

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## Index

---

- Academy of Medical Sciences, UK, 35, 65, 66
- access to data, 140–152
- agreements regarding, 141–144
- Certificates of Confidentiality, US, 133–135
- colleagues, allowing access to data by, 140
- consent
- conformance of access arrangements to, 143
  - open release of identifiable data with, 141
  - withdrawal of, with shared data, 143
- court, legal, and police demands for, 6, 132, 134, 159
- data access committees (DACs), 141, 151–152
- de-identified data, open release of, 141
- defined, 140
- ethics committee approval for, 144
- extremely restricted, 149–151
- freedom of information laws, demands under, 6, 133
- individual participation principle, OECD guidelines, 39
- jurisdictional conditions regarding, 144
- limitations on onward transfer, 144
- linking conditions, 144
- material transfer agreements for
- biopspecimen access, 142
- non-research access, requests for, 132–135, 159
- open access, 140–141
- oversight and governance of, 151–152
- privacy-preserving data linkage systems, 105, 146–149
- professional competency requirements for accessing, 142
- progress in future, actions and policies likely to contribute to, 159
- purpose limitation continuance, 143
- recontacting, conditions on, 143
- relocation or termination of project, conditions regarding, 144
- restricted access, 141
- return or destruction of data or biospecimens at conclusion of project, 144
- security requirements for, 144, 159
- terms and conditions of restricted access, 142–144
- accountability
- EU Data Protection Directive on, 42
  - as OECD privacy principle, 40
- Acquisti, Alessandro, 97
- activities preparatory to research, 80
- Agency for Healthcare Research and Quality, US, 54
- aggregate genomic data, resolution of DNA contributions in, 120
- ALSPAC (Avon Longitudinal Study of Parents and Children), 26
- American Medical Association (AMA)
- ethics code regarding privacy and confidentiality, 34
- ancestry, and data sensitivity, 21–22
- “anonymization” of data, 94, 105, 106
- APEC *see* Asia-Pacific Economic Cooperation
- Article 29 Data Protection Working Party, European, 42, 154
- on accountability, 45
  - on concepts of controller and processor, 128
  - on definition of consent, 44
  - determination of adequacy of protection from data transfers from EU/EEA, 154
- The Future of Privacy*, 46
- on geolocation services, 91
  - mandate of, 42
  - on personal data, 89–90, 107

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## Index

177

- Asia-Pacific Economic Cooperation (APEC)
  - broad privacy and data protection regimes in, 50–51
  - Privacy Framework, 51
- Australia
  - broad privacy and data protection regimes in, 49–50
  - health-related privacy regimes in, 64–65
  - research without consent, conditions allowing for, 81
  - Western Australia Data Linkage System, 28, 147
- Australian Law Reform Commission, 49, 65, 66, 89
- Australian National Health and Medical Research Council, 30, 50, 64
- Australian National Statement on Ethical Conduct in Human Research*, 64
- Australian Privacy Act (1988), 49–50
  - definition of personal data in, 88
  - review and revision of, xiii, 49, 64, 89
- Avon Longitudinal Study of Parents and Children (ALSPAC), 26
- behavioral/social research integrated with health research, 15
- Belmont Report (*Ethical Principles and Guidelines for the Protection of Human Subjects*, 1979), 55–56
- Biggs, Hazel, 33
- binding corporate rules, international transfers of data under, 155
- Biobanking and Biomolecular Resources Research Infrastructure project, 17
- biobanks, 16–17
- biospecimens
  - collections of, 13–17
  - defined, 13–14
  - see also data and biospecimens
- BioVU, Vanderbilt University, 28, 115, 148
- birth cohorts, defined, 18
  - see also cohort and other longitudinal studies
- breach of confidence, legal definition of, 33–34
- breaches of data security, notification requirements for, 135–136
- breaches of security, notification requirements for, 135–136
- Burton, Paul, 114
- Byers, Lord, 37
- Caldicott Guardians, 65, 128
- Canada
  - broad privacy and data protection regimes in, 48–49
  - ethics review system in, 63
  - health-related privacy regimes in, 53, 57, 63–64
  - Ontario Personal Health Information Protection Act (PHIPA), 53
  - Personal Information Protection and Electronic Documents Act (PIPEDA), 48–49, 53, 128, 153
  - Privacy Act, 48
  - privacy officers in, 128
  - research without consent, conditions allowing for, 81
  - roadmap on research use of electronic health information, 64, 65, 66
  - Statistics Act, 150
  - Statistics Canada, 150
  - transfers of data within and from, 153
- Canadian Institutes of Health Research, 57
- Canadian Standards Association, Model Code for the Protection of Personal Information, 48
- Canadian Tri-Council Policy Statement, *Ethical Conduct for Research Involving Humans*, 57, 63
- Cancer Research UK, 65
- Centers for Disease Control and Prevention (CDC), US, 54, 133–135
- Certificates of Confidentiality, US, 133–135
- certification of low identifiability risk under HIPAA Privacy Rule, 99–100
- Charter of Fundamental Rights of the European Union (2000), 30
- Church, George, 121
- Clarke, Roger, 29
- clinical trial regimes, 57–59
- Clinical Trials Regulations, UK, 65
- CNIL (*Commission nationale de l'informatique et des libertés*), 45
- cohort and other longitudinal studies
  - consent and, 74, 76
  - data sharing by, 139
  - defined, 18
- colleagues, allowing access to data by, 140
- collection limitation principle, as OECD principle, 39
- collections see under data and biospecimens
- Commerce Department, US, and Safe Harbor agreement, 155
- Commission nationale de l'informatique et des libertés* (CNIL), 45
- community consultation and engagement, 79–80

