### Index

| Aboy, M. 261 | Bekelman, J. 193–4 |
| access payments, and open bioresources | Belluz, J. 183 |
| 249, 250–51 | Benesova, L. 220 |
| Ahmad-Nejad, P. 222 | Benkard, G. 112 |
| Albert, M. 6–7 | Bentwich, M. 188 |
| Allen, C. 175 | Bernitz, U. 112–13 |
| Allen, N. 191 | Betsou, F. 234 |
| Almeling, R. 182 | Beyleveld, D. 93, 94, 100 |
| Anderson, W. 5, 14 | Bhandari, M. 194 |
| Andreoli-Versbach, P. 209 | Biobrick Public Agreement, open bioresources 249 |
| Andrews, L. 59 | biohazards, and health and safety 69–70 |
| Andries, P. 201 | biohoarding (low usage) concerns 123 |
| Annas, G. 161 | biomarker identification 47–8, 58, 157, 222–3, 229, 230, 231, 241 |
| Aplin, T. 249 | biopiracy claims 5 |
| Appelbaum, P. 14, 161 | Birch, K. 210 |
| Arzberger, P. 3 | Björk, B.-C. 246 |
| Asslaber, M. 230 | Bjugn, R 5 |
| Asveld, L. 190–91 | Blakemore, E. 178 |
| Atkinson-Grosjean, J. 131 | Blasimme, A. 4 |
| Auflage, C. 112 | Blok, V. 190 |
| Australia 121–2, 126 | Boddington, P. 120, 122 |
| Austria 220, 221, 226, 227 | Boggio, A. 28, 35 |
| autonomy protection 4–5, 8, 13, 17, 36–7, 79–80, 88, 128, 134 | Bolivia 160 |
| see also confidentiality; informed consent; privacy concerns | Borgman, C. 26, 36 |
| Azoulay, P. 207 | Borry, P. 37, 258, 259 |
| Bachmann, R. 132 | Bosk, C. 9 |
| Ballantyne, A. 160 | Bossow, T. 56–71 |
| Barnes, R. 59 | Botti, G. 46, 47, 50, 184 |
| Barry, A. 239 | Bovis, C. 88 |
| Baumbusch, J. 198 | Boyer, G. 53, 216 |
| | Broekstra, R. 135, 151 |
Index

Brownsword, R. 93, 100, 106, 107, 108, 243
Bruinenberg, M. 238
Bubela, T. 189
Budimir, D. 196
Budin-Ljøsne, I. 124, 151
Burk, D. 54
Burke, W. 179
Burstein, P. 180
Cadigan, R. 5, 53, 197
Caixeiro, N. 222
Cambon-Thomsen, A. 158, 255
Cambrosio, A. 3
Campbell, A. 130
Canada 182
Caplan, A. 158, 159
Capocasa, M. 258
Capron, A. 210, 258, 259
Carter, A. 234
Caso, R. 147
Catchpoole, D. 123
Chadwick, R. 255
Chalmers, D. 146, 243, 260
Chambliss, D. 9
Chandrasekharan, S. 207
Chapman, A. 74
Charo, R. 175
Chesbrough, H. 201, 204, 207, 246
Christakis, N. 161
Clark, B. 56–71
Clarke, L. 88
Clarysse, B. 212
Claude, R. 74–5
Clemence, M. 196, 197
Coathup, V. 125

collaboration international see international collaboration in genetic research responsible research and innovation (RRI) 189–90, 194–5, 199–200, 201, 206–8 and sharing of samples, Dynamic Consent concept 120, 128–9 see also harmonization approach; networks

