Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

INDEX

ABC v. St George's Healthcare NHS Trust, 159-60 absent autonomy acquired dignity and, 130-2 dignity and, 130-2 inherent dignity and, 130-2 proportionate benefits and, 130 - 1acquired dignity, 124-8 absent autonomy and, 130-2 respect for autonomy overridden by, 129 ACRCR. See Australian Code for the Responsible Conduct of Research actualising autonomy, 70-4 adequate options and, 70-6 addiction, 9. See also heroin-assisted treatment autonomy competence and, 48-9, 55-6, 60-2 autonomy impacted by, 51-4 coercive treatment and, 50 compulsory civil commitment and, 50-1, 55-6 decisional autonomy and, 9-10, 52-3,60 diminished autonomy and, 48-62 DSM-5 and, 51 executive autonomy and, 9-10, 52-4, 60 - 2as externalising disorder, 59 informed consent and, 60 internal sovereignty and, 70 mandatory treatment and, 48 resigned addicts and, 54-5, 61-2 spontaneous remission and, 48

Additional Protocol to the Convention on Human Rights and Biomedicine, 103 doing good in, 104-5 harm and, 105-9 proportionate benefits and, 109-12 special protections for the vulnerable and, 111-16 adequate options actualising autonomy and, 70-6 social gradient in health and, 75-7 socio-economic inequality and, 71 - 7Asch, Adrienne, 37 Australia Choosing Wisely and, 142, 145 data misuse and, 183 NS and, 183 public health campaigns and, 63 Australian Code for the Responsible Conduct of Research (ACRCR), 147-8, 183 autonomy. See formal liberal autonomy; specific topics autonomy at law, 9, 17-32 ABC v. St George's Healthcare NHS Trust and, 159-60 as burden, 28-9 Burke v. GMC and, 28, 31 Chester v. Afshar and, 155 cité and, 161-2 communitarian approach to, 160-7 as fiction, 29-31 as fundamental, 17-18, 21, 27 informed consent and, 19-26, 30-2 liberty and, 26-8, 155-8

200

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

INDEX

Montgomery v. Lanarkshire Health Board and, 156-7 as obligation, 28-30 R v. Brown and, 27 R v. Collins and, 27 relational autonomy and, 158-61, 167 self-determination and, 28, 32 UK and, 27-8, 31, 154-67 autonomy competence, 49 addiction and, 48-9, 55-6, 60-2 mental illness and, 55 availability bias, role virtues and, 137 Baehr, J., 140 balancing model, 82, 91-5 exploitation and, 83, 86-8 paternalism and, 82-6 self-determination and, 82-6, 88-9 self-ownership and, 83, 86-9, 92-3 Bartholome, Bill, 37 Batson, Daniel, 135 Battaly, H., 140 Beauchamp, Thomas, 10-11, 96, 99-101 Beecher, Henry, 11, 33-4 role virtues and, 134 Belmont Report, 6 benchmarks institutional environments, provided in, 142 UK and, 142 beneficence, 11, 96-116 altruistic understanding of, 100 Beauchamp and Childress on, 96, 99-101 dignity and, 120-1 as doing good, 99-101, 104-5 Frankena on, 99-102 harm, as avoiding, 99-101, 104-9 human research ethics guidelines and, 96-9, 102-16 as motivation, 102 non-maleficence and, 99-102 Nuremberg Code and, 4–5, 97 paternalism and, 96-7 pluralism and, 82