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## 178 Index

- competency requirements for access to data, 142
- computer linking of data, 146
- Confidential Information Protection and Statistical Efficiency Act, US, 150
- confidentiality
  - breach of, 33–34
  - defined, 33–34
  - distinguished from privacy, 32, 33
  - Hippocratic medical, 52–53
  - see also* privacy, confidentiality, and health research
- consent, 67–86
  - in access agreements *see under access to data*
  - agreement process, importance of, 71
  - broad consent, preferability of, 5, 74–77, 118
  - cohort studies and, 74, 76
  - community consultation and engagement, 79–80
  - in complicated research projects, 5
  - conventional application of, 69–70
  - Declaration of Helsinki on, 67, 68, 71, 78
  - duration/continuation/renewal of, 71
  - empowerment or control, questionably viewed as providing, 85
  - entrusting, viewed as, 85–86
  - European Article 29 Working Party on, 44
  - explicit versus implicit, 77
  - freely/willingly/voluntarily granted, 73–74
  - “fully” informed, problems with, 72, 116
  - future progress, actions and policies likely to contribute to, 158
  - in genetic and genomic studies, 116–118, 121–122, 123–124
  - inadequacy of standard accounts now, 68–69, 84–86
  - international transfers from EU/EEA on basis of, 155
  - legitimately sought, 71
  - meaningfully informed, 71–73
  - narrow consent, 74
  - Nuremberg Code on, 67
  - open release of identifiable data with, 141
  - opt-in versus opt-out agreements, 77–78
  - regulations and requirements, 75
  - research without, conditions allowing for, 81–84
  - as right, 67
  - to sharing of research data, 5
  - of vulnerable populations, 74
  - waiver of legal rights prohibited in agreements, 71
  - withdrawal of, 78–79, 143
- contractual agreements, international transfers under, 152–153, 154, 156
- cost of health care, and public interest in health research, 2
- Council of Europe
  - Convention 108 on Protection of Personal Data (1981)
    - current revising of, xiii
    - development of, 40
  - EU Data Protection Directive
    - embracing principles of, 42
  - distinguished from EU and its governing Council, 40
  - Recommendation on Profiling, 90
  - Recommendation on Research on Biological Materials of Human Origin, 36
- Council of International Organizations of Medical Sciences, 55
- court access to data, 6, 132–135, 159
- Craig, David, 120
- custodians, 126
- cyber security, concept of, 130–131
- data access committees (DACs), 141, 151–152
- data and biospecimens, 7–26
  - collections of, 11–17
    - biospecimen collections, 13–17
    - databases, 11–12
    - registries, 12–13
  - definitions pertaining to, 7–10, 13–14
  - direct control over, reduction of, 6
  - e-health revolution and, xiii–xiv, 10–11
  - electronic health records (EHRs), 10–11
  - electronic medical records (EMRs), 11
  - financial or other rewarding of subjects for use of, 24
  - information versus data, 7
  - as intellectual property, 23
  - metadata, 7
  - ownership of, 22–24
  - personal health records (PHRs), 11
  - primary versus secondary use of, 9–10
  - retention of, 129, 144
  - secondary use of data
    - EU Data Protection Directive on, 43
    - versus primary use, 9–10
  - vulnerability of health care versus health research data, 4
  - see also* access to data, de-identification of data, future use of data, linking of data, personal data and

