

*Sorted by category*

## Law and Ethics

### Assessment and Minimization of Risks of Nanomedicine Research to Human Subjects

Barke R. (2009) Balancing uncertain risks and benefits in human subjects. *Research Science Technology & Human Values* 34(3).

Henderson GE, Davis AM, King NMP, et al. (2004) Uncertain benefit: investigators' views and communications in early phase gene transfer trials. *Molecular Therapy* 10(2): 225-231.

Kimmelman J. (2005) Recent developments in gene transfer: risk and ethics. *BMJ (Clinical research ed)*330(7482): 79-82.

Kimmelman J. (2004) Valuing risk: the ethical review of clinical trial safety. *Kennedy Institute of Ethics Journal* 14(4): 369-393.

Marchant GE, Sylvester DJ, Abbott KW. (2008) Risk management principles for nanotechnology. *Nanoethics* 2(1).

Resnik DB, Tinkle SS. (2007) Ethics in nanomedicine. *Nanomedicine* 2(3): 345-350.

Spagnolo A, Daloiso V. (2009) Outlining ethical issues in nanotechnologies. *Bioethics* 23(7): 394-402.

### Assessment and Minimization of Risk to Others

Balbus JM, Florini K, Denison RA, Walsh SA. (2006) Getting it right the first time: Developing nanotechnology while protecting workers public health and the environment. *Annals of the New York Academy of Sciences* 1076: 331-342.

Chan VSW. (2006) Nanomedicine: An unresolved regulatory issue. *Regulatory Toxicology and Pharmacology: RTP* 46(3): 218-224.

Hausman DM. (2007) Third-party risks in research: Should IRBs address them? *IRB* 29(3): 1-5.

Kimmelman J. (2007) Missing the forest: Further thoughts on the ethics of bystander risk in medical research. *CQ: Cambridge Quarterly of Healthcare Ethics* 16(4): 483-490.

Kimmelman J. (2005) Medical research risk and bystanders *IRB* 27(4): 1-6.

Maynard AD. (2009) Commentary: Oversight of engineered nanomaterials in the workplace. *The Journal of Law, Medicine & Ethics: a journal of the American Society of Law Medicine & Ethics* 37(4): 651-658.

Maynard AD. (2006) Nanotechnology: A research strategy for addressing risk. *Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies*.

Oberdörster, et al. (2005) Principles for characterizing the potential human health effects from exposure to nanomaterials: Elements of a screening strategy. *Particle and Fibre Toxicology* 2(8).

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Priestly BG, Harford AJ, Sim MR. (2007) Nanotechnology: A promising new technology--but how safe? *The Medical Journal of Australia* 186(4): 187-188.

Resnik DB, Sharp RR. (2006) Protecting third parties in human subjects research *IRB* 28(4): 1-7.

Schulte PA, Murashov V, Zumwalde R, Kuempel ED, et al. (2010) Occupational exposure limits for nanomaterials: State of the art. *J Nanopart Res.* 12 (6): 1971-1987.

Wiesner M, Lowry G, et al. (2006) Decreasing uncertainties in assessing environmental exposure risk and ecological implications of nanomaterials. *Environmental Science & Technology* 40(14): 4336-4345.

### **Balancing Risks with the Anticipated Benefits to the Subject and Societal Importance of the Research**

Barke R. (2009) Balancing uncertain risks and benefits in human subjects. *Research Science Technology & Human Values* 34(3).

Miller FG, Joffe S. (2009) Limits to research risks. *Journal of Medical Ethics* 35(7): 445-449.

Nycum G, Reid L. (2007) The harm-benefit tradeoff in "bad deal" trials. *Kennedy Institute of Ethics Journal* 17(4): 321-350.

Weijer C, Miller PB. (2004) When are research risks reasonable in relation to anticipated benefits? *Nature Medicine* 10(6): 570-573.

### **Early Phase Trial and Protocol Design**

Aguilar LK, Aguilar-Cordova E. (2003) Evolution of a gene therapy clinical trial: From bench to bedside and back. *Journal of Neuro-Oncology* 65(3): 307-315.

Ferrari M, Downing G. (2005) Medical nanotechnology: shortening clinical trials and regulatory pathways? *BioDrugs: Clinical Immunotherapeutics Biopharmaceuticals and Gene Therapy* 19(4): 203-210.

Huang DT, Hadian M. (2006) Bench-to-bedside review: human subjects research--are more standards needed? *Critical Care* 10(6): 244-244.

Kinders et al. (2007) Phase 0 clinical trials in cancer drug development: From FDA guidance to clinical practice. *Molecular Interventions* 7(6): 325-334.

Lewis RM, Gordon DJ, Poole-Wilson PA, Borer JS, et al. (2008) Similarities and differences in design considerations for cell therapy and pharmacologic cardiovascular clinical trials. *Cardiology* 110(2): 73-80.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