201

prima facie duties derived from, 99-102 proportionate benefits and, 104, 109-12 respect for autonomy, tension with, 96-9 self-determination and, 84 special protections for the vulnerable and, 104, 111-16 universalistic understanding of, 100, 104 Berridge, Kent, 59 biases availability, 137 confirmation, 137, 142 institutional environments addressing, 141-2 regulatory environments addressing, 143-6 role virtues and, 134 selection, 144-5 bio-banking, informed consent and, 2 Bodin, Jean, 161, 163 boundaries of rights, 95 self-determination and, 89 self-ownership and, 89, 92 Brock, Dan, 84 Burke v. GMC, 28, 31 Byerly, M., 148-9 Byerly, T. R., 148-9 Caldicott, Fiona, 153 Campos, N. G., 175-6 capability theory, 45 cardiovascular disease, socio-economic inequality and, 66, 77 Care.data, 153-4 Cassell, Jackie, 161-3, 165 causation, informed consent and, 21-2 Celexa and Lexapro Marketing and Sales Practices Litigation, 185 character traits, role virtues as, 134-5 Charland, Louis, 57-8, 60 Chen, X., 197 Chester v. Afshar, 155 children

clinical trials and, 38–9, 42, 44, 46–7, 184–8

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

202

children (cont.) CureSMA and, 41 informed consent and, 37-8, 43 lack of autonomy and, 33-47 mutualism and, 45 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and, 36-8, 40-1, 43 parental consent and, 37-47 relational autonomy and, 45-6 respect for autonomy and, 9 SMA and, 41-3, 46-7 vicarious consent and, 43-4 Childress, James, 10-11, 96, 99-101 Choosing Wisely, 142, 145 CIOMS guidelines. See International Ethical Guidelines for Biomedical Research Involving Human Subjects citalopram, data misuse and, 184-8, 192 - 4cité, 161-2 clinical trials, 172-4 children and, 38-9, 42, 44, 46-7, 184 - 8data misuse and, 184-99 LDCs and, 169-82 oncology and, 145 regulatory environments for, 144-6 selection bias and, 144-5 coercive treatment, addiction and, 50 Coggon, John, 19-20, 27, 32, 155-6 collective cultural property, 94 collective virtues, 148-9 common goods, 12 communitarian approach to autonomy at law, 160-7 community-based research in LDCs, 180 - 2compromised autonomy, 2, 8 dignity and, 129-30 socio-economic inequality and, 10, 63-8, 71-7 special protections for, 111-16 compulsory civil commitment addiction and, 50-1, 55-6 autonomy competence and, 55-6

INDEX

confirmation bias, 142 role virtues and, 137 consent informed consent versus, 18-20 trespass and, 18-19 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention), 5-6. See also Additional Protocol to the Convention on Human **Rights and Biomedicine** Courtwright, Andrew, 73-4 Cullity, Garrett, 101-2 CureSMA, 41 data misuse, 13, 183-99 Australia and, 183 as breach of trust, 191-2 Celexa and Lexapro Marketing and Sales Practices Litigation and, 185 citalopram and, 184-8, 192-4 clinical trials and, 184-99 deception and, 194 exploitation and, 192-4 Forest companies and, 185-7, 192-4 frequency of, 187 harms of, 188-95 informed consent and, 193-5 open data addressing, 195-6 paroxetine and, 189 participants of research impacted by, 190-4, 197-8 patients impacted by, 188-9 professional integrity and, 183-4 public trust damaged by, 190 remedies for, 194-9 researcher culture and, 196-8 researchers impacted by, 189–90 restorative justice and, 197-8 scientific progress hindered by, 188 Vioxx and, 189 vulnerability analysis and, 13 data storage, informed consent and, 2 deception data misuse and, 194 psychological research and, 90-1, 94

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

INDEX

decisional autonomy, addiction and, 9-10, 52-3, 60 Declaration of Helsinki, 1964, 170 free consent and, 4-5 Declaration of Helsinki, 2013, 170 informed consent and, 5 respect for autonomy and, 5, 7 deferential wife example, 70, 73-5 Diagnostic and Statistical Manual of Mental Disorders (DSM-5), addiction in, 51 dignity, 11, 117-32 absent autonomy and, 130-2 acquired, 124-32 beneficence and, 120-1 compromised autonomy and, 129 - 30existential dimension of, 117, 124-5 hermeneutical ethics and, 117-18, 126 - 7human research ethics guidelines and, 121, 126-32 informed consent and, 129-30 inherent, 124-5, 127-32 justice and, 120-1 ontological dimension of, 117, 124 - 5paternalism and, 117-18, 131 proportionate benefits and, 128 respect for autonomy grounded in, 117-21, 127-9 respect for autonomy overridden by, 129 Tuskegee syphilis studies and, 120, 129 dignity talk, 121-2 embryonic stem cells and, 121 diminished autonomy, 1-2, 7-8 addiction and, 48-62 CIOMS guidelines and, 6 special protections for, 111-16 direct-to-consumer advertising (DTCA), 143 doctor-patient relationship, 29 doing good, beneficence as, 99-101, 104 - 5