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## Index

179

- identifiability, platforms, security of data, sensitivity of data, transfers of data
- data controllers, 42, 127
- data disclosure, defined, 8
- data enclaves, 149–151
- data handling or processing, defined, 8
- data processors, 127
- Data Protection Act, UK, 38
  - contractual transfers of data under, 153
  - coverage of research as a medical purpose, 45
  - data-subjects in, 8
- EU Data Protection Directive, transposition of, 41, 45, 47
- health-related privacy regimes and, 65
- personal data and identifiability under, 88, 90
- data quality principle, OECD guidelines, 39
- data safe havens/safe harbors/enclaves, 149–151
- data sharing, 138–140
  - access agreements, onward transfer limitations in, 144
  - advantages of, 138–139
  - by cohort or longitudinal studies, 139
  - defined, 9
  - organized pressures for, 138–139
  - Thomas and Walport report on, 81, 139, 150
- data stewards, 141
- data-subjects, definition of, 8
  - see also* subjects
- data use agreements, enforcement of, 136–137
- Database of Genotypes and Phenotypes (dbGaP), 27
- databases, 11–12
- dbGaP (Database of Genotypes and Phenotypes), 27
- de-identification of data
  - certification of low identifiability risk under HIPAA Privacy Rule, 99
  - genetic and genomic data, 118–119
  - importance of, 109–110
  - open release of de-identified data, 141
  - reduced consent and procedural requirements for de-identified data, 158
  - techniques for, 93–95
- Declaration of Helsinki, 36, 54–55, 60, 67, 68, 71, 78
- Department of Commerce, US, 155
- destruction or return of data or biospecimens at conclusion of project, 144
- disclosure of data, defined, 8
- discrimination, genetic, 137
- Duke University epilepsy genomics study, 116, 117
- Durant v. Financial Services Authority* (UK), 87, 90
- e-health revolution, 10–11
- Economic and Social Research Council, UK, 65
- electronic health records (EHRs)
  - described, 10–11
  - genomic discovery, EHR-driven, 115
  - integration of genetic and genomic data with, 123
- electronic medical records (EMRs), 11
- Electronic Medical Records and Genomics (eMERGE) Network, 115
- encryption of data, 104, 105, 136
- enforcement and sanctions, 135–137
- entrusting, consent viewed as, 85–86
- Ethical Conduct for Research Involving Humans* (Canadian Tri-Council Policy Statement), 57, 63
- Ethical Principles and Guidelines for the Protection of Human Subjects* (Belmont Report, 1979), 55–56
- ethics
  - access to data, ethics committee approval for, 144
  - Australian National Statement on Ethical Conduct in Human Research*, 64
  - consent as cornerstone of, 67
  - see also* consent
  - of genetics and genomics
    - exceptional treatment, need for, 111
    - mismatch of scientific advance and personal and social understanding, 6, 111
  - health, value placed on, 1
  - importance of privacy protection for research, 3–4
  - privacy, value placed on, 3
  - review systems, 60–61, 63, 65, 75, 107
  - sensitivity of data and biospecimens *see* sensitivity of data
- Ethics and Governance Council of UK Biobank, 152
- ethnicity, and data sensitivity, 21–22
- EU Clinical Trials Directive (2001), xiii, 58
- EU Data Protection Directive (1995), 41–47
  - on consent, 73
  - current revising of, xiii, 46

## 180 Index

- EU Data Protection Directive (1995), (cont.)  
   on data controllers and data processors, 127  
   data processing, definition of, 8  
   EU Clinical Trials Directive deference to, 58  
   national transpositions of, 41, 44  
   personal data and identifiability under, 87, 88, 89–90, 91  
   problems with, 44–47  
   on public interest, 44  
   on secondary use of data, 43  
   on sensitivity of data, 22, 42, 43, 44  
   suspension of subjects' right of access to data, on circumstances allowing, 43  
   on transfers from EU/EEA to other countries, 154–156  
   on transfers within EU/EEA, 153  
 Europe, Council of *see* Council of Europe  
 European Article 29 Data Protection Working Party *see* Article 29 Data Protection Working Party, European  
 European Commission, 154, 155  
 European Convention on Human Rights  
   applicability of, 30  
   as based on the Universal Declaration of Human Rights, 30  
   on exceptions to right to privacy, 31  
   on privacy as fundamental right, 30  
 European Union/European Economic Area (EU/EEA)  
   broad privacy and data protection strategies in, 37, 38, 41  
   Canadian approach to privacy compared, 49  
   Charter of Fundamental Rights of the European Union (2000)  
     applicability of, 30  
     on privacy, 30  
   Council of Europe distinguished from EU and its governing Council, 40  
   countries judged to provide adequate protection for personal data imported from, 154  
   countries modeling privacy and data protection strategies on, 41, 51  
   ethics review systems in, 61  
   personal data, data from everyday electronic transactions as, 91  
   privacy officers in, 128  
   transfers of data  
     under EU-US Safe Harbor Agreement, 154, 155  
     within Europe, 153  
     from Europe to other countries, 154–156  
   explicit versus implicit consent, 77  
   external access to data *see* access to data  
   fair information practices, 32  
   families of research subjects *see* relatives of research subjects  
 Federal Common Rule on Protection of Human Subjects, US (1991), 56–57  
   clinical trials and, 58  
   on consent, 77  
   current revising of, xiii  
   HIPAA Privacy Rule and, 56, 62  
   human subjects as defined by, 108  
   research as defined by, 24, 25–26  
   on withdrawal of consent, xiii, 78  
 Federal Trade Commission Act, US, 47  
 FOIA (Freedom of Information Act), US, 59, 135  
 Food and Drug Administration, US, 58, 133–135  
 Food, Drug, and Cosmetic Act, US, 57  
*For Your Information: Australian Privacy Law and Practice* (Australian Law Reform Commission, 2008), 49  
 Framingham Heart Study, 26  
 France  
   CNIL (*Commission nationale de l'informatique et des libertés*), 45  
   early privacy legislation in, 38  
   EU Data Protection Directive, national transposition of, 45  
 Freedom of Information Act (FOIA), US, 59, 135  
 freedom of information laws, demands for access to data under, 133  
 “fully” informed consent, 72, 116  
*The Future of Privacy* (European Article 29 Data Protection Working Party, 2009), 46, 73  
 future progress, actions and policies likely to contribute to, 158–159  
 future use of data  
   broad consent agreements and, 5, 74–77  
   clinical trial or product postmarketing surveillance, data collected during, 59  
   research without consent, conditions allowing for, 81–84  
 Gellman, Robert, 97  
 General Medical Council, UK, 65, 83  
 General Practice Research Database (GPRD), UK, 28, 148

