

## Index

- abortion protection, 316–317
- accountability principle, 179
- Acquired Immune Deficiency Syndrome (AIDS), 511, 512
- Act Concerning the Ethical Review of Research Involving Humans (*Lag om etikprövning av forskning som avser mänsklor – ERRIH*), 293, 300
- Act on Regulation of Human Cloning Techniques* (Human Cloning Regulation Law), 444
- Act on the Netherlands Organization for Scientific Research (*Wet op de Nederlandse organisatie voor wetenschappelijk onderzoek*), 322–323
- Act on the Organization of Health Research in The Netherlands (*Wet op de organisatie ZorgOnderzoek Nederland*), 322–323
- Act on Welfare and Management of Animals*, 456
- acute lymphoblastic leukemia, 14
- Additional Protocol on Biomedical Research, 174
- Additional Protocol on Transplantation, 173
- Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights ('Protocol of San Salvador'), 56, 134
- Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings, 173
- Administrative Measures for Gene Engineering Safety rule*, 489
- Administrative Measures for the Clinical Application of Medical Technology*, 495
- Administrative Safety Measures for Biotechnology Research and Development*, 493–494
- Advanced Therapy Medicinal Product Regulation, 211
- Africa, human rights protection, 57
- Agri-Food and Veterinary Authority (AVA), 524
- American Declaration of Human Rights, 54–55, 134
- American Society for Reproductive Medicine, 116
- American Society of Human Genetics, 115, 126
- Animal and Plant Health Inspection Service, 112, 120
- Animal Care Committees (ACC), 95, 112
- Animal Protection – Experimental Animal Ordinance (*Tierschutz-Versuchstierverordnung - TierSchVersV*), 262
- Animal Protection Act (*Tierschutzgesetz – TierSchG*), 261–262
- animal rights legal framework, 300–304, 371–372
- animal testing, 261–262, 302–303, 508–509. See also pre-clinical research in human germline modification
- Animal Welfare (Animal Experimentation) Law, 579–580
- Animal Welfare Acts, 112, 120, 294, 300–304, 306, 415
- Animal Welfare Ordinance (*Djur skyddsförordning*), 301, 421
- Animals (Scientific Procedures) Act 1986 (ASPA), 229–230
- Arab states, human rights protection, 57
- arrested embryos, 256, 260

- artificial insemination, 140, 177–178, 391, 494  
 asexually produced embryos, 257  
 Assisted Human Reproduction Act (AHRA),  
     86–87, 91–92, 96–99, 100–102  
 assisted reproductive technology (ART), 129,  
     140, 141–142, 352  
 Australia, 543  
 France, 391  
 Israel, 579  
 Italy, 352  
 Japan, 445  
 Mexico, 129, 140, 141–142  
 Singapore, 522–524  
 Spain, 367, 376–378  
 Switzerland, 419  
 Association of South-East Asian Nations  
     (ASEAN), 520  
 AUGMENT (autologous germline  
     mitochondrial transfer), 98–99, 376, 451,  
     459–460, 462, 467  
*Australian Code for the Care and Use of  
 Animals for Scientific Purposes* (8th  
 Edition, 2013) (*Animal Code*), 549–550,  
     561–562  
 Australian Constitution, 546  
 Australian Health Ethics Committee, 543, 549  
 Australian human germline modification  
     basic research, 590  
     current and future possibilities, 562–567  
     definitions, 550–552  
     introduction to, 543–546  
     oversight bodies, 552–553, 563–564 *t*  
     regulatory framework, 546–550  
     substantive provisions, 553–562  
 Australian Research Council, 548  
 Australian Senate Community Affairs  
     References Committee, 566  
 autonomous communities (*Comunidades  
 Autónomas*), 358, 368  
 ‘B centers’ in Belgium, 270  
 bacteria, 8  
 Basic Law (*Grundgesetz*), 242–244  
 basic research in germline engineering  
     Australia, 590  
     China, 488–494  
     European Union, 206–208  
     France, 394–399, 590  
     Germany, 253–261  
     human embryos in, 226–228, 253–256,  
         350–351, 394–398, 399, 429–430, 588–592  
     human rights framework, 587–592  
     introduction to, 16, 20  
     Italy, 350–353  
     Japan, 451–456, 455 *f*  
     Korea, 510–512  
     Singapore, 521–522, 589  
     Spain, 372–376  
     Switzerland, 427–431  
     United Kingdom, 226–232, 589  
     United States, 122–123, 589  
 Belgian Advisory Committee on Bioethics,  
     271–273  
 Belgian human germline modification  
     clinical applications, 279–280  
     clinical research, 412  
     definitions, 278–279  
     Embryo Research Law, 273–277  
     Federal Commission, 270–271  
     introduction to, 266–267  
     key bodies and institutions, 269–273  
     key laws, 267–269  
     local ethics committees, 269–270  
     MAR Law, 267, 272, 273–277  
     National Fund for Scientific Research, 273  
     regulatory framework, 267–273  
     substantive provisions, 273–280  
 ‘bench to bedside’ continuum, 16  
 Benda, Ernst, 243  
 benefit sharing principle, 35, 74–75, 586  
 Benouine, Karima, 59–60  
 Bill of Rights, UK (1689), 218  
 biobanks, 45  
 Biobanks in Medical Care Act (*Lagen om  
 biobanker i hälso- och sjukvården m.m.*),  
     293–294  
 bioethics. *See also* international bioethics law  
     fundamental principles of, 42  
     human germline genome engineering, 22  
     soft law and, 26, 72  
     UNESCO instruments, 72  
 Bioethics Advisory Committee (BAC),  
     516–517, 521–522, 524, 534  
 Bioethics and Safety Act (BSA), 501, 505–506,  
     510–512  
 Biomedicine Agency (*Agence de la  
 Biomédecine – ABM*), 386, 387, 392,  
     394–398  
 Biosafety Committee (*Comité de  
 Bioseguridad*), 147  
 Biotech Directive. *See Legal Protection of  
 Biotechnological Inventions*

- Biotechnological Inventions directive, 359  
 Biotechnology and Biological Sciences Research Council, 226  
 Biotechnology of the Association of German Engineers (*Verein Deutscher Ingenieure - VDI*), 248  
 Biotechnology Working Party (OECD), 50  
 blastocysts, 5, 280  
*Brüstle v. Greenpeace and International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks*, 198, 208
- Canadian Council on Animal Care (CCAC), 94–95, 96  
 Canadian human germline modification basic research on, 92–93  
 clinical research, 96–99  
 Constitution Act, 83, 84–85  
 current and future perspectives, 100–102  
 government regulations, 88–90  
 introduction to, 83–84  
 laws, 85–88  
 oversight bodies, 90–91  
 pre-clinical research, 94–96  
 regulatory environment, 84–90  
 substantive provisions, 91–100  
 Canadian Institutes of Health Research (CIHR), 88, 89, 90  
 ‘Care Programs for Reproductive Medicine,’ 270  
 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 444, 447, 453–456  
 Catholic Church, 70, 170  
 CCR5 gene in human embryos, 126  
 Center for Biologics Evaluation and Research (CBER), 120  
 Central Animal Ethics Board (*Centrala djurförsöksetiska nämnden*), 297  
 Central Committee on Research Involving Human Subjects (*centrale commissie voor medisch-wetenschappelijk onderzoek*), 320–321  
 Central Ethical Review Board (*Centrala etikprövningsnämnden*), 297  
 Central Military Commission, 470  
 Chambers of Physicians (*Ärtekammer*), 249  
 Charpentier, Emmanuelle, 10
- Charter of Fundamental Rights of the European Union, 68, 213, 236–237, 290, 340, 359  
 Charter of the Organization of American States, 56  
 chimeric embryos, 390–391, 420, 494–495  
 Chinese Food and Drug Administration (CFDA), 473, 474, 476  
 Chinese human germline modification basic research, 488–494  
 clinical research and applications, 494–496, 595  
 current and future possibilities, 477–484 *t*, 497–499  
 definitions, 488  
 funding, 486–488  
 introduction to, 469  
 political/legal system, 470–473  
 regulations and rules, 476–486  
 regulatory agencies, 473–476  
 regulatory environment, 470–488  
 Christian Democracy Party, Belgium, 273  
 Christianity and dignity, 70, 76–77  
 chromosomal abnormality, 463  
 Church, George, 10  
 Civil Code (*Burgerlijk Wetboek*), 314–316  
 civil freedom/rights, 28–29, 174  
 Civil Law tradition, 470, 599  
 civil society and human germline genome engineering, 50–52  
 claw back clause, 36  
 clinical applications in germline engineering Belgium, 279–280  
 China, 494–496  
 European Union, 210–212  
 France, 402–404  
 Germany, 263–264  
 human rights framework, 592–593  
 introduction to, 16, 20  
 Italy, 355–356  
 Japan, 460–461  
 Korea, 513  
 Spain, 372–376  
 Sweden, 305–306  
 Switzerland, 436–437  
 United Kingdom, 231–232  
 United States, 125–126  
*Clinical Applications Technical Norms on Assisted Reproduction*, 494  
 clinical research in germline engineering Belgium, 596–597