### Ethical Implications of Nanomedicine

- Bawa R, Johnson S. (2007) The ethical dimensions of nanomedicine. *The Medical Clinics of North America* 91(5): 881-887.
- Best R, et al. (2006) Introduction: A sympathetic but critical assessment of nanotechnology initiatives. *Journal of Law, Medicine & Ethics* 34:655-657.
- Best R, Khushf G. (2006) The social conditions for nanomedicine: Disruption systems and lock-in. *Journal of Law, Medicine & Ethics* 34(4): 733-740.
- Clisham M. (2005) Refining humanity: A review of the coevolution of human potential and converging technologies. *Journal of Law, Medicine & Ethics* 33: 380-383.
- Dupuy JP. (2007) Some pitfalls in the philosophical foundations of nanoethics. *J Med & Phil* 32: 237-261.
- Ebbesen M, Jensen TG. (2006) Nanomedicine: Techniques, potentials and ethical implications. *Journal of Biomedicine & Biotechnology* 2006: 1-11.
- Faunce TA. (2007) Nanotechnology in global medicine and human biosecurity: Private interests, policy dilemmas and the calibration of public health law. *Journal of Law, Medicine & Ethics* 35: 629-642.
- Ferrari M, et al. (2009) Nanomedicine and society. *Nature* 85: 466-467.
- Ferrari M. (2007) Address at President's Council on Bioethics Session 5 (June 29, 2007) 17 pages.
- Godman M. (2008) But is it unique to nanotechnology? *SCI. & Engineering Ethics* 14: 391-403.
- Gordijn B. (2006) Converging NBIC technologies for improving human performance: A critical assessment of the novelty and the prospects of the project. *Journal of Law, Medicine & Ethics* 34: 726-732.
- Grinbaum A. (2006) Cognitive barriers in perception of nanotechnology. *Journal of Law, Medicine & Ethics* 34: 689-694.
- Hansen SF. (2010) Multicriteria Mapping of Stakeholder Preferences in Regulating Nanotechnology. *J Nanopart Res* 12: 1959-1970.
- Jones R. (2009) Are you a responsible nanoscientist? *Nature Nanotechnology* 4: 336.
- Jotterand F. (2006) The politicization of science and technology: Its implications for nanotechnology. *Journal of Law, Medicine & Ethics* 34: 658-666.
- Kaiser M. (2006) Drawing the boundaries of nanoscience—rationalizing the concerns? *Journal of Law, Medicine & Ethics* 34: 667-674.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Lenk C, Biller-Andorno N. (2007) Nanomedicine—emerging or re-emerging ethical issues? A discussion of four ethical themes. *Medicine, Health Care & Philosophy* 10: 173-184.

Marchant GE, Sylvester DJ. (2006) Transnational models for regulation of nanotechnology. *Journal of Law, Medicine & Ethics* 34: 714-725.

Meaney ME. (2006) Lessons from the sustainability movement: Toward an integrative decision-making framework for nanotechnology. *Journal of Law, Medicine & Ethics* 34: 682-688.

Mehlman MJ, Berg JW. (2008) Human subjects protections in biomedical enhancement research: Assessing risk and benefit in obtaining informed consent. *Journal of Law, Medicine & Ethics* 36: 546-549.

Mnyusiwalla A, et al. (2003) Mind the gap: Science and ethics in nanotechnology. *Nanotechnology* 14 R9.

Resnik DB, Tinkle SS. (2007) Ethical issues in clinical trials involving nanomedicine. *Contemporary Clinical Trials* 28(4): 433-441.

Rip A. (2009) Futures of ELSA. *EMBO Reports* 10(7): 666-670.

Sandler R, Kay WD. (2006) The national nanotechnology initiative and the social good. *Journal of Law, Medicine & Ethics* 34: 675-681.

Schulte PA, Salamanca-Buentello F. (2007) Ethical and scientific issues of nanotechnology in the workplace. *Environmental Health Perspectives* 115: 5-12.

Thompson RE. (2007) Nanotechnology: Science fiction? Or next challenge for the ethics committee? *The Physician Executive* 33(3): 64-66.

Wardak A, Gorman ME. (2006) Using trading zones and life cycle analysis to understand nanotechnology regulation. *Journal of Law, Medicine & Ethics* 34: 695-703.

Wilson RF. (2006) Nanotechnology: The challenge of regulating known unknowns. *Journal of Law, Medicine & Ethics* 34: 704-713.

### **Ethical Issues in Xenotransplantation Clinical Trials**

Anderson M. (2006) Xenotransplantation: A bioethical evaluation. *Journal of Medical Ethics* 32(4): 205-208.

Bach FH, Iverson AJ, Weeramantry C. (2001) Ethical and legal issues in technology: Xenotransplantation. *American Journal of Law & Medicine* 27(2-3):283-300.

Daar AS. (1997) Ethics of xenotransplantation: Animal issues consent and likely transformation of transplant ethics. *World Journal of Surgery* 21(9): 975-982.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

- Einsiedel EF. (2004) Commentary: On the position paper of the ethics committee of the international xenotransplantation association. *Transplantation* 78(8): 1110-1.
- Ellison T. (2006) Xenotransplantation--ethics and regulation. *Xenotransplantation* 13(6): 505-9.
- Kaiser M. (2004) Xenotransplantation--ethical considerations based on human and societal perspectives. *Acta Veterinaria Scandinavica – Supplement* 99: 65-73.
- Morgan F. (1997) Babe, the magnificent organ donor? The perils and promises surrounding xenotransplantation. *The Journal of Contemporary Health Law and Policy* 14(1):127-160.
- Morris PJ, Monaco AP. (2004) Ethical issues and xenotransplantation. *Transplantation* 78(8): 1099-1100.
- Olakanmi O. (2006) Xenotransplantation: A rational choice?. *Penn Bioethics Journal* 2(2): 38-41.
- Ravelingien A, Mortier F, Mortier E, Kerremans I, et al. (2004) Proceeding with clinical trials of animal to human organ transplantation: A way out of the dilemma *Journal of medical ethics* 30(1): 92-98.
- Rood PPM, Cooper DKC. (2006) Islet xenotransplantation: Are we really ready for clinical trials? *American Journal of Transplantation* 6:1269–1274.
- Spillman MA, Sade RM. (2007) Clinical trials of xenotransplantation: Waiver of the right to withdraw from a clinical trial should be required. *Journal of Law Medicine & Ethics* 35(2): 265-272.
- Sykes M, Cozzi E. (2006) Xenotransplantation of pig islets into mexican children: Were the fundamental ethical requirements to proceed with such a study really met? *European Journal of Endocrinology* 154(6): 921-923.
- Sykes M, d'Apice A, Sandrin M. (2004) IXA ethics committee: Position paper of the ethics committee of the international xenotransplantation association. *Transplantation* 78(8): 1101-7.
- Welin S. (2000) Starting clinical trials of xenotransplantation—reflections on the ethics of the early phase. *J Med Ethics* 26: 231-236.

### **Ethics of First-In-Human Research**

- Kimmelman J. (2007) Ethics at phase 0: clarifying the issues. *Journal of Law, Medicine & Ethics* 35: 727.
- Kimmelman J. (2009) Ethics of cancer gene transfer clinical research. *Methods in Molecular Biology* 542:423-445.
- Kimmelman J. (2008) The gelsinger debacle: Translational clinical research and the morality of risk. *Nature Reviews Genetics* 9: 239-244.
- Kimmelman J. (2009) Launching invasive first-in-human trials against parkinson's disease: Ethical considerations. *Movement Disorders* 24(13): 1893-1901.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Kimmelman J. (2009) Tomorrow, interrupted?: risk, ethics, and medical advance in gene transfer. *Molecular Therapy* 17(11): 1838–1839.

