Abelson, J., 254-255	Bioethics Advisory Body, 284–285
Academia Platonica (Neoplatonic Florentine Academy),	future of health research regulation and, 222-224
218	health policy advice and, 215–216
Academy of Medical Sciences (AMS, UK), 358-359	advocates, public engagement with, 117
goals and mission of, 3–5	affected public
access to healthcare	classification of, 117
benefit sharing and, 154–156	data-intensive health research and, 118–119
orphan drug research and, 62	AFIRRM oversight model
solidarity and, 59–61	Big Data research and, 259–260
accountability	future challenges for, 265
governance and, 123–124	implementation of, 260–263
institutional decision-making and, 211	agency, automated healthcare regulation and, 268–269,
medical device failure and, 163–164	
non-traditional medicine and, 299	²⁷³ aggregated data, individual discrimination and
actor-networks	stigmatisation and, 242
Big Data research and, 257–259	aggregative theories, public interest and, 240
global health emergency guidelines and, 316–317	
adaptive governance principles	Alder Hoverson retention counted
	Alder Hey organ retention scandal, 212–213
Big Data research and, 257–265	Aldrick, Philip, 270
evolution of, 257–259	Allen, A. L., 75
structures and processes in, 263–265	All Post Politicative, 103–104
visibility, 264–265	All Party Parliamentary Group on Surgical Mesh
adaptivity, in health research governance, 259–260	Implants, 162–165
Addgene company, 142–144	alternative medicine
Additional Protocol (2005), 105–106	history and evolution of, 296–298
add-on services in reproductive medicine	research regulation of, 296–305
ethical issues with, 375–377	uncertainty of knowledges and practices and,
patient choice dynamic in, 380	303-304
regulation of, 377–379	as in vitro add-on, 375–377
risks of, 380–381	Althusser, L., 251–252
advanced therapies	animal research
Argentinian regulation of, 324–331	embryo research and, 356-364
regenerative medicine and, 324	human material in animals and, 358–359
advertising of innovative intervention, oversight of,	interspecies research and, 356-364
292-295	in neuroscience, 310–312
Advisory Commission on Regenerative Medicine and	regulation and oversight of, 359–362
Cellular Therapies (Argentina), 325–326	shifting regulatory boundaries in, 362–363
advisory committees	vulnerability issues in regulation of, 363–364
adaptive governance and, 263–265	Animals Containing Human Material (Academy of
Advisory Commission on Regenerative Medicine and	Medical Sciences), 358–359
Cellular Therapies (Argentina), 325–326	Annas, George, 352
in bioethics, 220–222	Ansell, C., 124–125, 128–129

anticipatory knowledge	Ballantyne, A., 23–24
emerging science and technology oversight and,	Barbazza, E., 123–124
397-399	Barber Surgeons of Edinburgh, 218
in global health emergency research, 322-323	Barsdorf, Nicola, 51–52
participatory health governance and, 285-286	Bea, Sara, 356-364
anti-science politics	Beauchamp, T. L., 39, 169-170
health policy formation and, 216–218	beliefs, facts and, health policy and, 217
health research regulation and, 222	Belmont Report (1979), 7–8
traditional and non-conventional medicine and,	autonomy guidelines in, 27–29
301–302	social values, 46–47
Argentina	vulnerability guidelines in, 17–18, 33
agricultural strength and health fragmentation in,	beneficence
324–325	autonomy guidelines and, 27–29
cell therapy research governance in, 325–326	informed consent and, 104–105
construction of research governance in, 328–329	proportionality and, 39
current health legal/regulatory framework in, 330–331	benefit analysis
health research regulation in, 324–331	risk-benefit analysis and, 132–134
Arnstein, S. R., 114, 116	social value and, 53–54
ArthritisPower network, 126–127	benefit evaluation, social value and, 54
artificial intelligence (AI)	benefits, defined, 149–151
best practices guidelines and, 175	benefit sharing
co-dependent human-technology embodiment and,	challenges to, 154–156
383–384	common heritage argument for, 150–151
continuous learning, research-therapy divide and,	data access agreements and, 191
277–286	descriptive argument for, 150–151
existence conditions and, 272	governance frameworks for, 151–153
as medical device, 277–286	health research regulation and, 148–157
regulatory responsibility and, 271–274	history and rationale for, 149–151
voluntariness in, 107–108	procedures for, 153–154
assisted reproduction, human germline research and,	benefit treatment, social value and, 54
348–350	Bennet, C. J., 241–243
Association of University Technology Managers, 142–143	Bennett, Alan, 145–146
Australia	Beresford, P., 121–123
cloning research in, 347–348	Berger, M., 251–252
evidence-informed health policy in, 216–218	best practices
Australian Academy of Learned Societies, 220	displacement of traditional medicine in, 299–301
authority. See governance	examples, 192–195
autologous mesenchymal stem cell case study, clinical	health research regulation, 173-175
innovation oversight and, 290–292	<i>in vitr</i> o fertilisation and, 374
automated healthcare regulation	Big Data research. See also data-driven research
balance of interests in, 267–268	adaptive governance in regulation of, 257–265
moral development and agency and, 273–274	analytical techniques in, 257–259
regulatory responsibility and, 271–274	deliberative participatory practices and, 125-126
self-development and agency issues and, 273	effective governance of, 260–263
stewardship responsibilities in, 268–269	participatory governance of research and, 121
autonomy	patient and public involvement in, 121–123
artificial intelligence and, 271	regulatory scholarship on, 257-259
disclosure of research findings and, 233-234	structures and processes in, 263-265
health research ethics guidelines, 27-29	systemic oversight framework for, 259–260
health research regulation and, 13-15	uncertainty in, 262–263
individualistic conceptions of, 29-30	voluntariness in, 107–108
informed consent and, 104-105, 108-109	biobanks
non-invasive prenatal testing and, 267–268	disclosure of research findings and role of, 233
privacy and, 246	regulation of, 6–7
relational conceptions of, 27–36	Biobricks Foundation, 142–143
availability heuristic, risk-benefit analysis and, 134–135	bioethics
Aviesan initiative, 103–104	advisory committees, 220–222, 284–285
/ / 1	French law on, 264
Baier, A., 84–85	medical device failure and, 162–165
balance of interests	Bioethics (journal), social value debate in, 51–52
automated healthcare regulation and, 272	biosecurity regulations, in Argentina, 324–325
health research regulation and, 268	blaming, medical device failure and, 163–164
nealth lesearch regulation and, 200	

Blasimme, Alessandro, 217	citizens
blinded trials, evidence-based medicine and, 298–299	identity interests in health research regulation and, 397–399
Blueprint for Dynamic Oversight of Emerging Science and Technologies, 397–399	public engagement with, 117 citizens' forums, participatory health systems governance
bottom-up participation	and, 125–126
participatory health governance and, 124–125	clarity of purpose
principles-based regulation and, 259	participatory governance and, 128
Boyd, Ian, 217	public engagement and, 118–119
Bracken-Roche, D., 20–22	clinical decision support (CDS) software
Bradwell, P., 118	AI/ML software, 278–281
Brandeis, S. D., 75	research-therapy divide and, 277-278
Brassington, Iain, 14–15	clinical equipoise, component analysis and, 135-136
Braun, K., 112–113, 117	clinical research
Breakthrough Device designation (FDA), 278–281	innovation in marketplace and, 287–295
Briggs (Lord Justice), 245–246	social value in, 51–52
bright line ideology, human germline research and,	ClinicalStudyDataRequest, 192–195
349-350	clinical trials regulatory paradigm
broad consent principle, 103–104	economics of clinical guidelines and, 301–302
Broad Institute, 143–146 Brownsword, Roger, 266–274	evidence-based medicine and, 298–299 medical device trials, 279–281
Bryant, R., 159–160	pay-to-participate clinical trials and, 290–292
burdened populations, solidarity in health research for,	regulatory research and, 5–9
59–61	social value and, 52
Burgess, Michael M., 14, 69-70, 248-256	traditional and alternative medicines and, 299–301
Bush, George W., 216–218, 222–223	clinical utility of information, disclosure of research
, , , ,	findings based on, 231
Caldicott Principles, 167–168	Clinton, Bill, 221–222
Caldicott Report, 248–249	Cloatre, Emilie, 296–305
Canada	cloning
autonomy guidelines in, 27–29	ethical review of, 221–222, 335–336
ethics review in, 200–201	international health policy frameworks on, 340-341
genetics research regulation in, 337–340	legislation involving, 347–348
Canadian Academy of Engineering, 219–220	terminology and definitions of, 347–348
Canadian Academy of Health Sciences, 219–220	clustered regularly interspersed palindromic repeats
Canadian Tri-Council, 19–20	(CRISPR) patents, 143–146
capacity perspective	ethical issues in, 267–268
cooperative tool for capacity building, 153 participatory governance and, 127	human gene editing regulation, 335–336 human germline research and, 345–346
vulnerability and, 24–25	co-dependent human-technology embodiment
in vulnerability research, 20–22	enhancement innovations and, 383–384
Care Act 2014 (UK), 182–184	identity and integrity issues in, 384–386
care.data scheme (UK), 118–119, 122–123, 248–249	coercive isomorphism, 213
Carroll, T., 159–160	cognitive bias, risk-benefit analysis and, 134–135
Carter, P., 69–70	cognitive disability, relational autonomy and, 34-36
Categorical Imperative (Kant), 78-79	Colbert, Jean-Baptiste, 218
cell therapy research, Argentinian governance of,	Coleman, Carl H., 14, 130–138
325–326	Coleman, S., 119–120
centralised supervision and coordination, participatory	collaborative licensing, 144–145
governance and, 128–129	patent regulation and, 144–145
Chambers, Simone, 252–253	collaborative research
Chan, Sarah, 344–355	Argentinian-University of Edinburgh research
Charities Commission (UK), 301–302	governance collaboration, 325–326
children, relational autonomy of, 34–36 Childress, J. F., 39, 169–170	Big Data research and, 257–259 categories of, 82–83
chimeric organisms	clinical innovation oversight and, 289–290
interspecies research and, 357–358	data sharing collaborations, trust in, 87–89
research guidelines involving, 360	human germline research, 350–352
shifting regulatory boundaries in research on, 362–363	in interspecies research, 363–364
vulnerability issues in research on, 363–364	in neuroscience, 308
China, human gene editing in, 337–341, 351, 353	participatory health governance and, 124–125, 285–286
Chuong, Kim H., 121–129	patent rights and, 141
circumstances, vulnerability and, 23-24	trust and, 81–82

