

# Index

Page numbers in *italics* refer to tables.

abuse risk 59, 69-71, 83, 85-7  
existing collections 102, 103, 104, 110  
American Society of Human Genetics  
(ASHG) 58, 171  
Annas, G.J. 31  
et al. 58, 59  
anonymization 45  
and coding 4, 5, 16-17, 28-9, 241-2  
contributions to current debate 184  
discussion and conclusions 183-4  
ethical consequences and terminology  
problem 167-8  
identifiable data and samples 167-9  
similarities and differences between  
subgroups of respondents 182-3  
*see also* coding  
international recommendations 93  
irreversible 105, 142-5, 172-3  
medical samples/existing collections  
(scenario D) 98-102  
and withdrawal of consent 142-5  
autonomy, respect for 24, 85, 86, 107  
balance of rights 85, 107  
balance of values 162-3, 183-4  
Barton, J. 208  
benefit-sharing 19, 245-6  
guidelines 19, 32-3, 217, 218  
procedural difficulties 218  
reasons for 217-18  
and remuneration (scenario C) 52-3,  
219-28  
Bermuda agreement 4, 242  
biopiracy 208, 245  
“blanket consent” *see* general consent/  
“blanket consent”  
Bonn Guidelines 19  
Canadian Science and Technology Ethics  
Committee (CEST) 123

CCNE *see* Comité consultatif national  
d'éthique  
Chadwick, R. 18, 19, 249  
and Berg, K. 2, 248  
Knoppers, B.M. and 169  
CIOMS *see* Council for International  
Organizations of Medical Sciences  
Clayton, E.W. 14  
Clinical Lab Improvement Act (CLIA) 244  
coding  
double 172, 173-82, 242  
issues 185-6  
published recommendations 169-72  
types 173-82  
*see also under* anonymization  
COE *see* Council of Europe (COE)  
collaborative study 39-56  
collective consent *see* group/collective  
consent  
colorectal polyp research *see* scenario A  
Comité consultatif national d'éthique  
(CCNE) 59  
commercialization 18-19, 20  
guidelines 31-2  
vs public domain sharing 207-14  
common heritage approach 19, 31, 217, 218,  
245-6  
communication of results *see* informing  
participants of research results  
confidentiality 3, 16-18, 20  
guidelines 28-30  
person-specific genome sequencing 6  
terminology 29-30  
third party access to data 30  
*see also* anonymization  
consent/informed consent 13-16, 20, 84-5  
colorectal polyp research (scenario A)  
49-50, 60-87  
guidelines 24-6, 58-60, 86-7  
*see also specific types*  
construed consent 49, 60-5, 84

- Convention on Biodiversity (CBD), Rio Earth Summit 19, 217
- cost recovery 212-13
- Council of Europe (COE)
- anonymization and coding 93, 168, 169-70
  - commercialization 32
  - confidentiality 28, 30
  - consent 25
  - medical samples/existing collections 90, 119, 120
  - withdrawal of consent 27, 134
- Council for International Organizations of Medical Sciences (CIOMS) 24-5, 26
- cultural differences
- collective consent 124, 125-6, 128-9
  - institutional review boards (IRBs)/ethics committees 242
  - medical samples/existing collections 95-6, 101-2, 116, 118, 119-20
  - multi-layered consent 77
  - respect for autonomy 86
- custodianship vs ownership role of biobanks 199-201
- data/information
- linking health and genetic 2-3
  - medical vs genetic 4
  - sharing 4, 231-2, 234-5, 242-3
  - third party access to 30
- deceased donors
- irreversible anonymization 105
  - withdrawal of consent 157-9
- Declaration of Helsinki 14, 15, 132, 241
- Declaration on the Rights of Indigenous People 200
- Denzin, K.K. and Lincoln, Y.S. 40
- Deschênes, M. et al. 59-60
- destruction of samples 51-2, 159-60, 244-5  
*see also under* withdrawal of consent
- diagnostic testing *see* medical samples/existing collections
- discrimination and stigmatization 72, 101, 109, 118, 169
- double coding 172, 173-82, 242
- Elger, B.
- and Caplan, A. 3, 16-17, 24, 26, 29, 168
  - and Mauron, A. 59
- Ethics Committee of the Swedish Medical Research Council 171
- ethics committees *see* institutional review boards (IRBs)/ethics committees
- European Agency for the Evaluation of Medicinal Products 171-2
- European Society for Human Genetics (ESHG)
- collective consent 26, 123
  - consent for broader use 58
  - medical samples/existing collections 90-2, 119
  - withdrawal of consent 133, 134
- existing collections 102-15  
*see also* medical samples/existing collections
- explicit consent 94-5
- exploitation, benefit-sharing and remuneration 226-7
- fee-based access system 212-13
- feedback *see* informing participants of research results
- free genetic testing 222-3
- funding
- public and private 45
  - see also* commercialization
- future perspectives 6, 247-8
- gradual normalization 248-9
  - international 250-1
  - non-maleficence principle 108-9
  - recontact for re-consent 14-15
- general consent/"blanket consent" 14, 15, 24, 45
- guidelines 58, 59
  - vs new informed consent for each new study 54, 65-74, 95-7
  - vs presumed consent 97-8
- Genetic Privacy Act (GPA) proposal 58
- "gift," donation as 3, 18-19
- Godard, B. et al. 171
- group/collective consent
- adequacy in representing individuals 128
  - benefit-sharing and remuneration (scenario C) 53, 219-28
  - characteristics 121, 127
  - current debate 121-2
  - discussion and conclusions 129-30
  - ethics committee approval as 107
  - guidelines 26-7, 123
  - objectives for 122-3

