

Index

AAMC. See American Association of Medical pediatric care discrepancies in, 117 prediction modeling through, 117 Colleges accordance with existing laws American Association of Medical Colleges in Healthcare Internet of Things design, 145-46 (AAMC), 258 American College of Medical Genetics and in TPDA policy, 150 Genomics (ACMG), 202-3 accountability as Healthcare Internet of Things design American Recovery and Reinvestment Act, U.S., consideration, 144-45 102-3 in TPDA mechanisms, 149-50 Americans with Disabilities Act (ADA), U.S., 69, ACMG. See American College of Medical 92-96 Genetics and Genomics data mining practices and, 96 disability definitions under, 93-96 active breaches of identity, 185 ad hoc groups, 188 discrimination protections under, 71-72 eligibility criteria for, 93 in analytics, 182 GINA and, 93-94 defined, 187 identity management for, 185-86, 189-90 privacy under, 260 ADA. See Americans with Disabilities Act public accommodations under, 92-93 advertisers and advertising, health-related Big Data "regarded as" provision in, expansion of, 94-96 for, 86 scope of, 85 Affordable Care Act, U.S., 211 analytics aggregated data ad hoc groups in, 182 in Big Data health care research, 254-55 algorithmic classification, 177-79, 182, 266 HIPAA and, limitations under, 258-59 behaviors and characteristics in, 175-76 sources of, 269 descriptive classification, 179 TPDAs and, 148-49 development of, 175 algorithm patents, 312-14 groups in, ethical significance of, 177-83 in European Union, 313–14 identity in, ethical significance of, 177-83 in U.S., 312-13 offline, 179 algorithmic analytics, 177-79, 182, 266 personalization systems, 181-82 profiling, 179-82 algorithmic classification, in analytics, 177-79, 182 all-payer claims databases (APCDs), 69, 112-13 shared ownership of, 180-81 predictive classification, 182 advantages of, 112 Gobeille v. Liberty Mutual Insurance Co. and, prescriptive classification, 179 116-19 responses to, 175 growth of, 113 Anderson, Chris, 50



342 Index

anonymization, of Big Data, 249 as commodity, 262 Expert Determination pathway, 281-82 under Common Rule, 28-29, 246-47 anti-discrimination laws, for group privacy, 187 electronic communications and, informed antimicrobial resistance, decrease of, 56-57 consent in, 246-47 defined, 1, 252 antitrust rules, 320–21 APCDs. See all-payer claims databases ethical guidelines for, 4 Apopehnia, 51 evolution of, 2, 311 ascriptive autonomy, 20 exclusions, 101-6 ascriptive groups, 187 FDA discretion over, 107-9 assimilation model, defined, 69 genomic data flood, 2 autonomy, individual after Gobeille v. Liberty Mutual Insurance Co., ascriptive, 20 122-23 Big Data and, 109 health care fraud and, 75-79 bioethics and, 20-22. See also Common Rule; through postmarket analysis, 75 Health Insurance Portability and regulatory requirements, 76-77 health disparities and, 101-6 Accountability Act Privacy Rule IRBs, 20-21 among racial and ethnic minorities, civic solidarity and, 22 104-5 under HIPAA Privacy Rule, 28-29 commonwealths and, formation of, 22 consumer-driven data commons and, as homogeneous, 98-99 23-26, 29 informed consent and, 5 advantages of, 25 through electronic communications, ethical standards of, 25-26 246-47 rules of access for, 24 integrated sets, 256 linkage of, from multiple sources, 254 value of, 24 longitudinal health records in, 252 critiques of, 28 evolution of, 20-22 longitudinal population health data in, 252 machine learning and, 31–32, 35–38, 40 Hobbes on, 22 Kantian notion of, 20 manufacturers' use of, 100-1 norm of common purpose, 19-20 with new technologies, 3-4 voice as result of, 22-26 organization of, 100-1 weakness of, 21-22 in pharmacoepidemiology, 270–71 Avastin, 81–82 pharmacovigilance and, 75-79 through postmarket analysis, 75 Bacon, Francis, 31 transformative role of, 75-76 best practices precision medicine and, 34-36, 101, 105 for Big Data health care research, 254 traditional approaches to, 34-35 Expert Determination pathways and, 280-82 machine learning and, 35-36 Big Data. See also deidentification; health care epistemological shift and, 34-36 research; health-related big data; healthprivacy and, 36-40, 109 related Big Data; intellectual property losses of, 37-38 rights violations of, 38-40 analytics of, 158 regulation guidelines for, 4 anonymization of, 249 epistemology of, 30-34 autonomy issues for, 109 causation vs. correlation, 32-33 biomedical, 190-91 theory vs. data, 30-32 genetics research, 190 explanation vs. prediction, 34 implementation of, 191 small data and, shift from, 15 collection of, 100-1 on social media, 3 through consumer data, 101-2 sorting of, 100-1 distrust of medical community as factor in, in targeted populations, 99 104 in twenty-first century, 26-28 through EHRs, 98-99, 102-4 as valuable commodity, 205 model for, 110-11 volume of data with, 252-53