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## Index

181

- generalizable knowledge, in definition of research, 8, 24, 25–26
- Genetic Information Nondiscrimination Act (GINA), US, 137
- genetics, defined, 112–113
- genetics and genomics, 111–123
- aggregate data, resolution of DNA contributions in, 120
  - consent in, 116–118, 121–122, 123–124
  - de-identification of data, 118–119
  - defined and distinguished, 112–113
  - discrimination based on, 137
  - electronic health records (EHRs)
    - genomic discovery, EHR-driven, 115
    - integration of genetic and genomic data with data from, 123
  - exceptional treatment, need for, 111
  - genome-wide association studies (GWAS), 114
  - genotype-driven recruitment of subjects, 115–116
  - identifiability of genomic data, 6, 118–121
  - incidental findings in, 117
  - Mendelian versus multifactor conditions, 112–113
  - mismatch of scientific advance and personal and social understanding, 6, 111
  - nature of the genome, 112
  - non-identified genomic data, means of identifying, 119–120
  - Personal Genome Project (PGP), 121–122
  - relatives of research subjects and *see* relatives of research subjects
- genome-wide association studies (GWAS), 114
- genomics, defined, 113
- genotype, defined, 113
- Germany
  - early privacy legislation in, 38
  - EU Data Protection Directive, national transposition of, 41
  - privacy officers in, 128
- GINA (Genetic Information Nondiscrimination Act), US, 137
- Good Clinical (Trial) Practices, 58
- Gostin, Lawrence, 24, 25–26, 29, 54
- GPRD (General Practice Research Database), UK, 28, 148
- Gross, Ralph, 97
- guidelines *see* laws, regulations, and guidelines
- Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, OECD *see* Organisation for Economic Co-operation and Development (OECD) privacy principles
- Guthrie, Robert, 15
- Guthrie spots (newborn blood screening specimens), 15
- GWAS (genome-wide association studies), 114
- Harvard University, Personal Genome Project (PGP), 121–122, 123–124, 141
- Health and Social Care Act, UK, 65, 83
- health data *see* data and biospecimens
- Health Information Technology Economic and Clinical Health (HITECH) Act, US, 10
- Health Insurance Portability and Accountability Act, US (HIPAA Privacy Rule, 2002)
  - on authorization of research use of data, 76
  - expected revision of, xiii
  - identifiability under, 99–103, 104
  - Limited Data Sets under, 95, 102–103
  - subjects, on approaching and selecting, 80
  - US Federal Common Rule on Protection of Human Subjects and, 56, 62
- health problems, reclassification of, via new research, 5
- health research *see* privacy, confidentiality, and health research, research
- healthcare costs and public-interest nature of health research, 2
- Helsinki, Declaration of, 36, 54–55, 60, 67, 68, 71, 78
- HIPAA, US *see* Health Insurance Portability and Accountability Act
- Hippocratic medical confidentiality, 52–53
- HITECH, US *see* Health Information Technology Economic and Clinical Health Act
- Hodge, James, 24, 25–26
- Hrynaszkiewicz, Iain, 102
- Human Fertilisation and Embryology Act, UK, 65
- Human Genetics Commission, UK, 65
- Human Genome Project, 113, 139
- human right, privacy viewed as, 30–32
- Human Rights Act, UK, 30
- human subjects *see* subjects

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## 182 Index

- Human Tissue Act, UK, 14, 65, 83–84
- Human Tissue Authority, UK, code of practice on research (2009), 83–84
- Iceland, subject to EU Data Protection Directive, 41
- identifiability, 87–110
- categories of identifiability, 105–107
  - certification of low identifiability risk, 99–100
  - concordance of identifiability terms, 106
  - future actions and policies likely to increase identifiability, 158
  - genetic and genomic identifiability, 6, 118–121
  - identifiers or identifying data
    - concept of, 92–93
    - US HIPAA Privacy Rule identifier list, 100–102
  - key-coding, 59, 104–105, 108, 118, 148
  - legal protections for identified or potentially identifiable data, need for, 159
  - linking data-sets with intent to identify, problem of, 96–98
  - no human subject if data not identifiable, policy of, 108–109, 159
  - non-identified data, means of identifying, 96–98, 119–120
  - ordering and retrievability of data
    - affecting status of data, 91
  - personal data, defined, 8, 42, 87–92
  - personal data, under EU Data Protection Directive, 87, 88, 89–90, 91
  - personally identifiable data, under US HIPAA Privacy Rule, 99–103, 104
  - rare data as identifiers, 95, 106
  - researchers, when data are not identifiable to, 107–108, 158
  - risk assessments, 99–100, 103
  - social/behavioral research integrated with health research, 15
  - terminology pertaining to, 105–107
  - US Office for Human Research Protections (OHRP) on, 108–109
    - see also* de-identification of data, re-identification of data
  - implicit versus explicit consent, 77
  - individual participation principle, OECD guidelines, 39
  - information
    - data versus, 7
    - see also* data and biospecimens
    - fair information practices, US tendency to cast privacy protections as, 32
  - Information Commissioner, UK, 76, 90, 107
  - informed consent *see* consent
  - Institute of Medicine, US, 62, 63, 65, 66, 77, 103, 105
  - Institutes of Health Research, Canada, 57
  - Institutional Review Board (IRB) system, US, 56, 60, 61, 77
  - integration of different fields of health research, 5
  - intellectual property, data and biospecimens as, 23
  - International Cancer Genome Consortium, 28, 114, 139
  - International Conference of Data Protection and Privacy Commissioners, 156
  - International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 58
  - international transfers of data, 152–156
    - under binding corporate rules, 155
    - from Canada, 153
    - with consent, 155
    - under contractual agreements, 152–153, 154, 156
  - EU Data Protection Directive on
    - exportation of personal data from EU, 42, 154–156
  - EU-US Safe Harbor Agreement, 154, 155
  - future progress, actions and policies likely to contribute to, 159
  - public interest exemption for, 155
  - special conditions in access agreements regarding, 144
  - universal standards, importance of developing, 156–157
  - US Safe Harbor self-certification framework for, 48
  - IRB (Institutional Review Board) system, US *see* Institutional Review Board (IRB) system, US
  - Japan
    - broad privacy and data protection regimes in, 50
    - health-related privacy regimes in, 58
  - Japanese Personal Information Protection Act, 50
  - Japanese Pharmaceuticals and Medical Devices Agency, 58



Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## Index

183

- jurisdictional conditions in access
  - agreements, 144
- Kaiser Permanente Research Program on
  - Genes, Environment, and Health, 27, 139
- key-coding, 59, 104–105, 108, 118, 148
- knowledge
  - defined, 8
  - generalizable, 8, 24, 25–26
- Kohane, Isaac, 115
- Laurie, Graeme, 30
- law enforcement access to data, 6, 132–135, 159
- laws, regulations, and guidelines
  - breaches of security, notification requirements for, 135–136
  - broad privacy and data protection regimes, 35–51
    - defined, 36
    - in APEC countries, 50–51
    - in Australia, 49–50
    - in Canada, 48–49
    - of Council of Europe, 40
    - of EU, 40–47
    - European strategies regarding, 37, 38, 41
    - historical background to development of, 36–38
    - in Japan, 50
  - confidentiality, as legal concept, 33–34
  - consent
    - legitimacy in seeking, 71
    - regulations and requirements, 75
    - waiver of rights not legally allowed in, 71
  - data use agreements, enforcement of, 136–137
  - enforcement and sanctions, use of, 135–137
  - health specific privacy regimes, 52–66
    - in Australia, 64–65
    - in Canada, 53, 57, 63–64
    - clinical trials, 57–59
    - described, 36
    - ethics review systems, 60–61, 63, 65
    - health care and payment regimes, 52–53
    - human-subject protection, 54–57
    - inconsistencies, complexities, and redundancies, problem of, 62–66
    - product postmarketing data, 58–59
    - public health regimes, 53–54
    - specialized laws and regulations, 59–60
      - in UK, 58, 65–66
      - in US, 52–53, 54, 55–57, 58, 60, 61, 62
    - identified or potentially identifiable data, specific protections for, 159
    - inconsistencies, complexities, and redundancies, 6, 35–36, 62–66
    - privacy, as legal concept, 30–32 *see under particular items by name or country*
- Lee, Lisa, 54
- Levin, Avner, 49
- Liddell, Kathleen, 73
- Liechtenstein, subject to EU Data Protection Directive, 41
- Limited Data Sets under US HIPAA Privacy Rule, 95, 102–103
- linking of data
  - access agreement limitations on, 144
  - defined, 146
  - as form of access, 146
  - with intent to identify, 96–98, 119
  - privacy-preserving data linkage systems, 105, 146–149
- longitudinal studies *see* cohort and other longitudinal studies
- Manitoba Centre for Health Policy (MHCP), University of Manitoba
  - “Pledge of Privacy,” 127
  - Population Health Research Data Repository, 28, 148
- Manson, Neil, 68, 71, 75
- matching of data, 96, 119, 146
- material transfer agreements for
  - biospecimen sharing, 142
- McGuire, Amy, 116
- McGuire, Sean, 116
- Medicaid, US, 53
- Medical Ethics* (Percival, 1849), 14
- Medical Research Council, UK, 65, 138
- Medicare, US, 53
- Medicines and Healthcare Products Regulatory Agency, UK, 58–59
- Mendelian genetic conditions, 112–113
- metadata, 7
- MHCP *see* Manitoba Centre for Health Policy
- Million Women Study, 27
- Morris, Andrew, 35
- multifactor genetic conditions, 112–113
- National Center for Health Statistics, US, 54, 150
- National Health and Nutrition Examination Study (NHANES), US, 27