Kimmelman J. Gene transfer and the ethics of first-in-human research: lost in translation. New York: Cambridge University Press, 2009.

Kong WM. (2005) Legitimate requests and indecent proposals: Matters of justice in the ethical assessment of phase I trials involving competent patients. *Journal of Medical Ethics* 31(4): 205-208.

Maschke K.J. Human research protections: time for regulatory reform? *Hastings Center Report* (2008); 38(2):19-22.

Nada A, Somberg J. (2007) First-in-man (FIM) clinical trials post-tegenero: A review of the impact of the tegenero trial on the design, conduct, and ethics of fim trials. *American Journal of Therapeutics* 14(6): 594-604.

Schwartz PH, Kalichman MW. (2009) Ethical challenges to cell-based interventions for the central nervous system: Some recommendations for clinical trials and practice. *American Journal of Bioethics* 9(5): 41-3.

Trommelmans L, Selling J, Dierickx K. (2009) An exploratory survey on the views of European tissue engineers concerning the ethical issues of tissue engineering research. *Tissue Engineering: Part B* 15(3):241-247.

Welin S. (2000) Starting clinical trials of xenotransplantation—reflections on the ethics of the early phase. *Journal of Medical Ethics* 26: 231-236.

### **Ethics of Moving from Bench Science to Animal Research to First-In-Humans Research**

Aguilar LK, Aguilar-Cordova E. (2003) Evolution of a gene therapy clinical trial: From bench to bedside and back. *Journal of Neuro-Oncology* 65(3): 307-315.

Huang DT, Hadian M. (2006) Bench-to-bedside review: Human subjects research--are more standards needed? *Critical Care* 10(6): 244-244.

Joffe S, Miller FG. (2008) Bench to bedside: Mapping the moral terrain of clinical research. *The Hastings Center Report* 38(2): 30-42.

Kimmelman J. Gene transfer and the ethics of first-in-human research: lost in translation. New York: Cambridge University Press, 2009.

Kimmelman J. (2009) Launching invasive first-in-human trials against parkinson's disease: Ethical considerations. *Movement Disorders* 24(13): 1893-1901.

Resnik DB, Tinkle SS. (2007) Ethical issues in clinical trials involving nanomedicine. *Contemporary Clinical Trials* 28(4): 433-441.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Sheremeta L. (2004) Nanotechnology and the Ethical Conduct of Research Involving Human subjects. *Health Law Review* 12(3): 47-56.

### **Informed Consent in First-In-Human Research**

Henderson GE, Davis AM, King NMP, Easter MM, et al. (2004) Uncertain benefit: Investigators' views and communications in early phase gene transfer trials. *Molecular Therapy: the Journal of the American Society of Gene Therapy* 10(2): 225-31.

Henderson GE, Easter MM, Zimmer C, King NMP, et al. (2006) Therapeutic misconception in early phase gene transfer trials. *Social Science & Medicine* 62(1): 239-253.

Jansen LA, Appelbaum PS, Klein WM, Weinstein ND, Cook W, Fogel JS, Sulmasy DP. (2011) Unrealistic optimism in early-phase oncology trials. *IRB* 33(1):1-8.

Jenkins VA, Anderson JL, Fallowfield LJ. (2010) Communication and informed consent in phase 1 trials: A review of the literature from January 2005 to July 2009. *Support Care Cancer* 18(9):1115-1121.

Kahn J. (2008) Informed consent in human gene transfer clinical trials. *Human Gene Therapy* 19(1).

Kim SYH, Holloway RG, Frank S, Wilson R, et al. (2008) Trust in early phase research: Therapeutic optimism and protective pessimism. *Medicine, Health Care, and Philosophy* 11(4): 393-401.

Kimmelman J, Palmour N. (2005) Therapeutic optimism in the consent forms of phase 1 gene transfer trials: An empirical analysis. *Journal of Medical Ethics* 31(4): 209-214.

King NMP, Henderson GE, Churchill LR, Davis AM, et al. (2005) Consent forms and the therapeutic misconception: The example of gene transfer research. *IRB: a Review of Human Subjects Research* 27(1): 1-8.

Knapp P, Raynor DK, Silcock J, Parkinson B. (2009) Performance-based readability testing of participant materials for a phase I trial: TGN1412. *Journal of Medical Ethics* 35(9): 573-578.

Kuehn B. (2011) Patients' unrealistic hopes for cancer trial benefits may hinder consent. *JAMA* 305(12):1186-7.

Lo B, Zettler P, Cedars MI, Gates E, et al. (2005) A new era in the ethics of human embryonic stem cell research. *Stem Cells* 23(10): 1454-1459.

Matutina RE. (2010) The concept analysis of therapeutic misconception. *Nurse Researcher* 17(4):83-90.

Resnik DB, Tinkle SS. (2007) Ethical issues in clinical trials involving nanomedicine. *Contemporary Clinical Trials* 28(4): 433-441.

Seidenfeld J, Horstmann E, Emanuel EJ, Grady C. (2008) Participants in phase 1 oncology research trials: are they vulnerable? *Archives Intern Medicine* 168(1):16-20.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Stenson K, Chen D, Tansey K, Kerkhoff TR, Butt L, Gallegos AJ, Kirschner K. (2010) Informed consent and phase I research in spinal cord injury. *PM&R* 2:664-670.

Weinfurt KP, Sulmasy DP, Schulman KA, Meropol NJ. (2003) Patient expectations of benefit from phase I clinical trials: Linguistic considerations in diagnosing a therapeutic misconception. *Theoretical Medicine and Bioethics* 24(4): 329-344.

### Larger Societal Issues

Bawa R, Johnson S. Emerging issues in nanomedicine and ethics. In Allhoff F, Lin P eds. *Nanotechnology and Society: Current and Emerging Ethical Issues*. Springer, 2009: 207-223.