n e cara	
collective interests	patient and public involvement and, 121–123
health research regulation and, 7, 14	in vitro fertilisation and, 375–377
public expertise mobilisation and, 253–255 commercialisation of research	consumers, public engagement with, 117 context
benefit sharing and, 154–156	
data access and, 192–195	in adaptive governance, 262 in global health emergency guidelines, 316–317
group vulnerability and, 97	health research regulation and role of, 275–276
health research regulation and, 7	in human germline research, 348–350
common good	of institutions, 207–208
automated health regulation and, 268–269	proportionality and, 37–38
privacy and, 78	rule-based and practice-based health regulation and,
common heritage argument for benefit sharing, 150–151	172–173
common interest theory	Contreras, Jorge, 141–142
group privacy and, 241–243	controlled access, data-driven research, 190-191
public interest and, 240–241	Convention for the Protection of Individuals with regard
Common Rule. See Federal Policy for the Protection of	to Automatic Processing of Personal Data (Council
Human Subjects (Common Rule, US)	of Europe), 243–245
common value theory, 240-241	Convention on Biological Diversity (CBD) (1992), 149
communitarian approach	cooperative practice, human germline research, 350-352
automated health regulation and, 268–269	cooperative tool for capacity building, benefit sharing and,
benefit sharing, 153–154	153
global health emergencies and, 319–320	co-optation, participatory governance and, 127
informed consent and, 108-109	costs of health research, solidarity on, 59-61
institutional decision-making and, 210	Council for International Organizations of Medical
risk-benefit analysis and, 138	Sciences (CIOMS), 18–20
community advisory boards, participatory health systems	benefit sharing guidelines and, 151–153
governance and, 125–126	global health emergency guidelines and, 316–317,
community values. See social value	320-322
Compangie du Gai Sçavoir, 218	guidelines, 47–49
comparative effectiveness research, minimal risk principle	health practices guidelines, 173-175
and, 199–200	informed consent and, 105–106, 200–201
competency	reasonable availability model of, 152–153
autonomy and, 31	risk-benefit analysis guidelines, 137
informed consent and, 106	social value in health research regulation and, 46-47,
competition, patent regulation and, 140–141	49–51, 199–200
complementarity, governance structures and, 264	on third-party risks, 130–132
complementary and alternative medicine (CAM). See	Council of Canadian Academies (CCA), 219–220
alternative medicine	Council of Europe
component analysis, risk-benefit analysis using, 135–136	data protection law and, 243–245
confidentiality	genetics research regulation and, 340–341
in Big Data research, 123	informed consent and, 105–106
duty of confidence and, 245–246	Council on Health Research for Development (COHJRED), 85–86
in neuroscience research, 308 privacy and, 79	COVID-19 pandemic
public interest guidelines and, 67–70	health practices guidelines and, 173–175
Confidentiality Advisory Group (CAG) (HRA, UK),	research exceptionalism and, 318–320
67–70, 212–213	credibility tactics, participatory governance and, 127
Confronting the Liminal Spaces of Health Research	Crick, Bernard, 96
Regulation project, 3	criminal law
consent. See informed consent	genetics research regulation and, 337–340
consent or anonymise regulation model, 4	human embryo research and, 358–359
consent to contact policies, 201–202	physical integrity and identity in, 385–386
consultation, public engagement through, 115–116	crisis research
consumerist approach	global health emergency guidelines and,
autologous mesenchymal stem cell case, 290–292	316–317
clinical innovation and intervention and, 289	human gene editing regulation and, 335–336
innovation oversight and limits of, 292-295	risk assessment in, 199–200
medical device regulation and, 386–389	social value of, 317–318
misinformation about reproductive medicine and, 379	criticism, of research ethics, 200-201
non-traditional medicine and, 299	cross-border data sharing, in Big Data research, 123

cultural issues	neuroscience research and, 310-312
disclosure of research findings and, 233-234	research governance and, 167-169
interspecies biomedical research regulations and,	Data Protection Regulation 2016/679 (GDPR) (EU),
362–363	75-77
medical device failure and, 163–164	data sharing
privacy and, 241–243	governance frameworks for, 187–188
culturally significant information, protection of, 242n.23	informed consent and, 105–108
Cunningham-Burley, Sarah, 14, 112–129	in neuroscience research, 308
Curran, William, 181–182	participatory learning in regulatory governance and,
cyborg perspective, enhancement innovations and,	284–285
383	privacy protection and, 73-74
	public engagement and, 116
D'Amour, D., 83	trustworthiness in, 87–89
data access	Datta, A. K., 376
agreements, 191	Davidson, S., 115–116
centralised access, genotype/phenotype database, 193	Dawson, A., 91, 97
challenges and future directions, 195-196	decision-making
governance of, 187–196	accountability and risk aversion issues in, 211
harmonisation of policies and processes in, 196	central objectives in, 208-209
independent, interdisciplinary access, 193–194	disclosure of research findings for purposes of, 231
multi-study access, EGA, 192	in global crisis emergencies, 317–318
oversight coordination, 195–196	health research regulation and, 99–101
producers' rights and interests and, 194	inclusion and equality in, 127
resources, effectiveness and efficiency in, 195	institutional influences on, 205–214
tiered access, International Cancer Genome	institutional structure and composition and, 209–211
Consortium/25K Initiative, 193	path dependencies and historical influences in, 212-213
transparency and reflexive governance, 194-195	privacy in, 75–77
Data Access Committees (DACs), 188–189	public interest and, 240–241
adaptive governance and, 263–265	public vs. private duties in, 211
controlled vs. open access data and, 190–191	social value and, 54
monitoring of data use and, 191–192	Declaration of Alma Ata (1978), 299–301
multi-study access, EGA, 192	Declaration of Chiang Mai, 300
oversight coordination, 195–196	Declaration of Helsinki
resources, effectiveness and efficiency in, 195	autonomy guidelines in, 27–29
data-driven research. See also Big Data research	benefit sharing in, 151–152
automated healthcare regulation and, 270	group access to research participation in, 172-173
controlled vs. open access data, 190–191	informed consent in, 105–107
current and future trends in, 198–199	post-trial obligations in, 152–153
disclosure of research findings and, 231–234	social value in, 46–47, 52–53
duty of confidence and privacy of, 245–246 EGA and, 192	vulnerability guidelines in, 18, 90–91 Declaration of Taipei on Ethical Considerations regarding
group privacy protections in, 243–245	Health Databases and Biobanks, 103–104
health research regulation and, 7–8	De Cleen, B., 251–252
informed consent and, 103–104	deep learning, medical devices and, 281
integrity and ethics protections, 188–189	deferred consent, 107–108
monitoring of data use and, 191–192	deficit model of public understanding, 112–113
in neuroscience, 308	Degeling, C, 117
privacy rights and, 75–77	deliberative practices
producer rights and interests in, 189–190	diversity theory and, 252–253
public engagement in, 116, 118–119	participatory health governance and, 124–126
public perceptions of, 217	public expertise mobilisation and, 248-256
relationality in, 59-61	Delphi policy study, 397–399
rules-based vs. practice-based approaches in regulation	democratic approach, patient and public involvement
of, 170–171	and, 121–123
subject rights and, 188–189	De Novo premarket review process (FDA), 278–281
trustworthiness of research governance and, 248-249	deontological theory, privacy and, 78-79
value and social values in, 394–396	descriptive argument for benefit sharing, 150–151
Data Protection Act 2018 (DPA, UK)	diabetic retinopathy, software as medical device for
enactment of, 69	diagnosis of, 278–281
HRR community lobbying and, 71–72	dialogue, public engagement and role of, 119–120

