

18 HUMAN EXPERIMENTATION

18.1 General

- ANDERSON, C.B. e.a., *A national survey of policies on disclosure of conflicts of interest in biomedical research*, The New England Journal of Medicine, November 30, 2000, vol 343, nr 22, pp. 1621-1626
- ANONIEM, *Code of Ethics*, The Endocrine Society, 2001
- ANONIEM, *Death of a volunteer*, British medical journal, 11 May 1985, vol 290 nr 6479, pp. 1369-1370
- ANONIEM, *Medical ethics: should medicine turn the other cheek?*, The Lancet, Oct. 6, 1990, vol 336, pp. 846-847
- ANONIEM, *Proceedings of the Royal College of Physicians of Edinburgh, Joint Consensus Conference on Misconduct in Biomedical Research*, supplement n° 7, January 2000, vol 30, n° 1
- ANONIEM, *Richtlijn 2001/20/EG van het Europees parlement en de raad betreffende de onderlinge aanpassing van de wettelijke en bestuurrechtelijke bepalingen van de lidstaten inzake de toepassing van goede klinische praktijken bij de uitvoering van klinische proeven met geneesmiddelen voor menselijk gebruik*, Europese unie, april 2001
- BRODY, B.A., *Taking issue: pluralism and casuistry in bioethics*, Georgetown University Press, Washington, 2003, pp. 293 – ISBN 0-87840-398-1 (boek nr. 256)
- BRODY, B.A., *The Ethics of Biomedical Research – An International Perspective*, Oxford University Press, New York, 1998, pp. 386 - ISBN 0-19-509007-1 (boek nr. 75)
- BRODY, H., en MILLER, F., *The Clinical-Investigator : Unavoidable but Manageable Tention*, Kennedy Institute of Ethics Journal, 2003, vol. 13, nr. 4, pp. 329-346
- CALLENS, S., *Goed geregeld? – Het gebruik van medische gegevens voor onderzoek*, Maklu Uitgevers, Antwerpen – Apeldoorn, 1995, pp. 538 - ISBN 90 6215 467 0 (boek nr. 46)
- CHERRY, M.J., *Persons and their Bodies: Rights, responsibilities, relationships*, Kluwer Academic Publishers, Dordrecht, 1999, pp. 113 - ISBN 0-7923-5701-9 (boek nr. 113)
- DOWRICK, C., en FRITH, L., *General Practice and Ethics – Uncertainty and responsibility*, Routledge, London, 1999, pp. 103 - ISBN 0-415-16498-2 (boek nr. 103)
- DOYAL, L., en TOBIAS, J.S., *Informed Consent in Medical Research*, BMJ Books, London, 2001, pp. 334 - ISBN 0-7279-1486-3 (boek nr. 135)
- DRAZEN, J.M., *Controlling research trials*, The New England Journal of Medicine, April 3, 2003, vol. 348, nr. 14, pp. 1377-1380
- DRAZEN, J.M., en KOSKI, G., *To Protect Those Who Serve*, The New England Journal of Medicine, November 30, 2000, vol 343, nr 22, pp. 1643-1645
- EDWARDS, R.B. en EDWARDS BITTAR, E., *Advances in Bioethics*, JAI Press Inc., Stamford, Connecticut, 1999, pp. 346 - ISBN 0-7623-0559-2 (boek nr. 68)
- EVANS, D., en EVANS, M., *A decent proposal – Ethical Review of Clinical Research*, John Wiley & sons, Chichester, 1996, pp. 218 - ISBN 0-471-96334-8 (boek nr. 27)
- FOSTER, C., *The ethics of medical research on humans*, Cambridge University Press, Cambridge, 2001, pp. 159 - ISBN 0 521 64196 9 (boek nr. 164)

18 HUMAN EXPERIMENTATION

18.1 General

- GALLIN, J.I., *Principles and practice of clinical research*, Academic Press, London, pp. 490 – ISBN 0-12-274065-3 (boek nr. 182)
- GETZ, K., BORFITZ, D., *Informed Consent – The Consumer’s Guide to the Risks and Benefits of Volunteering for Clinical Trials*, CenterWatch, Thomson Healthcare Inc., Boston, 2002, pp. 306 – ISBN 1-930624-09-3 (boek nr. 197)
- GINSBERG, D., *The Investigator’s Guide to Clinical Research*, Center Watch, Inc. Boston, 1999, pp. 281 – ISBN 0-9673029-0-0 (boek nr. 179)
- GODFRAIND, T., *Les enjeux éthiques dans la recherche de nouveaux médicaments*, onbekend
- GRUNBERG, S.M., CEFALU, W.T., *The Integral Role of Clinical Research in Clinical Care*, The New England Journal of Medicine, April 3, 2003, vol 348, nr. 14, pp. 1386-1388
- HADGU, A., *The discrepancy in discrepant analysis*, The Lancet, August 31.1996, vol 348, pp. 592-593
- HALPERN, S.A., *Lesser harms: the morality of risk in medical research*, University of Chicago Press, 2004, pp. 232 – ISBN 0-226-31451-0 (boek nr. 246)
- HERVE, C., en PENNEAU, M., e.a., *Ethique des pratiques en chirurgie – les Cahiers d’éthique médicale*, L’Harmattan 2003, pp. 264 – ISBN 2-7475-5265-9 (boek nr. 216)
- KING, N.M.P., HENDERSON, G.E. en STEIN, J., *Beyond Regulations – Ethics in human subjects research*, The University of North Carolina Press, Chapel Hill & London, 1999, pp. 279 - ISBN 0-8078-2468-2 (boek nr. 99)
- LEWIS, J.A., e.a., *Placebo-controlled trials and the Declaration of Helsinki*, The Lancet, April 13, 2002, vol 359, pp. 1337-1340
- LO, B., WOLF, L.E., BERKELEY, A., *Conflict-of-interest policies for investigators in clinical trials*, The New England Journal of Medicine, November 30, 2000, vol 343, nr 22, pp. 1616-1620
- MACKLIN, R., *Double standards in medical research in developing countries*, Cambridge University Press, 2004, pp. 280 – ISBN 0521 83388 4 (boek nr. 240)
- MARTIN, J.B. en KASPER, D.L., *In Whose Best Interest? Breaching the Academic – Industrial Wall*, The New England Journal of Medicine, November 30, 2000, vol 343, nr. 22, pp. 1646-1649
- McNAMEE, D., en HORTON, R., *Lies, damn lies, and reports of RCTs*, The Lancet, August 31, 1996, vol 348, p. 562
- MICHEL, L.A., *Contraintes et limites de la recherche médicale sur l’homme*, Louvain Med. 1997, vol 116, pp. S19-S24
- MILLER, F.G., en ROSENSTEIN, D.L., *The Therapeutic Orientation to Clinical Trials*, The New England Journal of Medicine, April 3, 2003, vol 348, nr. 14, pp. 1383-1386
- MUIR GRAY, J.A., *Evidence-Based Healthcare*, Churchill Livingstone, New York, 1997, pp. 270 - ISBN 0-443-05721-4 (boek nr. 30)
- NELSON, R.M., *Protocol 126 and “The Hutch”*, IRB: Ethics & Human Research, May-June 2001, pp. 14-16