Colledge, F. 3, 217
Collins, F. 49, 190

commercialization and consent problem 180–81 Dynamic Consent concept 122–3, 131–2, 137–8, 148–9 industry involvement concerns 194, 198–200 innovation infrastructure for translational medicine 53–4 responsible research and innovation (RRI) 193–203, 196–7, 208, 209–11, 212–14 scientific productions and human rights 79 commons framework see knowledge institutions, knowledge commons research framework computable consent, Dynamic Consent concept 135 confidentiality 16, 182–3, 248–9, 252–3 see also autonomy protection; privacy concerns conflicts of interest 15–16, 190–91, 193 consent developing countries see developing countries, exploitation and vulnerabilities in consent to biobank research
dynamic see Dynamic Consent headings
informed see informed consent approach
processes and standards, human biosamples in bioscience industries 67–8
sample collection see sample collection
withdrawal rights 75–7, 143, 151, 197
consent problem 173–84
broad consent approach 177
confidentiality risks 182–3
data breaches 181–2
free and informed consent 181
funding issues and commercialization 181
 genetic information concerns 179–80, 182–3
HeLa cell line controversy 178
legal uncertainty 175–6
media hype concern 178–9, 183
perceived rights of control 178–80
privacy and discrimination concerns 121, 128, 181–3
public perception 177–84
public trust and commercialization 180–81
public-private partnerships 180–81
technology opportunities 183–4
Contreras, J. 35
Cook-Deegan, R. 52, 54, 207, 244
Cooper, M. 5
Council for International Organizations of Medical Sciences’ (CIOMS) 163–4
Cranley, E. 54, 178
Crespo, M. 189–90
Critchley, C. 57, 130, 180, 192, 194, 196, 197, 198, 211, 213
Cunningham, H. 5
Cunningham, J. 178
Curtis, J. 49
D’Abramo, F. 181
Daley, B. 54, 178, 179
Dasgupta, P. 246
Data breaches 181–2
see also privacy concerns
data fragmentation challenge 44–5, 53–4
data sharing 4–5, 125
EU BBMRI network, MIABIS (Minimum Information About Biobank Data Sharing) 51, 235, 239
see also open access; privacy issues
David, P. 246
Davies, S. 191
De Souza, Y ix
De Vries, J. 121
De Vries, R. 177, 180
Debackere, K. 201
deferential vulnerability, developing countries 165–6, 168, 169–70
Denmark 11, 16, 96–7, 98, 104, 109–10, 231
developing countries, exploitation and vulnerabilities in consent to biobank research 156–72
biomarker identification 157
education and poverty levels effects 161
exploitation of research subjects 159–62
harmonization of guidelines 158–9, 171–2
informed consent issues and future projects 158–9
international research potential 157
invalid consent account 161–2, 163
legislation fragmentation 159
medical research exploitation 160–62
developing countries, exploitation and vulnerabilities in consent to biobank research, exploitation with consent and benefits 162–6
deferential vulnerability 165–6, 168, 169–70
juridic vulnerability 165–6, 169
layered approach to vulnerability 164–5
vulnerability to exploitation, understanding and labelling 163–4
developing countries, exploitation and vulnerabilities in consent to biobank research, Pakistan case study, blood samples 166–70
medical profession association as participant motivation 168, 169–70
participation motivation 167–8
vulnerabilities 168–70, 171–2
Dierickx, K. 37
digital technologies, Dynamic Consent concept 118–20
discrimination issues 78, 181–3
disease-based biobanks 232
Doerr, A. 184
Douglas, C. 46, 132
Douglas, S. 115
Dove, E. 3, 207, 244
Drake, A. 57
Dressler, L. 77–8
Dridi, H. 189–90
drug development 47, 57–8, 180, 191–2, 202, 247
Ducato, R. 147
Dynamic Consent concept and sustainability 117–29
biobank usage and sustainability 122–3
biohoarding (low usage) concerns 123
clinical care integration possibilities 127–8
collection of participants’ self-reported health and lifestyle data 124–5
digital technologies 118–20
Dynamic Consent definition 124–6
EnCoRE (Ensuring Consent and Revocation) project 128
ethical and legal standards 126–7
family members, inclusion of 119, 126, 127
global biobanking market value 122–3
informed consent approach 118–19
international collaborations and sharing of samples 120, 128–9
legal framework 120–22
participant autonomy and real and effective choice 128, 134
regulation fragmentation 120–22, 126
translational research systems, biobank involvement in 123
unforeseen studies, dealing with, and broad consent solution issues 119–21, 124–5, 126–8
Dynamic Consent concept and sustainability, trust challenges 130–55
Global genes, local concerns

commercialization challenges and translational research 131–2, 137–8, 148–9
computable consent 135
consultation and communication with communities and interest groups 145
Dynamic Consent as tool for generating trust 151–4
electronic consent 135, 151–2
encryption of sensitive data 151
funding issues 146, 148
future research opportunities 134, 153–4
governance mechanisms and consent procedures 145, 146–7, 153
information evaluation and transparency 143–4, 149, 152–4
informed consent principle 133–5, 142
ownership, access and use 146–9
participants and interpersonal support 138, 151–3
participation withdrawal rights 143, 151
transnational collaborations 148–9
trust challenges 139–50
trust concept 132–3, 136
trust levels 137–8, 141–2, 146–8
trust and trustworthiness distinction 136–7
uncertainty and risk factors 136–7

education and poverty level effects, developing countries 161
Edwards, T. 174
Egan, J. 202

Eilers, L. 22
Einsiedel, E. 211
Eiseeman, E. 218
Eisenberg, R. 44, 45, 49, 50, 54, 188
electronic consent, Dynamic Consent concept 135, 151–2
Elger, B. 158, 159
Emanuel, E. 160
EnCoRE (Ensuring Consent and Revocation) project 128
Estonia 238–9
ethical concerns 9–11, 62–4, 65, 126–7, 193, 196–7, 236
see also morality concerns

EU
BBMRI network, MIABIS
(Minimum Information About Biobank Data Sharing) 51, 235, 239
BBMRI-ERIC infrastructure see networks, EU BBMRI-ERIC infrastructure
Brüstle v Greenpeace 95, 99, 111
Casa Fleischhandels-GmbH v Bundesanstalt für landwirtschaftliche Markordnung 94
Deutsches Milch-Kontor GmbH v Hauptzollamt Hamburg-Jonas 94
General Data Protection Regulation 120–21
GenomeEUtwin project 237
Horizon2020 148, 190, 203
International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks 95
Karen Millen Fashions Ltd v Dunnes Stores 94
Index


responsible research and innovation (RRI) see responsible research and innovation (RRI)