digital consent technology, 110 DiMaggio, P., 210	Epstein, S., 127 equality
direct benefit	diversity theory and, 252–253
in RCTs, 133	non-invasive prenatal testing and, 267–268
social value as, 49–51, 53–54	Ethical and Policy Issues in International Research
disaster research	(National Bioethics Advisory Commission), 151–152
global health emergency guidelines and, 316-317	ethical issues in health research
public engagement in, 319–320	autonomy guidelines, 27–29
risk assessment in, 199–200	benefit sharing and, 151–153
social value of, 317–318	in Big Data research, 123
disclosure of research findings	bioethics advisory committees, 220-222
criteria for disclosure, 231	chimeric research oversight and guidelines and,
ethical issues linked to, 229–238	359–362
guidelines and recommendations about, 230–231	data protections and, 188–189
informed consent and, 107	disclosure of research findings and, 229–238
narrative function of results, 235–236	enhancement innovations and, 383
participant's interests and, 234–235	ethical approvals process and, 307–309
physical integrity and identity and, 385-386	ethical licensing, 145–146
discourse ethics, privacy and, 79–80	evaluation of regulatory changes and, 202–203
discrimination, in vulnerability research, 20–22	exemption for types of research, 200–201
distributed responsibility, governance and, 123–124	future directions in, 182–185
diversity, public expertise mobilisation and, 253–255	genome-editing and, 267–268
Dixon-Woods, Mary, 179–180	global health emergencies and, 315–323
Dove, Edward S., 30–31, 34–35, 99–101	health policy formation and, 217–218
downstream research, national policy frameworks for	human-technology embodiment and, 384–386
genetics and, 337–340	incidental findings and, 229–230, 309–310
duress, informed consent and, 107–108	interspecies research, 357–358
duty of care, disclosure of research findings and, 233	learned and academic societies' influence on, 220
duty to participate principal, disclosure of research	learning healthcare systems and, 391–394
findings and, 234–235	Learning Health Research Regulation System and,
Dworkin, Gerald, 29–30	394–396
Dworkin, Ronald, 272 dynamic consent, 110, 248–249	net risk test and, 136–137
dynamic consent, no, 240–249	neuroscience and, 304, 310–312 participants' interests and needs and, 234–235
Ebola outbreak	placebo controls in evidence-based medicine and, 299
experimental interventions and vulnerability in, 92–93	politics and, 92–93
randomized controlled clinical trials in, 132–134	prenatal testing and, 267–268
unregistered interventions in, 319	process simplification and harmonisation and, 200–201
Eckstein, Lisa, 231	protection of culture and, 242n.23
EC Regulation 141/2000, 62–63	randomized controlled clinical trial and, 132–134
Editas company, 143–146	regulatory design and, 182–184
Edwards, Robert, 373–374	regulatory process and, 178–180
effectiveness of medical devices, marginalised focus on,	relational autonomy and, 30–33
162–165	reproductive medicine and, 375-377
efficacy	research integrity and, 188-189
social value and estimation of, 53-54	review as regulatory process in, 178-180
in traditional medicine, research on, 299–301	review of, 177–186
egalitarian diversity and inclusiveness, 252-253	risk identification and, 130–132
Egelie, Knut, 143–144	standardisation of review processes, 182-184
Eisenberg, Rebecca, 141	vulnerability guidelines, 17–18
electronic signatures, informed consent and, 110	in vulnerability research, 20–22
Emanuel, E., 46–47, 180–181	ethical licensing, 145–146
empowerment	Ethics Advisory Board (US Dept. of Health, Education
participatory health governance and, 124–125	and Welfare), 366–368
public engagement and, 116	Ethics Guidelines for Trustworthy AI (EC), 271
enforceable norms, solidarity and, 58–59	Ethics Review Committee (WHO), 320–322
engagement, proportionality and, 44–45	The Ethics of Research Related to Healthcare in
enhancement innovations, development of, 383–384	Developing Countries (Nuffield Council on
epistemic injustice, relational autonomy and, 35–36	Bioethics), 151–152
epistemic integration, medical device failure and, 165–166	EU Directive 95/46/EC, 167–168, 171

EU Directive 2001/20/EC, 200–201	experts and expertise
EU Directive 2004/24/EC, 300–301	evidence-based medicine and, 298–299
EU Regulation 2017/745, 382-383	future of health research regulation and, 222–224
EU Regulation 2017/746, 382-383	health policy advice and, 215–224
Europe, health research regulation in, 1	learned and academic societies, 218–220
European Commission	mobilisation in health research regulation of, 248–256
benefit sharing guidelines, 154–156	representation and inclusiveness issues in, 251–253
Guidelines for Trustworthy AI, 175	explicability, artificial intelligence and, 271
risk-benefit analysis guidelines, 137	exploitation
European Convention on Human Rights (ECHR), 74–75,	group vulnerability to, 93–95
245–246	vulnerability in health research and, 91–92
European Court of Human Rights, 75, 245–246	externalist perspective, relational autonomy and, 31
European Directive on Traditional Herbal Medicine	external validity, in RCTs, 133
Products (THMPD), 297–298	
European General Data Protection Regulation, 105-106	facilitative leadership
European Genome-phenome Archive (EGA), 192	participatory governance and, 128–129
European Group on Ethics in Science and New	proportionality and, 42–43
Technologies to the European Commission, 151–152	failure in health research
European Medicines Agency (EMA)	expectations and, 159–162
advanced therapies regulation and, 324	history of, 158
Argentinian regulatory harmonisation with, 328–329	legal interpretations and constructions of, 161–162
regulatory science and, 394	risk assessment and prevention, 158–166
reproductive medicine add-on services regulation and,	systemic causes of harm and, 162–165
377-379	values failure, 395
European Open Science Cloud (EOSC), 7–8	failure of care data, public interest in HRR and, 69–70
European Union (EU)	fair benefits model, benefit sharing and, 153
Data Protection Regulation 2016/679 (GDPR), 75–77	Fairmichael, F., 395
data protection regulation in, 67–70, 167–169, 171,	fairness
243-245	artificial intelligence and, 271
medical device approvals by, 160–161	non-invasive prenatal testing and, 267-268
medical device regulation in, 386–389	fair participation, global health emergency research and,
regulatory regime in, 14, 56	318–320
traditional and herbal medicine regulation in, 300–301	Federal Advisory Committee Act (US), 220–221
European Union Clinical Trials Directive, 6–7, 130–132,	Federal Policy for the Protection of Human Subjects
199–200, 340–341, 347–348	(Common Rule, US), 46–47, 182–184, 199–201, 223
evidence-based healthcare. See also non-evidence-based	
· ·	Federal Regulations on Research With Human
medicine	Participants (US), 130–132
Big Data research and, 257–259	federal science advisor, 222–223
economics of clinical guidelines and, 301–302	feedback policies
health policy formation and, 216–218	disclosure of research findings and, 231–234
learned and academic societies' evaluation of, 220	ethical responsibilities in, 236–238
norms of evidence and, 303–304	participants' interest and, 234–235
placebo controls and, 298–299	Feeney, Oliver, 143–144
risk-benefit analysis and ethics review and, 137-138	fertility medicine. See in vitro fertilisation; reproductive
traditional and alternative medicines and, 296-305	medicine
excessive risk, risk-benefit analysis and, 136-137	fictional man paradigm, public interest litigation and, 69
exclusion criteria	final cause/objective, of institutional decision-making
proportionality and, 40	body, 208–209
in vulnerability research, 20–22	Financial Services Authority (FSA, UK), 257-259
existence conditions, automated healthcare regulation	Fineman, M. A., 19
and, 272	first-order proportionality, defined, 37–38
expectations in health research	Fish, Stanley, 210
Argentinian regulation of, 327–328	510(k) pathway, medical device trials, 279–281
failure and, 159–162	Flear, Mark, 158–166
neuroscience and, 308–309	flexibility, in health research governance, 259–260
reproductive immunology mythology and, 376–377	Foley, T., 395
reproductive medicine and role of, 374	follow-on research, non-exclusive research tool licensing
experimental interventions	and, 142–143
global health emergencies and, 318–320	Food, Drug and Cosmetic Act (US), medical device
vulnerability and, 92–93	definition in, 278–281

Food and Drug Administration (FDA, US) advanced therapies regulation and, 324 Argentian regulatory harmonisation with, 328–329 clinical decision support software and, 277–278 IDx-DR AI diagnostic system approval by, 278–281 medical device approvals and, 160–161 minimal risk principle in regulations and, 199–200 politics and, 216–218 premarket review proposal, 282–283 risk-based medical device classification, 279 risk-benefit analysis in, 134	Argentinian genetically modified crops, 324–325 co-dependent human-technology embodiment and, 383–384 cultural protections and, 242n.23 group vulnerability and, 95–97 harmonization of regulations on, 341–343 human gene editing, 335–343 interspecies research, 356–364 risk identification in, 130–132 genomic initiatives, 103–104 co-dependent human-technology embodiment and,
waivers of consent and, 200–201	383-384
foresighting, anticipatory knowledge and, 285–286	disclosure of research findings and, 231–234
forms of engagement, health regulation research and, 14	ethical licensing for, 145–146
for-profit health research, benefit sharing and, 154-156	human genome definitions in, 346-348
Foucault, Michel, 163, 383	normative systems regulation, 336-341
foundational research tools, non-exclusive research tool	participants' interest in, 234–235
licensing, 142–143	probabilistic vs. predictive results in, 232-233
Four Principles, 169–170	regulation of, 267–268
14-day rule	Genomics England initiative, 6, 103–104
embryo research and, 365-372	Genotype/Phenotype database (dbGaP), 193
evolution of, 366–368	Ghinea, Narcyz, 287–295
grounds for revisiting, 370–372	Giddens, Anthony, 257
in HFE ACT, 367	Global Alliance for Genomics and Health, 103-104, 195
special status principle and, 367–370	Global Code of Conduct for Research in Resource-Poor
theoretical basis for, 368-370	Settings, 152
Franklin, Benjamin, 220–221	global health emergency research (GHER)
free riders argument, enforceability of solidarity and,	data sharing in, 87–89
58–59	emergency context in, 316–317
Frewer, L. J., 114	future issues and challenges in, 322-323
Fricker, Miranda, 90nn.1–2	governance and oversight guidelines and practices,
Friedman, Marilyn, 31	320–322
Friesen, Phoebe, 202, 299	justification for, 318–320
Fukushima disaster, emergency healthcare and, 319–320	social value and ethics in, 51–52
functional complementarity, 264	trustworthy institutions in, 81–89
Fung, A., 124–125, 127–129	global non-autonomy, situational vulnerability and, 33 Glover, Anne (Dr.), 222–223
Gallagher, N., 118	Good Clinical Practice (WHO), 152
Ganguli-Mitra, Agomoni, 92–93, 275–276, 315–323	Good Clinical Practice Guidelines (ICH), 105–106,
Gash, A., 124–125, 128–129	173–175
gastrulation, human embryo research and, 368–370	good will, trust and, 84
Gelsinger, Jesse, 222	Google Deep Minds' health data processing project,
gender equity	118–119
autonomy and, 31	Gotze, J., 119–120
benefit sharing and marginalisation of, 152–156	Governance Arrangements for Research Ethics
medical device failure and marginalisation of, 162–165	Committees (GafREC), 179
physical integrity and identity and, 385–386	governance of research. See also participatory governance
reproductive medicine and, 354–355	adaptive governance, Big Data research regulation,
Gene Editing Summits, 335–336	257–265
gene-editing techniques, balancing of interests and,	Argentinian cell therapy research, 325–326
267–268	benefit sharing and, 151–153
General Data Protection Regulation (GDPR, EU), 67–70,	data governance frameworks, 59–61, 187–196
167–169, 171, 243–245	data subject rights, 188–189
procedural complementarity in, 264	defined, 257
General Guidelines for the Research of Non-Conventional	ethical approvals process and, 307-309
Medicines (WHO), 299–301	genomics research, normative framework in, 336–341
General Medical Council (GMC), 377–381	global health emergency research, 320–322
general public, classification of, 117	health research regulation and, 1–2, 14
gene therapy research, 222	implementation of effective models, 260–263
genetics research	inefficiencies in, 202