Big Data to Knowledge Initiative, 15 bioethics	CFR. See Code of Federal Regulations citizen education, 155
autonomy and, 20–22. See also Common Rule;	
Health Insurance Portability and	Civil Rights Act (1964), U.S., 95
•	clearinghouses, 138–41
Accountability Act Privacy Rule	CDIA, 139
top-down standards for, 23	CRAs and, 139
biological sequence information, 315	under FCRA, 139
biomarkers, 91	clients, for TPDAs, 148
biomedical Big Data, 190–91	clinical care, under Common Rule, 238–39
genetics research, 190	clinical decision support (CDS) products, 284,
HIPAA and, 255–61	287–93
implementation of, 191	development of
biospecimens, 197–99	advances in, 289–90
duty to share, 215–16, 218, 220–21	failures in, 288–89
identifiable, 227	medical liability law and, 300
non-identified, 227	new regulatory paradigms, 291–93
black box medicine, 296–98	next generation, 291, 294
benefits of, 297–98	CMS. See Centers for Medicare and Medicaid
epistemology of, 35–36	Services
implementation of, 298	Code of Federal Regulations (CFR), U.S., 196
informed consent and, 299	collection, of data
intellectual property rights for, 322	of Big Data, 100–1
legality of, 295	through consumer data, 101–2
medical liability law and, 298	distrust of medical community as factor in,
Precision Medicine Initiative and, 295	104
privacy and, 40	through EHRs, 98–99, 102–4
risk-based approach to, 302–3	model for, 110–11
black box software, 294	through clearinghouses, 139
	under HIPAA, 257
body scores, 58 BRAIN Initiative, 15, 19	by TPDAs, 152–53
breaches, of group privacy, 185–86	through data requests, 148
Breyer, Stephen (Justice), 115	collective agency, 188–89
Canaar Maanahat ar aa	collective identity, 188–89
Cancer Moonshot, 15, 19	collectives, 187
Caplan, Art, 157	Common Data Layout (CDL), 120–21
causation, 32–33	Common Rule, 20–21, 23–25
theories of, 32–33	Big Data under, 246–47
fairness and, 53–54	electronic communications and, informed
health-related Big Data correlations and,	consent in, 246–47
50-52	clinical care under, 238–39
law of, 52–54	confidentiality and, 244–46
CDIA. See Consumer Data Industry Association	control in research under, 244–46
CDL. See Common Data Layout	data access under, 28–29
CDRH. See Center for Devices and Radiological	data exemptions under, 242–43
Health	development of, 238–41
CDS products. See clinical decision support	ethics in, 241
products	National Commission for Protection of
Center for Devices and Radiological Health	Human Subjects of Biomedical and
(CDRH), 292	Behavioral Research and, 238-40
Centers for Medicare and Medicaid Services	privacy issues, 239-41
(CMS), 1	regulatory structure, 240–41
under FCA, 73	duty to share under, 218
claims processing rates, 83	ethical guidelines, 247–49
certification, of TPDAs, 147, 154–55	during development process, 241



More Information

Cambridge University Press 978-1-107-19365-9 — Big Data, Health Law, and Bioethics Edited by I. Glenn Cohen , Holly Fernandez Lynch , Effy Vayena , Urs Gasser Index

Index

failures within, 46-49

344

Common Rule (cont.) flexibility of, 247 health research under, 207-8, 238-39 HHS regulations for, 259-60 HIPAA and, 247-48 for identifiable private data, 243-44 under public health law, 245 individual privacy protections under, 223-25 exemptions from, 224 informed consent and, 26, 244-46 Big Data and, through electronic communications, 246-47 privacy and, under U.S. law, 196-97 IRBs and, 244 proactive approach to, 247 problems with, 242-46 distinction between research and non-research activities, 242-44 with number of activities, 242-44 professional standards, 247 public trust elements in, 247-48 regulatory structure of, 248-50 during development process, 240-41 standards, 247 revised versions of, 241 commonwealths, 22 completion technique, 194-95 confidentiality with Big Data health care research, 255 under Common Rule, 244-46 conscientious objection, to duty to share, 220-21 consent. See informed consent consumer data. See also consumer-driven data commons Big Data through, 101-2 Consumer Data Industry Association (CDIA), 139 Consumer Privacy Bill of Rights (CPBR), U.S., 62, consumer/credit reporting agencies (CRAs), 65-66 clearinghouses and, 139 consumer-driven data commons, 23–26, 29 advantages of, 25 ethical standards of, 25-26 rules of access for, 24 value of, 24 control, in research, 244-46 copyrights, 314-15 of biological sequence information, 315 data selection, 314-15 correlations Big Data and, 32-33 health-related Big Data and, 46-52

hypotheticals in, 46-49 mechanisms and, 47-48 costs, of Big Data health care research, 253 CPBR. See Consumer Privacy Bill of Rights CRAs. See consumer/credit reporting agencies data. See Big Data; small data data access mandates, 154 data analysis. See also analytics in Precision Medicine Initiative, 163 by TPDAs, 148 data brokers under FCRA, 60 under FTC guidelines, 64 for health-related Big Data, 60-62, 88-89 HIPAA guidelines, 61-62 data collection. See collection data determinism, 58 data manipulation, under FCA, 79-83 as direct false claim, 81-82 as reverse false claim, 82-83 data minimization, 62 data mining, 63 ADA and, 96 pharmacovigilance and, 78 data protection DPA, 194-95 EU General Data Protection Regulation, 192 for health-related Big Data, 58–60 conservative approach to, 59 FIPPs for, 59 FTC guidelines for, 63-67 reform proposals, 62-65 technology challenges, 59-60 reform proposals through data minimization, 62 for health-related Big Data, 62-65 through TPDAs, 147 data sharing schemes, 280 under Expert Determination Pathway, 282 database protections, in EU, 315 data-generating patents, 324-36 economic effects of, 329-30 deadweight loss extensions, 329-30 innovation incentives, 329 evolution of, 326-27 genetic disease marker proprietary databases, across technological fields, 327 legal consequences of, 327-29 problems with, 330-36 under antitrust rules, 333