18 HUMAN EXPERIMENTATION

18.1 General

- NYS, H., *Van Ethiek naar Recht? – Het raadgevend comité voor bio-ethiek en de medisch-ethische commissies in ziekenhuizen*, Maklu Uitgevers, Antwerpen – Apeldoorn, 1995, pp. 140 - ISBN 90 6215 488 3 (boek nr. 29)
- ØSTBYE, T., en RONCHON, J., *An early 'clinical trial' as a teaching exercise: the Book of Daniel*, Medical Education, 1993, vol 27, pp. 97-101
- RAMSAY, L.E., *Placebo run ins have some value*, BMJ, 19 April 1997, vol 314, pp. 1193
- SCHERMER, M., *The different faces of autonomy – Patient autonomy in ethical theory and hospital practice*, Kluwer Academic Publishers, Dordrecht, 2002, pp. 209 – ISBN 1-4020-0984-4 (boek nr. 195)
- SCHULZ, K.F., *Randomised trials, human nature, and reporting guidelines*, The Lancet, August 31, 1996, vol 348, pp. 596-598
- SENN, S., *Are placebo run ins justified?*, BMJ, 19 April 1997, vol 314, pp1191-1193
- SHUSTER, E., *Fifty years later: the significance of the Nuremberg Code*, *The New England Journal of Medicine*, November 13, 1997, vol 337, nr 20, pp. 1436-1440
- SHUSTER, E., *The Nuremberg Code: Hippocratic ethics and human rights*, The Lancet, March 28, 1998, vol 351, pp. 974-977
- SINGER, P.A., BENATAR, S.R., *Beyond Helsinki: a vision for global health ethics*, BMJ, 31 March 2001, vol 322, pp. 747-748
- STRICKER, B.H.Ch., *Privacy moet onderzoek naar pillen niet in de weg staan*, NRC 09/03/96
- THOMASMA, D.C. en KUSHNER, T., *Birth to Death – Science and Bioethics*, Cambridge University Press, Cambridge, 1996, pp. 381 - ISBN 0 521 46297 (boek nr. 49)
- THOMPSON, A., TEMPLE, N.J., *Ethics, Medical Research, and Medicine - Commercialism versus Environmentalism and Social Justice*, Kluwer Academic Publishers, Dordrecht, 2001, pp. 195 - ISBN 0 7923 7084 8 (boek nr. 165)
- TROUET, C., *Clinical trials in Belgium: the implementation of the European Clinical Trials Directive 2001/20/EC into the Belgian Law of May 7, 2004 concerning experiments on the human person – Operational Guidance*, Intersentia, 2004, pp. 258 – ISBN 90-5095-420-0 (boek nr. 251)
- VAN DEN HOONAARD, W.C., *Walking the tightrope: Ethical Issues for Qualitative Researchers*, University of Toronto Press, Toronto, 2002, pp. 218 – ISBN 0-8020-8523-7 (boek nr. 199)
- VERMEERSCH, E., *Ethical-philosophical aspects of human and animal experimentation*, edited by P.P. De Deyn, 1994 John Libbey & Company Ltd., pp. 3-12