European Charter for Access to Research Infrastructures 217

European Court of Human Rights

Anheuser-Busch v Portugal 80–81

Costa and Pavan v Italy 104

Evans v the United Kingdom 104

European patent law, free and informed consent in 92–116


Charter of Fundamental Rights of the European Union 105–6

ethical and moral principles and nonpatentability 99–101

European Convention on Human Rights (ECHR) 102–3, 104

European Patent Convention (EPC) 95, 96

health law 108–10

human biological material (HBM) 92, 93, 95, 97, 100, 101, 103, 107–8, 114–15

human embryonic stem cells 95, 99

large-scale population projects and donors’ consent issues 108–9

morality exclusion 95, 98, 100, 111, 112–16

patentability and balancing of interests 114–16

regulatory rule argument 98–9, 101, 111, 116

residual tissue use 108

European patent law, free and informed consent in, fundamental rights 99, 100–108, 111–13

persons participating in research projects 103

right to human dignity and integrity 103, 104–8

right to make autonomous decisions 107

right to private life 102–3

European Patent Office (EPO) 99–101, 111–12

Breast and ovarian cancer/UNIVERSITY OF UTAH 101

Euthanasia compositions/MICHIGAN STATE UNIV. 114

Howard Florey/Relaxin 100, 111

LELAND STANFORD/Modified Animal 101, 111

Plant cells/PLANT GENETIC SYSTEMS 100

Evans, B. 3, 28, 34–5, 51

Evans, D. 139

Evans, J. 179

Evers, K. 192, 193, 198, 210

expiration date for biobanks 216–28

biomarkers 222–3

collection strategies 219–21

collections with predefined expiry dates 220

data availability effects 223

data explosion vs useful information 224–5
expiration date definition

219–25

informed consent expiry date

218

open-ended diagnostic sample

collections 220–21

planned application effects

223–4

research infrastructure and

access policies 217–18

sample quality issues 220–23,

225–6

sample sharing barriers 217

storage conditions and duration

and sample types 220–23,

225–6

termination costs 218–19, 227

value analysis vs biospecimen

costs 225–6

see also quality standards

exploitation, developing countries see developing countries, exploitation

and vulnerabilities in consent to

biobank research

Eyal, N. 142, 158

FAIR Guiding Principles for data

management 50

family members, inclusion of, Dynamic

Consent concept 119, 126, 127

Fanni, S. 104

Ferrari, M. 145

Finland 13, 16, 232

Fobelets, G. 76, 78

Ford, R. 52, 53

Forrow, S. 50

Foster, M. 253

Frank, L. 231

free and informed consent, EU see

European patent law, free and

informed consent in

Freedman, L. 229

Friedewald, M. 174, 175

Friedman, J. 201, 204

Fries, C. 20

Friesike, S. 204

Frischmann, B. 28, 29, 48, 50, 51, 52

funding issues 51–2, 146, 148, 181,

197–8, 212, 238

future research 134, 153–4, 263

Gadarian, S. 182

Galli, J. 238

Gallini, N. 200

Gambetta, D. 137

Gandomi, A. 224

Gbadegesin, S. 160

Gee, S. 243, 250, 258

Geissler, P. 9, 16

genetic information concerns 18, 179–80,

182–3, 233

genetic research collaboration see international collaboration in

genetic research

Gervais, D. 84

Ghafel, R. 207

Gibbons, S. 249, 255

Gibson, S. 258, 259

Giddens, A. 137

Giesbertz, N. 183

Gikonyo, C. 170

Gitter, D. 147, 248, 253

Global Alliance for Genomics and Health

188–9

Gold, R. 147, 214, 243, 247–8, 251, 253,

258, 259

Gorges, T. 48

Gostin, L. 176

Gottweis, H. 37, 73, 76, 157, 193

governance structure

and consent procedures,

Dynamic Consent concept

and trust challenges 145,

146–7, 153
and knowledge institutions 26–7, 28–31, 32–3, 34–7
networks 239–40
and supply chains 58–61, 61, 62–4, 68–9
see also legal framework
Grabowski, H. 205
Grady, C. 161, 163
Greely, H. 37, 176, 179, 183
Greenbaum, D. 147
Griffin, M. 73
Grodin, M. 161
Guédon, J.-C. 246
Haddow, G. 132, 210
Haga, S. 182–3
Hainaut, P. 57
Haines, A. 198
Hall, B. 200
Hallinan, D. 174, 175
Hansson, M. 131, 134, 142, 147
Harhoff, D. 200
Habgood, R. 127
Hardin, R. 136
Harhoff, D. 200
Harmon, S. 252
harmonization approach 158–9, 171–2, 254–7
see also collaboration; networks
Harris, J. 132, 216
Hawkins, A. 130
Hawkins, J. 160
Hayden, C. 5
health law, and European patent law 108–10
health and safety, and biohazards 69–70
Heaney, C. 192
HeLa cell line controversy 178
Heller, M. 188
Hellstadius, Å. 92–116
Henderson, G. 24, 173, 197
Henderson, M. 237
Herder, M. 188
Herren, G. 193
Herrmann, J. 104
Hewitt, R. 58, 59, 230
Highsmith, J. 122
Hochschild, A. 20
Hodge, J. 176
Hoeyer, K. 2–21, 159, 194, 196, 234
Hoffman, S. 43, 44
Hoffmann, B. 134
Hoge, L. 234
Holm, S. 134
Holmes, A. 58
Holtmans, S. 152
Holtz, C. 112, 113
Holub, P. 233
Hong, S. 222
Hörig, H. 148
Horst, M. 191
Hubel, A 223
Hughes, J. 83
human biosamples in bioscience industries, responsible use of 56–71
biobanks, and downstream responsible use of biosamples 59–61
biohazard considerations 69–70
biomarkers of health and disease 58
consent processes and standards 67–8
ethical, societal, and legal status 62–4, 65
and European patent law 92, 93, 95, 97, 100, 101, 103, 107–8, 114–15
governance requirements and supply chains 58–61, 62–4, 68–9
health and safety 69–70
individuals, donations from 58
intermediaries between donors and companies 58–9
international conventions and guidelines, monitoring developments in 65–6
legitimacy requirement for use of biosamples 68–9, 70
new drugs, development and testing of 57–8
organizational management 64–5, 66, 67, 69–70
quality requirements 69, 70
storage control 69
use categories 57–8
see also responsible research and innovation (RRI)