DSM-5. See Diagnostic and Statistical Manual of Mental Disorders 203

DTCA. See direct-to-consumer advertising duties, communitarian, 162-3. See also prima facie duties duty to inform, 19-26, 30-1 Dworkin, R. B., 24-5 dvadic researcher-participant relationship, limits of, 169, 173-8 Edwards, Kelly, 147 embryonic stem cells, dignity talk and, 121 Emmanuel, Ezekiel, 101-2 Engelhardt, Tris, 37 Erikson, Erik, 45 ethic of care, 158 European Convention on Human Rights, 166 European Union, open data and, 195-6 evil. See moral evil; nonmoral evil executive autonomy, 53 addiction and, 9-10, 52-4, 60-2 external supports for, 60-2 as patient autonomy, 52-3 expertise, legitimacy and, 154-5 exploitation, 164 balancing model and, 83, 86-8 data misuse and, 192-4 LDCs and, 175-6, 178 self-ownership and, 83, 88-90 externalising disorders, addiction as, 59 Fanelli, D., 196 Farmer, P., 175-6 Fischer, B., 57 Forest companies, data misuse by, 185-7, 192-4 formal liberal autonomy, 69 as freedom from coercion, 69 Foster, Charles, 29, 160 Frankena, William, 99–102, 105–6, 108, 116 free consent Declaration of Helsinki, 1964, and, 4 - 5

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

204

free consent (cont.)

International Covenant on Civil and Political Rights and, 3-4 French, Robert Shenton, 26 Gawande, Atul, 138 generalizable medical knowledge, as goal of clinical research, 139-40 Gilbar, Roy, 160 Gilligan, Carol, 158 Glover, Jonathan, 148 Grady, Christine, 101-2 harm, 118-20, 128 Additional Protocol to the Convention on Human Rights and Biomedicine and, 105-9 beneficence as avoiding, 99-101, 104 - 9data misuse and, 188-95 informed consent and, 21-2, 24, 108 - 9moral evil and, 106 nonmoral evil and, 105-6 Harmon, Shawn H. E., 163 Hart, H. L. A., 85-6 Hastings Center, 35, 38, 40 HAT. See heroin-assisted treatment Hauerwas, Stanley, 37 hermeneutical ethics, 117-18, 126 - 7heroin addiction. See addiction heroin-assisted treatment (HAT), 48, 56 - 62ethics of, 57-9 informed consent and, 58-62 patient autonomy and, 53 self-narration and, 62 success rates of, 57 Herring, J., 158 hidden curriculum, role virtues and, 146 - 7Howard-Snyder, D., 140 human individuals, 122 human nature possessed by, 123 self-worth possessed by, 123-6 temporality of, 122-3 human nature, 123

INDEX

human research ethics guidelines, 2-7, 102, 108 beneficence and, 96-9, 102-16 dignity and, 121, 126-32 legal proceduralism in, 126-7 role virtues and, 146-8 human rights communitarian approach to autonomy and, 166-7 European Convention on Human Rights, 166 Human Tissue Act, 165 human tissue samples, 164-5, 167 Hume, David, 139 Hurka, Thomas, 70-1 Huxtable, R., 18 independent-mindedness, internal sovereignty and, 70 informed consent, 183. See also free consent; voluntary consent addiction and, 60 autonomy at law and, 19-26, 30-2 bio-banking and, 2 causation and, 21-2 Chester v. Afshar and, 155 children and, 37-8, 43 CIOMS guidelines and, 6 consent versus, 18-20 data misuse and, 193-5 data storage and, 2 Declaration of Helsinki, 2013, and, 5 dignity and, 129-30 duty to inform and, 19-26, 30-1 harm and, 21-2, 24, 108-9 HAT and, 58-62 list of risks approach and, 155-6 Montgomery v. Lanarkshire Health *Board* and, 156–7 Nuremberg Code and, 4–5, 97 Oviedo Convention and, 5-6 parental consent and, 37-47 proportionate benefits and, 111 Re Y (Mental Incapacity: Bone Marrow Donation) and, 165 right to information and, 19–21, 30 self-worth and, 129