disclosure-related issues, 334-35

background of, 46-49

causation and, 50-52



identification of, 330–31	insurance type classification, 219
innovation-related issues, 331–34	IRBs and, 221–22
sui generis protection of, 335	re-identification in, 215
trade secrets and, 327–29	
deadweight loss extensions, 329–30	economic disenfranchisement, from TPDAs,
DeCODE, 193–95	150–51
DPA and, 194	EHRs. See electronic health records
estimated data in, 193–94	electronic communication, informed consent
right to not know and, 202	through, 246–47
Defend Trade Secrets Act (DTSA), U.S., 318	electronic doctors, 266–67
deidentification, of data	electronic health records (EHRs), 73-74, 269-71
through Expert Determination pathway, 273-74,	Big Data through, 98–99, 102–4
278–80	duty to share through, 209
anonymization of data, 281–82	opt-ins, 211
best practices for, 280–82	opt-outs, 211
data sharing under, 282	TPDAs and, 152
HIPAA and, 273–75	Emmanuel, Ezekiel, 74
through Limited Data Set pathway, 274–76,	employers, health-related data for, 86
279–80	Employment Retirement Income Security Act
through Safe Harbor pathways, 273, 276–80	(ERISA) (1974), U.S., 69
Department of Health and Human Services	defined, 114
(HHS), 259–60	Gobeille v. Liberty Mutual Insurance Co. and,
descriptive analytics, 179	113–16
diagnostic patents, 312–14	
in European Union, 312–14	preemption clauses in, 114–15 end of theory claims, 31, 50
in U.S., 312–13	epidemic prediction, 56–58
difference-making causation, 32–33	epistemic probabilities, 37
dignitary harm, 230–31	epistemology of big data, 30–34
direct false claim, 81–82	Equal Credit Protection Opportunity Act, U.S., 66
disabilities, definitions of, 93–96	Equal Pay Act, U.S., 95
discrimination	ERISA. See Employment Retirement Income
ADA protections against, 71–72	Security Act
through health-related Big Data use, 58	Erlich, Yaniv, 194
through redlining, 58	ethics
disease modeling, 56–58	Big Data and, 4, 41
disruption model, defined, 70	in Common Rule
distrust of medical community, 104	during development process, 241
DPA. See Icelandic Data Protection Authority	guidelines for, 247–49
drug labeling, 76–77	Expert Determination pathway and, 279–80
misbranding in, 76	Limited Data Set pathway and, 279–80
DTSA. See Defend Trade Secrets Act	Safe Harbor pathway and, 279–80
duty to share, health-related Big Data	top-down standards, 23
arguments for, 212–21	ethnic minorities. See minorities
informed consent in, 214	EU General Data Protection Regulation, 192
for patients' property rights, 212–16	European Union, intellectual property rights in
reciprocity, 215–21	algorithm patents, 313–14
for biospecimens, 215–16, 218, 220–21	database protections in, 315
clarification of, 209–12	diagnostic patents, 313–14
under Common Rule, 218	regulatory exclusivities, 319
conditions for, 209–12	software patents, 313–14
conscientious objection to, 220-21	trade secrets, defined, 317
through EHRs, 209	Evans, Barbara, 262
opt-ins, 211	exceptionalism, health research for Big Data and,
opt-outs, 211	206



More Information

Cambridge University Press 978-1-107-19365-9 — Big Data, Health Law, and Bioethics Edited by I. Glenn Cohen , Holly Fernandez Lynch , Effy Vayena , Urs Gasser Index

346 Index

Expert Determination pathway, 273-74, 278-79 anonymization of data, 281–82 best practices for, 280-82 data sharing under, 282 ethical considerations for, 279-80 privacy protections in, 279-80 Faden, Ruth, 217 Fair Credit Reporting Act (FCRA), U.S., 60, 110 clearinghouses under, 139 CRA oversight under, 65-66 FTC and, 66 HIPAA and, 260 Fair Information Practice Principles (FIPPs), FTC and, 63-64 Healthcare Internet of Things and, 143 law of causation and, 53-54 law of reason and, 53-54 Fallon, Richard, 20 false claims. See direct false claim; reverse false False Claims Act (FCA), U.S., 6 amendments to, 80 CMS under, 73 claims processing rates, 83 data manipulation and, 79-83 as direct false claim, 81-82 as reverse false claim, 82-83 historical development of, 80-81 liability under, 81 Medicaid and, 80 Medicare and, 80 pharmacovigilance under, 73 Family Educational Rights and Privacy Act (FERPA) (1974), U.S., 260-61 FCA. See False Claims Act FCC. See Federal Communications Commission FCRA. See Fair Credit Reporting Act FDA. See Food and Drug Administration

Federal Policy for the Protection of Human Subjects (Common Rule). See Common Rule