human embryonic stem cells, European patent law 95, 99
Human Genome Organization 193
human rights see scientific productions and human rights
Hunt, P. 87
Hurst, S. 163, 171

industry involvement concerns 194, 198–200
see also commercialization

information
biobanks as repository for 47
data explosion vs useful information 224–5
evaluation and transparency 143–4, 149, 152–4
right to information and donor’s right not to be informed 77–8
see also knowledge institutions

informed consent approach
developing countries 158–9
Dynamic Consent concept 118–19, 133–5, 142
and expiration date for biobanks 218
and patent law, EU see European patent law, free and informed consent in scientific productions and human rights 75–7
see also autonomy protection; consent headings

Ingber, D. 58

innovation infrastructure for translational medicine 42–55
big data in medicine 43–7
biobanks as repository for information 47
biomarker identification 47–8
data fragmentation challenge 44–5, 53–4
health care data and research

data availability 46
patients’ retroactive involvement in trials 48
translational medicine development 47–8
unplanned analyses, potential for 46–7
see also responsible research and innovation (RRI)

innovation infrastructure for translational medicine, biobanks as data infrastructure 48–54
balancing data accessibility against privacy 52–3, 54
data fragmentation issues 53–4
FAIR Guiding Principles for data management 50
for-profit biobanks and competitiveness 53–4
intangible infrastructural resources 49
interoperability and resource and data sharing 50–51
nonprofit biobanks and incentives 54
researcher access funding 51–2
resources for future innovation 49–50
sample repositories 48–9
Institutional Analysis and Development (IAD) framework 30–31, 33
integration possibilities, and clinical care 127–8
intellectual property and human rights see biobanking, scientific productions and human rights knowledge commons research framework 31–2
open access/open science issues 206–9
patent rights in international research collaborations 189–90, 200, 201, 206–8 see also patents
intellectual property policies for large bioresources 242–63
future direction 257–62
future research 263
harmonization and consistency approach 254–7
Structural Genomics Consortium (SGC) 247
subsectors of bioresources industry 259–60
synthetic biology (SB) and genomics (Gx) 244, 249
intellectual property policies for large bioresources, open bioresources, fictional commitment to 244–54
access payments 249, 250–51
Biobrick Public Agreement 249
controlled eligibility policies 249
open source and open access contrast 247–8
openness and closedness mixed policy 250, 251–2, 253
openness concept and typology 244–8
restricted access databases 253
third party property rights 252
trade secrets or confidential information 248–9, 252–3
International Breakpoint Mapping Consortium (IBMC) 3, 4, 6, 7–8, 10, 11–16
International Charter of Principles for Sharing Bio-specimens and Data 255–6
international collaboration in genetic research 2–21
autonomy and privacy protection 4–5, 8, 13, 17
biopiracy claims 5
conflicts of interest 15–16
data protection 8, 11–12
ethics work and infrastructural flows as analytical objects 9–11
flows concept 11–15
genetic information concerns 18, 179–80, 182–3
International Breakpoint Mapping Consortium (IBMC), and chromosomal rearrangements (genetic study) 3, 4, 6, 7–8, 10, 11–16
medical record checks 11
nonflows concept 13, 15–17
open access and data sharing policies 17–19
organ donation concerns 18–19
overflows 17–19
overflows, positive test results, significance of 17–18
Pakistan samples 13–15, 16–18
sample collection 10–11, 13, 14–15, 16–17
sample sharing 120, 128–9
social scientific study 6–7, 8, 12–14
trust factors 14–17
International Covenant on Civil and Political Rights (ICCPR) 74–5, 104–5
International Covenant on Economic, Social and Cultural Rights (ICESCR) 80, 81, 84
Ioannidis, J. 131
Irion, S. 191
Italy 124–5
Jafarey, A. 167
Japan 125–6
Javaid, M. 125
Jeffers, B. 216
Joly, Y. 67, 207, 244, 258, 259
Jordan, M 242–63
Jordan, T. 178
Joskow, P. 200
Kaiser, J. 176
Kaitin, K. 201
Kamuya, D. 169, 170
Kaufman, D. 182
Kaye, J. 5, 37, 68, 73, 117–29, 134, 135, 151, 183, 234
Keating, P. 3
Keogh, B. 53
Kere, J. 233
Kessler, A. 45
Kinkorová, J. 122
Kipnis, K. 163, 165–6, 172
Kirby, E. 135
Knoppers, B. 258, 259
knowledge institutions 22–40
autonomy protection 36–7
Big Data and data science definition 25–6
biobanks definition 23–4
future challenges 37–9
governance definition 26–7
knowledge definition 24–5
knowledge interests, current and future 27
regulatory issues and conflict resolution 26–7
resources, complex character of 38–9
viability assessment 39
see also information
knowledge institutions, knowledge commons research framework 27–37
commons solutions in new institutional settings, potential for 30
governance applications 34–7
governance solutions for shared resources subject to social dilemmas 28–31, 32–3
Institutional Analysis and Development (IAD) framework comparison 30–31, 33
and intangible information 31
intellectual property 31–2
natural resource commons governance comparison 29, 31, 33, 35
openness and sharing of relevant resources, management of 29–30, 31–2
ownership interests 36
personal autonomy, privacy and security issues 36–7
spillovers from bilateral market transactions 30
see also open access
Kokkat, T. 222
Koktvedgaard, M. 113
Kondylakis, H. 183
Kongsholm, N. 156–72
Koskenniemi, M. 256
Kowal, E. 5–6, 14
Kreiner, T. 191
Kroeger, F. 138
Kulynych, J. 183