- Canada, 96–99
- China, 494–496, 595
- European Union, 210–212
- France, 400–402, 596–597
- Germany, 263
  - human rights framework, 593–597
  - introduction to, 16, 20
  - Italy, 354–355, 596–597
  - Japan, 457–460, 458<sup>f</sup>
  - Korea, 513
  - Mexico, 150–152
  - Singapore, 534–537, 538<sup>f</sup>
  - Spain, 372–376
  - Sweden, 304–305
  - Switzerland, 428, 433–436
  - United Kingdom, 230–231, 597
  - United States, 125
- Clinical Trial Certificate, 536–537
- Clinical Trials Directive/Regulation
  - European Union, 194, 196–197, 202–203, 211–212, 215
  - Sweden, 290–291, 292, 295, 304–305, 306–308
  - United Kingdom, 236
- Clinical Trials of Medicinal Products for Human Use regulation, 361
- cloning. *See human cloning*
- Code of Conduct for All Staff Conducting Assisted Reproductive Technology*, 494
- Code of Practice (HFEA), 221–222
- Code of Practice for Assisted Reproductive Technology Units*, 549
- Cold War, 27
- Commission of Experts for Human Genetic Testing (*Commission d'Experts pour l'Analyse Génétique Humaine*), 422
- Commission of Guarantee for the Donation and Use of Human Cells and Tissues (*Comisión de Garantías para la Donación y Utilización de Células y Tejidos Humanos*), 364–367
- Commission on Genetic Modification (*Commissie genetische modificatie – COGEM*), 321–322
- Committee of Ministers created the Ad hoc Committee of Experts on Bioethics (CAHBI), 159
- Committee on Bioethics (DH-BIO), 158, 170, 171, 172
- Committee on Economic, Social and Cultural Rights, 59, 61, 351, 471, 603, 606, 609
- Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly of the CoE, 171
- common law tradition, 217–219, 519
- Common Rule (DHHS), 110, 112, 117–119, 122–123
- condition of proportionality, 605–608
- conduct conditions on research, 37–38
- confidentiality of genetic data, 36
- Confucianism, 467
- Consolidated Appropriations Act, 111
- Constitution Act (1867), 83, 84–85
- Constitution of Japan, 467–468
- Constitution of the Fifth Republic, 381–384
- Constitution of the Italian Republic (*Costituzione della Repubblica Italiana*), 335–336, 337–344
- Constitution of the People's Republic of China, 470
- Constitution of the Republic of Korea, 502–505
- Constitution of the State of Singapore, 519–520
- Constitutional Council (*Conseil Constitutionnel*), 380
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, 178
- Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, 186, 208–210
- Costa and Pavan v. Italy*, 175–176, 341, 345–346
- Council for Science, Technology and Innovation (CSTI), 464, 465
- Council of Europe (CoE)
  - Belgium and, 268–269
  - European Convention on Human Rights and Fundamental Freedoms, 158–159, 174–178
  - European human germline modification, 32, 155, 157–179
  - France and, 381–382
  - introduction to, 157–159
  - Italy and, 343
  - legislative process, 216
  - Netherlands and, 313
  - Oviedo Convention, 159–173
  - relevant treaties, 178–179
  - Spain and, 358, 361
  - Sweden and, 286–289, 292
- Council of Science and Technology Policy, 445, 463
- Council of State (*Conseil d'Etat*), 380

- Council of the European Union, 181
- Court of Justice of the European Union (CJEU), 181, 197–201, 215, 268
- Covenant on Civil and Political Rights, 520
- Covenant on Economic, Social and Cultural Rights, 25, 59, 164, 188, 520
- Crimes Related to Genetic Engineering (*Delitos relativos a la ingeniería genética*), 362–363
- Criminal Code (*Wetboek van Strafrecht*), 314–316
- CRISPR Babies scandal, 496, 497, 498–499, 604
- CRISPR/Cas 9 gene editing tool
  - advancements in, 11–15, 126, 168
  - benefits of, 611
  - Chinese use of, 487
  - discovery of, 4, 71–72
  - Dutch use of, 311, 327
  - emergence of, 7–11, 9 f, 469, 609–610, freedom to use, 613–614
  - French use of, 388, 397, 401, 404–408
  - funding for, 226
  - human rights framework, 588, 601
  - introduction to, 1, 2, 103
  - Italy and, 347–348
  - Japan and, 441–442
  - Korean use of, 501
  - novelty of, 52
  - pre-clinical research regulations, 123–124
  - Singapore and, 516
  - Switzerland and, 435
  - in vitro* embryos, 12–13
  - in vivo* embryos, 13–14
  - cryopreserved embryos, 176, 212, 280, 350–351, 357
  - customary international law, 25, 69, 133–136
  - cytoplasmic hybrid embryos, 518, 526, 534
  - cytoplasmic transfer, 259, 463
  - data minimization principle, 179
  - De Gaulle, Charles, 380
  - de Jonge, Hugo, 331
  - Decision on Canceling Non-Administrative Licensing Approval Items*, 495–496
  - Declaration of Helsinki, 43, 578
  - Department of Health and Human Services (DHHS), 110, 112
  - Dickey-Wicker Amendment, 120–121, 126
  - Dickson v. United Kingdom*, 177
  - dignity. *See human dignity*
  - Christianity and, 70, 76–77
  - dignitas*, 70
  - duty to protect, 64–71
  - EU Charter and, 184
  - focus on meaning of, 86
  - human cloning and, 69
  - human rights framework, 513–515
  - Oviedo Convention and, 162–163
  - respect for, 76–77, 615–616
  - respect for human dignity principle, 76–77, 586
  - Dignity of Man (*Oratio de hominis dignitate*), 71
  - DNA (deoxyribonucleic acid)
    - genetic identity, 258
    - impact of, 3–4
    - mitochondrial DNA, 97–100, 441, 457, 575
    - molecular scissors, 8
    - recombinant DNA technology, 489
    - reproduction overview, 5–7, 6 f
  - Dolly the sheep, 543, 571
  - Doudna, Jennifer, 10
  - Drug Inspection Administration (DIA), 473, 474
  - Drugs Research Ethics Committees (*Comités Éticos de Investigación con Medicamentos*), 367
  - Dutch Council of State (*Raad van State*), 330
  - Dutch human germline modification
    - civil and criminal codes, 314–316
    - constitution and international law, 312–314
    - current and future perspectives, 327–334
    - Embryo Act, 310, 311, 317–319, 323–327, 332–334
    - Environmental Management Act, 321–322
    - funding, 322–323
    - general legal framework, 311–317
    - Health Act, 322
    - introduction to, 309–311
    - Medical Research on Human Subjects Act, 320–321
    - preimplantation genetic diagnosis, 320
    - progressive legal protection, 316–317
    - regulatory framework, 311–323
    - substantive provisions, 323–327
  - economic rights, 132, 164
  - Embryo Act, Netherlands, 310, 311, 317–319, 323–327, 332–334