innovation oversight and, 292–295	disclosure of research findings and, 231–234
institutional dimensions of health research and, 205-214	failure of care data, 69–70
international health policy frameworks and, 340-341	regulatory regimes vs., 6
learned and academic societies as experts for, 218–220	research and, 6
national policy frameworks for genetics and, 337–340	research-therapy divide in technology governance and
in neuroscience, 304, 310–312	277–286
patent regulation and, 141–142	resistance to participatory governance in, 125
principles-based regulation and, 257–259	health research, value-driving paradigm for, 394–396
privacy and, 77–80	Health Research Authority (HRA) (UK), 205
public engagement and, 119–120	Confidentiality Advisory Group (CAG), 212–213 institutional overview of, 208–209
rule, principles and guidance-based initiatives, 167–176	
structures and processes, 263–265 trustworthiness of, 248–249	Proportionate Review Service, 182–184 public interest guidelines, 67–70
group-level solidarity, 58–59	health research regulation
health research and, 59–61	Argentinian advanced therapies research, 324–331
groups	automated healthcare, 266–274
common interest and privacy of, 241–243	benefit sharing and, 148–157
legal privacy protection for, 243–246	best practices and, 173–175
risk identification in research on, 130–132	clinical innovation and barrier of, 287–290
vulnerability in health research for, 93-95	countervailing trends inf, 201–202
Guerrini, Christi, 145–146	current and future trends in, 197–203
Guideline 20 (CIOMS), 320–322	design innovations in, 182–184
Guidelines for Human Experimentation (Germany), 17–18	disclosure of findings, protocols for, 229-238
Guidelines for Methodologies on Research and	evaluation of changes to, 202-203
Evaluation of Traditional Medicine (WHO),	expert and advisory advice in, 215–224, 248–256
297–298	failure in, 158–166
Guidelines for Trustworthy AI (European Commission),	future issues for, 222–224
175	human embryo research, 365–372
Gusterson, Hugh, 285–286	human gene editing, 335–343
	human germline research, 350–352
H3Africa benefit sharing initiative, 153	institutional influence in, 205–214
Haas, Nayeli Urquiza, 296–305	interspecies research and, 356–364
Habets, M., 53–54	key concepts in, 13–15
Hacking, Ian, 285–286	learned and academic societies' influence on, 218–220
Hancock, Matt, 271	of medical devices, 277–286, 382–390
harm	in neuroscience research, 304
artificial intelligence and prevention of, 271	non-evidence based reproductive medicine and,
automated healthcare and, 266–274 in Big Data research, 123	373–381 patent regulation, 139–147
expectations and failure involving, 160–162	policy advice sources in, 215–224
future harm, prevention of, 158–166	privacy and public interest in, 239–247
in global crisis emergencies, 317–318	problems and issues with, 1–3
group vulnerability and, 97	process simplification and harmonisation and, 200–201
proportionality of, 39–40	public interest appeals in, 66–67
risk identification and, 130–132	recent changes in, 3-5
social value and, 54	responsive regulation development, 333-334
systemic causes of, 162–165	review as regulatory process and, 178–180
Harmon, Shawn H. E., 382-390	risk-benefit analysis in, 130–138
harmonization of regulation, genetics research and,	rule, principles and guidance-based initiatives, 167–176
341-343	shared practices in, 59-61
Harper, Steven, 216–218	software as medical device and, 277-286
Hastings Center Report, social value in, 51–52	solidarity in, 56–64
Havasupai tribe, 138	supplementary guidance and, 173–175
health research on, 130–132	traditional and non-conventional medicines, 296-305
protection for, 242n.23	visibility of, 264–265
Hawley, K. J., 88n.45	health research systems
Health and Care Act 2012 (UK), 301–302	informed consent and evolution of, 103-104
healthcare	participatory governance in, 123–126
access to, 59-62, 154-156	health systems research, social value in, 51–52
automated healthcare, 266–274	He Jiankui, 345–346, 351, 354–355

Hold V D avo	harmonization of regulations on au au
Held, V. P., 240 Heller, Michael, 141	harmonization of regulations on, 341–343
·	international health policy frameworks and, 340–341
hematopoietic progenitor cells (HPC), Argentinian regulation of research on, 326–328	national policy frameworks for, 337–340 normative regulatory framework for, 336–341
Hendl, Tereza, 287–295	overview, 345–346
Heneghan, Carl J., 160–161	regulation, responsibility and cooperative research in,
High Level Expert Group (HLEG), 7–8	
Hilgartner, Stephen, 139	350–352 terminology and definitions, 346–348
Hinterberger, Amy, 356–364	humanitarian crises
Hirsch Index, 47–49	health care regulation and, 199
historical influences, institutional decision-making and,	research ethics in, 315–323
212–213	social value of research in, 317–318
Ho, Calvin W. L., 277–286	humanity, threshold of
Hodgson, G. M., 207–208	enhancement innovations and, 383
Hoffmann (Lord), 245–246	human embryo research and, 370–372
homeopathic practices, guidelines for, 301–302	Human Medicines Regulations 2012 (UK), 377–379
homogeneity	Human Reproductive Cloning Act (2001, US), 347–348
of institutions, 213	human rights
vulnerability and, 33–34	automated healthcare regulation and, 270
Horizon Programme, 152	disclosure of research findings and, 233–234
human assemblage ideology, human-technology	duty of confidence and, 246
embodiment and, 384–386	genetics research regulation and, 340–341
human-centric governance, automated healthcare	human embryo research and, 366–368
regulation and, 272	identity as human right, 390n.49
human challenge trials, debate over, 318–320	privacy as, 74–75
human embryo research	Human Rights Act 1998 (UK), 245–246
admixed embryos, 358–359	Human Tissue Act 2004, 212–213
evolution of regulatory framework for, 366–368	Human Tissue Authority, 205
14-day rule and, 365–366	human values, health research regulation and, 7
interspecies research and, 356-364	Hunt, Matthew, 315–323
regulation of research on, 365-372	Hurricane Katrina, distrust of government response in,
revisiting 14-day rule in, 370–372	319–320
special status principle in, 367-368	Hurst, S. A., 21–22, 25
terminology and definitions of, 347–348	Hutter, B., 161–162
threshold of humanity principle and, 370-372	hypothesis-driven trials, social value of, 54
Human Fertilisation and Embryology Act and Authority,	Hyun, Insoo, 361
HFEA (1990, UK)	
Code of Practice, 378–379	idem principle of identity, 384-386
data protection regulation in, 171	identity
human embryo research and, 358-359, 365-368	disclosure of research findings and, 229–238
human germline research and, 346–350	human-technology embodiment and, 384-386
reproductive immunology warning and, 376-377	narrative as, health research participation and, 235-236
reproductive medicine add-on services and, 378-379	right to, 390n.49
revisions to, 368–370	IDx-DR AI diagnostic system, risk assessment and market
in vitro fertilisation licensing and, 374	approval, 278–284
human gene editing	IMDRF (International Medical Device Regulators
harmonization of regulations on, 341-343	Forum), software as medical device regulations and,
international health policy frameworks and, 340–341	282-283
moral concerns over, 336-341	Immergut, E., 208
national policy frameworks for, 337-340	incidental research findings, 229-230
normative regulatory systems for, 335-343	in neuroscience research, 309-310, 313
slippery slope ideology and, 349–350	inclusiveness
Human Genome Organization (HUGO), 149-151	in health research governance, 259-260
Human Genome Project, 103–104	non-invasive prenatal testing and, 267-268
open access and, 190–191	inclusive public engagement
human germline research	data intensive health research and, 118-119
context in, 348–350	public expertise and, 251–253
ethical debates over, 344-355	incommensurability, proportionality and, 41–42
future research challenges in, 354-355	independent, interdisciplinary data access, 193-194
global regulation and scientific justice, 352-353	independent review boards, privacy and, 75-77