Federal Trade Commission (FTC), 57 data brokers and, 64

FDCA. See Food, Drug & Cosmetic Act Federal Communications Commission (FCC),

Equal Credit Protection Opportunity Act and, 66

extant powers of, 65–67 FCRA and, 66 FIPPs and, 63–64 health-related Big Data and, protections for, 63--67

Internet of Things device regulation, 129, 136 regulation of privacy laws, 260

Federal Trade Commission Act, U.S., 110 FERPA. See Family Educational Rights and Privacy Act

financial institutions, health-related Big Data for, 86

FIPPs. See Fair Information Practice Principles Floridi, Luciano, 159–60, 183–85. See also informational privacy

Food, Drug & Cosmetic Act (FDCA), U.S., 81 Food and Drug Administration (FDA) Big Data and, enforcement guidelines for,

CDRH guidelines, 292

107-0

CDS products regulated by, 284, 287–93 development failures, 288–89 development of, 288–90 medical liability law and, 300 new regulatory paradigms, 291–93 next generation, 291, 294

Internet of Things devices and, regulation of, 129

medical software regulation, 284–88, 301 for black box software, 294 under Draft Software Policy, 285–86 of IVDMIAs, 286–87 mHealth applications and, 134–35

pharmacoepidemiologic studies, 78–79 pharmacovigilance by, 69

SDAs and, 78-79

fraud

health care, statutes against, 74 for overbilling, 74 in health-related Big Data, 56–57 free TPDAs, 151 FTC. See Federal Trade Commission

GAIN Act. See Generating Antibiotic Incentives

Now Act GDPR. See General Data Protection Regulation Genera Morborum (Linnaeus), 34–35

General Data Protection Regulation (GDPR), 45 TPDAs under, 152

Generating Antibiotic Incentives Now (GAIN) Act (2012), U.S., 319

genetic disease marker proprietary databases, 326-27

Genetic Information Nondiscrimination Act (GINA), U.S., 93–94, 190

genetic testing, 101 genetics research, 190



genome sequencing, 101	best practices standards, 254
genomic data flood, 2	confidentiality issues, 255
GINA. See Genetic Information	linkage of data from multiple sources, 254
Nondiscrimination Act	under Common Rule, 207–8, 238–39
Ginsburg, Ruth Bader (Justice), 115	compared to other research uses, 225–35
Gobeille v. Liberty Mutual Insurance Co., 113–24	cost savings from, 253
APCDs and, 116–19	data facilitation in, 205
Department of Labor regulations influenced by,	data protection for, 206–7
119–21	exceptionalism and, 206
ERISA and, 113–16	in Gobeille v. Liberty Mutual Insurance Co.,
incentives for data sharing after, 122-23	117–19
long-term legal impact of, 115–19	HIPAA and, 206–7
on health services research, 117–19	aggregated data limitations, 258–59
on Medicaid, 118	collaborative research under, 258
on Medicare, 118	deidentification of data, 273–75
on states' programs and initiatives, 116	enhancement strategies for, 261-63
voluntary data contributions by payers after,	limited data sets in, 272-73
121–22	sharing observational research, 271-75
government subsidies, for TPDAs, 150–51	human subjects in, 226-28
Gramm-Leach-Bliley Act, U.S., 260	Common Rule standards for, 226–28
group privacy, 176–77, 183. See also collectives	individually identifiable, 226–28
for ad hoc groups, 188	IRBs and, 228–30
defined, 187	privacy protections and, societal lapses in, 230
identity management for, 185–86, 189–90	sensitivity of health information, 229-30
anti-discrimination laws for, 187	social media and, 230
for ascriptive groups, 187	overview of, 252–53
in biomedical Big Data, 190–91	policy options for, 235–36
genetics research, 190	of private information, 228
implementation of, 191	professional cooperation in, 337-39
breaches of, 185–86	public trust in, 263
for collectives, 187	risk assessment of, 230-35
moderate interpretation of, 186	administrative burdens of, 232
right to inviolate personality and, 185–90	application of uniform daily life risks
strong interpretation of, 186	standard, 232–34
weak interpretation of, 186	dignitary harm and, 230–31
	mediation of risk in, 234-35
Hatch-Waxman Act, U.S., 319	minimal risk determination, 231-33
HCUP. See Healthcare Cost and Utilization	recognition of risk in, 230–31
Project	volume of data, 252–53
Health Care Cost Institute, 121–22	health disparities, 101-6
health care data. See health care research; health-	among racial and ethnic minorities, 104-5
related Big Data	Health Information Technology for Economic
health care fraud. See also False Claims Act	and Clinical Health (HITECH) Act
Big Data and, 75–79	(2009), U.S., 102–3, 269
through postmarket analysis, 75	HIPAA and, 272
regulatory requirements, 76–77	Health Insurance Portability and Accountability
transformative role of, 75-76	Act (HIPAA), U.S.
through overbilling, 74	Big Data health care research and, 206-7
pay and chase model, 79–80	aggregated data limitations, 258-59
statutes against, 74	collaborations in, 258
health care research, for Big Data. See also	deidentification of data, 273-75
deidentification; genetics research	enhancement strategies for, 261-63
challenges for, 253-55	limited data sets in, 272-73
with aggregated data, 254–55	sharing observational research, 271-75