- practical reasons for 124
- principle-based reasons for 124-5
- processes for 125-7
- research use of samples taken for clinical purposes 98
- similarities and differences between subgroups of respondents 128-9
- study method 123-4
- guidelines *see* international guidelines
- HapMap Project 1, 198, 245
- harm-prevention
  - individual vs population perspective 2
  - see also* abuse risk; non-maleficence principle
- Harris, D. and Kanehe, L.M. 200
- health and genetic data, linking 2-3
- Human Genome Organisation (HUGO)
  - anonymization and coding 171
  - benefit-sharing 19, 33, 217
  - collective consent 26, 123
  - commercialization 32
  - confidentiality 29, 30
  - consent 25, 58, 59-60, 86
  - future uses and recontact 14
  - medical samples/existing collections 92, 119
  - ownership of samples 31
  - withdrawal of consent 133-4
- Human Genome Project 1, 4, 19, 242
- human genomes 1-4
- identifiable data and samples 167-9
  - see also* anonymization
- independent key-holder and double coding 173-81
- indigenous populations
  - anonymization and coding 174
  - benefit-sharing and remuneration (scenario C) 53, 219-28
  - collective consent 98, 123-30
  - and developing countries, abuse risk 69-71, 83, 85-7, 102, 103, 104, 110
  - gene patenting 208
  - medical samples/existing collections 98, 102, 103, 104
  - ownership of samples 200-1
- individual(s)
  - adequacy of representation in collective consent 128
  - vs population perspective 2
  - information *see* data/information
  - informed consent *see* consent/informed consent
  - informing participants of research results 17-18, 50, 189-95, 243-4
  - institutional review boards (IRBs)/ethics committees 67, 68, 70-1
    - anonymization and coding 169, 170
    - approval as collective consent 107
    - cultural differences 242
    - medical samples/existing collections 109, 110, 112, 119-20
  - intellectual property
    - rights (IPR) 224-5, 243
    - vs public good 4
    - see also* ownership of samples/data
  - international framework 239-46
  - international guidelines 23-4
    - anonymization and coding 93, 169-72
    - benefit-sharing 19, 32-3, 217, 218
    - commercialization 31-2
    - confidentiality 28-30
    - consent/informed consent 24-6, 58-60, 86-7
    - general consent/"blanket consent" 58, 59
    - group/collective consent 26-7, 123
    - medical samples/existing collections 90-3, 118-20
    - ownership of samples 31-2
    - withdrawal of consent and destruction of samples/data 133-4
  - international participants 40-1, 42-3
  - international perspective on future research 250-1
  - interview questions, scenarios and 47-55
  - irreversible anonymization 105, 142-5, 172-3
- Jensen, K. and Murray, F. 208
- Knoppers, B.M. 2, 14, 17, 23, 25, 31
  - Abdul-Rahman, B.M. and Bédard, K. 13, 16, 17
  - and Chadwick, R. 169
  - Joly, Y. et al. 17, 189
  - and Kent, A. 14
  - and Saginur, M. 3, 4, 16, 29
- Kohane, I.S. 195
  - Mandl, K.D. et al. 2, 5