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

INDEX

Smith v. Barking, Havering & Brentwood Health Authority and, 22 - 4special protections for the vulnerable and, 113 Tuskegee syphilis studies and, 119, 129 UK and, 155-8, 164-5 vicarious consent and, 43-4 infrastructure building in LDCs, 180 inherent dignity, 124-5, 127-8 absent autonomy and, 130-2 respect for autonomy overridden by, 129 insensitivity in research, 94 institutional environments, 141-9 benchmarks provided in, 142 biases addressed by, 141-2 Choosing Wisely and, 142, 145 hidden curriculum addressed by, 146 - 7intellectual humility, 140-1, 145-6 internal sovereignty addiction and, 70 autonomy as, 69-70, 73 deferential wife example and, 70, 73 - 5independent-mindedness and, 70 smoking and, 75 International Covenant on Civil and Political Rights, 3-4 International Ethical Guidelines for **Biomedical Research Involving** Human Subjects (CIOMS guidelines), 6-7. See also Belmont Report diminished autonomy and, 6 informed consent and, 6 Janssens, Louis, 122 Jennings, Bruce, 44-5 Jonsen, Albert, 40-1 Jureidini, J., 185

Kahan, B. C., 144 Kennedy, Ian, 154–5

justice, dignity and, 120-1

205

lack of autonomy, 8 children and, 33-47 social gradient in health and, 66-8 stress and, 66-7 Lacks, Henrietta, 164 Lambert, Olly, 49-50 least developed countries (LDCs), 168 - 9clinical trials and, 169-82 community-based research in, 180-2 exploitation and, 175-6, 178 infrastructure building in, 180 paternalism and, 181-2 protection of autonomy in, 178-82 voluntary consent in, 169-73 legal capacity, Nuremberg Code and, 3 - 5legal proceduralism, human research ethics guidelines and, 126-7 legitimacy, expertise and, 154-5 Levy, Neil, 58-9 Lewis, Marc, 55 liberty, 44-5 autonomy at law and, 26-8, 155-8 list of risks approach, 155-6 Litton, Paul, 139 Liu, X., 197 Locke, John, 3 low socioeconomic status groups (low SES groups), 75-6 public health campaigns for, 63, 66-8, 76-7 MacLean, Alasdair, 157 mandatory treatment addiction and, 48 coercive treatment as, 50 compulsory civil commitment as, 50-1, 55-6 Marmot, Michael, 63-6, 68, 71-7 materiality, test of, 19-20 McBride, William, 146 McCormick, Richard, 37-8, 43-4 McLean, S. A. M., 30-1

McMahan, Jeff, 90

Mendelson, D., 28

Mental Capacity Act, UK, 158–9, 163 Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

206

mental illness autonomy competence and, 55 voluntary consent and, 170 meticulousness, 136-8, 143-4 Miller, Franklin, 139 Montgomery v. Lanarkshire Health Board, 156-7 moral evil, 106, 118 moral ineptitude, 136-7 moral norms, objective, 124-6, 129 moral rights, 85-6 will theory of, 85-6 mutualism, 45 Naik, A. D., 52-3 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 36-8, 40-1, 43. See also Belmont Report National Health Service, UK (NHS), 153-4, 161-7 National Statement on Ethical Conduct in Human Research, Australia (NS), 183 Nedelsky, Jennifer, 45-6 NHS. See National Health Service non-maleficence, 99-102 nonmoral evil, 105-6, 118 Nordt, C., 57 NS. See National Statement on Ethical Conduct in Human Research Nuremberg Code, 4-5, 33-4 beneficence and, 97 informed consent and, 97 legal capacity and, 3 respect for autonomy and, 1, 3, 99 voluntary consent and, 3, 34, 36 Nuremberg trials, 121 obligation, autonomy at law as, 28 - 30oncology, clinical trials and, 145 O'Neill, Onora, 29 open consent, 174