18 HUMAN EXPERIMENTATION

18.2 Policy Guidelines/Inst. Review Boards

- ANNAS, G.J., *Medical Privacy and Medical Research – Judging the New Federal Regulations*, New England Journal of Medicine, January 17, 2002, vol. 346, n° 3, pp. 216-220
- ANONIEM, *Directive du Parlement européen et du Conseil concernant le rapprochement des dispositions législatives, réglementaires et administratives des Etats membres relatives à l'application de bonnes pratiques cliniques dans la conduite d'essais cliniques de médicaments à usage humain, Directive 2001/ /CE du Parlement européen et du conseil OE-CONS 3605/01*
- ANONIEM, *Nieuwe regels voor klinische proeven*, Nieuwsbrief Gezondheidszorg, 11 februari 2003, nr. 3, pp. 1-2
- ANONIEM, *Richtlijn 2001/20/EG van het Europees parlement en de raad betreffende de onderlinge aanpassing van de wettelijke en bestuursrechtelijke bepalingen van de lidstaten inzake de toepassing van goede klinische praktijken bij de uitvoering van klinische proeven met geneesmiddelen voor menselijk gebruik*, 4 april 2001, PE-CONS 3605/1/01 REV 1
- ANONIEM, *Voorstel voor een richtlijn van het Europees Parlement en de Raad betreffende de onderlinge aanpassing van de wettelijke en bestuursrechtelijke bepalingen inzake de invoering van goede klinische praktijk bij de uitvoering van klinische proeven op geneesmiddelen voor gebruik bij de mens*, Publicatieblad van de Europese Gemeenschappen, 8.10.97, pp. C306/9-C306/15
- ANONIEM, *Proeven met geneesmiddelen: stopzetting van een studie*, Tijdschrift van de Nationale Raad, september 2001, nr 93,
- ANONIEM, *The next step: ensuring integrity of scientific research*, The Lancet, August 17, 2002, vol 360 – pp. 499
- BANYARD, P., en FLANAGAN, C., *Ethical issues and guidelines in psychology*, Routledge, Londen & New York, 2005, pp. 173 – ISBN 0-415-26881-8 (boek nr. 283)
- BRENNAN, T.A., *Proposed Revisions to the Declaration of Helsinki – Will They Weaken the Ethical Principles Underlying Human Research?*, The New England Journal of Medicine, August 12, 1999, vol 341, nr 7, pp. 527-531
- BRYANT, J, en POWELL, J., *Payment to healthcare professionals for patient recruitment to trials: a systematic review*, BMJ, 2005, 10 December, vol 331, pp. 1377-1378
- CHRISTIAN, M.C., *A Central Institutional Review Board for Multi-Institutional Trials*, New England Journal of Medicine, May 2, 2002, vol 346, n° 18, pp. 1405-1408
- DOWRICK, C., en FRITH, *General Practice and Ethics – Uncertainty and responsibility*, Routledge, London, 1999, pp. 196 - ISBN 0-415-16498-2 (boek nr. 103)
- ELLENBERG, S.S., TEMPLE, R., *Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments, Pratical Issues and Specific Cases*, Annals of Internal Medicine, 19 september 2000, vol. 133, n° 6, pp. 464-470
- EZEKIEL, J.E., MILLER, F., *The Ethics of Placebo-Controlled Trials – A Middle Ground*, New England Journal of Medicine, september 20, 2001, vol. 345, n° 12, pp. 915-919
- FOSTER, C., *The ethics of medical research on humans*, Cambridge University Press, Cambridge, 2001, pp. 159 - ISBN 0 521 64196 9 (boek nr. 164)

18 HUMAN EXPERIMENTATION

18.2 Policy Guidelines/Inst. Review Boards

- HALPERN, S.A., *Lesser harms: the morality of risk in medical research*, University of Chicago Press, 2004, pp. 232 – ISBN 0-226-31451-0 (boek nr. 246)
- HYMAN, S.E., *An NIMH Perspective on the Use of Placebos*, *Biol. Psychiatry*, 2000, 47, pp. 689-691
- KELCH, R.P., *Maintaining the Public Trust in Clinical Research*, *New England Journal of Medicine*, 24 January 2002, vol. 346, n° 4, pp. 285-287
- LEBER, P., *The Use of Placebo Control Groups in the Assessment of Psychiatric Drugs: An Historical Context*, *Society of Biological Psychiatry*, 2000, 47, pp. 699-706
- LEVINE, R.J., *The need to revise the declaration of Helsinki*, *New England Journal of Medicine*, August 12, 1999, vol. 341, n° 7, pp. 531-534
- LEVINSKY, N.G., *Nonfinancial Conflicts of Interest in Research*, *New England Journal of Medicine*, September 5, 2002, vol 347, n° 10, pp. 759-761
- LEWIS, J.A., e.a., *Placebo-controlled trials and the Declaration of Helsinki*, *The Lancet*, April 13, 2002, vol 359, pp 1337-1340
- MACKLIN, R., *Double standards in medical research in developing countries*, Cambridge University Press, UK, 2004, pp. 280 – ISBN 0 521 83388 4 (boek nr. 240)
- MELTON, J.L., *The threat to medical-records research*, *New England Journal of Medicine*, November 13, 1997, vol. 337, n° 20, pp. 1466 -1470
- MILLER, F.G., *Placebo-Controlled Trials in Psychiatric Research: An Ethical Perspective*, *Biol. Psychiatry*, 2000, 47, pp. 707-716
- MOSS, J., YUAN, C. S., *Selective Postoperative Inhibition of Gastrointestinal Opioid Receptors*, *New England Journal of Medicine*, 2002, vol. 346, n° 6, pp. 455-456
- NAYMAN, M., *Trials, tribulations & the EORTC – Pan-European cancer research*, *Odyssey*, 1996, vol. 2, Issue 2, pp. 9-13
- NOACH, E.L., *Ethische beoordeling van biomedische experimenten in Nederland*
- PIERARD, N., *Gezocht: proefpersonen voor klinische proeven...*, *Het Medisch Weekblad*, 5 februari 2004, nr. 283, pp. 2
- RAO, J.N. & SANT CASSIA, L.J., *Ethics of undisclosed payments to doctors recruiting patients in clinical trials*, *BMJ*, 6 July 2002, vol 325, pp 36-37
- ROTHMAN, K.J., en EVANS, S., *Extra scrutiny for industry funded trials*, *BMJ*, 2005, 10 December, vol. 331, pp. 1350-1351
- SINGER, P.A., en BENATAR, S., *Beyond Helsinki: a vision for global health ethics – Improving ethical behaviour depends on strengthening capacity*, *BMJ*, 2001, vol. 322, pp. 747-748
- SLATER, E.E., *IRB Reform*, *New England Journal of Medicine*, May 2, 2002, vol 346, n° 18, pp. 1402-1404
- STEIN, M., PINCUS, T., *Placebo-controlled studies in rheumatoid arthritis: ethical issues*, *The Lancet*, January 30, 1999, vol. 353, pp. 400-403
- STEINBROOK, R., *Improving Protection for Research Subjects*, *New England Journal of Medicine*, May 2, 2002, vol 346, n° 18, pp. 1425-1430