Lander, B. 131
Landes, W. 200
Langhof, H. 242, 249, 258
Lau, B. 178
Laurie, G. 252
Laurie, R. 207
Lauss, G. 15
Lee, P. 34–5, 36

legal, ethical, and societal issues (ELSI) 62–4, 65, 236
legal framework
  consent problem and uncertainty 175–6
  Dynamic Consent concept 120–22, 126–7
  legislation fragmentation, developing countries 159
see also governance structure
legitimacy requirement for use of biosamples 68–9, 70
Lehtimäki, H. 232
Lemke, A. 193
Lemmens, P. 190
Lemmens, T. 215
Lemrow, S. 258, 259
Leonelli, S. 9, 244
Lévesque, M. 262
Levin, M. 113
Levin, N. 244
Levine, C. 164
Levy, R. 199
Lewis, J. 136

Liddell, K. 51, 52, 54, 242–63
Liddicoat, J. 51, 52, 54, 242–63
Lidz, C. 161
Liede, S. 232
Light, D. 200
Lipworth, W. 158
liquid biopsy tool (plasma sequencing) 220
Liu, P. 252
López, C. 86
Lou, J. 222
Luna, F. 163, 164–5
Luther, L. 215
Lynch, H. 176
McCain, K. 205
McDonald, S. 197
McGoey, L. 15, 16
McGuire, A. 175
Macheiner, T. 218
Macklin, R. 160
McLauchlan, C. 212
Madison, M. 22–40
Mager, S. 58
Maggiolino, M. 247, 252
Mallette, A. 256
Mansfield, E. 199
Margoni, T. 255, 262
Marks, J. 6
Marshall, E. 179
Mascalzoni, D. 4, 256
Massett, H. 221
Master, Z. 120, 174, 176, 177, 193, 196
Mayrhofer, M. 5, 73, 118, 237
media hype concern, consent problem 178–9, 183
Meijer, I. 5, 197
Merino-Martinez, R. 54
Meslin, E. 3
Meyer, M. 202
Michalowski, S. 102, 105, 107
Millien, R. 207
Global genes, local concerns

Minari, J. 126, 127
Minssen, T. 46, 47, 53, 96, 243
Mitchell, R. 196, 234
Moazam, F. 167, 168
Mol, A. 20
Möllering, G. 136
Montagnani, M. 247, 252
Moodley, K. 130
morality concerns 12–13, 95, 98, 100, 111, 112–16

see also ethical concerns
Moran, N. 199
Moreno, P. 67, 176
Moufang, R. 100
Mueller-Langer, F. 209
Muilu, J. 237
Mullard, A. 204
Murdock, B. 67, 173–84
Murdoch, C. 189
Murphy, J. 177
Murray, K. 179
Murtagh, M. 191
Myriad Genetics 42, 51–2, 54

Nanibaa’A, G. 177
Nelkin, D. 59

networks 229–41

and biomarkers 229, 230, 231, 241
common ontology requirement 235
disease-based biobanks 232
EU BBMRI network, MIABIS (Minimum Information About Biobank Data Sharing) 51, 235, 239
EU GenomeEUtwin project 237

genetic association studies 233
governance structure 239–40
irreproducibility issues 229
legal, ethical, and societal issues (ELSI) 236

‘omics’ platforms 230, 238
policy setting role 234, 239
population-based biobanks 231–2
research collaborations 234, 235
sample quantity and quality issues 235–6
samples and preanalytical variables 230
social norms and standards, establishment of 234

see also collaboration; harmonization approach

networks, EU BBMRI-ERIC infrastructure 118, 157, 202, 236–40
common services 239–40

and European research infrastructure (ERA) 237–8
Expert Centre (EC), academia and industry expertise combination 238–9

funding commitments and memorandum of understanding (MoU) 238

interoperability of biobanks and data 237

quality standards 240

Nicol, D. 57, 115, 130, 145, 147, 148–9, 154, 180, 194, 196, 197, 214, 243, 247–8, 251, 253, 258, 259