348 Index

Health Insurance Portability and Accountability correlations and, 46-52 Act (HIPAA), U.S. (cont.) background of, 46-49 biomedical data and, 255-61 causation and, 50-52 Common Rule and, 247-48 failures within, 46-49 data brokers under, 61-62 hypotheticals in, 46-49 data collection under, 257 data brokers for, 60-62, 88-89 data disclosure exceptions, 123 HIPAA guidelines, 61-62 data sharing schemes, 280 data protection policies for, 58-60 draft development of, 255-56 conservative approach to, 59 FCRA and, 260 FIPPs for, 59 FERPA and, 260-61 FTC guidelines for, 63-67 HITECH Act and, 272 reform proposals, 62-65 individual privacy protections under, 224 technology challenges, 59-60 overview of, 251-52 debate over, 56-58 PHI and, 257-59 decrease in antimicrobial resistance, 56-57 reclassification of, 259-60 defined, 44-45, 98 privacy laws and, 260-61, 269, 279-80 by GDPR, 45 purpose and function of, 261 deprecation of, 59-60 regulations under, 126, 257-58 discriminatory uses of, 58 reforms of, 259-60 disease modeling, 56-58 risk assessment and, 257 disease prediction and, 91–92 wearable technology under, 257 for employers, 86 Health Insurance Portability and Accountability epidemic prediction, 56-58 Act (HIPAA) Privacy Rule, 20-21, 23-25 expansion of, 2-3 data access under, 28-29 for financial institutions, 86 data brokers under, 61-62 fraud in, 56-57 data disclosure exceptions, 123 FTC guidelines for, 63-67 health-related data and, 90 after Gobeille v. Liberty Mutual Insurance Co., informed consent in, 26 health records. See electronic health records; high-risk patients and, identification of, 56-57 under HIPAA Privacy Rule, 90 longitudinal health records health services research, 117-19 for interested parties, 86–87 Healthcare Cost and Utilization Project (HCUP), Internet of Things and, 45-46 law of causation and, 52–54 Healthcare Internet of Things (IoT). See also fairness and, 53-54 law of reason and, 52-54 Third-Party Data Auditors CPBR and, 143 fairness and, 53-54 design considerations for, 143-46 legal implications of, 45 accordance with existing laws and norms, for marketing and advertising, 86 145-46 misuse of, 56 accountability in, 144-45 from non-biomedical sources, 2-3 individual awareness in, 143-44 through open data sources, 89-90 innovation protections, 146 patients' property rights for, 212-16 transparency in, 144-45 pharmacovigilance and, 56-57 FIPPs and, 143 studies of, 3 health-related Big Data, 44–46. See also privacy protections for, 90 deidentification; duty to share; Gobeille v. professional cooperation strategies with, 337-39 Liberty Mutual Insurance Co.; health care as public good, 262 research public health surveillance and, 56-58 APCDs, 112–13 regulatory arbitrage and, 60-62 body scores in, 58 through social media, 87-88 commercial use of, 57-58 subsumption approach, 5-6 as commodity, 262 through wellness programs, 88



HHS. See Department of Health and Human	historical development of, 223
Services	IRBs and, 223–25
high-risk patients, identification of, 56–57	in U.S., 225
HIPAA. See Health Insurance Portability and	informational identity, 183
Accountability Act	informational privacy, 176, 183–85
HIPAA Privacy Rule. See Health Insurance	informed consent
Portability and Accountability Act Privacy	in analytics, 185
Rule	Big Data and, 5
HITECH Act. See Health Information	through electronic communications,
Technology for Economic and Clinical	246–47
Health Act	black box medicine and, 299
Hobbes, Thomas, 22	under Common Rule, 26, 244–46
hospital referral regions (HRRs), 121–22	Big Data and, through electronic
human subjects	communications, 246–47
in Big Data health care research, 226–28	in duty to share, 214
Common Rule standards for, 226–28	in HIPAA Privacy Rule, 26
individually identifiable, 226–28	privacy and, under U.S. law, 196–202
National Commission for Protection of Human	of biospecimens, 197–99
Subjects of Biomedical and Behavioral	in CFR, 196
Research, 238–40	under Common Rule, 196–97
hypothetico-deductive method, 30–31	denial of consent, 201
	individual perspectives on, 199–202
Icelandic Data Protection Authority (DPA),	under NPRM, 197–200
194–95	innovation protections
identifiable biospecimen, 227	in Healthcare Internet of Things design, 146
identifiable private data, under Common Rule,	in TPDAs, 150
243-44	Institutional Review Boards (IRBs), 20–21
public health law and, 245	Big Data health research for, 228–30
identifiable private information, 227	privacy protections, societal lapses in, 230
identity	sensitivity of health information, 229–30
active breaches of, 185	on social media, 230
of ad hoc groups, 185–86, 189–90	Common Rule and, 244
in analytics, ethical significance of, 177–83	duty to share and, 221–22
offline, 179	individual privacy protections, 223–24
personalization systems, 181–82	right not to know and, 203–4
profiling, 179–82	integrated Big Data sets, 256
shared ownership of, 180–81	intellectual property rights (IPRs), Big Data and
collective, 188–89	algorithm patents, 312–14
informational, 183	in European Union, 313–14
passive breaches of, 185–86	in U.S., 312–13
identity-constitutive privacy, 183	antitrust rules, 320–21
in vitro diagnostic multivariate index assays	for black box medicine, 322
(IVDMIAs), 286–87	challenges with, 311
individual autonomy. See autonomy	copyrights, 314–15
individual awareness	of biological sequence information, 315
in Healthcare Internet of Things design, 143–44	data selection, 314–15
TPDAs and, 149	database protections, in EU, 315
individual privacy, protections for	diagnostic patents, 312–14
additional structures for, 223-24	in European Union, 313–14
for biospecimens, 224	in U.S., 312–13
under Common Rule, 223–25	for large research infrastructures, 321–22
exemptions from, 224	overview of, 312–19
under HIPAA, 224	for private sector use of public data, 322-23