Bawa R, Johnson S. (2007) The Ethical Dimensions of Nanomedicine. *The Medical Clinics of North America* 91(5): 881-887.

Best R, Khushf G. (2006) The social conditions for nanomedicine: Disruption systems and lock-in. *The Journal of Law Medicine & Ethics* 34(4): 733-740.

Best R, Khushf G, Wilson R. (2006) A sympathetic but critical assessment of nanotechnology initiatives. *Journal of Law Medicine & Ethics* 34(4): 655-657.

Faunce T, Shats K. (2007) Researching safety and cost-effectiveness in the life cycle of nanomedicine. *Journal of Law and Medicine* 15(1): 128-135.

Ferrari M, Philbert MA, Sanhai WR. (2009) Nanomedicine and society. *Clinical Pharmacology and Therapeutics* 85(5): 466-467.

Jones R. (2008) When it pays to ask the public. *Nature Nanotechnology* 3(10): 578-579.

Kyle R, Dodds S. (2009) Avoiding empty rhetoric: Engaging publics in debates about nanotechnologies. *Sci Eng Ethics* 15: 81-96.

Roco MC, Bainbridge WS. (2005) Societal implications of nanoscience and nanotechnology: Maximizing human benefit. *Journal of Nanoparticle Research* 7(1): 1-13.

### Long-Term (Post-Market) Surveillance of Nanomedicine Products

Bawa R. (2008) Nanoparticle-based Therapeutics in Humans: A Survey. *Nanotechnology Law and Business* 5(2).

Faunce TA. (2007) Nanotechnology in global medicine and human biosecurity: private interests policy dilemmas and the calibration of public health law. *The Journal of Law Medicine & Ethic* 35(4).

Kuszler PC. (2006) Biotechnology entrepreneurship and ethics: principles paradigms and products. *Medicine and law* 25(3): 491-502.

Maynard AD. (2009) Commentary: oversight of engineered nanomaterials in the workplace. *The Journal of Law, Medicine & Ethics* 37(4): 651-658.



Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Spagnolo A, Daloiso V. (2009) Outlining ethical issues in nanotechnologies. *Bioethics* 23(7): 394-402.

Staggers N, McCasky T, Brazelton N, Kennedy R. (2008) Nanotechnology: The coming revolution and its implications for consumers clinicians and informatics. *Nursing Outlook* 56(5): 268-274.

Virdi J. (2008) Bridging the knowledge gap: Examining potential limits in nanomedicine. *Spontaneous Generations* 2(1).

### **Oversight Approaches for Early Phase Trials of New Biomedical Technologies**

Editorial. (2009) Gene therapy deserves a fresh chance. *Nature* 461(7268):1173.

Liedert B, Bassus S, Schneider CK, Kalinke U, Löwer, J. (2007) Safety of phase I clinical trials with monoclonal antibodies in germany--the regulatory requirements viewed in the aftermath of the tgn1412 disaster. *International Journal of Clinical Pharmacology and Therapeutics* 45(1): 1-9.

Lo B, Grady D. (2009) Strengthening institutional review board review of highly innovative interventions in clinical trials. *JAMA* 302(24): 2697-2698.

Mathews DJ, Sugarman J, Bok H, et al. (2008) Cell-based interventions for neurologic conditions: ethical challenges for early human trials. *Neurology* 71(4):288-93.

Nicholas J. (2010) NCI's clinical trial system: efficiencies grow, debate goes on. *Journal of National Cancer Institute* 102(23):1750-1751.

Scott CT. (2008) Stem cells: new frontiers of ethics, law, and policy. *Journal of Neurosurgery* 24: 3-4.

Williams DA. (2009) Gene therapy continues to mature and to face challenges. *Molecular Therapy* 17(8): 1305–1306.

### **Oversight of Human Subjects Research in Nanomedicine**

Allhoff F. (2009) The coming era of nanomedicine. *American Journal of Bioethics* 9 (10): 3-11.

Allhoff F. (2009) Response to open peer commentaries on "the coming era of nanomedicine." *American Journal of Bioethics* 9 (10): W1-W2.

Allhoff F. (2007) On the autonomy and justification of nanoethics. *Nanoethics* 1: 185-210.

Barke R. (2009) Balancing uncertain risks and benefits in human subject research. *Science Technology Human Values* 34: 337-64.

Bawa R. (2010) Regulating Nanomedicine – Can the FDA Handle It? Correspondence: Dr. Raj Bawa, Bawa Biotechnology Consulting LLC.

Bawa R, Johnson S. (2009) Emerging issues in nanomedicine and ethics. In Allhoff F, Lin P eds. *Nanotechnology and Society: Current and Emerging Ethical Issues*. Springer: 207-223.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Bawa R, Johnson S. (2007) The Ethical Dimensions of Nanomedicine. *The Medical Clinics of North America* 91(5): 881-887.

Capurro R. (2007) EGE opinion no. 21: Ethical aspects of nanomedicine. PowerPoint presentation delivered at Oxford on March 12, 2007.

Chan VSW. (2006) Nanomedicine: An unresolved regulatory issue. *Regulatory Toxicology and Pharmacology* 46: 218-224.

Crowe S. Understanding the ethical implications of nanotechnology: Highlights of a limited inquiry by the president's council on bioethics.

Culliton BJ. (2008) Is special fda regulation of nanomedicine needed? A conversation with Norris E. Alderson. *Health Affairs* web exclusive, w315-w317.

DeVillie KA. (2008) Law, regulation and medical use of nanotechnology. In Jotterand F (ed.) *Emerging Conceptual, Ethical and Policy Issues in Bionanotechnology*.

Editorial. (2007) The risks of nanotechnology for human health. *The Lancet* 369:1142.

Fadeel B, Garcia-Bennet AE. (2009) Better safe than sorry: Understanding the toxicological properties of inorganic nanoparticles manufactured for biomedical application. *Advanced Drug Delivery Reviews*

Faunce TA. (2007) Nanotherapeutics: New challenges for safety and cost-effectiveness regulation in Australia. *Med J Australia* 186(4): 189-91.

Faunce T, Shats K. (2007) Researching safety and cost-effectiveness in the life cycle of nanomedicine. *Journal of Law and Medicine* 15(1): 128-135.