18 HUMAN EXPERIMENTATION

18.2 Policy Guidelines/Inst. Review Boards

- TEMPLE, R., ELLENBERG, S.S., *Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments, Ethical and Scientific Issues*, Annals of Internal Medicine, 19 september 2000, vol. 133, n° 6, pp. 455-463
- TER HEERDT, J., *Het experiment beproefd: een juridische analyse van medische experimenten met mensen*, Maklu, Antwerpen – Apeldoorn, 2000, pp. 722 – ISBN 90 6215 741 6 (boek nr. 138)
- TOLLMAN, S.M., *What are the effects of the fifth revision of the Declaration of Helsinki – Fair partnerships support ethical research*, BMJ, 15 December 2001, vol 323, pp 1417-1423
- TROUET, C., *Clinical trials in Belgium: the implementation of the European Clinical Trials Directive 2001/20/EC into the Belgian Law of May 7, 2004 concerning experiments on the human person – Operational Guidance*, Intersentia, 2004, pp. 258 – ISBN 90-5095-420-0 (boek nr. 251)
- WEIJER, C., CRANLEY GLASS, K., *The Ethics of Placebo-Controlled Trials*, New England Journal of Medicine, 31 January 2002, vol. 346, n° 5, pp. 382

18 HUMAN EXPERIMENTATION

18.3 Informed Consent

- BASTIAN, H., en CONROY, C., *Is caesarean section a treatment for medical paranoia?*, BMJ, 19 April 1997, vol 314, p. 1187
- BEWLEY, S., *Bad medicine and bad law*, BMJ, 19 April 1997, vol 314, pp. 1184-1185
- BHAGWANJEE, S., *Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? A prospective double blind study*, BMJ, 12 April 1997, vol 341, pp. 1077
- BURGERMEISTER, V.J., *Greek authorities probe illegal clinical studies on elderly people*, BMJ, 2004, 12 June, vol. 328, pp. 1398
- CHILDRESS, J.F., MESLIN, E.M. en SHAPIRO, H.T., *Belmont revisited: Ethical principles for research with human subjects*, Georgetown University Press, Washington D.C., 2005, pp. 279, ISBN 1-58901-062-0 (boek nr. 285)
- CLARCK, M.A., e.a., *Registries and Informed Consent*, New England Journal of Medicine, 5 August 2004, vol. 351, n°6, pp. 612-614
- DENNIS, M., *Why we didn't ask patients for their consent*, BMJ, 12 April 1997, vol 314, pp. 1077
- DENNIS, M., e.a., *Evaluation of a stroke family care worker: results of a randomised controlled trial*, BMJ, 12 April 1997, vol 314, pp. 1071
- DICKERT, N., & GRADY, C., *What's the Price of a Research Subject? Approaches to Payment for Research Participation*, The New England Journal of Medicine, July 15, 1999, vol 341, n° 3, pp. 198-203
- DOLAN, B., & PARKER, C., *Caesarean section: a treatment for mental disorder?*, BMJ, 19 april 1997, vol 314, pp. 1183-1184
- DOYAL, L., *Informed consent in medical research*, BMJ, 12 April 1997, vol. 314, pp. 1107-1111
- FOSTER, C., *Ethics of clinical research without patients' consent*, BMJ, 1996 vol. 312, pp. 817-818
- GRUBB, A., *Decision-Making and Problems of Incompetence*, John Wiley & sons, Chichester, 1994, pp. 203 - ISBN 0 471 94236 7 (boek nr. 43)
- HALPERN, S.A., *Lesser harms: the morality of risk in medical research*, University of Chicago Press, 2004, pp. 232 – ISBN 0-226-31451-0 (boek nr. 246)
- HERXHEIMER, A., *The Rights of the Patient in Clinical Research*, The Lancet, November 12, 1998, pp. 1128-1130
- HORNG, S., e.a., *Descriptions of benefits and risks in consent forms for phase 1 oncology trials*, The New England Journal of Medicine, December 26, 2002, vol. 347, n° 26, pp. 2134-2140
- KING, P.N., HENDERSON, G.E., en STEIN J., *Beyond Regulations – Ethics in human subjects research*, The University of North Carolina Press, Chapel Hill & London, 1999, pp. 279 - ISBN 0-8078-2468-2 (boek nr. 99)
- KODISH, E., *Ethics and research with children: a case-based approach*, Oxford University Press, 2005, pp. 361 – ISBN 0-19-517178-0 (boek nr. 262)