	1 10 1770
Indian Ocean tsunami, emergency healthcare and,	Institutional Animal Care and Use Committee (IACUC),
317–320	360
indirect benefit, in RCTs, 133	institutional capture, public engagement and, 118–119
individuals and individualism	institutional review boards (IRBs)
autonomy guidelines in research ethics and, 29–30	design and performance criticism of, 180–181
data governance and, 59–61	purpose of, 177–178
group vulnerability and, 95–96	risk-benefit analysis and, 137–138
health research regulation and, 7, 14	single board (sIRB), 200–201
individual vulnerability in research, 92–93	institutions
institutional decision-making and role of, 211	accountability and risk aversion issues in, 211
informational privacy, 75	context of, 207–208
data protection and, 75-77	decision-making body objectives in, 208-209
risks to, 130	decision-making body structure and composition,
information technology, collaborative licensing, 144-145	209–211
informed consent	defined, 207–208
alternate models of, 200-201	design of, participatory governance and, 127–129
basis for, 104–105	health research regulation and, 14–15, 205–214
in Big Data research, 123	influences on decision-making in, 208–213
consent to contact policies and, 201–202	inter-institutional influences in, 213
cultural factors in, 242n.23	path dependencies and historical influences in, 212-213
data protection and, 67n.15	public vs. private duties in, 211
digital consent mechanisms and, 110	solidarity of, health research and, 59–61
evolution of health research and, 103–104	trust in, 86–87
fetishisation of, 181–182	instrumentality, public engagement and, 113–116
group vulnerability and, 95–96	integrity, human-technology embodiment and, 384–386
legal requirements for, 105–108	intellectual property rights
limitations of, 108–109	collaborative licensing and, 144–145
overview of, 103	patent regulation and, 140–141
	intended research findings, 229–230
privacy and, 75–77	interconnectedness
proportionality and, 40	
relational autonomy and, 30–31, 34–36	in health research regulation, 2
right of refusal and, 108	learning healthcare systems and, 391–394
solidarity in health research and, 59–61	inter-institutional design
trust and, 248–249	health research regulation and, 213
vulnerability and, 17–18, 20–22	learning healthcare systems and, 391–394
waivers of, 199–200	Interministerial Commission for Research and
written forms of, 108–109	Medicaments of Advanced Therapies (Argentina),
infrastructural vulnerability, health research regulation	328–329
and, 396, 23–24	internal validity, in RCTs, 133
inherent vulnerability, 33	International Bioethics Committee (UNESCO), 340–341
innovative health research	International Cancer Genome Consortium/25K Initiative,
autologous mesenchymal stem cell intervention, 290–292	193
clinical innovation in medical marketplace, 287–295	International Council for Harmonisation of Technical
collaborative licensing and, 144–145	Requirements for Pharmaceuticals for Human Use
conflicts of interest in, 292–295	(ICH), 105–106
disturbance of regulation from, 382-383	International Covenant on Civil and Political Rights
emerging science and technology oversight and,	(UN), 105–106
397-399	International Ethical Guidelines for Health-related
enhancement innovations, 383–384	Research, 46–47
ethical licensing and, 145–146	International Ethical Guidelines for Health-Related
government intervention and, 141–142	Research Involving Humans (CIOMS), 35–36, 46–47,
market forces and, 140–141, 292–295	169, 199–200
medical device regulation and, 386-389	international health policies
national policy frameworks for genetics and, 337–340	genetics research regulation and, 340-341
oversight and, 287–290, 292–295	human germline research, 352-353
overuse of non-evidenced based therapies, 292-295	International Organization for Standards (ISO), 167–168,
patent regulation and, 139–147	282–283
patent rights and, 141	interpersonal solidarity, 58–59
self-regulatory patent rights models and, 142–146	interpretive community, 210
Institute of Medicine (IOM, US), 124, 391-394	disclosure of research findings and, 236-238

interspecies biomedical research chimeric organisms, 357–358 regulation of, 356–364 shifting regulatory boundaries in, 362–363	participatory health governance and, 285–286 risk-benefit analysis and, 132–134 Koops, Bert-Jaap, 273 Kurunmäki and Miller, 159
vulnerability issues, 363–364	
interventions autologous mesenchymal stem cell case study, 290–292	labelling approach, vulnerability research and, 20–22 ladder of public participation, 114, 116
clinical innovation oversight and, 287–290	Lane, Neal, 223–224
component risk-benefit analysis, 135–136	Lange, M. Meeke, 23–24
risk identification in, 130–132	Langwick, Stacey, 304
social value of, 49–51, 53–54	Laurie, Graeme, 1–10, 165, 264–265, 277–278, 285–286,
in vitro fertilisation add-on procedures, 375–377	391–400
intrauterine culture, absence of effectiveness research on,	laws and legislation
379 investigational therapeutics, global health emergencies	Argentinian health research regulation and, 330–331 data protection law, 243–245
and use of, 319	fetishisation of consent and, 181–182
	,
In Vitro Diagnostic Medical Devices Regulation (IVDR),	genomics research and, 336–341
382–383, 386–389	group privacy protections and, 243–246
in vitro fertilisation (IVF)	human embryo special status in, 367–368
add-on procedures in, 375–377	informed consent and, 108–109
costs of, 375	institutional decision-making and, 212–213
culturing technological advances in, 368–370, 373–374	medical device regulation and, 388–389
failure rate in, 375–377	physical integrity and identity in, 385–386
14-day rule and, 365–366	politics and barriers to, 223
non-evidence-based medicine in, 373–381	privacy and, 241–243
patient choice dynamics in, 380	public interest and, 67–70
special status principle in, 367–368	shifting regulatory boundaries in animal research and,
threshold of humanity principle in, 370–372	362–363
time pressures in, 374–377	traditional and non-conventional medicines and,
Warnock Report findings and, 366–368	303-304
ipse principle of identity, 384–386	leadership support, participatory governance and, 127–129
Isasi, Rosario, 335–343	learning healthcare systems
isomorphism	continuous learning and research-therapy divide in,
institutional decision-making and, 210	277–286
inter-institutional influences and, 213	current and future trends in, 199
issue characteristics, rare disease research, 61-62	disclosure of research findings and, 231–234
	minimal risk principle and, 199–200
Jackson, Emily, 373–381	patient engagement in, 124
Jacobs, Marie Andree, 304	regulatory science and, 391–394
Jasanoff, Sheila, 306–307	risk identification in, 130–132
Johnson, Summer, 218	Learning Health Research Regulation System (LHRRS)
justice	basic goals and features of, 399-400
autonomy guidelines and, 27–29	ecosystem for, 397–399
as benefit sharing argument, 150–151, 154–156	learning healthcare systems and regulatory science and
human germline research, 352-353	391-394
informed consent and, 104–105	overview of, 1–10
medical device failure and, 162–165	proposals for, 5, 391–400
	value and social values in, 394–396
Kant, Immanuel, 78–79	legitimacy
Kaye, Jane, 103–111	medical device failure and, 163-164
Kerasidou, Angeliki, 14–15, 81–89	of public engagement, 250–251
Kerridge, Ian, 287–295	public interests and, 240–241
Kieslich, Katharina, 14, 56-64	Lemley, Mark, 140–141
Kipnis, K., 396, 23–24	Leopoldina Society, 218, 220
Klitzman, R., 203	licensing
Knight, D., 159–160	collaborative licensing, 144–145
knowledge production	ethical licensing, 145–146
failure as tool for, 162–165	mixed licensing models, 143–144
medical device failure and organisation of, 162–165	non-exclusive research tool licensing, 142–143
participatory government and forms of, 126–127	reproductive medicine add-on services, 377–379
1 1 70	1

temporary licensing, 165	current and future regulation concepts and
in vitro fertilisation and, 374	perspectives, 382–390
lifecyle assessment, software as medical device regulations	expectations for, 160–162
and, 282–283	failure of, 158–166
liminality	future challenges in regulation of, 389–390
advisory bodies and, 221	knowledge base for, 162–165
AI/ML device regulation and, 278	market forces in regulation of, 386–389
artificial intelligence and, 277–278	participatory learning in regulatory governance of,
health policy advice and, 215–216	284–285
health research regulation and, 222–224	post-market surveillance of, 388–389
Liminal Spaces Project, 3	re-embedded risk and sociality and, 281–284
emerging science and technology oversight and,	risk-based FDA classification of, 279 temporary licensing for, 165
397–399 limited disclosure of information, informed consent and,	1 ,
	Medical Devices Regulation (MDR, EU), 161, 386–389 Medicines and Healthcare Products Regulatory Agency
107 Lipworth, Wendy, 287–295	(UK), 205, 377–379
Lloyd-Bostock, S., 161–162	Médicins sans Frontières, 132–133
local governance reviews	Medina, José, 35–36
global health emergencies and, 319–320	Megan's Law, 285–286
inefficiencies with, 202	mental health research, risk identification in, 130–132
Long Term Plan (NHS), 271	Meslin, Eric M., 215–224
low-and-middle income countries (LIMC)	Mesmer, Anton, 220–221
benefit sharing in, 152–156	METADAC (Managing Ethical, Sociotechinical and
biotechnology regulation in, 324–325	Administrative issues in Data Access), 193–196
global health emergencies in, 317–318	metal-on-metal hips, expectations and failure involving,
regulatory thresholds in, 353	160–162
trust in health research in, 81–82, 85–86	MEURI (monitored emergency use of unregistered and
vulnerability of groups in, 93–95	experimental interventions) scheme, 319
Lowi, Theodore, 61–62	Mexican General Health Law, 97
Luna, F., 23–24	Mill, John Stuart, 78
Lysagt, Tamra, 287–295	Miller, Franklin, 235, 399–400
-/·8·4 - ·(4)	Millum, Joseph, 51–52
MacCormick, N., 208–209	mimetic isomorphism, 213
machine learning	minimal risk principle, health research regulation and,
IDx-DR AI diagnostic system, 281–284	199–200
as medical device, 277–286	mitochondrial replacement therapy (MRT)
Mackenzie, Catriona, 32	emergence of, 344–345
maker movement, evolution of, 382-383	terminology and definitions of, 347
Managing Ethico-social, Technical and Administrative	mixed licensing models, patent regulation and, 143-144
Issues in Data ACess (METADAC, UK), 126	Mode 2 research, social values and, 47–49
March, J., 209–211	Moffett, A., 376
Margulis, S. T., 242	monitoring, in health research governance, 259–260
market forces	moral agency
autologous mesenchymal stem cell case, 290-292	automated healthcare regulation and, 273-274
clinical innovation and, 287–295	global health emergencies and, 321-322
medical device regulation and, 382-383, 386-389	human-technology embodiment and, 384–386
overuse of non-evidenced based therapies and, 292-295	trust and, 85
patent regulation and, 140–141	trustworthy institutions and, 86-87
in reproductive medicine, 375-377	moral hazard, mixed licensing model and, 143-144
Markingham, Dan, 21	multi-agency research networks
May, William, 178	learning healthcare systems and, 391-394
Mayo Clinic Biobank deliberation, 125–126	participatory health systems governance and, 126
McLeod, Carolyn, 32, 34–35	multi-disciplinary efforts
McMillan, Catriona, 333-334, 365-372	institutional decision-making and, 210–211
Medical Assistance in Dying and When Antibiotics Fail	learning healthcare systems and, 391–394
(CCA), 219–220	multilevel engagement strategies, participatory
medical devices. See also software as medical device	governance and, 128
(SaMD)	Munsie, Megan, 287–295
artificial intelligence/machine learning as, 277–286	Murtagh, M. J., 126
clinical trials for, 279–281	my data phenomenon, health research regulation and, 8-9