Fielder FA, Reynolds GH. (1994) Legal problems of nanotechnology: An overview. *S Cal Interdisc LJ* 3: 593-629.

Harris S. (2009) The Regulation of Nanomedicine: Will the Existing Regulatory Scheme of the FDA Suffice? *Richmond Journal of Law and Technology* 17 (2): 1-25.

Hoet P, et al. (2009) Do nanomedicines require novel safety assessments to ensure their safety for long-term human use? *Drug Safety* 32(8): 625-636.

International Risk Governance Council. (2007) Nanotechnology risk governance: recommendations for global, coordinated approach to the governance of potential risks. *IRGC White Paper*.

Johnson S, McGee G. (2007) Nanotechnologies in health care: A needs assessment regarding ethics and policy in nanomedicine. *Harvard Health Policy Review* 8 (1): 156-164.

Khushf G. (2007) Upstream ethics in nanomedicine: A call for research. *Nanomedicine* 2(4): 511-521.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

- Kuiken T. (2011) Nanomedicine and ethics: Is there anything new or unique? *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology* 3(2):111-118.
- Lasagna-Reeves C, et al. (2010) Bioaccumulation and toxicity of gold nanoparticles after repeated administration in mice. *Biochemical and Biophysical Research Communications* 393(4):649-655.
- Lenk C, Biller-Andorno N. (2007) Nanomedicine—emerging or re-emerging ethical issues? A discussion of four ethical themes. *Medicine, Health Care & Philosophy* 10: 173-184.
- Litton P. (2007) Nanoethics? What’s new? *Hastings Center Report* 37(1): 22-25.
- Marchant GE, et al. (2008) Risk management principles for nanotechnology. *Nanoethics* 2: 43-60.
- McGee EM. (2009) Nanomedicine: Ethical concerns beyond diagnostics, drugs, and techniques. *American Journal of Bioethics* 9(10): 14-15.
- Metha, MD. (2003) The future of nanomedicine looks promising, but only if we learn from the past. *Health Law Review* 13(1): 16-18.
- Miller J. (2003) Beyond Biotechnology: FDA Regulation of Nanomedicine. *The Columbia Science and Technology Law Review* 4: 1-35.
- Murday JS, et al. (2009) Translational nanomedicine: status assessment and opportunities. *Nanomedicine* 5(3): 251-273.
- Qu G, et al. (2009) The effect of multiwalled carbon nanotube agglomeration on their accumulation in and damage to organs in mice. *Carbon* 47(8):2060-2069.
- Resnik DB, Tinkle SS. (2007) Ethical issues in clinical trials involving nanomedicine. *Contemp Clin Trials* 28(4): 433-41.
- Resnik DB, Tinkle SS. (2007) Ethics in nanomedicine. *Nanomedicine* 2(3): 345-50.
- Rip A. (2009) Futures of ELSA. *EMBO Reports* 10 (7): 666-670.
- Schulte PA, Salamanca-Buentello F. (2007) Ethical and scientific issues of nanotechnology in the workplace. *Environmental Health Perspectives* 115 (1): 5-12.
- Sheremeta L. (2004) Nanotechnology and the ethical conduct of research involving human subjects. *Health Law Rev* 12: 47-56.
- Slade C. (2008) Equity issues facing nanotechnology development in cancer research: Exploring the potential for greater racial disparities in health, a public value mapping analysis (working title). *Unpublished*.
- Spagnolo AG, Daliso V. (2009) Outlining ethical issues in nanotechnologies. *Bioethics* 23(7): 1467-8519.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Staggers N, McCasky T, Brazelton N, Kennedy R. (2008) Nanotechnology: the coming revolution and its implications for consumers clinicians and informatics. *Nursing Outlook* 56(5): 268-274.

Stern ST, McNeil SE. (2007) Nanotechnology safety concerns revisited. *Tox Sci* advance published.

Virdi J. (2008) Bridging the knowledge gap: examining potential limits in nanomedicine. *Spontaneous Generations* 2(1): 25-44.

Wagner V, et al. (2006) The emerging nanomedicine landscape. *Nat Biotech* 24: 1211-17.

Wolf SM, Jones CM. (2011) Designing oversight for nanomedicine research in human subjects: Systematic analysis of exceptional oversight for emerging technologies. *Journal of Nanoparticle Research* 13(4):1449-65.

Youan BBC. (2008) Impact of nanoscience and nanotechnology on controlled drug delivery. *Nanomedicine* 3(4): 401-406.

### **Selection of Subject Population and Recruitment into First-In-Human Research Trials**

Dresser R.(2009) First-in-human trial participants: Not a vulnerable population, but vulnerable nonetheless. *Journal of Law, Medicine & Ethics* 37(1): 38-50.

Menikoff J. (2009) The vulnerability of the very sick. *Journal of Law, Medicine & Ethics* 37(1):51-58.

Nickel PJ. (2006) Vulnerable populations in research: The case of the seriously ill. *Theoretical medicine and bioethics* 27(3): 245-264.

Park SS, Grayson M. (2008) Clinical research: Protection of the "vulnerable"? *The Journal of Allergy and Clinical Immunology* 121(5): 1103-1107.

Shamoo AE, Resnik DB. (2006) Strategies to minimize risks and exploitation in phase one trials on healthy subjects. *American Journal of Bioethics* 6(3): W1-13.

## **Government Policies**

### **Department of Defense**

Defense Nanotechnology Research and Development Program. 2007.

### **Department of Energy**

Environmental Assessment for the Center for Integrated Nanotechnologies at Sandia National Laboratories/New Mexico. DOE/EA-1457. Final Environmental Assessment. 2003.

Audit Report. Nanoscale Materials Safety at the Department's Laboratories. 2008.

Department Of Energy. Secretarial Policy Statement on Nanoscale Safety in September 2005. Approach to Nanomaterial ES&H. 2008.

Department of Energy. Approach to Nanomaterial ES&H. May 2008.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

### Department of Health and Human Services

Emanuel EJ, Menikof J. Reforming the Regulations Governing Research with Human Subjects. *The New England Journal of Medicine*. July 25, 2011, DOI: 10.1056/NEJMs1106942.