- Embryo Protection Act  
*(Embryonenschutzgesetz - ESchG)*, 169, 244, 251–252, 253–256
- Embryo Research Law, 273–277
- Embryo Research Licensing Committee (ERLC), 552–553, 560
- Embryonic Stem Cell Research Oversight Committee (ESCRO), 485
- embryonic stem cells, 5, 198, 420
- embryos. *See also* surplus embryos
  - arrested embryos, 256, 260
  - basic research regulation, 226–228, 253–256, 350–351, 394–398, 399, 429–430, 588–592
  - CCR5 gene in, 126
  - cryopreserved embryos, 176, 212, 280, 350–351, 357
  - cytoplasmic hybrid embryos, 518, 526, 534
  - defined, 93, 137, 169, 222–223, 251–252, 278–279, 368–369, 390, 420, 448–449
  - hSCNT embryos, 457
  - importing for research, 257
  - ne plus ultra* prohibitions, 606–608
  - pregnancy with edited embryos, 403–404, 436–437
  - prohibition of creation of, 605–606
  - research prohibitions, 323–327
  - research regulations, 117–119, 207, 221, 533–534
  - restrictive definition of, 199, 243
  - subsidiarity principle regarding embryo research, 275
  - supernumerary embryos, 140, 276, 277, 605
  - surplus embryos, 319
  - transgenic embryos, 390–391
  - tripronuclear embryos, 260
- Environment Canada, 96
- Environmental Management Act (*Wet Milieubeheer*), 321–322
- Estates General of Bioethics (*États généraux de la bioéthique*), 386
- Ethical, Legal and Social Implications (ELSI) research projects, 265
- Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (2002), 43
- Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 549
- Ethical Guiding Principles for Research on the Human Embryonic Stem Cells, 492–493
- Ethical Review Agency  
*(Etikprövningsmyndigheten)*, 296–297
- Ethical Review of Research Involving Humans Act, 306
- Ethics Committee of the French National Institute for Health and Medical Research (*Institut National de Santé et Recherche Médicale – INSERM*), 388
- Ethics Committees on Animal Experimentation (*Comités de ética de experimentación animal*), 368
- Ethics of Animal Investigation policy statement, 94
- EU Data Protection Regulation (*Lag med kompletterande bestämmelser till EU:s dataskyddsförordning*), 293
- Eugenics Protection Law, 500
- eugenics, 184, 235–239, 272, 340, 352
- European Atomic Energy Community (EEC), 180
- European Clinical Trial Regulation, 401
- European Coal and Steel Community, 180
- European Commission, 181, 201–203
- European Communities Act, 219
- European Constitution, 180
- European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, 178, 179
- European Convention on Human Rights and Fundamental Freedoms (ECHR), 67, 158–159, 174–178, 186, 188, 286, 288, 313, 345–346
- European Court of Human Rights (ECtHR), 67, 175–176, 289, 313, 341, 600
- European Court of Justice (ECJ). *See* *Court of Justice of the European Union*
- European Economic Community (EEC), 180
- European Group on Ethics in Science and New Technologies (EGE), 202, 203–205, 333
- European Medicines Agency (EMA), 203, 291
- European Parliament, 181
- European Research Council (ERC), 205–206
- European Union (EU) human germline modification, 32, 155–157
  - basic research, 206–208
  - CJEU decisions, 197–201
  - clinical applications/research, 210–212
  - Community/Union law, 219, 598–600
- Council of Europe, 32, 155, 157–179

- European Union (EU) (cont.)  
 human rights protection, 57, 595–596  
 international law, 186–189  
 introduction to, 155–157, 179–182  
 oversight and supervisory bodies, 201–206  
 pre-clinical research in human germline modification, 208–210  
 primary law, 182–185  
 regulation of, 206–212  
 regulatory environment, 182–206  
 relevant regulations and directives, 189–197  
 summary of, 212–216  
 Sweden and, 289–292  
 euthanasia, 273, 309  
*Evans v. United Kingdom*, 177  
 ex vivo embryos, 14, 210, 593–594
- FDA. *See Federal Drug Administration*
- Federal Act on Human Genetic Testing (*Loi fédérale sur l'analyse génétique humaine*), 414
- Federal Act on Medically Assisted Reproduction (*Loi fédérale sur la procréation médicalement assistée*), 413, 415, 416, 428, 429
- Federal Act on Non-Human Gene Technology (*Loi fédérale sur l'application du génie génétique au domaine non humain*), 414, 420, 428, 431–433
- Federal Act on Non-Human Gene Technology, the Animal Welfare Ordinance (*Ordonnance sur la Protection des Animaux*), 418
- Federal Act on Research Involving Embryonic Stem Cells, 416, 420, 428, 429
- Federal Act on Research involving Human Beings (*Loi fédérale relative à la recherche sur l'être humain*), 414
- Federal Act on Research Involving Human Beings, the Human Research Ordinance (*Ordonnance relative à la recherche sur l'être humain à l'exception des essais cliniques*), 417, 430
- Federal Act on the Transplantation of Organs, Tissues and Cells of 2004 (*Loi fédérale sur la transplantation d'organes, de tissus et de cellules*), 414, 415
- Federal Commission (*Commission fédérale pour la recherche médicale et scientifique sur les embryons in vitro - Federale Commissie voor medisch en wetenschappelijk onderzoek op embryo's in vitro*), 270–271
- Federal Commission for the Protection against Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios-COFEPRIS*), 143–144, 151
- Federal Constitution of Malaysia, 519
- Federal Constitution of the Swiss Confederation, 410–416
- Federal Coordination Centre for Biotechnology, 433
- Federal Drug Administration (FDA), 109–112, 120, 127
- Federal Ethics Committee on Non-Human Biotechnology, 422
- Federal Food Safety and Veterinary Office (*Office Fédéral de la sécurité alimentaire et des affaires vétérinaires – OSAV*), 418
- Federal Ministry of Education and Research (*Bundesministerium für Bildung und Forschung – BMBF*), 247
- Federal Office for the Environment (*Office fédéral de l'environnement*), 422
- Federal Office of Public Health, 413, 422
- fetus, defined, 137, 420
- First Knesset (Israel), 570, 574
- Forte research council, 298
- Fourth Amendment of US Constitution, 108
- Framework Programmes for Research and Technological Development, 194–195, 214
- Francis Crick Institute, 226
- freedom of religion, 466, 520
- freedom of research, 60, 73–74, 586, 597–598, 604. *See also* right to science/rights of science
- French Civil Code, 396, 596–597
- French human germline modification basic research, 394–399, 590  
 clinical applications, 402–404  
 clinical research, 400–402, 596–597  
 constitution and treaties, 381–384  
 current and future possibilities, 404–408, 405–407 t  
 definitions, 390–392  
 funding, 393  
 guidelines and policy documents, 388–390  
 introduction to, 380  
 laws and codes, 384–388  
 legal framework, 381–390  
 oversight bodies, 392  
 pre-clinical research, 399–400