Nabatchi, T., 254–255	research regulation of, 296–305
Nagoya Protocol on Access and Benefit-Sharing, 149	uncertainty of knowledges and practices and, 303-304
narrative tools, research findings as, 235-236	non-evidence based medicine, in vitro fertilisation and,
National Academies of Sciences, Engineering and	373–381
Medicine (NASEM, US), 219–220	non-exclusive research tool licensing, patent rights and,
National Academy of Science (NAS), chimera research	142-143
guidelines, 359–362	non-identifiable data, duty of confidence and, 246
National Administration of Drugs, Food and Medical	non-invasive prenatal testing (NIPT), regulation of,
Technology (ANMAT), 325–329	267–268
National Agency of Promotion of Science and	non-maleficence
Technology (ANPCYT, Argentina), 325–326	informed consent and, 104-105
National Bioethics Advisory Commission (NBAC, US),	proportionality and, 40
221–222	normative rationales
National Bioethics Advisory Commission (US), 151–152	autonomy and, 32
National Commission for Agricultural Biotechnology	disclosure of research findings and, 233–234
(CONABIA) (Argentina), 324–325	genomics research, 336–341
National Consultative Committee on Ethics (France), 221	human embryo research and challenges of, 366–370
National Electronic Health Record System (NEHRS)	human gene editing regulations, 335–343
(Australia), 118–119	incidental research findings and, 309–310
National Health Service (NHS)	learning healthcare systems and, 391–394
fertility treatment funding in, 375	in neuroscience research, 308–312
non-conventional treatment regulation and, 301–302	normative isomorphism, 213
research ethics and, 179	normic diversity, 252–253
National Institute for Health and Care Excellence (NICE,	• • • • •
	principles-based regulation and, 259
UK), 173–175, 301–302	privacy protection and, 73–74
in vitro fertilisation guidelines in, 375	public engagement and, 113–116
National Institute for Transplantation (INCUCAI,	rules- and principles-based regulation and, 169, 172–173
Argentina), 325–328	North, D., 207–208
National Institutes of Health (NIH, US), 142–143	Notice of Proposed Rule Making, 202–203
chimeric research moratorium, 359–362	Nowotny, H., 48–49
national policy frameworks, genetics research and,	Nuffield Council on Bioethics, 151–153, 221, 267–268,
337-340 N. C. 150 (1997)	320–322
National Statement on Ethical Conduct in Human	Nuremberg Code, 17–18, 105–108, 169
Research (Australia NHMRC), 105–106	Nuu-chahnulth people, genetics research and, 242n.23
natural ecosystem, health regulation and role of,	
268–269	Obama, Barack, 216–218
natural killer cells, reproduction medicine and mythology	O'Doherty, Kieran C., 121–129
about, 375–377	OECD Guidelines on the Protection of Privacy and
negative function, innovation oversight and, 292–295	Transborder Flows of Personal Data, 75–77
net risk test, risk-benefit analysis and, 136–137	off-label use of medicines, reproductive medicine add-ons,
networks of actors, adaptive governance and, 263–265	377–379
neuroimaging techniques, ethical issues and, 307-309	off-target humanised tissue, interspecies research and
neuroscience research	problem of, 360–361, 363–364
ethics, governance and practice in, 304	Olsen, J., 209–211
incidental findings in, 309–310, 313	O'Mathuna, D., 321–322
'A New Pathway for the Regulation and Governance of	100,000 Genomes project,231–235
Health Research' (AMS report), 3–4	O'Neill, Onora, 9, 248–249
New Zealand, evidence-informed health policy in,	Ontario Cancer Research Ethics Board (OCREB),
216–218	200–201
NHS Act 2006, 167–168	open data and open science
Section 251, 68	data-driven research, 190–191
NHS Trusts, 205	disclosure of research findings and, 231–234
NHSX (UK), 271	health research regulation and, 8–9
Nicholls, Stuart G., 197–203	patent regulation and, 141–142
Nickel, P. J., 23–24	trust and, 87–89
Nicol, Dianne, 139–147	Opinion on Ethical Aspects of Clinical Research in
Nielsen, Jane, 139–147	Developing Countries (European Group on Ethics),
non-assertion covenants, patent regulation, 145-146	151–152
non-conventional medicine	optimism bias, overuse of non-evidenced based therapies
history and evolution of, 296–298	and, 292–295

organ donation/retention, regulations concerning, 212-213	Patient-Centered Outcomes Research Institute (POCRI,
Organisation for Economic Co-operation and	US), 126–127
Development (OECD), data governance and,	patient choice dynamics, reproductive medicine
190–191	regulation and, 380
orphan drugs research societal reframing of, 63	patient health data consent to contact policies and, 201–202
solidarity in, 61–63	disclosure of research findings and role of, 233
Oshana, Marina, 31	research regulations for use of, 167–168
Ostrom, Elinor, 262–264	Patient Network for Advanced Therapies (APTA Network,
Osuji, P., 108–109	Argentina), 329
outputs of health research, 100	patterns of action, institutional decision-making and,
over-inclusive labelling, vulnerability in research and,	210-211
21–22	PAWORNET system (Riles), 284–285
Oviedo Convention, 105–106, 340–341	perceptions of risk, risk-benefit analysis and, 134–135
	performance of medical devices, research focus on,
pain relief protocols, vulnerability and, 19	162–165
Pang, T., 124	permission to contact policies, 201–203
participants in health research	permissive function, innovation oversight and, 292–295
benefit sharing with, 154–156	permitted embryo concept, 348–349n.26
disclosure of research findings and, 229–238	personal data protection, privacy and, 75–77
feedback to, 230	Personal Genome Project, 103–104
interests of, disclosure guidelines and, 234–235	pharmaceutical industry, solidarity-based research and,
in neuroscience research, 308 participatory governance. <i>See also</i> governance of research	62–63 placebo controls, evidence-based medicine and, 298–299
clinical innovation oversight and, 289–290	placental sampling, autonomy and consent to, 30–31
enabling conditions for, 126–127	planned adaptations, research governance and, 264
health research regulation and, 99–101, 121–129	policy formation in health research
health research systems, 123–126	Delphi policy study, 397–399
institutional designs for, 127–129	disclosure of research findings and, 229–238
international initiatives in, 124–125	evidence and evidence gathering and, 216-218
participatory learning systems, regulatory governance and,	expert and advisory advice in, 215-224
284–286	future issues in, 222-224
patent aggregation, 145	genetics research regulation and, 336-341
patent pledges, 145–146	international policy frameworks and, 340–341
patent pools, 144–145	learned and academic societies as experts for, 218–220
patent rights and regulation	national genetics research frameworks for, 337–340
benefit sharing principle and, 150–151	panaceas ideology in, 262–263
ethical licensing, 145–146	politics in health research
government intervention and, 141–142	anti-science politics and, 216–218
health research innovation and, 139–147	group replaceship and, 95–96
mixed licensing models, 143–144 non-exclusive research tool licensing, 142–143	group vulnerability and, 93–95 health research regulation and, 14–15
as private regulation, 140–141	human germline research and, 352–353
self-regulatory models for, 142–146	individual vulnerability, 92–93
paternalism, vulnerability in research and, 22	interspecies biomedical research regulations and,
path dependency, institutional decision-making and,	362–363
212–213	non-traditional medicine and, 299
pathogenic vulnerability, 91	patent regulation and, 140–141
patient and public involvement (PPI). See also public	policy advice experts and advisory committees and,
engagement	215–224
benefit treatment and, 54	protection and, 97
consumerist and democratic approaches to, 121-123	public expertise and, 251–252
disclosure of research findings and, 231–234	trustworthiness and, 248–249
health research regulation and, 46, 48–49, 250–251	vulnerabilities and power in, 90–98
identity interests in, 397–399	polycentricity, Big Data research and, 257–259
increased demand for, 70–71	population groups
participatory governance in health research and,	data on, 118–119
121–129	in health research regulation, 59–61
patient-centered care, learning healthcare systems and,	positive function, innovation oversight and, 292–295
391-394	Postan, Emily, 229–238