## 184 Index

- National Health Service (NHS), UK  
 Caldicott Guardians, 65, 128  
 consent requirements, 75  
 Data Protection Act and, 65  
 Information Centre for Health and Social Care, 148  
 Million Women Study, based on NHS Breast Screening Centres, 27  
 Proportionate Review Service, fast-track review, 107  
 research without consent, conditions allowing for, 82  
 subjects, approaching and selecting, 81  
 UK Biobank data from, 17  
 use of data without patient consent, 45  
 National Health Service (NHS) Act, UK, 65, 82, 83–84  
 National Information Governance Board, UK, 65, 82, 83, 131  
 National Institutes of Health, US, 121, 133–135, 138  
 National Research Act, US (1974), 60  
 National Research Council, US, 106  
 Nazi doctors, medical experiments prosecuted, 67, 68  
*A New Pathway for the Regulation and Governance of Health Research* (Academy of Medical Sciences, UK, 2011), 65, 66  
 newborn blood screening, 15, 112  
 NHANES (National Health and Nutrition Examination Study), US, 27  
 Nicholson, Mary Jo, 49  
 non-identified data, means of identifying, 96–98, 119–120  
 non-research access, requests for, 132–135, 159  
 Norway, subject to EU Data Protection Directive, 41  
 notification requirements  
   breaches of security, in case of, 135–136  
   de-identified data, in case of incidental identification of, 144  
 Nuffield Council on Bioethics, UK, 65  
 Nuremberg Code, 67  
 OECD *see* Organisation for Economic Co-operation and Development (OECD) privacy principles  
 Office for Human Research Protections (OHRP), US, 108–109, 149  
 O'Neill, Onora, 68, 71, 75  
 Ontario Personal Health Information Protection Act (PHIPA), Canada, 53  
 openness and transparency  
   access to data, open, 140–141  
   EU Data Protection Directive on, 42  
   as OECD privacy principle, 39  
 opt-in versus opt-out consent agreements, 77–78  
 Organisation for Economic Co-operation and Development (OECD) privacy principles, 38–40  
 Canadian Standards Association, Model Code for the Protection of Personal Information based on, 48  
 Council of Europe Convention 108 compared to, 40  
 Japanese Personal Information Protection Act aligned with, 50  
 ownership of data and biospecimens, 22–24  
 participants *see* subjects  
 patient outcome registries, 13  
 penalties and enforcement, 135–137  
 Percival, Thomas, 14  
 personal data, identifiability of *see* identifiability  
 Personal Genome Project (PGP), Harvard University, 121–122, 123–124, 141  
 personal health records (PHRs), 11  
 Personal Information Protection and Electronic Documents Act (PIPEDA), Canada, 48–49, 53, 128, 153  
*Personal Privacy in an Information Society* (US Congressional Commission, 1977), 38  
 PHIPA (Ontario Personal Health Information Protection Act), Canada *see* Ontario Personal Health Information Protection Act (PHIPA), Canada  
 PIPEDA (Personal Information Protection and Electronic Documents Act), Canada *see* Personal Information Protection and Electronic Documents Act (PIPEDA), Canada  
 platforms, 18  
   consent problems with, 5, 85  
   data flow via, 18  
   defined, 18  
   examples of, 26–28  
   opportunities afforded by, 5  
 police access to data, 6, 132–135  
 pooling data, 146, 147  
 Population Health Research Data Repository, MHCP, 28, 148  
 primary versus secondary use of data, 9–10

- principal investigators (PIs), 126, 141  
 Privacy Act, Australia *see* Australian Privacy Act  
 Privacy Act, Canada, 48  
 Privacy Act, US, 38, 47, 59, 92  
 privacy, confidentiality, and health research,  
   1–6, xiii–xiv  
   access to data, 140–152  
     *see also* access to data  
   conflict between privacy and research,  
     problem with framing issue as, 1  
   consent issues, 67–86  
     *see also* consent  
   counterclaims to right to privacy, 31  
   data and biospecimens, 7–26  
     *see also* data and biospecimens  
   data sharing, 138–140  
     *see also* data sharing  
   definitions  
     confidentiality, 33–34  
     distinguishing privacy and  
       confidentiality, 32, 33  
     privacy, 29–33  
     research, 24–26  
     safeguards, 34  
   e-health revolution and, 10–11,  
     xiii–xiv  
   fundamental human right, privacy as,  
     30–32  
   future progress, actions and policies likely  
     to contribute to, 158–159  
   genetics and genomics, 111–123  
     *see also* genetics and genomics  
   importance of privacy protection to  
     successful research process, 3–4  
   integration of different types of health  
     research, 5  
   laws, regulations, and guidelines on,  
     35–51, 52–66  
     *see also* laws, regulations, and guidelines  
   personally identifiable data, 87–110  
     *see also* personal data and identifiability  
   as public-interest cause *see* public interest  
   safeguards and responsibilities regarding,  
     125–137  
     *see also* safeguards and responsibilities  
   scale-based problems with, 5  
   scientific opportunities, new  
     developments in, 5  
   vulnerability of health care versus health  
     research data, 4  
 privacy officers, 128  
 privacy-preserving data linkage systems,  
   105, 146–149  
 privacy risk assessments, 131–132  
 product postmarketing regimes,  
   58–59  
 professional competency requirements for  
   access to data, 142  
 profiling, 89, 90, 96, 119  
 “pseudonymized” or “pseudoanonymized”  
   data, 104, 106  
 public access to data  
   *see* access to data  
 public health practice distinguished from  
   research, 25–26  
 public health regimes, 53–54  
 Public Health Service Act, US, 54  
 public interest  
   cost of health care and, 2  
   EU Data Protection Directive on, 44  
   future progress, actions and policies likely  
     to serve, 159  
   health research as, 1–3  
   international transfers from EU/EEA on  
     grounds of, 155  
   privacy protection in, 3–4  
 Public Population Project in Genomics,  
   17  
 public research resource platforms  
   *see* platforms  
 purpose limitations on access to  
   data, 143  
 purpose specification principle, OECD  
   guidelines, 39  
 race, and data sensitivity, 21–22  
 re-identification of data  
   non-identified data, means of identifying,  
     96–98  
   retaining possibility of, 98–99  
 recontacting subjects  
   access agreements, conditions in, 143  
   genotype-driven recontact, 115–116  
 records *see* electronic health records;  
   electronic medical records; personal  
   health records  
*Records, Computers, and the Rights of Citizens*  
   (US HEW Advisory Committee on  
   Automated Personal Data Systems,  
   1973), 37  
 registries, 12–13  
   defined, 12–13  
   EU Data Protection Directive failing to  
     accommodate, 44  
   *Medical Ethics* (Percival, 1849), on  
     research use of hospital, 14  
   patient outcome registries, 13  
 regulatory regimes *see* laws, regulations,  
   and guidelines