- substantive provisions, 393–404
- French National Institute of Health and Medical Research (INSERM), 389
- French Society of Gene and Cell Therapy (*Société Française de Thérapie Cellulaire et Génique*), 389
- French Society of Human Genetics (*Société Française de Génétique Humaine*), 389
- ‘From Ethics to Law: Life Sciences’ (*De l’éthique au droit: sciences de la vie*), 384
- Fundamental Policy Regarding Handling of Human Embryos* (Fundamental Policy), 442–448, 451–456, 455 f, 462–463,
- funding germline engineering
  - China, 486–488
  - France, 393
  - Germany, 250–251
  - introduction to, 20
  - Japan, 451
  - Korea, 510
  - Mexico, 145–147
  - Switzerland, 426–427
  - United Kingdom, 225–226
  - United States, 120–122
- gametes
  - basic research regulation of, 228–229, 253, 351–353, 587
  - defined, 398–399
  - donor permission, 143
  - editing of, 4, 117–119
  - pregnancy with edited gametes, 403, 436
- gametogenesis, 231, 398–399, 427, 450–451, 587, 601
- gastrulation, 5–7
- gene technology, defined, 400, 551–552
- Gene Technology Act 2000 (GT Act), 546–550, 551–552, 553–562
- Gene Technology Regulator (GTR), 552–562
- gene transfer, 89, 243, 461–462
- General Health Law (GHL) (*Ley general de salud*), 129, 130, 137–139, 143–145
- general principles of law, 26
- general welfare of a democratic society, 603
- Genetic Engineering Act (*Gentechikgesetz – GenTG*), 252–253
- Genetic Engineering Promotion Act, 500
- genetic engineering to plants, 241
- genetic heritage, 165, 195, 196–197, 214, 344, 346, 349, 352, 355, 373
- Genetic Integrity Act (*Lag om genetisk integritet - GIA*), 292–295, 299, 304–305, 306–308
- Genetic Manipulation Advisory Committee, 545–546
- genetic traits, 127, 399, 403, 597
- genetically modified animals, 421
- genetically modified organisms (GMOs), 130, 321, 421, 434, 545
- genome, 97–98, 166–167, 168, 237–239, 372–376
- genome editing, defined, 252–253, 369, 516
- genome modification. *See human genome*
- Genomic Sovereignty Amendments, 130
- germ cell/germline cells, defined, 4, 5–7, 6 f, 137, 251–252, 420, 449
- German Constitution, 70
- German Constitutional Court (*Bundesverfassungsgericht - BVerfG*), 242
- German Criminal Code (*Strafgesetzbuch*), 245
- German Ethics Council (*Deutscher Ethikrat*), 248
- German Federal Ministry of Education and Research (*Bundesministeriums für Bildung und Forschung - BMBF*), 265
- German human germline modification
  - arrested embryos, 256, 260
  - basic research regulations, 253–261
  - clinical applications, 263–264
  - clinical research regulations, 263
  - current and future possibilities, 264–265
  - cytoplasmic transfer, 259
  - definitions, 251–253
  - funding, 250–251
  - government regulations, 247
  - importing human embryos, 257
  - induced pluripotent stem cells, 261
  - introduction to, 241
  - laws on, 244–245
- Mitochondrial Replacement Therapy, 259
- official opinions on, 247–248
- oversight bodies, 249–250
- pre-clinical research on, 261–262
- regulatory framework, 242–244
- Somatic Cell Nuclear Transfer, 257–259
- substantive provisions, 251–264
- tripronuclear embryos, 260
- German National Academy of Sciences Leopoldina (*Deutsche Akademie der Naturforscher Leopoldina*), 247–248

- German Society of Human Genetics (*Deutsche Gesellschaft für Humangenetik – GfH*), 248
- German Weimar Constitution (1919), 132
- germline engineering. *See human germline genome engineering*
- Germline Modification Working Group, 524
- Gewirth, Alan, 71
- global commons, 35
- Good Animal Practice (GAP), 96
- Good Manufacturing Practices (GMP) certification, 491
- governance, defined, 23
- Green Party, Belgium, 273
- gRNA, 8
- Gross Domestic Product (GDP), 145
- Guide to the Care and Use of Experimental Animals* ethical basis, 94–95
- Guidelines on: Transgenic Animals* (CCAC), 95
- Guidelines on Genetically Engineered Animals Used in Science*, 95–96
- Guiding Principles for Human Gene Therapy Research and Preparation Quality Control*, 490–492, 494, 595
- Halacha (Jewish orthodox law), 568, 573
- Haloferax mediterranei* microbe, 8
- Handbook on Health Law (*Handboek gezondheidsrecht*) (Leenen), 309
- hard law, 17, 26, 44, 284
- He, Jiankui, 496, 497, 498–499, 604
- Health, Labour and Welfare Committee of the National Diet (House of Councilors), 466
- Health Act (*Gezondheidswet*), 322
- Health and Family Planning Commission (HFC), 473, 476–485
- Health Canada, 96, 99
- Health Council and Netherlands Commission on Genetic Modification, 332–334
- Health Institute Carlos III (*Instituto de Salud Carlos III*), 364
- Health Sciences Authority (HSA), 536
- healthcare discrimination, 29
- Helsinki Committees, 580
- heritable alterations, 554, 556
- heritage of humanity, 34, 35
- HLA (Human Leukocyte Antigen) type, 272
- Horizon 2020 regulation, 195–196, 298–299, 349
- horizontal direct effect, 190
- Hospital Bioethical Committee (*Comité Hospitalario de Bioética*), 148
- human-animal hybrids, 114–115
- human being, defined, 173
- Human Biomedical Research Act (HBRA), 525–534, 537–540
- human cloning
- Australian regulations, 543–545
  - defined, 420
  - embryo protection, 118
  - French regulations, 391–392
  - human dignity and, 69
  - Israeli regulations, 571–576
  - Korean regulations, 506
  - prohibition of, 45, 160, 196, 469, 488, 494–495
  - United States regulations, 114
- Human Cloning and Other Prohibited Practices Act (Human Cloning Act), 521–522
- Human Cloning Regulation Law, 445, 446–447, 448–450, 457–460, 461–468
- human embryonic nuclear transfer embryos, 450, 457
- human embryonic stem cell (hESC), 201, 386, 387, 391, 394–398, 413, 430–431
- Human Fertilisation and Embryology Act (1990), 219–221
- Human Fertilisation and Embryology Authority (HFEA), 220–222, 226–228, 230–231, 233
- human genetic data, defined, 39
- Human Genetic Resources Management Office (HGRMO), 490
- Human Genetics Programme, 47
- Human Genome Project, 38–41
- Human Genomics in Global Health Initiative, 47
- human germline genome engineering. *See also CRISPR/Cas 9 gene editing tool*
- civil society and, 50–52
  - defined, 15, 19
  - Dutch ban on, 325–327
  - EU Charter and, 192, 196–197
  - European Union regulations, 206–212
  - international standards and, 48
  - introduction to, 1–3
  - involuntary transgressions of, 203
  - methodology of, 15–21
  - science of, 3–5
- human immunodeficiency virus (HIV), 126