Office of the Secretary, Department of Health & Human Services and the Food and Drug Administration. *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators* 45 CFR Parts 46, 160 and 164 and 21 CFR Parts 50 and 56. July 2011.

### Environmental Protection Agency

Nanotechnology under the Toxic Substances Control Act. <http://www.epa.gov/oppt/nano/>

Potential Nano-Enabled Environmental Applications for Radionuclides. 2009.

Research Investigates Human Health Effects of Nanomaterials.  
[http://www.epa.gov/ord/nanoscience/quickfinder/hh\\_effects.htm](http://www.epa.gov/ord/nanoscience/quickfinder/hh_effects.htm)

Concept Paper for the Nanoscale Materials Stewardship Program under TSCA.

Final Meeting Summary Report Risk Management Practices for Nanoscale Materials. External Review Draft, Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and in Topical Sunscreen. 2009.

Nanotechnology: an EPA Research Perspective Factsheet. 2007.

Nanomaterial Research Strategy. Office of Research and Development. 2009.

EPA Report 100/B-07-001: Nanotechnology White Paper. 2007.

Proceedings. Nanotechnology and the Environment: Applications and Implications Progress Review Workshop III. 2005.

Proceedings of the Interagency Workshop on the Environmental Implications of Nanotechnology. 2007.

### European Commission

Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research. July 2, 2008.

### Food and Drug Administration

Nomination and Review of Toxicological Literature. 2006.

Guidance for Industry: Developing Medical Imaging Drug and Biological Products. Part 3: Design, Analysis, and Interpretation of Clinical Studies. 2004.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Guidance for Industry: Developing Medical Imaging Drug and Biological Products. Part 1: Conducting Safety Assessments. 2004.

Guidance for Industry: Liposome Drug Products. 2002.

Frequently Asked Questions. 2009.

Nanotechnology: A report of the U.S. Food and Drug Administration Nanotechnology Task Force. 2007.  
FDA Regulation of Nanotechnology Products. 2009.

### **National Cancer Institute**

Nanotechnology Characterization Laboratory. Date not available.

Nanotechnology Characterization Laboratory. (2006) Accelerating the transition of concepts to clinical application. *NCL News*. 1(1):2-4.

### **National Institute for Occupational Safety and Health**

A Global Perspective on Safe Nanotechnology. 2009.

The Nanotechnology Information Library (NIL).

Progress Toward Safe Nanotechnology in the Workplace. A Report from the NIOSH Nanotechnology Research Center. 2010.

Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps.

Health and Human Services. Safe Nanotechnology in the Workplace: An Introduction for Employers, Managers, and Safety and Health Professionals. 2008.

Progress Toward Safe Nanotechnology in the Workplace. DHHS (NIOSH) Publication No. 2007-123. 2007.

Department of Health and Human Services. Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials. DHHS (NIOSH) Publication No. 2009-125. 2009.

NIOSH Draft Offers Interim Guidance on Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles. 2007.

### **National Institute of Environmental Health Sciences/National Toxicology Program**

National Toxicology Program Annual Report for FY 2008. 2009.

NTP Nanotechnology Safety Initiative.

NanoHealth Enterprise Initiative. Engineered Nanomaterials Research and Training.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Nanotechnology Working Group (NWG). Minutes from the June 2005 Meeting of the NTP Board of Scientific Counselors Nanotechnology Working Group (NWG). 2005.

Developing Experimental Approaches for the Evaluation of Toxicological Interactions of Nanoscale Materials. 2004.

National Toxicology Program, Current Directions and Evolving Strategies. 2004.

### **National Institute of Standards and Technology**

Celotta R. (2008) Engineered Nanoparticle Safety. Letter from NIST Engineered Nanoparticle Safety Committee.

Nanoparticle Characterization. (Jan. 1, 2006).

### **National Institutes of Health**

Roadmap for Medical Research: Nanomedicine Overview. 2009.

Nanotechnology Task Force 2008 Statement of Purpose. 2008.

### **National Nanotechnology Initiative**

Testimony to the House Subcommittee on Research and Science Education. 2007.

Strategic Plan. 2007.

Bell TE. Understanding Risk Assessment of Nanotechnology. National Nanotechnology Coordination Office. 2006.

National Nanotechnology Initiative. Ethical, Legal, and Other Societal Issues.

### **National Science and Technology Council**

National Nanotechnology Initiative: The Initiative and its Implementation Plan. 2000.

Public Meeting on Research Needs Related to the Environmental, Health, and Safety aspects of engineered nanomaterials. 2007.

Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials. 2006.

Nanobiotechnology. Report of the National Nanotechnology Initiative Workshop. 2003.

Nanotechnology in Space Exploration. Report of the National Nanotechnology Initiative Workshop. 2004.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Nanotechnology and the Environment. Report of the National Nanotechnology Initiative Workshop. 2003.

Prioritization Of Environmental, Health, And Safety Research Needs For Engineered Nanoscale Materials. 2007.

Sustainable nanomanufacturing – Creating the industries of the Future. 2010.

Manufacturing at the Nanoscale. Report of the National Nanoscale Initiative Workshops. 2002-2004.

### **National Science Foundation**

Nanoscale Science and Engineering: FY2006 Budget Request to Congress. 2005.

Division Plan: Division of Chemical, Bioengineering, Environmental, and Transport Systems (CBET), December, 2007.

National Science Foundation-European Commission. Workshop on Nanomaterials and Nanotechnology Summary Report. 2002.

National Nanotechnology Initiative. 2009.

FY 2009 NSF Budget Request to Congress: National Nanotechnology Initiative. 2008.

FY 2008 NSF Budget Request to Congress: National Nanotechnology Initiative. 2008.

National Science Foundation-European Commission. Workshop on Nanomanufacturing and Processing Summary Report. 2002.

Emerging Issues in Nanoparticle Aerosol Science and Technology. 2003.

### **Other**

Environment Agency of the United Kingdom. Using Science to Create a Better Place: Technology Roadmapping — An Opportunity for the Environment? 2007.

European Commission. 3rd Joint EC - NSF Workshop on Nanotechnology: Nanotechnology Revolutionary Opportunities & Societal Implications. 2002.