open data, data misuse addressed by, 195-6

INDEX

Oviedo Convention. See Convention for the Protection of Human Rights and Dignity of the Human Being

parental consent, 37-47 paroxetine, data misuse and, 189 paternalism, 35, 174 balancing model and, 82-6 beneficence and, 96-7 dignity and, 117-18, 131 LDCs and, 181-2 self-determination and, 82-6, 88-90 patient autonomy executive autonomy as, 52-3 HAT and, 53 permissible infringements of rights, 90, 95 property rights and, 90 redress and, 90-1, 93-4 self-ownership and, 90-1, 93 phronesis (practical intelligence) meticulousness and, 136-8, 143-4 moral ineptitude and, 136-7 role virtues and, 137-8 virtues and, 135-6 pluralism, 81-2 beneficence and, 82 practical intelligence. See phronesis Prasad, Vinay, 192 prima facie duties, 99-102 principles, cases and, 9-10, 40-1 principlism, 81-2 privacy, European Convention on Human Rights and, 166 professional integrity data misuse and, 183-4 role virtues and, 138-41 property rights collective cultural property and, 94 permissible infringements of, 90 self-ownership and, 87-8 proportionate benefits, 118-19 absent autonomy and, 130-1 Additional Protocol to the Convention on Human Rights and Biomedicine and, 109–12

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

INDEX

beneficence and, 104, 109-12 dignity and, 128 informed consent and, 111 special protections for the vulnerable and, 113 protection of autonomy as structural and political, 178-82 psychological research, deception and, 90-1, 94 public health campaigns Australia and, 63 effectiveness of, 64 low SES groups and, 63, 66-8, 76-7 US and, 63 public trust, data misuse damaging, 190 R v. Brown, 27 R v. Collins, 27 Ramsey, Paul, 37-8, 43-4 Raz, Joseph, 71 Re Y (Mental Incapacity: Bone Marrow Donation), 165 redress, 90-1, 93-4 regulatory environments, 141-9 biases addressed by, 143-6 clinical trials and, 144-6 DTCA and, 143 role virtues undermined in, 142-3 Reibl v. Hughes, 19 relational autonomy, 158-61 ABC v. St George's Healthcare NHS Trust and, 159-60 autonomy at law and, 158-61, 167 children and, 45-6 ethic of care and, 158 Mental Capacity Act and, 158-9 researcher culture, data misuse and, 196 - 8resigned addicts, 54-5, 61-2 respect, expressive reasons of, 94 respect for autonomy. See specific topics respect for persons, 6-7 restorative justice, data misuse and, 197 - 8Retained Organs Commission, 164 - 5Richards, Norvin, 94 right to information, 12

207

informed consent and, 19-21, 30 test of materiality and, 19-20 Roberts, Robert C., 146 Rogers, Ben, 49-57, 61-2 role virtues, 133-49 availability bias and, 137 Beecher on, 134 biases and, 134 as character traits, 134-5 collective virtues as, 148-9 confirmation bias and, 137 generalizable medical knowledge and, 139-40 hidden curriculum and, 146-7 human research ethics guidelines and, 146-8 institutional environments and, 141 - 9intellectual humility as, 140-1, 145-6 phronesis and, 137-8 professional integrity and, 138-41 regulatory environments and, 141-9 regulatory environments undermining, 142-3 respect for autonomy as, 141 scientific objectivity as, 140 selection bias and, 144-5 Ross, W. D., 81-2 Russell, Daniel, 135-7 Ryan, Kenneth J, 36-7 sanctity of human life, 122 scientific objectivity, 140 scientific progress, data misuse hindering, 188