- human parthenogenic stem cells (hpSCs), 201  
 human proteomic data, 40  
 Human Research Ethics Committee, 561  
 human rights framework. *See also* right to science/rights of science  
     analysis of, 597–598  
     basic research in germline engineering, 587–592  
     clinical applications, 592–593  
     clinical research, 593–597  
     condition of proportionality, 605–608  
     European Union, 57, 595–596  
     evidence in, 587–597  
     introduction to, 585–587  
     legal certainty principle, 598–600  
     legitimate aim of restrictions, 602–608  
     *ne plus ultra* prohibitions, 606–608  
     obsolete regulatory frameworks, 608–611  
     proportionality principle, 179, 191, 559, 603  
     recommendations for, 611–617  
 human rights law, 16, 24, 53, 187, 332–334  
 human somatic cell nuclear transfer (hSCNT)  
     embryos, 457  
 Human Tissues and Cells Directive, 210, 211  
 Huriet Law (*la Loi Huriet*), 385  
 hybrid formation, defined, 420
- ideation stage methodology, 15–19  
 importing human embryos, 257  
 impregnated ovum, defined, 420  
*in utero* genome modification, 254–255, 350  
*in vitro* fertilization (IVF)  
     clinical applications regulation, 125–126,  
     263–264  
     Costa Rica’s ban, 135  
     CRISPR modification of, 12–13  
     defined, 7, 420  
     embryos, defined, 169  
     experimentation on, 7  
     French protocols, 392, 394, 397, 402  
     gametogenesis, 231, 398–399, 427, 450–451,  
     587, 601  
     human rights framework, 591, 593–594  
     Japanese use of, 442, 445  
     Korean use of, 503–504  
     maturation of spermatogonial stem cells,  
     393–394  
     mitochondrial replacement therapy, 97  
     regulation of, 217, 254, 279–280, 350  
     research prohibitions, 113–115, 118  
     residual embryos, 505, 511  
     social concerns over, 85  
     supernumerary IVF embryos, 140  
     surplus embryos, 319  
     *in vitro* gametogenesis (IVG), 328  
     *in vitro* maturation (IVM), 328  
     *in vivo* embryos, 7, 13–14, 591  
     ‘inclusion-exclusion’ two-stage test, 526–527  
     induced pluripotent stem cells (iPSCs), 12, 261,  
     446, 526, 531, 587  
     informed consent right, 36, 160, 417, 523  
     Initiative on Genomics & Public Health, 47  
     insemination, defined, 419  
     Institute for Basic Research (IBS), 510  
     Institutional Animal Care and Use Committee  
         (IACUC), 112, 525  
     Institutional Bioethics Committee, 509, 512  
     Institutional Review Board (IRB), 112, 450, 485,  
     516–517, 526–528, 537–540, 578  
     Institutional Revolutionary Party (PRI), 139  
     intellectual property rights, 49, 73–74, 192  
     Inter-American Convention on Human  
         Rights, 134, 135  
     Inter-American Court on Human Rights, 135  
     *Interim Administrative Measures for Human  
         Genetic Resources*, 490  
     internal market, 191  
     International Bill of Rights, 21, 66–67, 78, 586  
     International Bioethics Committee (IBC), 33,  
     41, 44–46, 65, 73, 357  
     international bioethics law, 3, 30–32, 586,  
     597–598  
     International Convention against the  
         Reproductive Cloning of Human  
         Beings, 69  
     International Covenant on Civil and Political  
         Rights (ICCPR), 27, 55, 67, 163, 565  
     International Covenant on Economic, Social  
         and Cultural Rights (ICESCR)  
         Australia and, 565  
         Belgium and, 269  
         benefit sharing principle, 35, 74–75  
         bioethics and, 21  
         Canada and, 85, 101  
         China and, 471  
         EU Charter and, 186  
         Europe and, 164  
         France and, 383  
         German laws and, 245–246  
         human genome and, 237–238  
         human rights and, 27–28, 55, 63–64, 67, 77,  
         382, 586, 600, 602

- International Covenant on Economic (cont.)
  - Italy and, 337–344, 351
  - Japan and, 444
  - Korea and, 504, 514
  - Mexico and, 134–135
  - Netherlands and, 312
  - overview of, 56
  - Sweden and, 283–284
  - Switzerland and, 411–412
  - United States and, 104
- International Declaration on Human Genetic Data, 38–41, 65, 73
- International Dialogue on Bioethics, 203–205
- International Human Genome Organisation Committee of Ethics, Law, and Society, 76
- International Human Genome Sequencing Consortium, 39
- international law/human rights law. *See also*
  - United Nations Educational, Scientific and Cultural Organization
  - applicable standards, 53–78
  - basic notions, 23–30, 616
  - European Union, 186–189
  - human dignity and, 64–71
  - introduction to, 1, 22
  - key terms, 23
  - recognition of, 58–61
  - right to science, 15, 71–78, 597–598
  - summary of, 78–79
- international management principle, 35
- International Society for Stem Cell Research (ISSCR), 116
- International Stem Cell Corporation *v. Comptroller General of Patents, Designs and Trade Marks*, 200, 201
- Investigation Committee (*Comité de Investigación*), 147
- Investigation Ethics Committee (*Comité de Ética en Investigación*), 147
- Investigational New Drug (IND) application, 109, 111
- Israeli human germline modification
  - current and future possibilities, 581–582
  - introduction to, 568–569
  - oversight bodies, 580–581
  - ratified treaties, 570–571
  - regulatory framework, 569–580
- Italian Agency for Drugs (*Agenzia Italiana del Farmaco*), 356
- Italian human germline modification
  - basic research, 350–353
  - clinical applications, 355–356
  - clinical research, 354–355, 596–597
  - Constitution of the Italian Republic, 335–336, 337–344
  - CRISPR/Cas 9 gene editing tool, 347–348
  - current and future possibilities, 356–357
  - funding, 349
  - general legal system, 335–336
  - introduction to, 335
  - Medically Assisted Reproduction law, 344–346
  - oversight bodies, 348–349
  - pre-clinical research, 353–354
  - regulatory environment, 337–349
  - substantive provisions, 350–356
- Japan Society of Obstetrics and Gynecology (JSOG), 442, 447, 450
- Japanese human germline modification
  - basic research, 451–456, 455 f
  - clinical applications, 460–461
  - clinical research, 457–460, 458 f
  - current and future possibilities, 461–468
  - definitions, 448–450
  - fundamental policy on, 442–448, 451–456, 455 f, 462–463,
  - funding, 451
  - introduction to, 441–442
  - lack of legislation on medical use of, 465–468
  - oversight bodies, 450–451
  - pre-clinical research, 456
  - regulatory framework, 442–448, 443 f
  - substantive provisions, 451–461, 455 f
- Juengst, Eric T., 102
- jurisprudence Schubert*, 412
- jus cogens* in customary international law, 27, 28
- just reparation for damage right, 36
- Kant, Immanuel, 71
- karyoplast, defined, 458
- Korean human germline modification
  - basic research, 510–512
  - clinical research and application, 513
  - current and future possibilities, 513–515
  - funding, 510
  - governmental bodies, 509
  - introduction to, 500–502
  - pre-clinical research, 512–513
  - regulatory framework, 502–509

- Laboratory Animal Act (LAA), 508–509, 512–513  
 Lander, Eric, 9  
 Law on Biosafety of Genetically Modified Organisms, 149  
 Law Reform Commission of Canada, 87  
 Law regarding Research on Embryos In Vitro (Embryo Research Law), 267  
 Leenen, Henk, 309  
 legal certainty principle, 598–600  
 Legal Protection of Biotechnological Inventions (Biotech Directive), 192–194, 198, 201–203, 204, 212, 214–215  
 legal regime, defined, 23  
 Lisbon Treaty, 182, 186, 190  
 living modified organism, defined, 453–454  
 living organism, defined, 453  
*Loi sur les activités cliniques et de recherche en matière de procréation assistée* (Act Respecting Clinical and Research Activities Related to Procreation), 88  
 Mancisidor, Mikel, 59, 61  
*Margarine Reference* case, 87–88  
 maternal spindle transfer, 231, 236–237, 457, 459, 460, 555  
 Mathews, Debra, 75  
 McLaren, Anne, 239  
 Medical Products Agency (*Läkemedelsverket*), 296  
 Medical Research Council, 226  
 Medical Research on Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen - WMO*), 320–321  
 Medically Assisted Reproduction (Law 40/2004), 344–346  
 Medically Assisted Reproduction and the Disposition of Embryos and Gametes (MAR Law), 267, 272, 273–277  
 Medicines Act, 534–536  
 Mendel, Gregor, 500  
 messenger RNA (mRNA), 454, 456, 459, 460, 595  
 Metaphysics of Morals (*Die Metaphysik der Sitten*) (Kant), 71  
 Mexican human germline modification basic research on, 147–149 clinical trials, 150–152 current and future perspectives, 152 federal laws, 136–139 funding, 145–147 government regulations, 139–141 introduction to, 129–130 official standards, 140–141 oversight bodies, 143–145 Political Constitution of the United Mexican States, 132–133 pre-clinical research, 149–150 regulatory environment, 147–152 regulatory framework, 130–143 state legal framework, 141–143 treaties and customary international law, 133–136 Mexican Revolution (1917), 132 microbes, 8, 9, 10 Miescher, Friedrich, 500 Ministry of Drug and Food Safety (MDFS), 507 Ministry of Education, Culture, Sports, Science, and Technology (MEXT), 445–446, 448, 450–456, 457, 459–460, 462 Ministry of Health (MOH), China, 473 Ministry of Health (MOH), Israel, 578, 581 Ministry of Health (MOH), Singapore, 516–517, 532–533 Ministry of Health, Labour, and Welfare (MHLW), 445–446, 448, 450–456, 459–460, 462 Ministry of Health and Consumption (*Ministerio de Sanidad y Consumo*), 364 Ministry of Health and Welfare (MOHW), 506 Ministry of Science and Information and Communications Technology, 510 Ministry of Science and Technology (MoST), 473, 474–476, 486–487, 489 Mirandola, Giovanni Pico della, 71 Mitalipov, Shoukhrat, 12, 250f mitochondrial DNA (mtDNA), 97–100, 441, 457, 575 mitochondrial donation, 224, 233–239 mitochondrial manipulation techniques (MMT), 353 Mitochondrial Replacement Therapy (MRT), 97–100, 259, 457–459, 461–462, 518 Model Professional Code for Physicians in Germany (*Musterberufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte – MBO*), 249 Modification of the Genome of Human Germline Cells and Embryos (*Les modifications du génome des cellules germinales et de l'embryon humains*), 388–389

