantation. *See* Medical transplantation; Nuclear transplantation cloning; Organs, transplant

U

UAGA. *See* Uniform Anatomical Gift Act (UAGA)

UCLA. *See* University of California at Los Angeles (UCLA)

UNESCO. *See* United Nations Educational, Scientific, and Cultural Organization (UNESCO)

Uniform Anatomical Gift Act (UAGA), HSC-32, 33, 36, 48, 73, 74

- cadaveric fetuses as sources of stem cells, state laws on, HSC-32-33
- fetal material donation for research on embryonic germ cells, state laws on, HSC-32-33

Uniqueness, sense of. *See* Individuality

United Church of Christ

- “Genetic Manipulation” study booklet, CHB-39

See also Christianity; Protestantism; Religion

United Kingdom

- assisted reproductive technologies/embryo research, regulatory boards for, HSC-77
- British Warnock Committee, HSC-49
- Cheddar, England, DNA from 9,000 year old skeleton, 3
- cloning, human, laws on, CHB-100
- England, Sanger Centre, genome center, HBM-15
- fetal tissue use in research, HSC-81
- Great Britain human cloning laws, CHB-3

Great Britain in vitro fertilization, first birth, CHB-39
 House of Commons, DMC-37
 human embryo/fetal tissue use in research, policy statement, HSC-3
 National Health Service, HBM-15
 Scotland sheep cloning experiment, CHB-i, 1, 13, 103
 United Nations. *See* United Nations Educational, Scientific, and Cultural Organization (UNESCO); United Nations General Assembly
 United Nations Educational, Scientific, and Cultural Organization (UNESCO), CHB-3, 100
 International Bioethics Committee, CHB-100
 Universal Declaration on the Human Genome and the Protection of Human Rights, CHB-100
 United Nations General Assembly, HBM-47
 Universal Declaration on the Human Genome and Human Rights, HBM-47
 Universities
 genetics databases, collaboration with private industry in creating, HBM-15
 See also Cornell University; Georgetown University; George Washington University; Harvard Medical School; Johns Hopkins University; Loma Linda University; University of California at Los Angeles (UCLA); University of Oxford; University of Pennsylvania; University of Wisconsin; Washington University; Yale University
 University of California at Los Angeles (UCLA), DMC-3, 49
 School of Medicine Institutional Review Board, DMC-54
 See also California
 University of Oxford, HBM-3
 University of Pennsylvania, HSC-61
 See also Pennsylvania
 University of Wisconsin, HSC-1, 7
 U.S. Army
 medical monitor for research activities, DMC-49
 See also Armed forces
 U.S. Congress, CHB-iv, 54, 83, 85, 105; DMC-31, 32; HBM-5, 35, 36; HSC-xi, 29-30, 31, 33, 35, 37, 38, 61, 70, 75, 80, 96
 See also Federal government; Federal legislation
 U.S. Constitution, CHB-7, 91, 92
 See also Constitutional law
 U.S. Court of Appeals, HBM-38
 USDA. *See* U.S. Department of Agriculture (USDA)
 U.S. Department of Agriculture (USDA)
 Food Safety and Inspection Service, HBM-82
 U.S.-foreign relations
 cloning, human, cooperation with other nations, CHB-iv, 9, 89, 93, 99-101, 106
 See also Foreign countries; Foreign laws
 U.S. National Center for Human Genome Research
 human biological materials use in research, statement comparison, HBM-100
 USSR *See* Soviet Union
 U.S. Supreme Court, HSC-96-97
 cloning, human, and, CHB-75, 89, 90, 91, 92, 93
 cloning, human, procreation and fundamental liberties, CHB-91-93
 See also Case law
 Utah
 family relationships, legislation on, CHB-87
 fetal/embryonic tissue use, legislation on, HSC-43

V

Values

mentally impaired research subjects, protections for and, DMC-8-9
personal, projection of, decisionmaking role for mentally disabled persons in research, DMC-29-30
See also Religion; Social values
Varmus, Harold, HSC-34, 35, 94
Vatican, CHB-40, 48, 50, 54
Instruction on Respect for Human Life (Donum Vitae), CHB-50, 54
Venipuncture, DMC-42
Verhey, Allen, CHB-40, 43, 51
Vescovi, Angelo, HSC-13
Virginia
family relationships, legislation on, CHB-87
fetal/embryonic tissue use, legislation on, HSC-43
mentally disabled persons with affected decisionmaking capacity in research, legislation on, DMC-71
See also Richmond, Virginia
Viruses
tracking of, screening human biological materials archives for, HBM-20
See also Diseases and disorders
Voluntary consent. *See* Consent; Informed consent

W

Waiver
consent requirements for human biological materials research use, conclusions/recommendations, HBM-
v-vi, 66-70
Washington University, HBM-15
Washout studies, DMC-3, 13-14
Webster v. Reproductive Health Services, CHB-90
Weisstub, David V., DMC-31
Wellcome Trust of London, HBM-15
Wertz, D., HBM-45
West Virginia
cloning, human, legislation on, CHB-86
WHI. *See* Women's Health Initiative (WHI)
Whitehead Institute/Massachusetts Institute of Technology Center for Genome Research, HBM-15
White House
Genetic Information and the Workplace, HBM-5
See also Office of the White House Press Secretary
White House Press Secretary. *See* Office of the White House Press Secretary
Wills. *See* Living will
Wilmut, Ian, CHB-i, 1, 16, 21, 22, 27
Windom, Robert E., HSC-30
Wisconsin. *See* University of Wisconsin
WHO. *See* World Health Organization (WHO)
Women's Health Initiative (WHI), HBM-21
See also National Institutes of Health
Worcester, Massachusetts, HSC-1, 7, 19
See also Massachusetts
World Council of Churches, CHB-39
World Health Organization (WHO), CHB-9, 96, 100; DMC-4, 5
human biological materials research use, perspectives on, HBM-33, 34
Human Genetics Programme, HBM-34
International Classification of Disease, DMC-5
Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services, HBM-34

World Medical Assembly Declaration, HBM-82

World Medical Association, CHB-9, 95, 96

World War II, DMC-12; HSC-47

Wrongs

human biological materials research use and, minimization of, ethical issues, HBM-42-43

See also Harms; Ethics

Wyngaarden, James B., HSC-30

Y

Yale University, HSC-50

Z

Zeneca Group, HBM-15

Zygote

definition of, HSC-5, 86