## 186 Index

- relatives of research subjects
  - communication of genetic findings to, 123, 159
  - familial risk data, improvements in collection, storage, and retrieval of, 122–123
  - implications of a person's genotype for, 120
  - privacy and confidentiality protections needed for, 5
  - recruitment, genotype-driven, 115–116
- relocation of projects, access agreement conditions regarding, 144
- Report of the Committee on Privacy* (Younger Report, UK House of Lords, 1972), 37
- research
  - activities preparatory to, 80
  - defined, 24–26
  - EU Data Protection Directive's failure to define, 44
  - public health practice distinguished, 25–26
  - see also* privacy, confidentiality, and health research
- research data centers (data enclaves), 149–151
- research participants/subjects *see* subjects
- research platforms *see* platforms
- researchers
  - data controllers and processors, 127
  - non-identifiability of data in hands of, 107–108, 158
  - responsibilities of *see* safeguards and responsibilities
  - third-party access to data, legal power to resist, 6
- resource platforms *see* platforms
- responsibilities *see* safeguards and responsibilities
- restricted access to data, 141
- retention of data and biospecimens, 129, 144
- Rethinking Informed Consent in Bioethics* (Manson and O'Neill), 68
- return or destruction of data or biospecimens at conclusion of project, 144
- Richards, Martin, 73
- rights
  - consent as, 67
  - disassociated data or biospecimens, adhering to, 67
  - to know data about self, 23, 39, 43
  - privacy, 30–32
  - waiving of legal rights not allowed in consent agreements, 71
  - to withdraw consent, 67
- risk assessments
  - identifiability, 99–100, 103
  - privacy, 131–132
  - security, 130
- rules *see* laws, regulations, and guidelines
- safe harbors
  - data safe harbors/data havens/data enclaves/data research centers, 149–151
  - EU-US Safe Harbor Agreement on transfers of data, 154, 155
  - four different arrangements termed as, 100
  - US HIPAA Privacy Rule, removal of prohibited identifiers under, 100–102
- safeguards and responsibilities, 125–137
  - accountability principle, OECD guidelines, 40
  - broad consent, as supporting, 77
  - day-to-day operational safeguards, listing of, 125–126
  - definition of safeguard, 34, 125
  - enforcement and sanctions, 135–137
  - formal responsibility roles, 126–129
  - MHCP pledge of privacy, 127
  - non-research access, requests for, 132–135
  - privacy risk assessments, 131–132
  - retention of data and biospecimens, 129
  - security and cybersecurity, importance of attention to, 130–131
  - security safeguards principle, OECD guidelines, 39
  - stewardship, concept of, 129
  - sanctions and enforcement, 135–137
- secondary use of data
  - distinguishing from primary use, 9–10
  - EU Data Protection Directive on, 43
- security of data
  - access to data, security as condition of, 144, 159
  - breaches, documented incidents of, 4
  - concept and elements of, 130–131
  - as distinguished from privacy and confidentiality, 34
  - as OECD privacy principle, 39
  - sensitivity of data, 18–22
  - ancestry, race, and ethnicity as controversial categories, 21–22

Cambridge University Press

978-1-107-02087-0 - Privacy, Confidentiality, and Health Research

William W. Lowrance

Index

[More information](#)