- Mojica, Francisco, 8–9  
 molecular scissors, 8  
 Mother and Child Act, 500
- nasciturus* fiction, 314  
 National Academy of Medicine, 115, 126, 388  
 National Academy of Sciences, 115, 126, 607  
 National Action Party (PAN), 139  
 National Advisory Commission on Biomedical Ethics, 421, 437  
 National Advisory Committee for Laboratory Animal Research (NACLR), 525  
 National Bioethics Committee, 509  
 National Commission of Bioethics (*Comisión Nacional de Bioética*-CONBIOÉTICA), 144–145, 148  
 National Commission on Human Assisted Reproduction (*Comisión Nacional de Reproducción Humana Asistida*), 367  
 National Committee for Human Medical Research, 577, 579, 580–581  
 National Consultative Ethics Committee for health and life sciences (*Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé* – CCNE), 384, 389, 390, 404–408  
 National Council of Science and Technology (*Consejo Nacional de Ciencia y Tecnología*-CONACyT), 146  
 National Eugenics Law, 500  
 National Fund for Scientific Research, 273  
 National Health and Medical Research Council (NHMRC), 543–544  
 National Health Commission (NHC), 473–474  
 National Human Genome Research Institute, 39  
 National Institute for Genomic Medicine (*Instituto Nacional de Medicina Genómica* – INMEGEN), 146, 147  
 National Institute of Perinatology (INPeR), 148  
 National Institutes of Health (NIH), 110, 116, 121, 122, 146  
 National Natural Science Foundation, 487  
 National People's Congress (NPC), 470  
 National Population and Family Planning Commission, 473  
 National Register of Biobanks (*Registro Nacional de Biobancos*), 370  
 National Registry of Clinical Trials (*Registro Nacional de Estudios Clínicos*, RNEC), 150
- National School of Public Administration (*École Nationale d'Administration* – ENA), 380  
 National Supervisory Commission, 470  
 National System of Researchers (*Sistema Nacional de Investigadores* – SNI), 146  
 National Transplant Centre (*Centro Nacional de Trasplantes* – CENATRA), 145  
 Natural Sciences and Engineering Research Council of Canada (NSERC), 88  
*ne plus ultra* prohibitions, 606–608  
 The Netherlands. *See Dutch human germline modification*  
 Netherlands Organization for Scientific Research (*Nederlandse Organisatie voor Wetenschappelijk Onderzoek* – NWO), 322–323  
 neurula/neurulation, 7  
 New Hope Fertility Center, 129, 151–152  
 Newcastle Fertility Centre, 233, 235  
 NHMRC *National Statement on Ethical Conduct in Human Research* (*National Statement*), 548, 559  
 Niakan, Kathy, 226  
 non-appropriation principle, 35  
 Nordberg, Ana, 373–374  
 norm-making through soft law, 44  
 nuclear genome transfer (NGT), 328, 330  
 nuclease mRNA, 454  
 Nuffield Council on Bioethics, 224–225, 233, 607
- obligation to respect and to protect the rights and individual freedoms of others principle, 77, 586  
 Office of Technology Assessment, 247  
 Official Mexican Standard ‘Technical Specification for the Production, Care and Handling of Laboratory Animals,’ 149  
 Official Mexican Standards (*Normas Oficiales Mexicanas* – NOMs), 140–141  
 one-cell embryo. *See zygotes*  
 One of Us, 207  
 oocyte (female gamete), 5–7, 6 f, 11, 259, 276, 506, 533–534  
*opinio juris* in customary international law, 25, 26, 36, 52  
*Opinion on Ethical Considerations Surrounding Gene Editing and CRISPR-CAS9 Technique*, 347–348

- Ordinance of the National Commission of Ethics in the Field of Human Medicine (*Ordonnance sur la Commission nationale d'éthique dans le domaine de la médecine humaine*), 421–422
- Ordinance on Clinical Trials in Human Research (*Ordonnance sur les essais cliniques dans le cadre de la recherche sur l'être humain*), 418
- Ordinance on Handling Organisms in Contained Systems (*Ordonnance sur l'utilisation des organismes en milieu confiné*), 418, 421
- Ordinance on Human Genetic Testing (*Ordonnance sur l'Analyse Génétique Humaine*), 417
- Ordinance on Informatics Systems to Manage Experiments of Animals (*Ordonnance sur le Système Informatique de Gestion des Expériences sur Animaux*), 419
- Ordinance on Research involving Embryonic Stem Cells (*Ordonnance relative à la recherche sur les cellules souches embryonnaires*), 417
- Ordinance on Transplantation of Human Organs, Tissues and Cells (*Ordonnance sur la transplantation d'organes, de tissus et de cellules d'origine humaine*), 417
- Ordinance Regarding Detention of Test Animals, the Production of Genetically Modified Animals and the Methods Used in Animal Experimentation (*Ordonnance de l'OSAV Concernant la Détenzione des Animaux d'Expérience, la Production d'Animaux Génétiquement Modifiés et les Méthodes Utilisées dans l'Expérimentation Animale*), 418
- Organisation for Economic Co-operation and Development (OECD), 32, 49–50, 285, 292
- Organization Health Research Netherlands (*Organisatie ZorgOnderzoek Nederland - ZON*), 322–323
- oversight bodies
- Australia, 552–553, 563–564 *t*
  - European Union, 201–206
  - in germline engineering, 19
  - Israel, 580–581
  - Switzerland, 421–426
- Oviedo Convention (Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine)
- additional protocols, 173–174
  - Belgium and, 266, 268–269, 271, 274
  - Council of Europe and, 66, 159–173
  - EU Charter and, 183, 213–214, 596
  - France and, 382, 397
  - human dignity and, 162–163
  - human genome and, 237
  - Italy and, 341–343
  - Netherlands and, 310, 313, 314, 332
  - overview of, 159–173
  - Spain and, 361–362, 372, 375, 379
  - Sweden and, 286, 288, 307
  - Switzerland and, 412–413
  - Ovum Donation Law, 577–578
- Parliamentary Office of Evaluation of Scientific and Technological Options (*Office Parlementaire d'Évaluation des Choix Scientifiques et Technologiques – OPECST*), 385, 389
- Parrillo v. Italy*, 176, 346
- parthenogenesis, 117, 119, 199, 200, 505
- parthenote, defined, 420
- pathogenic mutations, 97
- pathogens, 3
- Paul-Ehrlich-Institute (PEI), 250
- peaceful use and preservation principle, 35
- People's Action Party (PAP), 519
- People's Party for Freedom and Democracy (*Volkspartij voor Vrijheid en Democratie – VVD*), 328
- People's Republic of China (PRC). *See Chinese human germline modification*
- persistent objector in customary international law, 25
- Pharmaceutical Affairs Act (PAA), 507–508
- pharmacogenetics, 50
- Political Constitution of the United Mexican States, 132–133
- political freedom/rights, 28–29, 174
- Popularization of Science and Technology Act, 472
- post-natal gene therapy, 14
- potential human being (*personne humaine potentielle*), 390
- practice in customary international law, 25, 26