18 HUMAN EXPERIMENTATION

18.3 Informed Consent

- MARQUIS, D., *How to Resolve an Ethical Dilemma Concerning Randomized Clinical Trials*, The New England Journal of Medicine, August 26, 1999, vol 341, nr 9, pp 691-693
- McLEAN, S., *No consent means not treating the patient with respect*, BMJ, 12 April 1997, vol 314, p. 1076
- MELTON, L.J., *The Threat to Medical-Records Research*, The New England Journal of Medicine, November 13, 1997, vol 337, nr. 20, pp. 1466-1470
- OLICK, R.S., *Taking advance directives seriously: prospective autonomy and decisions near the end of life*, Georgetown University Press, Washington, 2001, pp. 228 – ISBN 0-87840-868-1 (boek nr. 250)
- PETO, J., e.a., *Data protection, informed consent, and research – Medical research suffers because of pointless obstacles*, BMJ, 1 May 2004, vol. 328, pp. 1029-1030
- PINDER, M., e.a., *Critical care research and pre-emptive informed consent: a practical approach used in Chris Hani Baragwanath ICU*, Intensive Care Med, 1998, vol 24, pp. 353-357
- RENAER, M. *Goed geregeld? Het gebruik van medische persoonsgegevens voor onderzoek*, Boekrecensie
- SAYERS, G.M., MAIR, J., *Getting consent for autopsies: who should ask what, and why?*, BMJ, 1 September 2001, vol 323, p. 521
- SCHNEIDER, C.E., *The Practice of Autonomy – Patients, Doctors and Medical Decisions*, Oxford University Press, New York, 1998, p. 307 - ISBN 0-19-511397-7 (boek nr. 95)
- SHELDON, T., *Consent is not always essential, say Dutch experts*, BMJ, 27 MAY 1995, vol 310, pp. 1355-1356
- SHUSTER, E., *Fifty Years Later: The Significance of the Nuremberg Code*, The New England Journal of Medicine, November 13, 1997, vol 337, n° 20, pp. 1436-1440
- SMITH, R., *Informed consent: the intricacies*, BMJ, 12 April 1997, vol 314, pp. 1059-1060
- SMITH, T., *Ethics in Medical Research*, Cambridge University Press, Cambridge, 1999, pp. 346 - ISBN 0 521 62619 6 (boek nr. 105)
- TER HEERDT, J., *Het experiment beproefd: een juridische analyse van medische experimenten met mensen*, Maklu Antwerpen – Apeldoorn, 2000, pp. 722 - ISBN 90 6215 741 6 (boek nr. 138)
- THOMPSON, A., TEMPLE, N.J., *Ethics, Medical Research, and Medicine – Commercialism versus Environmentalism and Social Justice*, Kluwer Academic Publishers, Dordrecht, 2001, pp. 195 - ISBN 0 7923 7084 8 (boek nr. 165)
- TOBIAS, J.S., *BMJ's present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct*, BMJ, 12 april 1997, vol 314, pp. 1111-1114
- VANSWEEVELT, T., *Medical experimentation and informed consent*, Acta Clinica Belgica, 1995, 50-1
- VISSER, H.K.A., *Non-therapeutic research in the EU in adults incapable of giving consent?*, The Lancet, March 17, 2001, vol 357, pp. 818-819

18 HUMAN EXPERIMENTATION

18.3 Informed Consent

- WEAR, S., *Informed Consent, Patient Autonomy and Physician Beneficence within Clinical Medicine*, Kluwer Academic Publishers, Dordrecht, 1993, pp. 167 - ISBN 0-7923-2029-8 (boek nr. 48)
- WHITFIELD, A., *A decision that stretches the law too far*, BMJ, 19 April 1997, vol 314, p. 1185

18 HUMAN EXPERIMENTATION

18.4 Behavioral Research

- COSYNS, P., en CASSIERS, L., *Ethische Regels in het psychiatrisch onderzoek – Psychofarmacologie en psychotherapie*, onbekend, 26 februari 1997
- SEEDHOUSE, D., *Health Promotion – Philosophy, Prejudice and Practice*, John Wiley & Sons Ltd, Chichester, 1997, pp. 202 - ISBN 0 471 93910 2 (boek nr. 47)
- VAN DEN HOONAARD, W.C., *Walking the tightrope: Ethical Issues for Qualitative Researchers*, University of Toronto Press, Toronto, 2002, pp. 218 – ISBN 0-8020-8523-7 (boek nr. 199)
-

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.1 General

- ENKIN, M.W., *Clinical equipoise and not the uncertainty principle is the moral underpinning of the randomised controlled trial*, BMJ, 23 september 2000, vol. 321 pp. 756-758
- GIFFORD, A.L., *Participation in Research and Access to Experimental Treatments by HIV-infected patients*, New England Journal of Medicine, May 2, 2002, vol 346, n° 18, pp. 1373-1382
- GINSBERG, D., *The Investigator's Guide to Clinical Research*, CenterWatch, Boston, 1999, pp. 281 – ISBN 0-9673029-0-0 (boek nr. 179)
- KING, T.E., *Racial Disparities in Clinical Trials*, New England Journal of Medicine, May 2, 2002, vol 346, n° 18, pp. 1400-1402
- KUSHNER, T.K., THOMASMA, D.C., *Ward ethics – Dilemmas for medical students and doctors in training*, Cambridge University Press, Cambridge, 2001, pp. 265 - ISBN 0 521 80291 1 (boek nr. 157)
- LEMAIRE, F, BLANCH, L, COHEN, S.L. en SPRUNG, C., *Statement on Informed Consent for Research Purposes in Intensive Care Patients in Europe*, European society of intensive care medicine,
- LUCE, J.M., *Is the concept of informant consent applicable to clinical research involving critically ill patients?*, Critical Care Medicine 2003 vol. 31, no 3 pp S153-160,
- MASON, S, en MEGONE, C., *European Neonatal Research – Consent, ethics committees and law*, Ashgate, Hants, 2001, pp. 272 - ISBN 0 7546 1301 1 (boek nr. 143)
- SANGER, A, *Beyond choice - Reproductive freedom in the 21st century*, PublicAffairs, New York, 2004, pp. 340 - ISBN 1-58648-116-9 (boek nr. 223)
- SHALALA, D., *Protecting Research Subjects – What Must Be Done*, The New England Journal of Medicine, September 14, 2000, vol. 343, n° 11, pp. 808-810
- SMITH, T., *Ethics in Medical Research – A Handbook of Good Practice*, Cambridge University Press, Cambridge, 1999, pp. 346 - ISBN 0 521 62619 6 (boek nr. 105)
- TORGERSON, D.J. en CAMPBELL, K., *Use of unequal randomisation to aid the economic efficiency of clinical trials*, BMJ, 23 September 2000, vol. 321, p. 759
- WEAR, S., *Informed Consent – Patient Autonomy and Physician Beneficence within Clinical Medicine*, Kluwer Academic Publishers, Dordrecht, 1993, pp. 167 - ISBN 0-7923-2029-8 (boek nr. 48)