International Risk Governance Council. Survey on Nanotechnology Governance: Volume B. The Role of Industry. 2006.

President's Council of Advisors on Science and Technology. The National Nanotechnology Initiative: Second Assessment of the National Nanotechnology Advisory Panel (NNAP). Report of the President's Council of Advisors on Science and Technology. 2008.

RAND Corporation. Nanomaterials in the Workplace: Policy and Planning Workshop on Occupational Safety and Health. 2005.



Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Woodrow Wilson International Center for Scholars. Nanotechnology and Life Cycle Assessment. A systems approach to nanotechnology and the Environment. 2007.

## Science

### Nanomedicine Product-Specific References

Acusphere. (nd) Retrieved September 26, 2010.

Alakhov V, Klinski E, Li S, Pietrzynski G, Venne A, Batrakova E, Bronitch T, et al. (1999) Block copolymer-based formulation of doxorubicin. From cell screen to clinical trials. *Colloids and Surfaces B: Biointerfaces* 16(1-4) 113–134.

Ambri Biosensor Technology. (nd) Retrieved September 26, 2010.

Artimplant – Selected publications. (nd) Retrieved September 26, 2010.

Bandak S. (2005) Novavax Inc. Retrieved.

Bao A. (2003) Direct <sup>99m</sup>Tc labeling of pegylated liposomal doxorubicin (Doxil) for pharmacokinetic and non-invasive imaging studies. *The Journal of pharmacology and experimental therapeutics*, 308(2), 419.

BBInternational. (nd) Retrieved September 26, 2010.

BioDelivery Sciences International | Bioral® Amphotericin B. (nd) Retrieved September 26, 2010.

BIOMET 3i Implant Systems – NanoTite™ Implant – Introduction. (nd) Retrieved September 26, 2010.

Bissett D, Cassidy J, de Bono J. S, Muirhead F, Main M, Robson L, Fraier D, et al. (2004) Phase I and pharmacokinetic (PK) study of MAG-CPT (PNU 166148): a polymeric derivative of camptothecin (CPT). *British Journal of Cancer*, 91(1), 50-55. doi:10.1038/sj.bjc.6601922.

Blue Membranes: Products: Medical Devices: Drug Delivery Coatings. (nd) Retrieved September 26, 2010.

Booser DJ. (2002) Phase II study of liposomal anamycin in the treatment of doxorubicin-resistant breast cancer. *Cancer Chemotherapy and Pharmacology* 50(1) 6.

Boulikas T. (2007) Designing platinum compounds in cancer: structures and mechanisms. *Cancer therapy*, 5, 537.

Canelas DA, Herlihy KP, DeSimone JM. (2009) Top-down particle fabrication: Control of size and shape for diagnostic imaging and drug delivery. *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology* 1(4) 391–404.

Capsulation: Nanocapsules. (nd) Retrieved September 26, 2010.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Caruthers S. D, Cyrus T, Winter PM, Wickline SA, Lanza GM. (2009) Anti-angiogenic perfluorocarbon nanoparticles for diagnosis and treatment of atherosclerosis. *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology* 1(3) 311–323.

Ceram-X: Nano Ceramic Restorative. (nd) Retrieved.

Chang S. (2009) A novel vaccine adjuvant for recombinant flu antigens. *Biologicals* 37(3) 141.

Chaudhry P. (2006) Malaria— the cause of heartburn among scientists and funding agencies alike. *Current Science* 91(11) 1441.

Christensen D. (2009) CAF01 liposomes as a mucosal vaccine adjuvant: In vitro and in vivo investigations. *International journal of pharmaceutics*. Retrieved.

Chu TC. (2002) Biodegradable calcium phosphate nanoparticles as a new vehicle for delivery of a potential ocular hypotensive agent. *Journal of ocular pharmacology and therapeutics*, 18(6), 507.

Cinvention AG. (nd) Retrieved September 26, 2010.

Constantinides PP. (2007) Advances in the use of lipid-based systems for parenteral drug delivery. Retrieved.

de Araujo DR. (2008) Pharmacological and local toxicity studies of a liposomal formulation for the novel local anaesthetic ropivacaine. *Journal of Pharmacy and Pharmacology*, 60(11), 1449.

Debiotech – Medical Devices – Switzerland. (nd) Retrieved September 26, 2010.

DiagNano – Technology | DiagNano: Revolutionizing Diagnostics through Nanotechnology. (nd) Retrieved September 26, 2010.

eBiosciences: eFluor® Nanocrystals. (nd) Retrieved September 26, 2010.

Elamanchili P. (2004) Characterization of poly (,-lactic-co-glycolic acid) based nanoparticulate system for enhanced delivery of antigens to dendritic cells. *Vaccine*, 22(19), 2406.

EMD Chemicals USA | NanoJuice® Transfection Reagent Kit – EMD4Biosciences. (nd) Retrieved September 26, 2010.

Eurand | Pharmaceutical Technologies. (nd) Retrieved September 26, 2010.

Filtek™ Supreme Plus Universal Restorative: A True Nanocomposite. (2005) Retrieved.

Flamel Technologies Inc. (nd) Retrieved September 26, 2010.

Fox CB. (2009) Squalene emulsions for parenteral vaccine and drug delivery. *Molecules* 14(9) 3286-3312. doi:10.3390/molecules14093286

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

García-Gallont R. (2004) Impact of C2 measurement on cyclosporine neoral dosing in a Latin-American transplant program: The Guatemalan experience. *Transplantation Proceedings* 36(2) S451.

Gelmon KA. (1999) Phase I study of liposomal vincristine. *Journal of clinical oncology*, 17(2), 697.

Griese N. (2002) Determination of free and liposome-associated daunorubicin and daunorubicinol in plasma by capillary electrophoresis. *Journal of Chromatography A* 979(1-2) 379.

Guggenbichler JP. (2003) Central venous catheter associated infections pathophysiology, incidence, clinical diagnosis, and prevention-a review. *Materialwissenschaft und Werkstofftechnik* 34(12) 1145.