posthumanism	public interest and, 239–247
enhancement innovations and, 383	research governance and, 77–80
identity and integrity issues and, 384–386	risk to violation of, 130
post-market surveillance, medical device regulation and,	private sector healthcare
388–389	genomics research and, 336–341
post-trial obligations, benefit sharing and, 152-153	learning healthcare systems and, 391–394
Potter, N. Nyquist, 84–85	medical device regulation and, 386-389
poverty, vulnerability and, 92-93	misinformation about reproductive medicine and, 379
Powell, W., 210	patents as, 140-141
power	reproductive medicine, 374, 377
benefit sharing and role of, 154-156	procedural ambiguity, neuroscience research and, 310-312
definitions and analysis of, 90-91	procedural complementarity, 264
group vulnerability and, 95–96	professionalised lay experts, participatory governance and,
participatory governance and devolution of, 127–129	127
patent regulation and, 140–141	Professional Standards Authority (PSA, UK), 301–302
resource imbalance with, 126–127	progressive value, benefit analysis and, 53-54
trust and parity in, 85–86	proportionality
vulnerabilities in health research politics and, 90–98	analytical complexities, 41–42
vulnerability and, 14–15	defined, 37–38
Prainsack, Barbara, 14, 56–64	emerging science and technology oversight and,
precarity	397–399
in global crisis emergencies, 317–318	in global health emergency research, 322–323
vulnerability and, 23–24	of harms, 39–40
Precision Medicine Initiative (PMI, US), 103–104, 122–123	health research regulation and, 13–15
predictive influences, institutional decision-making in health regulation and, 208	procedural approaches to, 42–45 of review, 39–40
pregnancy	social value and, 40–41
non-invasive prenatal testing and, 267–268	protected experimental use, patent regulation and, 141–142
in vitro fertilisation risks in, 375	protection, politics in health research and, 97, 141–142
vulnerability of, 20–22, 33–34	protocol risks, vulnerability of participants and, 21
preparedness principles, in global health emergency	Public Accountability for Health-Related Research,
research, 322–323	CIOMS guidelines and, 47-49
preponderance theory, public interest and, 240	public engagement. See also patient and public
prescriptive influences, institutional decision-making in	involvement; patient and public involvement (PPI)
health regulation and, 208	anti-science politics and, 216-218
Prictor, Megan, 103-111	consultation and, 115–116
primary research, findings from, 229–230	critique in, 112–113
primitive streak development, human embryo research	empowerment and, 116
and, 367–370	evaluation of, 119–120
principles-based regulation	forms of, 113–116
AFIRRM model and, 260–263	global health emergencies and, 319–320
Big Data research, 257–259	health research regulation and, 7, 99–101
development of, 169–172	human germline research and, 354–355
health research regulation and, 167–176	inclusive approach to, 118–119
limitations, 172–173 privacy	layers of, 114–115 narrative of findings as tool for, 235–236
atomistic conception of, 241–243	overview, 112
in Big Data research, 123	participatory learning in regulatory governance and,
data access governance and, 188–189	284–285
data protection law and, 243–245	public expertise mobilisation and, 248–256
defined, 241–243	representation and inclusiveness issues in, 251–253
duty of confidence and, 245-246	trust and legitimacy challenges in, 250–251
group privacy, 241–243	trustworthiness of research governance and, 248-249
health research regulation and, 8–9, 14	types of publics in, 117
as human right, 74–75	public expertise, mobilization of
informed consent and, 75-77	deliberation and, 253–255
legal protection of group privacy, 243-246	health regulation research and, 14
in modern context, 73	public funding, patent regulation and, 141–142
normativity of, 73-74	Public Health England, Value of Vaccines campaign, 115
in personal data protection, 75-77	public interest

automated healthcare and balancing of, 267-268	AI/ML medical devices and, 281-284
CIOMS Public Engagement guidelines and, 47–49	to health research, 167–168
common interests and, 240–241	participatory learning systems and, 284–286
contested concepts of, 65–66	regulatory lapse, emerging technologies and, 167–168
data acceptability and, 70–71	regulatory regimes
data protection law and, 243-245	clinical care vs., 6
decision-making in, 211	clinical innovation oversight and, 289
deliberative public engagement and, 252–253	inefficiencies in committees, 201–202
health research regulation and, 13–15	innovation oversight and, 292–295
holistic concepts of, 71–72	medical devices and changes in, 279–281
as legal device, 67–70	recent challenges for, 4–5
privacy and, 78, 239–247	regulatory responsibility
trust and legitimacy challenges in, 250–251	automated healthcare regulation and, 271–274
public-private models	human germline research, 350–352
genomics research regulation, 336-341	regulatory science, learning healthcare systems and,
learning healthcare systems and, 391–394	391-394
public reason, public interest and, 240–241	relational autonomy
pure public, classification of, 117	informed consent and, 34-36
	participatory governance and, 127–129
Quality-Adjusted Life Years, proportionality and social	principles of, 30–33
value, 40–41	vulnerability and, 33–34
Quality-Adjusted Time Without Symptoms and Toxicity	reliability, trustworthiness and, 88n.45
(Q-TWIST) test, 138	Reliable Replacement Warhead (RRW) program, 285–286
Quality Management System (QMS), AI/ML medical	reliance, trust in global health research and, 85–86
device regulation and, 283–284	representation and representativeness
quandary ethics, medical device failure and, 163	group vulnerability and, 95–96
	participatory governance and, 126–127
Raab, C. D., 241–243	in public engagement, 251–253
Rahmizadeh, V., 203	representative diversity, 252-253
Rai, R., 376–377	reproductive autonomy, non-invasive prenatal testing and,
randomised clinical trials (RCTs)	267–268
design in reproductive medicine for, 374–377	reproductive immunology
evidence-based medicine and, 298–299	lack of research and regulation of, 375–377
global health emergency research and challenges of,	off-label use of, 377–379
318–320	reproductive medicine. See also cloning
reproductive medicine and lack of, 373–374	add-on services regulation in, 377–379
risk-benefit analysis and, 132–134	alternative treatments in, 375–377
range of sensitivities, privacy and, 79	context in research on, 348–350
rare disease research, solidarity in, 61–63	disclosure guidance in, 231, 233–234
Rawls, John, 49, 78–79, 240n.7	evolution of regulatory framework for, 366–368
Raz, Joseph, 31	14-day rule and, 365–372
REACH platform, 284–285	global regulations and policies and, 352, 354–355
real-time responsiveness, global health emergencies and,	human gene editing and, 267–268, 336–341
320–322 reasonable availability model, benefit sharing and, 152–153	innovation oversight in, 292–295
	non-evidence-based medicine in, 373–381
reasonableness and reason-giving, diversity theory and,	patient choice dynamics in, 380
252–253 reasonable risk, risk-benefit analysis and, 136–137	pre-implantation genetic diagnosis and, 336–341
	risks of add-ons in, 380–381 threshold of humanity principle in, 370–372
redundancy, Big Data research and, 257–259	7 1 1 27 37
Reed, Chris, 277–278 reflexivity, in health research governance, 259–260	researchers ethical capacities, global health emergencies and, 321–322
refusal, informed consent and right of, 108	research ethics boards (REBs)
regenerative medicine	purpose of, 177–178
advanced therapies in, 324	risk-benefit analysis and, 137–138
Argentinian governance of research in, 325–326	research ethics committees (RECs), 46
regulation and oversight of, 359–362	design and performance criticism of, 180–181
vulnerability issues in, 363–364	fetishisation of consent and, 181–182
registrant risk assessment scale (RRAS), 285–286	future directions for, 184–185
regulatory committees, institutional context for, 205	innovation oversight and, 292–295
regulatory/governance approach (RGA)	neuroscience research and, 304
U 7 U 11 - \ /	~/ J:1

research ethics committees (RECs) (cont.)	Rogers, Wendy A., 13, 17–26
purpose of, 177–178	Rose v. Secretary of State for Health, 385–386
regulatory role of, 178–180	Rowe, G., 114
risk-benefit analysis and, 137–138	Royal Academy of Sciences, 218
social value and, 52–53	Royal Society (UK), 218, 220
standardisation of procedures for, 182–184	Royal Society of Canada, 219–220
Research Involving People Living in Developing Countries: Position Statement and Guidance Notes for	Rudge, Chris, 287–295 rules-based approaches (RBAs)
Applicants (Wellcome Trust), 151	automated healthcare regulation and, 270–271
research-therapy divide, continuous learning systems and,	development of, 169–172
277–286	health research regulation and, 167–176
Resnik, D. B., 52	limitations, 172–173
resource/power imbalance, participatory governance and,	R (Source Informatics) v. Department of Health, 246
126–127	R (W,X,Y and Z) v. Secretary of State for Health (2015),
respect for persons, autonomy guidelines and, 27–29	245–246
responsiveness, in health research governance, 259–260	
review, proportionality of, 39-40	safety
revisionism, scientific claims and, 49	expectations and failure involving, 160-162
Richardson, Megan, 246	of traditional medicine, research on, 299-301
Richert, Lucas, 303-304	Salter, B., 288–289
Rid, A., 49–52, 71–72	Schaefer, Gerald Owen, 13–14
The Right to Privacy (Richardson), 246	Schulz, S., 112–113, 117
right to try principle	science and technology studies (STS)
clinical innovation and, 288–289	health research regulation in, 48–49
misinformation about reproductive medicine and, 379	public engagement in, 112–113
rigorous justification, proportionality and, 43	traditional and non-conventional medicines and,
Rijke, J., 263	303-304
Riles, Annelise, 284–285	scientific truth
Rip, A., 159–160	health policy and, 217
risk defined, 130	negotiation and agreement over, 49
	scientific uncertainty, risk-benefit analysis and, 134–135
failure in health research and, 158–166 in health research governance, 259–260	secondary research findings from, 229–230
identification of, 130–132	institutional decision-making on, 212–213
institutional aversion to, 211	regulation of, 199–200
medical device classification based on, 279	second-order proportionality, defined, 37–38
re-embedded risk in medical devices, 281–284	security, data access governance and, 188–189
of reproductive add-on treatments, 380-381	self-development, automated healthcare regulation and,
SaMD risk characterization framework, 282–283	273
social value of research and, 199–200	self-narrative, health research participation and, 235-236
risk-benefit analysis	self-regarding attitudes, relational autonomy and, 32
benefits identification, 132–134	self-trust, relational autonomy, 32
disclosure of research findings and, 230-231	semi-autonomous consent, 110
first-order proportionality and, 37–38	sequencing, in health research regulation, 395-396
in health research regulation, 130–138	Serwadda, D., 87–89
health research regulation and, 14	Seth, Nayha, 99–101, 167–176
medical devices and, 160–162	Sherkow, Jacob, 141–142
methodologies for, 135–137	Shreve, N., 376
procedural issues, 137–138	Simm, Kadri, 148–157
public interest and role of, 250–251	single institutional review board (sIRB), proposals for,
quantification of, 134–135	200–201
risk identification in, 130–132	situational vulnerability, 33
risk object designation	slippery slope ideology, human germline research and,
AI/ML algorithm and, 279–281 medical device regulation and, 386–389	349–350 social conditions
re-embedded risk and sociality and, 281–284 regulatory governance and, 285–286	adaptive governance and, 262–263 Big Data research and, 123
software as medical device, 277–278	relational autonomy and, 31
Robertson, John, 178	social learning, adaptive governance and, 263–265
Roche, Ellen, 21	social practices of healing, 299–301
, ,	r