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.2 Newborns and Minors

- CASSIDY, R.C. en FLEISCHMAN, A.R., *Pediatric Ethics – From Principles to Practice*, Harwood Academic Publishers, Amsterdam, 1996, pp. 215 - ISBN 3 7186 57562 2 (boek nr. 13)
- CHAMBERS, T.L. en KURZ, R., *Ethical overview of paediatric research and practice in Europe from the Ethical Working Group of the Confederation of European Specialists in Paediatrics (CESP)*, Eur J Pediatr, 1999, 158, 537-540
- DOMURAT DREGER, A., *Intersex in the Age of Ethics*, University Publishing Group, Maryland, 1999, pp. 227 - ISBN 1-55572-100-1 (boek nr. 150)
- FRANKEL, L.R., e.a., *Ethical Dilemmas in Pediatrics – Cases and Commentaries*, Cambridge University Press, UK, 2005, pp. 270 – ISBN 0-521-84744-3 (boek nr. 270)
- FRIEDMAN ROSS, L.; *Children, Families, and Health Care Decision Making*, Clarendon Press, Oxford, 1998, pp. 197 - ISBN 0-19-823763-4 (boek nr. 93)
- FRIEDMAN ROSS, L., *Informed consent in pediatric research*, Cambridge Quarterly of Healthcare Ethics, Cambridge University Press, 2004, vol. 13, pp. 346-358
- GETZ, K., BORFITZ, D., *Informed Consent – The Consumer’s Guide to the Risks and Benefits of Volunteering for Clinical Trials*, CenterWatch, Thomson Healthcare Inc., Boston, 2002, pp. 306 – ISBN 1-930624-09-3 (boek nr. 197)
- GILL, D., *Ethical principles and operational guidelines for good clinical practice in paediatric research. Recommendations of the Ethics Working Group of the Confederation of European Specialists in Paediatrics (CESP)*, European Journal of Paediatrics, 10 january 2004, vol 163 pp 53-57
- KING, N.M.P., HENDERSON, G.E. en STEIN, J., *Beyond Regulations – Ethics in Human Subjects Research*, The University of North Carolina Press, London, 1999, pp. 279 - ISBN 0-8078-2468-2 (boek nr. 99)
- KODISH, E., *Ethics and research with children: a case-based approach*, Oxford University Press, 2005, pp. 361 – ISBN 0-19-517178-0 (boek nr. 262)
- MASON, S. en MEGONE, C., *European Neonatal Research – Consent, ethics committees and law*, Ashgate, Aldershot, 2001, pp. 272 - ISBN 0 7546 1301 1 (boek nr. 143)
- MORTIER, F., TEMMERMAN, M., BENOIT, Y. en MATTHYS, D., *Ethische problemen bij minderjarigen*, 88^e reeks avondcolloquia voor de Practicus, 21 juni 2000
- MOULIN, D. *L’enfant “ignoré”*, Louvain Med., vol. 117, 1998, S197-S202
- SAUER, P.J.J., *Research in children. A Report of the Ethics Working Group of the CESP*, Eur J Pediatr (2002) vol 161, pp. 1-5
- SMITH, R., *Babies and consent: yet another NHS scandal*, BMJ, vol. 320, 13 may 2000, p. 1285-1286
- SMYTH, R.L., WEINDLING, A.M., *Research in children: ethical and scientific aspects*, The Lancet, vol. 354, september 1999, p. su21-su24

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.3 Women

- BUCKLE, S., e.a., *Embryo Experimentation – Ethical, legal and social issues*, Cambridge University Press, 1990, pp. 263 - ISBN 0-521-43588-9 (boek nr. 44)
- CIOFFI, A., *The Fetus as Medical Patient – Moral Dilemmas in Prenatal Diagnosis from a Catholic Perspective*, University Press of America, Lanham, 1995, pp. 303 - ISBN 0-8191-9780-7 (boek nr. 45)
- GETZ, K., BORFITZ, D., *Informed Consent – The Consumer’s Guide to the Risks and Benefits of Volunteering for Clinical Trials*, CenterWatch, Thomson Healthcare Inc., Boston, 2002, pp. 306 – ISBN 1-930624-09-3 (boek nr. 197)
- TÄNNSHJÖ, T., *Coercive care – The ethics of choice in health and medicine*, Routledge, London, 1999, pp. 163 - ISBN 0-415-20849-1 (boek nr. 100)