Nielsen, J. 11
Nielsen, M. 115

Nilstun, T. 193, 198

nonflows concept, and international collaboration 13, 15–17

Nordberg, A. 96
Norlin, L. 51, 226, 235
Nozick, R. 83
Nys, H. 76, 78
<table>
<thead>
<tr>
<th>Name</th>
<th>Page(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Brien, S.</td>
<td>243</td>
</tr>
<tr>
<td>Odeh, H.</td>
<td>53, 234</td>
</tr>
<tr>
<td>O’Doherty, K.</td>
<td>130</td>
</tr>
<tr>
<td>OECD Guidelines</td>
<td>78–9, 119, 188</td>
</tr>
<tr>
<td>Ogbogu, U.</td>
<td>120, 178, 183</td>
</tr>
<tr>
<td>Olson, J.</td>
<td>191</td>
</tr>
<tr>
<td>‘omics’ platforms,</td>
<td>230, 238</td>
</tr>
<tr>
<td>networks</td>
<td></td>
</tr>
<tr>
<td>Onisto, M.</td>
<td>194</td>
</tr>
<tr>
<td>open access</td>
<td>17–19</td>
</tr>
<tr>
<td>and innovation</td>
<td>see responsible</td>
</tr>
<tr>
<td>research and innovation</td>
<td>open access/open</td>
</tr>
<tr>
<td>science issues</td>
<td></td>
</tr>
<tr>
<td>intellectual property policies</td>
<td>see intellectual property policies</td>
</tr>
<tr>
<td>for large bioresources,</td>
<td>open bioresources, fictional</td>
</tr>
<tr>
<td>commitment to</td>
<td></td>
</tr>
<tr>
<td>see also</td>
<td>data sharing;</td>
</tr>
<tr>
<td>knowledge institutions,</td>
<td></td>
</tr>
<tr>
<td>knowledge commons</td>
<td></td>
</tr>
<tr>
<td>research framework</td>
<td></td>
</tr>
<tr>
<td>organ donation concerns</td>
<td>18–19</td>
</tr>
<tr>
<td>Ortega-Paino, E.</td>
<td>229–41</td>
</tr>
<tr>
<td>Ostrom, E.</td>
<td>28–9, 30, 31, 33, 36, 39</td>
</tr>
<tr>
<td>Overby, C.</td>
<td>130</td>
</tr>
<tr>
<td>Owens, P.</td>
<td>199</td>
</tr>
<tr>
<td>ownership, access and use</td>
<td>Dynamic</td>
</tr>
<tr>
<td>Consent concept</td>
<td>146–9</td>
</tr>
<tr>
<td>ownership interests, knowledge commons research framework</td>
<td>36</td>
</tr>
<tr>
<td>Pakistan</td>
<td>13–15,16–18</td>
</tr>
<tr>
<td>blood samples</td>
<td>see developing countries, exploitation and vulnerabilities in consent to biobank research, Pakistan case study, blood samples</td>
</tr>
<tr>
<td>Pantel, K.</td>
<td>48</td>
</tr>
<tr>
<td>Papoutsi, C.</td>
<td>182</td>
</tr>
<tr>
<td>Park, A.</td>
<td>173, 230</td>
</tr>
<tr>
<td>Parkman, A.</td>
<td>183</td>
</tr>
<tr>
<td>participation consent</td>
<td>see consent headings</td>
</tr>
<tr>
<td>participation withdrawal rights</td>
<td>see withdrawal rights</td>
</tr>
<tr>
<td>Patczu, G.</td>
<td>36, 147</td>
</tr>
<tr>
<td>Paterson, G.</td>
<td>112</td>
</tr>
<tr>
<td>Pathmasiri, S.</td>
<td>192, 193, 197, 242, 257, 260</td>
</tr>
<tr>
<td>Patra, P.</td>
<td>10, 14</td>
</tr>
<tr>
<td>Pecci, A.</td>
<td>182</td>
</tr>
<tr>
<td>Peek, N.</td>
<td>44</td>
</tr>
<tr>
<td>Peisssl, W.</td>
<td>218</td>
</tr>
<tr>
<td>Penders, B.</td>
<td>6</td>
</tr>
<tr>
<td>Pépin, J.</td>
<td>192</td>
</tr>
<tr>
<td>Perlman, R.</td>
<td>57</td>
</tr>
<tr>
<td>Perren, A.</td>
<td>52</td>
</tr>
<tr>
<td>Perry, M.</td>
<td>147, 259</td>
</tr>
<tr>
<td>Petersen, A.</td>
<td>37, 73, 76</td>
</tr>
<tr>
<td>Petroni, C.</td>
<td>108, 114</td>
</tr>
<tr>
<td>Picciocchi, C.</td>
<td>124</td>
</tr>
<tr>
<td>planned application effects, and expiration dates</td>
<td>223–4</td>
</tr>
<tr>
<td>Plomer, A.</td>
<td>77, 107, 108</td>
</tr>
<tr>
<td>Plotkin, H.</td>
<td>25</td>
</tr>
<tr>
<td>Ploug, T.</td>
<td>134</td>
</tr>
<tr>
<td>Podgurski, A.</td>
<td>44</td>
</tr>
<tr>
<td>population-based biobanks</td>
<td>231–2</td>
</tr>
<tr>
<td>Posner, R.</td>
<td>200</td>
</tr>
<tr>
<td>Poste, G.</td>
<td>229</td>
</tr>
</tbody>
</table>
Global genes, local concerns