- pre-clinical research in human germline modification
  - Canada, 94–96
  - European Union, 208–210
  - France, 399–400
  - Germany, 261–262
  - introduction to, 16, 20
  - Italy, 353–354
  - Japan, 456
  - Korea, 512–513
  - Mexico, 149–150
  - Singapore, 524–525
  - Sweden, 300–304
  - Switzerland, 431–433
  - United Kingdom, 229–230
  - United States, 123–124
- pre-embryo, defined, 369
- Pre-implantation Genetic Diagnosis and Germ-line Intervention report, 357
- Precision Medicine Initiative (PMI), 486
- precision/personalized medicine, 45
- pregnancy with edited embryos, 403–404, 436–437
- pregnancy with edited gametes, 403, 436
- preimplantation genetic diagnosis (PGD)
  - Council of Europe, 175–176
  - France, 401–402
  - Germany, 249, 250, 264
  - Italy, 341, 345–346
  - Japan, 403
  - Korea, 515
  - Netherlands, 320, 329–330
  - Oviedo Convention, 165
  - Singapore, 540
  - United Kingdom, 224, 238
- primary law of European Union, 182–185
- privacy by design principle, 179
- Proceed with Care* report, 86
- programmed cell death, 8
- progressive legal protection, 316–317
- Prohibition of Cloning of Human Beings (1998), 173
- prohibition of discrimination, 36
- Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 571–576
- Prohibition of Human Cloning Act (2002), 544, 550
- Prohibition of Human Cloning for Reproduction Act 2002 (PHCR Act), 544, 546–550, 551, 553–562
- Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act (2006), 544, 550
- ProLife Alliance, 223
- pronuclear transfer
  - eugenic practices and, 236–237
  - as most common technique, 457
  - prohibition of, 457, 458–459, 460, 461
  - safety concerns, 524, 593
  - treatment licenses for, 230–231, 233, 555, 597
- proof-of-principle experiments, 13
- proportionality principle, 179, 191, 559, 603
- Protection of Animals Used for Scientific Purposes, 353–354, 370
- Protection of Human Embryos (*Protection de l'Embryon Humain*), 387
- Protocol on Genetic Testing for Medical Purposes, 174
- Public Access to Information and Secrecy Act (*Offentlighets- och sekretesslag*), 293
- Public Health (Medical Experiments on Humans) Regulations, 578–579, 580
- Public Health Service, 124
- Ragnar Söderbergs Foundation (*Ragnar Söderbergs stiftelse*), 298
- Rathenau Instituut, 330, 332
- recombinant DNA technology (rDNA), 489
- Recommendation on Genome Editing Technology in Medical Sciences and Clinical Applications in Japan*, 464–465
- regional authorities (*Comunidades Autónomas*), 364
- regulatory framework methodology, 19
- Religion & Public Life Project, 466
- religion and reproductive medicine, 466–467, 614, 616
- reproductive cell, defined, 573
- reproductive medicine and religion, 466–467
- Reproductive Medicine Ordinance (*Ordonnance sur la procréation médicalement assistée*), 417
- Republic of Singapore Independence Act, 519
- research institution, defined, 527
- Research Involving Human Embryos Act 2002 (RIHE Act), 544, 546–550, 551, 553–562
- residual embryos. *See supernumerary embryos*
- Resolution on Ethical, Scientific and Social Implications of Cloning in Human Health (WHO), 69

- respect for human dignity principle, 76–77, 586  
 right to a private life, 176–177  
 right to health, 185  
 right to information, 160, 161, 174  
 right to life considerations  
     China, 471  
     European Union, 208  
     Germany, 242  
     Japan, 468  
     Korea, 502–504, 514  
     Mexico, 133, 136  
 right to science/rights of science. *See also*  
     human rights framework  
     benefit sharing principle, 35, 74–75  
     European Convention and, 174  
     France and, 383  
     freedom of research, 60, 73–74  
     as human rights, 15, 71–78, 585–587,  
         597–598, 609  
     introduction to, 1, 15, 22  
     Japan and, 444  
     Korea and, 504  
     legal certainty principle, 598–600  
     limits to, 62–64  
     origin and development, 54–57  
     proportionality principle, 179, 191, 559, 603  
     recognition of, 58–61  
     solidarity principle, 75–76  
     Venice Statement, 58  
 Roman law, 314  
 Romano-Germanic (Civil) legal tradition, 599  
 Rome Statute of the International Criminal Court, 184  
*Rules for the Digital Human Park* report, 331–332  
 Rules on Medically Assisted Reproduction, 335  
 Russian Constitution (1918), 132  
     ‘savior siblings,’ 272  
 Schippers, Edith, 328–329, 331  
 Science and Technology Progress Act, 472  
 Science Council of Japan (SCJ), 456, 464–465  
 self-determination principle, 309–311, 332  
 self-regulation in research, 74  
*S.H. and Others v. Austria*, 177–178  
 Shadeed, Farida, 59–60, 338  
 shared competence, 191, 192, 197, 304  
 Singapore human germline modification  
     appropriate consent, 528–530  
     assisted reproduction centres and services, 522–524  
     basic research, 521–522, 589  
     clinical research, 534–537, 538 *f*  
     current and future possibilities, 537–540  
     human tissue regulation, 530–531  
     introduction to, 516–518  
     legal and political overview, 518–521  
     legal and regulatory requirements, 525–534  
     pre-clinical research, 524–525  
     restricted research requirements, 531–534  
 single-guide RNA, 10  
 social rights, 67, 132, 164  
 Social Sciences and Humanities Research Council of Canada (SSHRC), 88  
 soft law  
     bioethics and, 26, 72  
     human rights as, 53  
     importance of, 26–27  
     introduction to, 3  
     norm-making through, 44  
     UNESCO declaration, 33–34  
 solidarity principle, 75–76, 586  
 Somatic Cell Nuclear Transfer (SCNT), 257–259  
 somatic cells  
     cloning regulations, 495  
     defined, 4, 99  
     editing, 14  
     FDA jurisdiction, 110  
     gametes created through reprogramming  
         of, 398  
     gene therapy to correct defects, 165  
     research exclusions, 196  
 South East Asia, human rights protection, 57  
 Spanish Agency for Medicines and Health Products (*Agencia Española de Medicamentos y Productos Sanitarios*), 367, 368  
 Spanish Committee for the Protection of Animals used for scientific purposes (*Comité español para la protección de los animales utilizados con fines científicos - CEPAFIC*), 368  
 Spanish Criminal Code, 375  
 Spanish human germline modification  
     animal regulation research, 371–372  
     assisted reproductive technology, 367,  
         376–378  
     basic research, 372–376  
     clinical application, 372–376