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.4 Embryos and Fetuses

- ANONIEM, *Proefnemingen op menselijke embryo's - Binnenkort een wettelijk kader in België*, Artsenkrant, 25 oktober 2002, 1463, pp. 18
- BUCKLE, S., e.a., *Embryo Experimentation – Ethical, legal and social issues*, Cambridge University Press, New York, 1990, pp. 263 - ISBN 0-521-38359-5 (boek nr. 44)
- DE LIMAN J., e.a., *Infant and neonatal pain: anaesthetists' perceptions and prescribing patterns*, BMJ, 28 september 1996, vol 313, p. 787
- DERBYSHIRE, S.W.G, FUREDI, A., *Do fetuses feel pain?*, BMJ, 28 september 1996, vol. 313, p. 795-799
- DUNSTAN, G.R., *The Human Embryo – Aristotle and the Arabic and European Traditions*, University of Exeter Press, Exeter, 1990, pp. 235 - ISBN 0 85989 340 5 (boek nr. 36)
- FRANKEL, L.R., e.a., *Ethical Dilemmas in Pediatrics – Cases and Commentaries*, Cambridge University Press, UK, 2005, pp. 270 – ISBN 0-521-84744-3 (boek nr. 270)
- HOLLAND, S., LEBACQZ, K., en ZOLOTH, L., *The Human Embryonic Stem Cell Debate*, The MIT Press, Massachusetts, 2001, pp. 257 - ISBN 0-262-08299-3 (boek nr. 169)
- JONES, D.A., *The soul of the embryo: An enquiry into the status of the human embryo in the Christian tradition*, Continuum, 2004, pp. 266 – ISBN 0 8264 6296 0 (boek nr. 247)
- MASON, S.A., ALLMARK, P.J., *Obtaining informed consent to neonatal randomised controlled trials: interviews with parents and clinicians in the Euricon study*, The Lancet, December 16, 2000, vol 356, p. 2045-2051
- MULKAY, M., *The embryo research debate – Science and the politics of reproduction*, Cambridge University Press, Cambridge, 1997, pp. 212 - ISBN 0 521 57180 4 (boek nr. 77)
- ONBEKEND, *Baby trial papers 'forged'*, BBC news, 9/2/99
- RUMBELOW, H., *Trust denies forging consents*, The Times, 2 september 1999,
- SCHROEDEL, J.R., *Is the fetus a person? – A comparison of policies across the fifty states*, Cornell University Press, New York, 2000, pp. 223 – ISBN 0-8014-3707-5 (boek nr. 137)
- STEINBOCK, B., *Life before Birth – The Moral and Legal Status of Embryos and Fetuses*, Oxford University Press, Oxford, 1992, pp. 256 - ISBN 0-19-505494-6 (boek nr. 37)
- STRONG, C, *Ethics in Reproductive and Perinatal Medicine*, Yale University Press, Pennsylvania, 1997, pp. 247 - ISBN 0-300-06832-8 (boek nr. 39)
- TYSON, J.E., KNUDSON, P.L., *Views of neonatologists and parents on consent for clinical trials*, The Lancet, December 16, 2000, vol 356, p. 2026-2027
- VAN STEIRTEGHEM, A.C., DEVROEY, P., LIEBAERS, I., *Research op embryo's*, Tijdschr. voor Geneeskunde, 1991, vol 47, nr. 3, p. 181-188

18 HUMAN EXPERIMENTATION

18.5 Research on Special Population

18.5.5 Prisoners

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.6 Mentally Disabled Persons

- MICHELS, R., *Are Research Ethics Bad for Our Mental Health?*, The New England Journal of Medicine, May 6, 1999, vol. 340, n° 18, pp. 1427-1430
- MORGAN CAPRON, A., *Ethical and Human-Rights Issues in Research on Mental Disorders That May Affect Decision-Making Capacity*, The New England Journal of Medicine, May 6, 1999, vol. 340, n° 18, p. 1430-1434

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.7 Elderly and Terminally Ill Persons

- MEZEY, M.D., e.a., *Ethical Patient Care*, The Johns Hopkins University Press, Baltimore, 2002, pp. 354 – ISBN 0-8018-6770-3 (boek nr. 181)
- RANDALL, F., DOWNIE, R.S., *Palliative Care Ethics – A Good Companion*, Oxford University Press, Oxford, 1996, pp. 202 - ISBN 0 19 262632 9 (boek nr. 51)
- REES, E., en HARDY, J., *Novel consent process for research in dying patients unable to give consent*, BMJ, 26 July 2003, vol. 327, pp. 198
-

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.8 Military and Government Personnel

18 HUMAN EXPERIMENTATION

18.5 Research on Special Populations

18.5.9 Foreign Nationals

- KOSKI, G., NICHTINGALE, S., *Research Involving Human Subjects in Developing Countries*, New England Journal of Medicine, July 12.2001, vol 345, No. 2, p. 136-138
- MULLINGS, A.M.A., e.a., *The Ethics of Research in Developing Countries*, The New England Journal of Medicine, August 3, 200, vol 343, n° 5, p. 361-365
- SHAPIRO, H.T., MESLIN, E.M., *Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries*, New England Journal of Medicine, July 12.2001, vol 345, No 2, p. 139-142
- TAN-TORRES EDEJAR, T., *North-South research partnerships: the ethics of carrying out research in developing countries*, BMJ, 14 August 1999, vol. 319, p. 438-441
- WILMSHURST, P., *Scientific imperialism*, BMJ, 22 March 1997, vol 314, p. 840-841