poverty and education level effects, developing countries 161
Prainsack, B. 5
Pressman, L. 262
Price, W. 42–55
Prictor, M 117–29, 134, 135, 151
privacy concerns 4–5, 13, 30, 36–7, 45, 52–3, 54, 218, 255
and consent problems 121, 128, 181–3
data breaches 181–2
and human rights 74–5, 77, 78–9, 85, 88
see also autonomy;
confidentiality; data sharing
private biobanks and Guiding Principles on Business and Human Rights 85–6, 88, 89–90
Proctor, R. 16
public perception, and consent problem 177–84
public trust see trust factors
public–private partnerships 87–90, 180–81
Pullman, D. 192–3, 196
quality standards 69, 70, 145, 197, 220–23, 225–6, 232–6, 240
see also expiration date for biobanks
Quinlan, P. 219
Quinlan, Z. 206

Rai, A. 54, 244
Rasmussen, M 2–21
Reardon, J. 6
Reardon, S. 176
regulation fragmentation, Dynamic Consent concept 120–22, 126
regulatory rule argument, European patent law, free and informed consent in 98–9, 101, 111, 116
Reichman, J. 35
residual tissue use, European patent law 108
Resnik, D. 196
responsible research and innovation (RRI) 186–215
commercialization effects 193–203, 208, 209–11, 212–14
implementation confusion and conflicts of interest 190–91, 193
industry-sponsored research concerns 194, 198–9
intellectual property management and patent rights in international research collaborations 189–90, 200, 201, 206–8
patent protection debate 192
societal opposition to new innovations, reducing risk of 188–9
see also human biosamples in bioscience industries, responsible use of; innovation infrastructure for translational medicine
responsible research and innovation (RRI), open access/open science issues 186–7, 188–9, 203–14
holistic innovation framework 208–14
and intellectual property 206–9
patent donations from industry to research institutions 209, 212
patent rights, use of 209, 213–14
patentability inventive step and novelty 206, 208

Timo Minssen, Janne R Herrmann and Jens Schovsbo - 9781788116190
Downloaded from Elgar Online at 08/29/2019 07:12:14AM
via free access
time delays between knowledge and application 204–5, 206, 208
responsible research and innovation (RRI), stakeholders role in biobanking and medical research 191–203, 210, 211–14
collaboration and competing interests 194–5

collaborative partnerships between industry and public research organizations 199–200
donors’ withdrawal rights 197
ethical responsibility of researchers to inform donors about potential commercial applications 196–7
fundings and sustainability 197–8, 212
government involvement and socioeconomic growth 202–3
public research organization and researchers 201–2
public trust issues 195–9, 213–14
translational process and contributions required from stakeholders, lack of understanding of 198–9
value chains 211–13
restricted access databases, and intellectual property policies for large bioresources 253

Rial-Sebbag, E. 255
Ried, J. 130
Riegman, P. 59
risk factors 88, 89, 136–7
Rochet, J.-C. 139
Roessner, D. 201, 204
Rosas, A. 106
Rose, H. 5

Rothstein, M. 37
Rousseau, D. 136, 137
Ruggie, J. 86
Ruhleder, K. 9
Ruse-Khan, H. 256
St. Laurent, A. 251–2

sample collection

time delays between knowledge and application 204–5, 206, 208

responsible research and innovation (RRI), stakeholders role in biobanking and medical research 191–203, 210, 211–14
collaboration and competing interests 194–5
collaborative partnerships between industry and public research organizations 199–200
donors’ withdrawal rights 197
ethical responsibility of researchers to inform donors about potential commercial applications 196–7
fundings and sustainability 197–8, 212
government involvement and socioeconomic growth 202–3
public research organization and researchers 201–2
public trust issues 195–9, 213–14
translational process and contributions required from stakeholders, lack of understanding of 198–9
value chains 211–13
restricted access databases, and intellectual property policies for large bioresources 253

Rial-Sebbag, E. 255
Ried, J. 130
Riegman, P. 59
risk factors 88, 89, 136–7
Rochet, J.-C. 139
Roessner, D. 201, 204
Rosas, A. 106
Rose, H. 5