350

machine learning, 31-32, 35-38, 40 intellectual property rights (IPRs), Big Data and marketing, health-related Big Data for, 86 mechanisms, 47-48 regulatory exclusivities, 318-19 in European Union, 319 accountability, 149-50 transparency, 149-50 in U.S., 319 Medicaid. See also Centers for Medicare and software patents, 312-14 in European Union, 313-14 Medicaid Services in U.S., 312-13 FCA and, 80 for specific applications, 321-23 after Gobeille v. Liberty Mutual Insurance Co., for specific areas of science, 321-23 sui generis rights, 312-19 medical devices. See Internet of Things devices; for data-generating patents, 335 mobile Health applications for SysBio, 321 Medical Electronic Data Technology Enhancement for Consumers Health trade secrets, 316-18 EU definition of, 317 (MEDTECH) Act, U.S., 134 in U.S., 318 medical liability law, 298-304 international law, privacy in, 176 for black box medicine, 298 Internet of Things (IoT) devices. See also CDS products, 300 Healthcare Internet of Things; mobile future recommendations for, 304-5 Health applications for health care enterprises, 303-4 ethical frameworks for, 125 medical malpractice by providers, 299–303 FCC regulation of, 129, 136 patient recovery under, 298-99 FDA regulation of, 129 purpose of, 298 medical software, FDA regulation of, 284-88, 301. FTC regulation of, 129, 136 health-related Big Data and, 125 See also clinical decision support products; legal frameworks for, 125 Internet of Things devices; mobile Health regulatory frameworks for, 125 applications IPRs. See intellectual property rights for black box software, 294 IRBs. See Institutional Review Boards under Draft Software Policy, 285-86 of IVDMIAs, 286-87 IVDMIAs. See in vitro diagnostic multivariate index assays Medicare. See also Centers for Medicare and Medicaid Services Kant, Immanuel, 20 FCA and, 80 after Gobeille v. Liberty Mutual Insurance Co., Kennedy, Anthony (Justice), 114-15 Kyllo v. United States, 39-40 medicine. See black box medicine MEDTECH Act. See Medical Electronic Data labeling. See drug labeling laboratory developed tests (LDTs), 286-87 Technology Enhancement for Consumers Lacks, Henrietta, 215 Health Act minorities, racial and ethnic large research infrastructures, 321-22 LDTs. See laboratory developed tests distrust of medical community by, 104 legal rights, 176 health disparities among, 104-5 legislation, for health-related data. See specific MMAs. See mobile medical applications legislation and acts mobile Health (mHealth) applications LHRs. See longitudinal health records through apps, 132 liability law. See medical liability law clearinghouses and, 138-41 Lifeline program, 110-11 CDIA, 130 Limited Data Set pathway, 274-76 data collection in, 139

regulation of, 139

quantified-self, 131

regulation of, 129

practical concerns with, 135-38

concerns over, 134–35 by FDA, 134–35

Index

ethics and, 279-80

Linnaeus, Carolus, 34–35

252

privacy protections in, 279-80

longitudinal health records (LHRs), 252

longitudinal population health data (LPHD),



Index 351

smartphones, 130–34	Parasidis, Efthimios, 100
software platforms for, 133	passive breaches of identity, 185-86
wearables, 131–32	patents. See algorithm patents; data-generating
under HIPAA, 257	patents; diagnostic patents; software
mobile medical applications (MMAs), 133	patents
moderate interpretation, of group privacy, 186	patienthood, 189
moral informational privacy, 176	patients' property rights, for health-related Big
moral rights, 176	Data, 212–16
,	pay and chase model, 79-80
NAHDO. See National Association of Health Data	PCAST. See President's Council of Advisors on
Organizations	Science and Technology
naïve inductivism, 31	pediatric care, discrepancies in, 117
Narayanan, Arvind, 194	Personal Genome Project, 229
NASHP. See National Academy for State Health	personalization systems, 181–82
Policy	pharmacoepidemiology
natalizumab, 118, 270	Big Data in, 270–71
National Academy for State Health Policy	studies in, 78–79
(NASHP), 120	pharmacovigilance. See also False Claims Act
National Association of Health Data Organizations	Big Data and, 75–79
(NAHDO), 120	through postmarket analysis, 75
National Commission for Protection of Human	transformative role of, 75–76
Subjects of Biomedical and Behavioral	data mining and, 78
Research, 238–40	defined, 77–78
National Institutes of Health (NIH), 107, 198-99	under False Claims Act, 73
National Research Act, U.S., 242	by FDA, 69
National Research Council, 235	health-related Big Data and, 56-57
next generation CDS products, 291, 294	studies of, 3
NIH. See National Institutes of Health	SDAs and, 78–79
Nissenbaum, Helen, 39	studies of, 3
non-identified biospecimens, 227	World Health Organization on, 79
non-identified information, 227	PHI. See protected health information
norm of common purpose, 19–20	Pietsch, Wolfgang, 31
Notice of Proposed Rulemaking (NPRM), 197-200	post-approval research pathways, 274-79
	Expert Determination, 273–74,
Obama, Barack, 319	278–79
Obermeyer, Ziad, 74	anonymization of data, 281–82
objective probabilities, 37-38	best practices for, 280-82
Office for Civil Rights (OCR), of Department of	data sharing under, 282
Health and Human Services, 129	ethical considerations for, 279–80
Office for Human Research Protections (OHRP), 244	privacy protections in, 279-80
Office of the National Coordinator for Health	Limited Data Set, 274–76
Information Technology (ONC), 129	ethics and, 279–80
offline identity, 179	privacy protections in, 279–80
OHCAs. See organized health care arrangements	Safe Harbor, 273, 276–78
OHRP. See Office of Human Research	ethical considerations for, 279–80
Protections	privacy protections in, 279–80
Okediji, Ruth L., 322–23	precision medicine
ONC. See Office of the National Coordinator for	Big Data and, 34–36, 101, 105
Health Information Technology	traditional approaches to, 34-35
open data sources, 89–90	machine learning and, 35–36
opt-ins, duty to share, 211	epistemological shift and, 34–36
opt-outs, duty to share, 211	genetic testing and, 101