social value	autologous mesenchymal stem cell case, 290–292
application of, 52–55	regulation and oversight of, 359-362
automated health regulation and, 270–271	shifting regulatory boundaries in, 362-363
benefit analysis and, 53-54	vulnerability issues in regulation of, 363-364
benefit evaluation and, 54	Stem Cell Research Oversight (SCRO) committees,
benefit treatment and, 54	interspecies research oversight, 360
decision-making and, 54	stereotyping, in vulnerability research, 20–22
of global health emergency research, 317–318	stewardship
global health emergency research and, 318-320	ethics in health research and, 182–184
health research regulation and, 14, 46-55, 199-200, 268	health research regulation and, 268, 397-399
meaning of, 49–51	participatory health research governance and, 124
proportionality and, 40–41	Stewart, Cameron, 287–295
re-embedded risk in medical devices and, 281-284	Stilgoe, J., 112
scholarly debate on, 51–52	Stoljar, Natalie, 13, 27–36
in sociology of science, 47-49	study design and size, RCTs and, 133
solidarity as, 58–59	subjectivity, public engagement and, 113-116
values and, 49-51, 394-396	substantial equivalence principle, medical device risk and
sociology of science	160–162
neuroscience research and, 306-307	supplementary guidance, health research regulation,
social value in, 47–49	173–175
therapeutic interactions research, 299	surrogate licensing, patent regulation and, 141–142
soft law	systemic oversight
on benefit sharing, 152	AFIRRM model and, 262
genomics research and, 336-341	Big Data research and, 259–260
software as medical device (SaMD)	context in, 262
IDx-DR AI diagnostic system, 278–281	structures of governance and, 263
regulation of, 277–278	systems approach
risk characterization framework, 282–283	participatory governance in health research and,
solidarity	123–126
applicability and adjustments in HHR and, 58–59	to research regulation, 4–5
automated health regulation and, 270–271	system value, solidarity as, 58–59
as benefit sharing argument, 150–151	T 1 W 1 60 6
as community and system value, 58–59	Taylor, Mark, 68–69, 71–72, 239–247
in health research regulation, 14, 56–64	technology
meaning of, 56–58	Argentinian regulation of, 324–325
rare diseases and orphan drugs research and, 61–63	automated healthcare, 266–274
Somatic Gene and Engineered Cell Therapies (CCA),	automated healthcare regulation and, 270–271
219–220	collaborative licensing and, 144–145
somatic gene therapy, regulation of, 336–341	disturbance of regulation from, 382–383
somatic/germline distinction, human germline research	failure of, 158–166
and, 350 Sorauf, F. J., 240	health research regulation and, 99–101, 198–199
Sorbie, Annie, 14, 65–72	informed consent and evolution of, 103–104 non-exclusive research tool licensing and, 142–143
Spanish Agency for Medicaments, Argentinian	patent rights and innovation in, 141
collaboration with, 329	regulatory lapse and, 167–168
special vulnerability paradigm, 19–20	regulatory responsibility and, 271–274
health research ethics and, 19–20	Tello, J. E., 123–124
stakeholder engagement	temporary licensing, for medical devices, 165
automated health regulation and, 268–269	ten Have, H., 91
Big Data research and, 257–259	Ter Muelen, Ruud, 58–59
data protections and, 189	Testlin, Henri, 218
failure in health research and, 158–159	theory-practice gaps, rule-based and practice-based health
independent, interdisciplinary data access and, 193-194	regulation and, 172–173
marginalisation in vaginal mesh failure and, 162-165	therapeutic misconception, benefit sharing and, 154-156
principles-based approaches and, 171–172	third-party risks, identification of, 130-132
value-driving paradigm for, 394–396	Thompson, J., 127
stare decisis, institutional decision-making and, 212-213	threshold of humanity principle
Stark, Laura, 178–179	enhancement innovations and, 383
stem cell research	human embryo research and, 370-372
Argentinian regulation of, 326–328	Tietjens, Diana, 31

tokenism public engagement and, 118–119	United Kingdom data protection law in, 243–245
resistance to participatory governance and, 125	duty of confidence and privacy protection in,
Tongan people, cultural protections for, 242n.23	245–246
tools for health research regulation, overview, 99–101	evidence-informed health policy in, 216–218
top-down public engagement, 112	interspecies biomedical research regulations in,
Townsend, David, 14, 73–80	362–363
Traditional Chinese Medicine (TCM), 299–301, 303–304 Traditional Herbal Medicine Products (THMPD),	medical device regulation in, 162–165
European Directive on, 297–298	research process simplification and harmonisation and,
traditional medicine	United States
economics of clinical guidelines for, 301–302	patient and public involvement in health research in,
history and evolution of, 296–298	122–123, 126
integration and regulation as subordination, 299-301	third-party risk protocols in, 130–132
research regulation of, 296–305	Universal Declaration of Human Rights, 74-75
uncertainty of knowledges and practices and, 303-304	Universal Declaration on Bioethics and Human Rights
tragedy of the anticommons, 141	(UNESCO), 152
translational value	Universal Declaration on the Human Genome and
benefit treatment and, 54	Human Rights (UNESCO), 340-341
hypothesis-driven trials, 54	universality, of vulnerability, 19
transnational dynamics, human germline research and,	upper limit on permissible risk, risk-benefit analysis
353	guidelines, 137
transparency	
in benefit sharing, 153–154	vaginal mesh
in collaborative research, 82–83 data across governance and, 189–190, 192	expectations and failure involving, 160–162 gender marginalisation of harm from, 162–165
informed consent and, 104–105	validity in health research
proportionality and, 43	disclosure of findings criteria and, 231, 236–238
public engagement and, 118–119	external vs. internal validity, 133
Trudeau, Justin, 216–218, 222–223	values
Trump, Donald, 220–223	automated health regulation and, 270–271
trust	commonly-held value, public interest and, 240-241
automated health regulation and, 268–269	disclosure of research findings based on, 231, 236-238
in data sharing collaborations, 87–89	learning healthcare systems and, 391–394
global health emergencies and building of, 319–320	patent regulation and, 140–141
in global health research, 81–89	social value and, 49–51, 394–396
health research regulation and, 9, 222	Valverde, Mariana, 285–286
in institutions, 86–87	van Delden, Johannes JM, 14, 46–55
Learning Health Research Regulation System and,	van der Graaf, Rieke, 14, 46–55
394–396 participatory governance and, 127–129	van Gannep, Arnold, 278, 389 van Lente, H., 159–160
risk-benefit analysis and, 134–135	virtuous action, global health emergencies and, 321–322
trustworthiness and, 83–85, 248–249, 254–255	voluntariness
trustworthiness, public expertise and, 248–249, 254–255	disclosure of research findings criteria based on, 231,
Trustworthy Institutions in Global Health Research	236–238
Collaborations, 14–15	informed consent and, 104-108
Turner, Victor, 278	of trust, 84–85
Tuskegee syphilis study, 28, 34-35	vulnerability
	ambiguity in HRR and, 19–20
UK Biobank, 194–195	benefit sharing and, 154–156
uncertainty	definition and analysis of, 23–24, 90–91
governance and, 262–263	global health emergency guidelines and, 316–317
in neuroscience research, 310–312	of groups, 93–95
traditional and non-conventional medicines and,	health research regulation and, 13
3°3–3°4 UN Declaration on Human Cloning, 34°–341	individuals' vulnerability, 92–93 interspecies biomedical research and realignment of,
Understanding Patient Data and National Health Service	363–364
England report, 70–71, 394–396	labelling approaches to research on, 20–22
undue inducement, benefit sharing and, 154–156	layers of, 396, 23–24
unitary theory, public interest and, 240	politics of health research and, 90–98

power and, 14-15 WHO Guidance for Managing Ethical Issues in in rare disease research, 62 Infectious Disease Outbreaks, 173-175 relational autonomy and, 33-34 Wiersma, Miriam, 287-295 in research ethics guidelines, 17-18 Wilcox, D., 115–116 risk assessment and, 199-200 Willis, R., 119-120 taxonomy, 24 Wilsdon, J., 119–120 trust and, 83-85 Working Group on Disaster Research Ethics (WGDRE), universal capacity and, 24-25 317-318 World Health Organization (WHO) Wainwright, Steven, 313 bioethics advisory committees and, 221 Waldby, Catherine, 287-295 CIOMS collaboration with, 46-47, 59-61 Warnock Committee of Inquiry into Human Fertilisation global health emergency guidelines and, 320-322 and Embryology, report by, 366-368 Good Clinical Practice, 152 health practices guidelines, 173-175 Warren, Mark, 251-252 Weijer, Charles, 46-47, 96 health systems framework, 123-124 welfare state, enforceability of solidarity and, 58-59 traditional medicine and, 296-301 Wellcome Trust World Medical Association (WMA), 103-104 on benefit sharing, 151 Wright, E. O., 124-125, 127-129 Blueprint for Dynamic Oversight of Emerging Science Wrigley, A., 91, 97 and Technologies, 397-399 written assessments, risk-benefit analysis and, 137-138 public interest and, 68-69 Wynne, B., 112–113 Understanding Patient Data initiative, 70-71 Yishai, Y., 125 Wendler, D., 49-52 Wenner, Danielle, 51-52 Wertheimer, A., 52 Zhan, Mei, 303-304 Zhang, John, 346, 353 Western Herbalism, 299-301 Whitton, Tess, 239-247 Zita West fertility clinic blog, 376-377