Rothstein, M. 37
Rousseau, D. 136, 137
Ruggie, J. 86
Ruhleder, K. 9
Ruse-Khan, H. 256
St. Laurent, A. 251–2
human rights framework 74–80, 81–2
Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines 87
International Covenant on Civil and Political Rights (ICCPR) 74–5
International Covenant on Economic, Social and Cultural Rights (ICESCR) 80, 81, 84
nondiscrimination and nonstigmatization issues 78
OECD Guidelines on Human Biobanks and Genetic Research Databases 78–9
privacy rights 74–5, 77, 78–9, 85, 88
private biobanks and Guiding Principles on Business and Human Rights 85–6, 88, 89–90
public biobanks 85
public–private partnership biobanks 87–90
right to information and donor’s right not to be informed 77–8
Universal Declaration on the Human Genome and Human Rights 78
Universal Declaration of Human Rights (UDHR) 74–5, 80, 81, 84
scientific productions and human rights, intellectual property rights 80–84
Scotchmer, S. 200
Scudellari, M. 123
Seatzu, F. 104
self-reporting, Dynamic Consent concept 124–5
Seok, J. 57
Shabani, M. 258, 259
Shapiro, C. 203–4
Sharp, R. 253
Shaver, L. 77
Sheller, M. 9, 21
Sheremeta, L. 211
Shickle, D. 73
Shockley, E. 132
Silberman, J. 201, 204
Silvola, S. 110
Siminoff, L. 182
Simon, C. 135
Singh, S. 130
Skelcher, C. 87
Skloot, R. 178
Skopek, J. 252
Sleeboom-Faulkner, M. 10, 14
Smith, J. 176
Somiari, S. and R. 180–81
Spruessel, A. 222
stakeholders role in biobanking and medical research see responsible research and innovation (RRI), stakeholders role in biobanking and medical research
Stallman, R. 247
Star, S. 9
Index

Steinsbekk, K. 67, 159, 214
Stephan, P. 205
Stephens, N. 197, 219
Sterckx, S. 149
Stewart, C. 108
Stilgoe, J. 190
storage conditions 69, 74, 220–23, 225–6
see also sample collection
Strandburg, K. 34, 38
Strange, H. 255
Stranger, M. 37, 73
Straus, J. 100
Strech, D. 118
Structural Genomics Consortium (SGC) 247
Suber, P. 246
supply chains 58–61, 62–4, 68–9
sustainability
Dynamic Consent concept see
Dynamic Consent concept and sustainability
responsible research and innovation (RRI) 197–8, 212
Sweden 97, 98, 104, 109, 113, 231, 232, 238
Tamminen, S. 51, 239
Tassé, A. 118, 135
Taupitz, J. 130
Teare, H. 125, 127, 152
termination costs, expiration date for biobanks 218–19, 227
Terry, S. 174
Thailand 160
Thornton, H. 130, 143, 144
Thorogood, A. 68
Thursby, M. 209
time delays between knowledge and application, responsible research and innovation (RRI) 204–5, 206, 208
Timmermans, S. 21
Tindana, P. 169
Tirole, J. 139
Tomlinson, E. 144
Tomlinson, T. 180
translational research
commercialization challenges, Dynamic Consent concept 131–2, 137–8, 148–9
innovation infrastructure see innovation infrastructure for translational medicine
responsible research and innovation (RRI), stakeholders role in biobanking and medical research 198–9
transparency, and information evaluation, Dynamic Consent concept 143–4, 149, 152–4
trials, patients’ retroactive involvement in 48
Trinidad, S. 193
trust factors 14–17, 180–81, 195–9, 213–14
and Dynamic Consent see
Dynamic Consent concept and sustainability, trust challenges
Tupasela, A. 197, 229–41
Turner, A. 210–11
Turney, L. 197
Tutton, R. 131, 143, 145, 196
Tyfield, D. 210
UK 120, 125, 127, 152, 174, 188, 250–51, 255
UNESCO International Declaration on Human Genetic Data 120, 188
unforeseen studies, dealing with, Dynamic Consent concept 119–21, 124–5, 126–8
Universal Declaration on the Human Genome and Human Rights 78
Universal Declaration of Human Rights (UDHR) 74–5, 80, 81, 84
Urry, J. 9, 21
US 42, 49, 54, 84, 125, 174, 176, 182, 218

Alice Corporation v CLS Bank International 260
Association for Molecular Pathology v Myriad Genetics 260, 261
Mass. Eye & Ear Infirmary v QLT Phototherapeutics 204, 206
Mayo Collaborative Services v Prometheus Laboratories 260, 261
Texas blood samples litigation 184

value chains, responsible research and innovation (RRI) 211–13
Van Hoyweghen, I. 183
Van Looy, B. 201
Van Ommen, G.-J. 191, 238
Van Overwalle, G. 35, 99
Van Zimmeren, E. 130–55
Varmus, H. 49
Vaught, J. 173, 234
Verlinden, M. 53
Vitullo, M. 77
Vogl, F. 216–28
Von Schomberg, R. 188, 190, 203, 215
Vuorio, E. 118

Wack, J.-P. 192
Wagner, J. 175

Waldby, C. 5, 196, 234
Walsh, J. 188, 199, 260
Warburton, R. 200
Warth, R. 52
Watson, P. 59, 230
Wauters, A. 183
Webster, A. 132
Wee, R. 128
Wehling, M. 131
Weigert, A. 136
Wendler, D. 160
Wertheimer, A. 162
Whipple, W. 53
Whitesy, E. 119, 123, 127, 128
Wilkinson, M. 50
Williams, H. 135
withdrawal rights 75–7, 143, 151, 197

see also consent headings
Womack, C. 58
World Medical Association (WMA) 4, 118, 119
Wyndham, M. 77
Yoly, J. 176
Yu, H. 37, 186–215
Yu, P. 73–91

Zaheer, A. 132, 138
Zaman, R. 167
Zatloukal, K. 57, 157, 230
Zawati, M. 68
Zerhouni, E. 190
Zheng, Y. 152
Ziegler, N. 209
Zika, E. 159, 242, 258, 259