selection bias clinical trials and, 144–5 role virtues and, 144–5

self-creation, socio-economic inequality and, 10 self-determination, 10–11, 32, 52 as authoritative, 84 autonomy at law and, 28, 32

balancing model and, 82–6, 88–9

beneficence and, 84 as bounded, 89

paternalism and, 82–6, 88–90

self-ownership versus, 88

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index More Information

208

INDEX

self-governance, autonomy as, 68-9 self-narration autonomy as, 52 HAT and, 62 self-ownership, 11, 83 balancing model and, 83, 86-9, 92-3 as bounded, 89, 92 exploitation and, 83, 88-90 permissible infringements of, 90-1, 93 property rights and, 87-8 self-determination versus, 88 self-worth human individuals possessing, 123-6 informed consent and, 129 moral norms, objective, and, 124-6, 129 Sen, Amartya, 73-4 SMA. See Spinal Muscular Atrophy Smith v. Barking, Havering & Brentwood Health Authority, 22-4 smoking internal sovereignty and, 75 socio-economic inequality and, 67-8, 72, 74 social gradient in health adequate options and, 75-7 lack of autonomy and, 66-8 socio-economic inequality and, 65-8 social participation, 66, 73 socio-economic inequality, 12-13. See also least developed countries adequate options and, 71-7 cardiovascular disease and, 66, 77 compromised autonomy and, 10, 63-8, 71-7 dyadic researcher-participant relationship ignoring, 169, 173-8 low SES groups and, 63, 66-8, 75 - 7self-creation and, 10 smoking and, 67-8, 72, 74 social gradient in health and, 65 - 8voluntary consent and, 170-81 Whitehall Studies and, 65

special protections for the vulnerable Additional Protocol to the Convention on Human Rights and Biomedicine and, 111-16 beneficence and, 104, 111-16 Declarations of Helsinki and, 170 informed consent and, 113 proportionate benefits and, 113 Spinal Muscular Atrophy (SMA), 41-3, 46 - 7CureSMA and, 41 spontaneous remission, addiction and, 48 Stapel, Diederik Alexander, 189-90 Stohler, R., 57 stress, lack of autonomy and, 66-7 Stroebe, W., 188 Swan, Norman, 146 Swanton, Christine, 136 Thomson, Judith Jarvis, 88 Toulmin, Stephen, 40-1 trespass, consent and, 18-19 Tuskegee syphilis studies dignity and, 120, 129 informed consent and, 119, 129 United Kingdom (UK) autonomy at law and, 27-8, 31, 154-67 benchmarks and, 142 Care.data and, 153-4 Human Tissue Act and, 165 informed consent and, 155-8, 164 - 5Mental Capacity Act and, 158-9, 163 NHS and, 153-4, 161-7 Retained Organs Commission and, 164 - 5United States (US) open data and, 195-6 public health campaigns and, 63 unmeticulousness. See meticulousness US. See United States van der Graaf, R., 193 Veatch, Robert, 35, 37, 136

Cambridge University Press 978-1-108-74130-9 — Beyond Autonomy Edited by David G. Kirchhoffer , Bernadette J. Richards Index <u>More Information</u>

INDEX

209

vicarious consent, children and, 43–4 Vioxx, data misuse and, 189 virtues, 11–12, 133, 135. *See also* role virtues collective, 148–9 *phronesis* and, 135–6 voluntary consent LDCs and, 169–73 mental illness and, 170 moralised account of, 172–5 Nuremberg Code and, 3–5, 34, 36 socio-economic inequality and, 170–81 vulnerability analysis, data misuse and, 13 vulnerable adults. *See also* special protections for the vulnerable communitarian approach to autonomy and, 162–7

Wagner, Karen, 184–5 Wall, Steven, 70–1 Warnock, Mary, 164 Wendler, David, 39, 101–2 Wertheimer, Alan, 172 Whitcomb, D., 140 Whitehall Studies, 65 will theory of moral rights, 85–6

Young, Allan, 161-3, 165