18 HUMAN EXPERIMENTATION

18.6 Social Control of Human Experimentation

- ANONIEM, *Six in intensive care after drug trial*, The Independent, March 15, 2006
- BANYARD, P., en FLANAGAN, C., *Ethical issues and guidelines in psychology*, Routledge, Londen & New York, 2005, pp. 173 – ISBN 0-415-26881-8 (boek nr. 283)
- CITRO, C.F., en ILGEN, D.R., e.a., *Protecting Participants and Facilitating Social and Behavioral Sciences Research*, The National Academies Press, 2003, pp 258 - ISBN 0-309-08852-6 (boek nr. 231)
- CHILDRESS, J.F., MESLIN, E.M. en SHAPIRO, H.T., *Belmont revisited: Ethical principles for research with human subjects*, Georgetown University Press, Washington D.C., 2005, pp. 279, ISBN 1-58901-062-0 (boek nr. 285)
- DECULLIER, E., LHERITIER, V., CHAPUIS, F., *Fate of biomedical research protocols and publication bias in France: retrospective cohort study*, BMJ, June 20, 2005, vol. 331, pp. 19
- DRAZEN, J.M., *Institutions, Contracts, and Academic Freedom*, The New England Journal of Medicine, October 24, 2002, vol. 347, n°17, pp. 1362-1363
- DYER, O., *GlaxoSmithKline faces US lawsuit over concealment of trial results*, BMJ, 12 juni 2004, vol. 328, pp 1395
- DYER, O., *Human Tissue Bill is modified because of research needs*, BMJ, 16 juni 2004, vol. 328, pp 1518
- FOSTER, C., *The ethics of medical research on humans*, Cambridge University Press, Cambridge, 2001, pp. 159 - ISBN 0 521 64196 9 (boek nr. 164)
- GIBSON, L. , *GlaxoSmithKline to publish clinical trials after US lawsuit*, BMJ, 26 juni 2004, vol. 328, pp 1513
- GINSBERG, D., *The Investigator's Guide to Clinical Research*, CenterWatch, Inc., Boston, 1999, pp. 281 – ISBN 0-9673029-0-0 (boek nr. 179)
- GOTTLIEB, S., *Researchers deny any attempt to mislead the public over JAMA article on arthritis drug*, BMJ, 11 August 2001, vol. 323, p. 301
- GRIFFITHS, R., STACEY, T.E., STRUTHERS, J., *Response from members of the Grittiths inquiry*, BMJ, 2000, vol 321, p. 755-756
- HALPERN, S.A., *Lesser harms: the morality of risk in medical research*, University of Chicago Press, 2004, pp. 232 – ISBN 0-226-31451-0 (boek nr. 246)
- HEY, E., CHALMERS, I., *Investigating allegations of research misconduct, the vital need for due process*, BMJ, 2000, vol 321, p. 752-6
- HOPKINS, J., *Infectious diseases expert sentenced to prison and fined*, BMJ, 20 march 2004, vol. 328, pp 662-663
- JONSSON, L.J.A., *Ethics of testing drugs with readily available alternatives*, The Lancet, August 24, 2002, vol 360, pp. 647
- KELCH, R.P., *Maintaining the Public Trust in Clinical Research*, New England Journal of Medicine, January 24, 2002, vol 346, no 346
- LANSANG, M.A., CRAWLEY, F.P., *The ethics of international biomedical research*, BMJ, 2000, vol 321, p. 777-778

18 HUMAN EXPERIMENTATION

18.6 Social Control of Human Experimentation

- LEVICK S.E. , *Clone Being - Exploring the psychological and social dimensions*, Rowman & Littlefield Publishers INC. , 2004, pp 317 - ISBN 0-7425-2990-8 (boek nr. 229)
- LOCK, S., WELLS, F., *Fraud and Misconduct in Medical Research*, BMJ publishing group, London, 1993, pp. 293 - ISBN 0-7279-0996-7 (boek nr. 32)
- MACKLIN, R., *Double Standards in Medical Research in Developing Countries*, Cambridge University Press, 2004, pp. 280 - ISBN 0521 83388 4 (boek nr. 240)
- MAYOR, S., *New governance framework for NHS research aims to stop fraud*, BMJ, 2000, vol 321, p. 725
- MELLO, M.M., en BRENNAN, T.A., *Due process in investigations of research misconduct*, The New England Journal of Medicine, September 25, 2003, vol. 349, n° 13, pp. 1280 – 1286
- MELTON, L. J., *The Treat to Medical-records Research*, The New England Journal of Medicine, 12 november 1977, vol. 337, n° 20, pp. 1466-1470
- MOSES III, H., BRAUNWALD, E., MARTIN, J.B. & THIER, S.O., *Collaborating with Industry – Choices for the Academic Medical Center*, The New England Journal of Medicine, October 24, 2002, vol. 347, n° 17, pp. 1371-1375
- NATHAN, D.G., WEATHERALL, D.J., *Academic Freedom in Clinical Research*, The New England Journal of Medicine, October 24, 2002, vol. 347, n°17, pp. 1368-1371
- ONBEKEND, *Ethical considerations in HIV preventive vaccine research*, Unaid's guidance document, May 2000
- SCHULMAN K.A., e.a., *A national survey of provisions in clinical-trial agreements between medical schools and industry sponsors*, The New England Journal of Medicine, October 24, 2002, vol. 347, n° 17, pp. 1335-1341
- SINGER, E.A., DRUML, C., *Collateral damage or apocalypse now for European academic research*, Intensive Care Med., 2005, vol. 31, pp. 271
- SINGH, D., *Ethical issues of pharmacogenetics must be addressed, says Nuffield Council*, BMJ, September 27, 2003, vol. 327, p. 701
- SMITH, R., *Inquiring into inquiries*, BMJ, 2000, vol 321, p. 715-716
- SMITH, T., MOORE, E.J.H., TUNSTALL-PEDOE, H., *Review by a local medical research of approved research projects, by examination of patients' case notes, consent forms, and research records and by interview*, BMJ, 1997, vol 314, p. 1588-1590
- TER HEERDT, J., *Het experiment beproefd: een juridische analyse van medische experimenten met mensen*, Maklu, Antwerpen, 2000, pp. 722 - ISBN 90 6215 741 6 (boek nr. 138)
- THOMASMA, D.C., WEISSTUB, D.N., en HERVE, C., *Personhood and Health Care*, Kluwer Academic Publishers, Dordrecht, 2001, pp. 449 – ISBN 1-4020-0098-7 (boek nr. 176)
- THOMPSON, A., TEMPLE, N.J., *Ethics, Medical Research, and Medicine – Commercialism versus Environmentalism and Social Justice*, Kluwer Academic Publishers, Dordrecht, 2001, pp. 195 - ISBN 0 7923 7084 8 (boek nr. 165)

18 HUMAN EXPERIMENTATION

18.6 Social Control of Human Experimentation

- TROUET, C., *Clinical trials in Belgium: the implementation of the European Clinical Trials Directive 2001/20/EC into the Belgian Law of May 7, 2004 concerning experiments on the human person – Operational Guidance*, Intersentia, 2004, pp. 258 – ISBN 90-5095-420-0 (boek nr. 251)
- VAN DEN HOONAARD, W.C., *Walking the tightrope: Ethical Issues for Qualitative Researchers*, University of Toronto Press, Toronto, 2002, pp. 218 – ISBN 0-8020-8523-7 (boek nr. 199)