- Spanish human germline modification (cont.)  
 clinical research, 372–376  
 current and future possibilities, 378–379  
 definitions, 368–371  
 general legal framework, 359–364,  
     360 *t*  
 introduction to, 358–359  
 regulatory agencies, 364–368,  
     365–366 *t*  
 regulatory environment for, 368–378
- Special Medical Procedures Act (*Wet op de Bijzondere Medische Verrichtingen*), 320
- sperm (male gamete), 5–7, 6 *f*, 11
- State Administration for Market Regulation (SAMR), 474
- status nascendi*, 316–317
- status potentialis*, 316
- Statute of the International Criminal Court, 340
- Steering Committee on Bioethics (CDBI), 160,  
     167, 169
- Stem Cell Act (*Stammzellgesetz - StZG*),  
     250, 257
- Stem Cell Oversight Committee (SCOC), 90
- stricto sensu*, stem cells, 391
- subsidiarity principle, 275
- supernumerary embryos, 140, 276, 277, 505, 511,  
     590, 605
- supervisory bodies, 201–206
- supranational, defined, 23
- surplus embryos  
     defined, 420  
     destruction of, 437  
     informed consent and, 417, 523  
     legal framework surrounding, 248, 317–319,  
         324–325, 326, 426–427  
     legal provisions for, 328, 413, 416, 417,  
         429–430, 448, 455 *f*  
     legality of cryopreservation, 176  
     moral status of, 86, 329  
     preventing misuse of, 428  
     residual embryos, 505, 511  
     supernumerary embryos, 140, 276, 277, 505,  
         511, 590, 605
- sustainability principle, 528
- Swedish Board of Agriculture (*Jordbruksverket*), 296, 301
- Swedish Data Protection Authority (*Datainspektionen*), 296
- Swedish Gene Technology Advisory Board (*Gentekniknämnden*), 296, 307
- Swedish human germline modification  
 basic research regulations, 299–300  
 clinical applications, 305–306  
 clinical research, 304–305  
 Council of Europe and, 286–289  
 current and future perspectives, 306–308  
 definitions, 294–296  
 funding, 297–299  
 international legal obligations, 282–285  
 introduction to, 281–282  
 legal framework, 282–294  
 national legal framework, 292–294  
 OECD and, 285  
 oversight bodies, 296–297  
 pre-clinical research, 300–304  
 regional legal obligations, 286–292  
 UNESCO and, 284–285  
 United Nations and, 283–284
- Swedish National Council on Medical Ethics (*Statens medicinska råd*), 296,  
     307–308
- Swedish Research Council (*Vetenskapsrådet*), 297
- Swiss Agency for Therapeutic Products (*Swissmedic, Institut suisse des produits thérapeutiques*), 422, 434
- Swiss Confederation (*Schweizerische Eidgenossenschaft/Confédération suisse/Confederazione Svizzera/Confederaziun svizra*), 409
- Swiss Expert Committee for Biosafety (*Commission fédérale d'experts pour la sécurité biologique*), 422
- Swiss Federal Constitution, 587
- Swiss human germline modification  
 basic research, 427–431  
 binding guidelines, 416–419  
 clinical applications, 436–437  
 clinical research, 428, 433–436  
 current and future possibilities, 437  
 definitions, 419–421, 425 *t*  
 funding, 426–427  
 introduction to, 409–410  
 legislative sources, 410–416  
 non-binding guidelines, 419  
 oversight bodies, 421–426  
 pre-clinical research, 431–433  
 regulatory framework, 410–419  
 substantive provisions, 427–437
- Swiss National Advisory Commission on Bioethics (*Commission nationale*)

*Index*

635

- d'éthique dans le domaine de la médecine humaine),* 410, 419
- Swiss Therapeutic Product Act, 434
- Taoism, 467
- Termination of Pregnancy Act (*Wet Afbreking Zwangerschap*), 315, 316
- β-thalassemia blood disorder, 14
- Therapeutic Goods Act (1989), 548
- Tissue and Research Application System (TIARAS), 532
- Torts Liability Law, 471
- trans*-activating CRISPR RNA, 10
- transcription activator-like effector nucleases (TALENs), 400–401
- transgenic embryos, 390–391
- transparency principle, 179
- transplant products, 434
- treating, 24–25, 133–136, 178–179, 381–384, 570–571
- Treaty of Lisbon, 182, 186, 190
- Treaty of the European Union (TEU), 182–183
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), 89, 90, 93, 99
- tripronuclear embryos, 260
- trophectoderm biopsy, 280
- UN Committee on Economic, Social and Cultural Rights (UNCESCR), 382
- UN General Assembly, 26, 32, 55, 69, 411
- UN Human Rights Committee, 600
- UN Human Rights Council, 32, 58–59
- unfertilized egg, defined, 449
- United Kingdom human germline modification
  - basic research regulations, 226–232, 589
  - clinical applications, 231–232
  - clinical research, 230–231, 597
  - current and future possibilities, 232–239
  - definitions, 222–224
  - embryo regulation, 226–228
  - funding, 225–226
  - gamete regulation, 228–229
  - gene editing and eugenics, 235–239
  - Human Fertilisation and Embryology Act, 219–221
  - Human Fertilisation and Embryology Authority, 220–222
  - introduction to, 217
  - legal system overview, 217–219
- mitochondrial donation, 233–239
- oversight bodies, 224–225
- pre-clinical research, 229–230
- regulatory framework, 219–222
- substantive provisions, 226–232
- summary of, 239–240
- United Nations (UN), 32, 283–284, 312
- United Nations Educational, Scientific and Cultural Organization (UNESCO)
  - benefit sharing principle, 35, 74–75
  - bioethics instruments, 72
  - cross-disciplinary discussions, 48
  - declarations, 31, 33–38, 78–79
  - human rights and, 77
  - International Declaration on Human Genetic Data, 38–41
  - introduction to, 21, 31, 32–33
  - Japan and, 444
  - Netherlands and, 312
  - overall assessment of, 43–46
  - respect for human rights, 53
  - solidarity principle, 75–76
  - standard-setting by, 48–49
  - Sweden and, 284–285, 292
- Universal Declaration on Bioethics and Human Rights, 41–43, 45
- Universal Declaration on Human Genome and Human Rights, 31, 33–38, 40, 45, 332
- Venice Statement, 58
- United States (US) Constitution, 104–109
- United States (US) human germline modification
  - basic research, 122–123, 589
  - clinical research regulations, 125
  - current and future perspectives, 126–128
  - definitions, 117–120
  - federal legislation, 105–106 *t*, 109–112
  - federal regulations, 112–113
  - funding, 120–122
  - germline cell editing in human reproduction, 119–120
  - in humans, 109–111
  - introduction to, 103–104
  - in non-humans, 111
  - oversight bodies, 120
  - policies and guidelines, 115–116
  - pre-clinical research regulations, 123–124
  - regulatory framework, 104–116
  - research on gametes and embryos, 117–119
  - state regulations, 113–115, 124 *t*

Cambridge University Press

978-1-108-49987-3 — Human Germline Genome Modification and the Right to Science

Edited by Andrea Boggio , Cesare P. R. Romano , Jessica Almqvist

Index

[More Information](#)

636

*Index*

- United States (US) (cont.)  
substantive provisions, 122–126  
US Constitution, 104–109
- Universal Declaration of Human Rights  
(UDHR), 26, 27, 55, 62, 67, 101  
EU Charter and, 188  
European human germline  
modification, 164  
Mexican human germline modification,  
134  
Netherlands and, 332  
Singapore and, 520
- Universal Declaration on Bioethics  
and Human Rights, 41–43, 45,  
65–66
- Universal Declaration on Human Genome  
and Human Rights, 31, 33–38, 40, 45, 60,  
64, 73
- US Department of Energy, 39
- US National Bioethics Advisory  
Commission, 574
- US Supreme Court, 128
- Vasak, Karel, 75
- Venice Statement on the Right to Enjoy the  
Benefits of Scientific Progress and its  
Applications, 58
- vertical direct effect, 190
- Vienna Convention on the Law of Treaties,  
288, 295–296, 342
- Vienna Declaration and Programme of  
Action, 520
- Vienna World Conference on Human  
Rights, 58
- Vinnova, 297
- vitrification, 212, 279
- Vogel, Jörg, 10
- Waldron, Jeremy, 71
- Wallenberg Foundations, 297
- Warnock, Mary (Warnock Report), 219, 239
- Weltethik*, 2
- Working Party on Biotechnology,  
Nanotechnology and Converging  
Technologies, 49
- World Health Organization (WHO), 32,  
46–49, 69
- World Heritage sites, 33
- World Medical Association, 43
- World Treaty Organization (WTO), 186
- xenogeneic gene therapy, 321, 494, 495
- Zhang, Feng, 10
- Zhang, John, 129, 151
- Zhou Qi, 497
- zinc-finger nuclease (ZFN), 400
- Zionist narratives in germline  
modification, 569
- zygotes, 5–7, 6 f, 12, 256, 259, 260, 390