## Index

187

- Canadian PIPEDA on, 48
- categories of sensitive data, 20
- de-identification considerations and, 94
- EU Data Protection Directive on, 22, 42, 43, 44
- key-coding, encryption of, 104
- as policy issue, 22
- sharing data *see* data sharing
- single nucleotide polymorphisms (SNPs), 114
- social/behavioral research integrated with health research, 15
- Social Security Numbers (SSNs), US, 96–98
- Solove, Daniel, 29
- Statistics Act, Canada, 150
- Statistics Canada, 150
- stewardship, 129
- subjects
  - access agreements, conditions regarding recontacting subjects in, 143
  - access to data about self
    - EU Data Protection Directive on suspension of, 43
    - as general principle, 23
  - approaching and selecting for research, 80–81, 158
  - in clinical trials, 57–59
  - communication of genetic findings to, 123, 159
  - consent of *see* consent
  - data-subjects, definition of, 8
  - Declaration of Helsinki on protection of, 36, 54–55, 60, 67, 68, 71, 78
  - financial or other payback for use of data, issue of, 24
  - genotype-driven recontacting and recruitment of, 115–116
  - individual participation principle, OECD guidelines, 39
  - policy of no human subject if no personal data involved, 108–109, 159
  - terminology alternatives for, 8
  - see also* relatives of research subjects
- Sweden, early privacy legislation in, 38
- Switzerland, data protection law parallel to EU data protection laws, 41
- termination of projects, access agreement conditions regarding, 144
- third-party access to data *see* access to data
- Thomas, Richard, 81, 139, 150
- transfers of data
  - access agreements, onward transfer limitations in, 144
  - within Canada, 153
  - within EU/EEA, 153
  - see also* international transfers of data
- transparency *see* openness and transparency
- trust, consent viewed as delegation of, 85–86
- UK Biobank, 17, 27, 78–79, 132, 139, 152
- UK Biobank Ethics and Governance Council, 152
- UK Data Archive, 27, 139
- Understanding Privacy* (Solove, 2008), 29
- unique bits of data, and identifiability, 95, 106
- United Kingdom
  - breach of confidence in English common law, 33
  - Caldicott Guardians in, 65, 128
  - health-related privacy regimes in, 58, 65–66
  - Principle Investigators (PIs) in, 126
  - Report of the Committee on Privacy* (1972, Younger Report), 37
  - research without consent, conditions allowing for, 82–84
- United Kingdom laws and regulations
  - Clinical Trials Regulations, 65
  - Data Protection Act *see* Data Protection Act, UK
  - Health and Social Care Act, 65, 83
  - Human Fertilisation and Embryology Act, 65
  - Human Rights Act, 30
  - Human Tissue Act, 14, 65, 83–84
  - National Health Service (NHS) Act, 65, 82, 83–84
- United Kingdom organizations and agencies
  - Academy of Medical Sciences, 35, 65, 66
  - Cancer Research UK, 65
  - Economic and Social Research Council, 65
  - General Practice Research Database (GPRD), 28, 148
  - Human Genetics Commission, 65
  - Human Tissue Authority, 83–84
  - Information Commissioner, 76, 90, 107
  - Medical Research Council, 65, 138
  - Medicines and Healthcare Products Regulatory Agency, 58–59
  - National Health Service (NHS) *see* National Health Service (NHS), UK
  - National Information Governance Board, 65, 82, 83, 131
  - Nuffield Council on Bioethics, 65

## 188 Index

- United States
  - Canadian approach to privacy compared, 49
  - Certificates of Confidentiality in, 133–135
  - consent not involving waiver of legal rights in, 71
  - few omnibus privacy and data protection regimes in, 47–48
  - health-related privacy regimes in, 52–53, 54, 55–57, 58, 60, 61, 62
  - IRB system, 56, 60, 61, 77, 149
  - Medicare and Medicaid, 53
  - Personal Privacy in an Information Society* (1977), 38
  - principal investigators (PIs) in, 126
  - privacy protections generally cast as fair information practices in, 32
  - Records, Computers, and the Rights of Citizens* (1973), 37
  - research without consent, conditions allowing for, 81, 84
  - Social Security Numbers (SSNs), 96–98
  - transfers of data from EU/EEA to academic, noncommercial, and governmental organizations, 156
  - EU-US Safe Harbor arrangement for commercial organizations, 154, 155
- United States laws and regulations
  - Confidential Information Protection and Statistical Efficiency Act, 150
  - Federal Common Rule *see* Federal Common Rule on Protection of Human Subjects, US
  - Federal Trade Commission Act, 47
  - Food, Drug, and Cosmetic Act, 57
  - Freedom of Information Act (FOIA), 59, 135
  - Genetic Information Nondiscrimination Act (GINA), 137
  - Health Information Technology Economic and Clinical Health (HITECH) Act, 10
  - Health Insurance Portability and Accountability Act (HIPAA) *see* Health Insurance Portability and Accountability Act
  - National Research Act, 60
  - Privacy Act, 38, 47, 59, 92
  - Public Health Service Act, 54
  - United States organizations and agencies
    - Agency for Healthcare Research and Quality, 54
    - Centers for Disease Control and Prevention (CDC), 54, 133–135
    - Food and Drug Administration, 58, 133–135
    - Institute of Medicine, 62, 63, 65, 66, 77, 103, 105
    - National Center for Health Statistics, 54, 150
    - National Institutes of Health, 121, 133–135, 138
    - National Research Council, 106
    - Office for Human Research Protections (OHRP), 108–109, 149
    - Veterans Health Administration, 53
  - United States v. Karl Brandt et al.*, 67
  - Universal Declaration of Human Rights, 30
  - universal standards for international transfers, importance of developing, 156–157
  - University of Manitoba *see* Manitoba Centre for Health Policy (MHCP), University of Manitoba
  - use limitation principle, OECD guidelines, 39
  - Vanderbilt University BioVU Program, 28, 115, 148
  - Veterans Health Administration, US, 53
  - vulnerable people
    - consent by, 74
    - data sensitivity and, 21
    - laws and regulations protecting, in research, 59–60
    - public health regimes aimed to help, 54
  - waiver of legal rights prohibited in consent agreements, 71
  - Walport, Mark, 81, 139, 150
  - Wellcome Trust, 65, 121, 138
  - Wellcome Trust Case Control Consortium, 27, 153
  - Western Australia Data Linkage System, 28, 147
  - withdrawal of consent, 78–79, 143
  - World Medical Association, 54
  - Younger Report (*Report of the Committee on Privacy*, UK House of Lords, 1972), 37