Orphan Drug Act, U.S., 319

organized health care arrangements (OHCAs), 258

genome sequencing and, 101

NIH and, 107



Precision Medicine Initiative, 15, 19, 106–7 black box medicine and, 295	Privacy Act (1974), U.S., 59, 240 privacy laws
defined, 271	ADA, 260
methods of, 161–63	FCRA, 60, 110
data analysis, 163	clearinghouses under, 139
data collection, 162–63	CRA oversight under, 65–66
for participants, 161–62	FTC and, 66
	HIPAA and, 260
results, 163–72	FERPA, 260–61
participant characteristics, 163–64	
risk assessment in, 163–72	FTC regulation of, 260
for longitudinal study design, 171–72	Gramm-Leach-Bliley Act, 260
of nature of genetic information, 170–71	HIPAA and, 260–61, 269, 279–80
overview of, 172–74	HITECH Act, 102–3, 269
for permitted but unwanted use of	PHI under, 257–59
information, 167–70	reclassification of, 259-60
for unintended access to identity, 163–67	private information, health research for, 228
prediction modeling, 117	profiling, of identity, 179–82
predictive analytics, 182	protected health information (PHI), 257–59
prescriptive analytics, 179	reclassification of, 259–60
President's Council of Advisors on Science and	protection. See data protection
Technology (PCAST), 63	public accommodations, under ADA, 92–93
Price, Nicholson, 291, 312, 322. See also black box	public good, health-related Big Data as, 262
medicine	public health law, 245
privacy. See also group privacy; Health Insurance	public health surveillance, 56–58
Portability and Accountability Act Privacy	public trust. See also distrust of medical
Rule; individual privacy	community
under ADA, 260	in Big Data health care research, 263
Big Data and, 36–40, 109	in Common Rule, 247–48
losses of privacy, 37–38	
violations of privacy, 38–40	racial minorities. See minorities
for Big Data health research, IRBs and,	Racketeer Influenced and Corrupt Organizations
230	Act (RICO), U.S., 81
under Common Rule, 239–41	Ramirez, Edith, 138
contextual integrity theory, 39	reason, law of, 52–54
in Expert Determination pathway, 279–80	fairness and, 53–54
family resemblance theory, 39	reasonable expectation of privacy, 39
identity-constitutive, 183	reciprocity argument, 215–21
informational, 176, 183–85	redlining, through health-related Big Data, 58
informed consent and, under U.S. law,	regulations, on data
196–202	adjustment of, 6
of biospecimens, 197–99	Big Data and, 4
in CFR, 196	for health care fraud, 76–77
under Common Rule, 196–97	under Common Rule, 248–50
denial of, 201	during development process, 240–41
individual perspectives on, 199-202	standards for, 247
under NPRM, 197–200	under GDPR, 45
in international law, 176	TPDAs under, 152
in Kyllo v. United States, 39–40	after Gobeille v. Liberty Mutual Insurance Co.
in Limited Data Set pathway, 279-80	119–21
right to inviolate personality and, 183-85	health-related Big Data, 60-62
group privacy and, 185–90	under HIPAA, 126, 257–58
technological challenges to, 256	reforms of, 259–60
top-down standards for, 23	Internet of Things devices, 129, 136