- Lin, Z. 168
- Owen, A.B. et al. 4, 28
- linkage studies 2-3
- Lipworth, W., Ankeny, R. et al. 2, 15
- Lowrance, W.W. and Collins, F.S. 208
- Marshall, E. 4, 6, 242
- Marshall, P.A. and Berg, J.W. 122
- Material Transfer Agreements (MTA) 45, 50, 231-2, 233-4, 243
- medical equipment, donation of 223-4
- medical findings 46
- informing participants of research results 17-18, 50, 189-95, 243-4
- Medical Research Council of Canada 59
- medical samples/existing collections
- challenge 89-90
- published recommendations 90-3, 118-20
- types of consent (scenario D) 54, 93-120
- medical vs genetic data 4
- multi-layered consent 14, 15, 59, 77-83
- National Bioethics Advisory Commission (NBAC), US 14
- anonymization and coding 170, 171
- consent 26, 59, 91-2
- withdrawal of consent 134
- Network of Applied Genetic Medicine (RMGA) 59
- new informed consent *see* re-consent
- non-maleficence principle 2, 28, 104, 192
- anonymization and coding 174, 177
- future patients 108-9
- Nuffield Council 26, 31
- Nuremberg Code 15, 131, 241
- Office for Human Research Protection (OHRP), US 168-9
- one-time general consent *see* general consent/"blanket consent"
- ownership of samples/data 3, 18-19, 242
- colorectal polyp research (scenario A) 47
- guidelines 31-2
- research issues 197-9
- and territorial restrictions 201-4
- vs custodial role of biobanks 199-201
- see also* intellectual property
- participants
- informing, of research results 17-18, 50, 189-95, 243-4
- international 40-1, 42-3
- payments to 46
- US 40-1, 43, 44
- patent-sharing by families 19
- patenting 207-8, 209
- public-funded research 211-12
- patrimonial rights 46
- person-specific genome sequencing 6
- physicians, informing participants of results 50
- vs researchers 193-5
- presumed consent 59-60, 74-7, 86
- vs general consent 97-8
- privacy *see* anonymization; confidentiality
- profit sharing with local hospital 223
- "Project Jim" 6
- public domain sharing 46, 210-11
- vs commercialization 207-14
- public interest argument 108
- Public Population Projects in Genomics 6
- qualitative methodology 40-4
- re-consent 15, 46
- anonymization 29, 98-102
- existing collections 102-15
- vs general consent 54, 65-74, 95-7
- re-identification procedures 181-2
- recontacting *see* re-consent
- remuneration
- and benefit-sharing (scenario C) 52-4, 219-28
- options 222-5
- payments to participants 46
- research interests vs autonomy rights 85, 107
- researchers
- fee-based access system 212-13
- sharing of data/results 231-2, 234-5, 242-3
- vs physicians, informing participants of results 193-5
- Rio Earth Summit, Convention on Biodiversity (CBD) 19, 217
- RMGA *see* Network of Applied Genetic Medicine
- Robertson, J.A. 18, 19
- SAMS *see* Swiss Academy of Medical Sciences
- scenario A (colorectal polyp research) 47-51

- anonymization and coding 48, 172-83
- consent 48-9, 60-87, 123-30
- informing participants of results 50, 189-95
- Material Transfer Agreements (MTA) 50, 231-2
- ownership of samples/data 51
- withdrawal of consent policies 48, 134-61
- scenario B (territorial limitations of samples/reimbursement) 51-2, 198-204
- scenario C (benefit-sharing/collective permission) 52-4, 219-28
- scenario D (medical samples/existing collections) 54, 93-120
- “semi-blanket” consent 59
- sharing
  - of data/results 4, 231-2, 234-5, 242-3
  - see also* benefit-sharing
- Simm, K. 217-18
- single coding 172
- single nucleotide polymorphisms (SNPs) 1, 208
- stigmatization and discrimination 72, 101, 109, 118, 169
- Swiss Academy of Medical Sciences (SAMS) 90
- termination of biobank 244-5
- terminology issues 3-4, 29-30, 167-8
- territorial restrictions (scenario B) 52, 201-4, 245
- third party access to data 30
- transfer of samples 232-4
  - Material Transfer Agreements (MTA) 45, 50, 231-2, 233-4, 243
- trust 68, 72, 74
  - anonymization and coding 174, 177, 182
  - medical samples/existing collections 106, 111, 116-17, 118, 119
  - withdrawal of consent 141-2, 162
  - see also* abuse risk
- umbilical cord blood biobanks 31
- UN Declaration on the Rights of Indigenous People 200
- UNESCO
  - anonymization and coding 169-70, 171
  - benefit-sharing 32, 218
  - confidentiality 28, 30
  - consent 25, 27, 90, 92
  - cross-national exchange of samples and data 198
  - ownership of samples 31
  - withdrawal of consent 133, 134
- US participants 40-1, 43, 44
- Watson, James 6
- Wendler, D. 15, 85, 86
- Williams, G. and Schroeder, D. 19
- withdrawal of consent 15-16, 27, 46, 241-2
  - and destruction of samples/data
    - adequate policies 134-5
    - contributions to debate 163-4
    - debate 131-2
    - discussion and conclusions 161-4
    - policies 134-61
    - published recommendations 133-4
    - similarities and differences between subgroups of respondents 160-1
  - disagreement on meaning of 161-2
  - and irreversible anonymization 142-5
- World Health Organization (WHO)
  - anonymization and coding 170-1
  - anonymity 25, 28-9, 29-30
  - benefit-sharing 32-3, 227
  - “blanket consent” 58
  - collective consent 26-7
  - commercialization 32
  - confidentiality 28-30
  - consent 25
  - Department of Ethics, Trade, Human Rights and Health Law 239
  - medical samples/existing collections 92
  - ownership of samples 31
  - withdrawal of consent 27, 133
- World Medical Association (WMA) 14, 15
  - anonymization and coding 167, 171
  - confidentiality 28
  - consent 25-6
  - withdrawal of consent 132, 133