through mHealth applications, 129	scientific inquiry and knowledge, Big Data as
clearinghouses, 139	influence on, 30–34
concerns over, 134–35	causation vs. correlation, 32-33
by FDA, 134–35	theory vs. data, 31
under SOFTWARE Act, 134	explanation vs. prediction, 34
regulatory arbitrage, 60-62	SDAs. See signal detection algorithms
regulatory exclusivities, 318-19	security, TPDA limitations, 152-53
in European Union, 319	self-service TPDAs, 151
in U.S., 319	self-subsidized TPDAs, 151
Rehabilitation Act (1973), U.S., 94	Sensible Oversight for Technology which
reidentification, in duty to share, 215	Advances Regulatory Efficiency
relationality, defined, 159	(SOFTWARE) Act, U.S., 134
reports, by TPDAs, 148-49	sensitivity of health information, 229-30
aggregate, 148–49	Sentinel Initiative, 100
research. See also genetics research; health care	Sentinel System, 6
research	shared ownership of identity, 180-81
defined, 243	The Signal and the Noise (Silver), 51
reverse false claim, 82-83	signal detection algorithms (SDAs), 78-79
RICO. See Racketeer Influenced and Corrupt	Silver, Nate, 51
Organizations Act	Skopek, Jeffrey, 202, 210
right not to know, 202-4	small data, Big Data and, 15
ACMG recommendations, 202–3	social media
DeCODE and, 202	Big Data health research on, 230
IRB members and, 203–4	Big Data on, 3
limitations of, 204	health-related Big Data through, 87–88
right to inviolate personality, 183–85	software. See medical software
group privacy and, 185–90	SOFTWARE Act. See Sensible Oversight for
Riley, Margaret Foster, 205	Technology which Advances Regulatory
risk assessment. See also high-risk patients	Efficiency Act
of Big Data health research, 230–35	software patents, 312–14
administrative burdens of, 232	in European Union, 313–14
application of uniform daily life risks	in U.S., 312–13
standard, 232–34	solidarity, civic
dignitary harm and, 230–31	autonomy and, 22
mediation of risk, 234–35	development of, 26–28
minimal risk determination, 231–33	
	Solove, Dan, 39
recognition of risks, 230–31	Steffanson, Kari, 202
HIPAA and, 257	strong interpretation, of group privacy, 186
in Precision Medicine Initiative, 163–72	subsumption approach, 5–6
for longitudinal study design, 171–72	sui generis rights, 312–19
of nature of genetic information, 170–71	for data-generating patents, 335 Sweeney, Latanya, 229
overview of, 172–74	
for permitted but unwanted use of	systems biology (SysBio), 321
information, 167–70	to be also Constant and afficient to the
for unintended access to identity,	technology. See also Internet of Things devices;
163–67	medical software; mobile Health application
Rorty, Richard, 22	Big Data and, 3–4
Cl. Dl.l	data protection challenges, for health-related
Sachs, Rachel, 312	Big Data, 59–60
Safe Harbor pathway, 273, 276–78	under HITECH Act, 102–3
ethical considerations for, 279–80	under MEDTECH Act, 134
privacy protections in, 279–80	ONC and, 129
Schauer, Fred. 256	PCAST and, 63



Cambridge University Press 978-1-107-19365-9 - Big Data, Health Law, and Bioethics Edited by I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena, Urs Gasser More Information

354

technology (cont.) under SOFTWARE Act, 134 TPDAs and, 147 Third-Party Data Auditors (TPDAs), 142-43, 146–55 benefits of, 147 certification of, 147, 154-55 client hiring of, 148 considerations of, 150-54 data analysis by, 148 data collection by, 152-53 through data requests, 148 data policy considerations, 149-50 accordance with existing laws, 150 accountability mechanisms, 149-50 for individual awareness, 149 for innovation protections, 150 transparency mechanisms, 149-50 data protection through, 147 defined, 146-47 EHR systems and, 152 free, 151 under GDPR, 152 government subsidies for, 150-51 limitations of, 150–54 economic disenfranchisement as, with expanding amounts of data, processing issues, 151-52 security issues, 152-53 technical, 152 in user education, 153-54 policy goals of, 147 policy recommendations for, 154-55 for certification process, 154-55 for citizen education, 155 data access mandates, 154 for regulations process, 154-55 report formulation by, 148-49 through aggregate reports, 148-49 self-service, 151 as self-subsidized, 151 setup completion by, 147 technological advances and, 147 TPDAs. See Third-Party Data Auditors trade secrets, 316-18 data-generating patents and, 327-29 EU definition of, 317

Index

transparency as Healthcare Internet of Things design consideration, 144-45 in TPDA mechanism, 149-50 21st Century Cures Act, U.S., 271 Tysabri. See natalizumab uniform daily life risks standard, 232-34 Uniform Trade Secrets Act, U.S., 318 United States (U.S.). See also Americans with Disabilities Act: False Claims Act: Federal Trade Commission; Food and Drug Administration algorithm patents in, 312-13 CFR in, 196 Consumer Privacy Bill of Rights, 62 CPBR, 62, 143 diagnostic patents, 312-13 GINA, 93-94 health-related Big Data and FTC protections and, 63-67 under HIPAA Privacy Rule, 90 HHS, 259-60 HIPAA Privacy Rule, 20-21, 23-25 data access under, 28-29 data brokers under, 61-62 health-related Big Data under, 90 informed consent in, 26 informed consent in, privacy and, 196-202 of biospecimens, 197-99 in CFR, 196 under Common Rule, 196-97 denial of, 201 individual perspectives on, 199-202 under NPRM, 197-200 regulatory exclusivities in, 319 RICO, 81 software patents in, 312-13 trade secrets in, 318 user education, TPDAs and, 153-54 Venter, Craif, 195-96 voluntary data contributions by payers, 121-22 weak interpretation, of group privacy, 186 wellness programs, health-related Big Data through, 88

Wertheimer, Alan, 216-17 World Health Organization, 79

in U.S., 318