Hamaguchi T, Matsumura Y, Nakanishi Y, Muro K, Yamada Y, Shimada Y, Shirao K, et al. (2004) Antitumor effect of MCC-465, pegylated liposomal doxorubicin tagged with newly developed monoclonal antibody GAH, in colorectal cancer xenografts. *Cancer Science* 95(7) 608–613.

Han J. (2001) Physical properties and stability of two emulsion formulations of propofol. *International journal of pharmaceuticals*, 215(1-2), 207.

Hayashi H, Uchiyama N, Kawamata H, Takagi R, Abe Y, Kumazaki T. (2000) Interaction between non-ionic contrast medium and prostaglandin E1 incorporated in lipid microspheres: In-vitro comparative study of direct and non-direct mixing. *Radiation Medicine* 18(4) 219–226.

Hayman ML. (2009) The emerging product and patent landscape for nanosilver-containing medical devices. *Nanotechnology Law & Business* 148 148-148-158.

Hosokawa T. (2002) Formulation development of a filter-sterilizable lipid emulsion for lipophilic KW-3902, a newly synthesized adenosine A 1-receptor antagonist. *Chemical Pharmaceutical Bulletin* 50(1) 87.

Huang Z, Huang. (2008) Development and evaluation of lipid nanoparticles for camptothecin delivery: a comparison of solid lipid nanoparticles, nanostructured lipid carriers, and lipid emulsion. *Acta Pharmacologica Sinica (monthly)* 29(9) 1094.

Huckriede A. (2005) The virosome concept for influenza vaccines. *Vaccine* 23 S26.

Ino Y, Guan Y, Nishiyama N, Cabral H, Koyama H, Kataoka K, Todo T. (2005) Development of novel polymeric micelle drug carrier systems for brain tumor therapy. *Proceedings of the American Association for Cancer Research* 2005(1) 330.

Invitrogen: Labeled Beads. (nd) Retrieved September 26, 2010. [products.invitrogen.com](http://products.invitrogen.com)

Ito I. (2004) Liposomal vector mediated delivery of the 3p FUS1 gene demonstrates potent antitumor activity against human lung cancer in vivo. *Cancer Gene Therapy* 11(11) 733.

Jamil H. (2004) Liposomes: The next generation. *Modern drug discovery*, 7, 36.

Kanaoka E. (2001) A novel and simple type of liposome carrier for recombinant interleukin-2. *Journal of Pharmacy and Pharmacology* 53(3) 295.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Kereos | Targeted Therapeutics and Molecular Imaging. (nd) Retrieved September 26, 2010.

Knight V. (2006) 9-Nitrocamptothecin liposome aerosol treatment of human cancer subcutaneous xenografts and pulmonary cancer metastases in mice. *Annals of the New York Academy of Sciences* 922(The camptothecins: Unfolding their anticancer potential) 151.

Koizumi F. (2006) Novel SN-38-incorporating polymeric micelles, NK012, eradicate vascular endothelial growth factor-secreting bulky tumors. *Cancer Research* 66(20) 10048.

Li W. (2007) Lower extremity deep venous thrombosis: Evaluation with Ferumoxytol-enhanced MR imaging and dual-contrast mechanism—preliminary experience1. *Radiology* 242(3) 873.

Li Z. (2008) Characterization of nebulized liposomal amikacin (Arikace™) as a function of droplet size. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* 21(3) 245.

Lindner LH. (2008) Dual role of hexadecylphosphocholine (miltefosine) in thermosensitive liposomes: Active ingredient and mediator of drug release. *Journal of Controlled Release* 125(2) 112.

Liquidia Technologies. (nd) Retrieved September 26, 2010.

Lu S, Lu. (2008) Construction, application and biosafety of silver nanocrystalline chitosan wound dressing. *Burns*, 34(5), 623.

Luna nanoWorks | Nanotechnology – Carbon Nanomaterials. (nd) Retrieved September 26, 2010.

Masse A, Bruno A, Bosetti M, Biasibetti A, Cannas M, Gallinaro P. (2000) Prevention of pin track infection in external fixation with silver coated pins: Clinical and microbiological results. *Journal of Biomedical Materials Research Part B: Applied Biomaterials* 53(5) 600–604.

Matsumura Y, Gotoh M, Muro K, Yamada Y, Shirao K, Shimada Y, Okuwa M, et al. (2004) Phase I and pharmacokinetic study of MCC-465, a doxorubicin (DXR) encapsulated in PEG immunoliposome, in patients with metastatic stomach cancer. *Annals of Oncology* 15(3) 517.

Matsumura Y, Kataoka K. (2009) Preclinical and clinical studies of anticancer agent-incorporating polymer micelles. *Cancer Science* 100(4) 572–579.

Mayer LD. (2007) Optimizing combination chemotherapy by controlling drug ratios. *Molecular Interventions* 7(4) 216.

Mebiopharm – Product, Technologies. (nd) Retrieved September 26, 2010.

Medical applications of liposomes. (1998) Amsterdam; New York: Elsevier.

Miltenyi Biotec – FeraSpin™. (nd) Retrieved September 26, 2010.

Mischler R. (2002) Inflexal® V a trivalent virosome subunit influenza vaccine: production. *Vaccine* 20 B17.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

MPharma VJ, Vyas SP, Kohli DV. (2009) Well-defined and potent liposomal hepatitis B vaccines adjuvanted with lipophilic MDP derivatives. *Nanomedicine* 5(3) 334.

Mraz S. (nd) A new buckyball bounces into town. Retrieved September 26, 2010.

Muggia FM. (2001) Liposomal encapsulated anthracyclines: new therapeutic horizons. *Current Oncology Reports* 3(2) 156.

NanoCarrier | Pipeline | Research and Development. (nd) Retrieved September 26, 2010.

Nanoco Technologies. (nd) Retrieved September 26, 2010.

NanoCyte: Products. (nd) Retrieved September 26, 2010.

NanoMedical Systems. (nd) Retrieved September 26, 2010.

Nanoprobes – Direct Order Catalog. (nd) Retrieved September 26, 2010.

Nanotope. (nd) Retrieved September 26, 2010.

Nanovis Incorporated. (nd) Retrieved September 26, 2010.

Negishi T, Koizumi F, Uchino H, Kuroda J, Kawaguchi T, Naito S, Matsumura Y. (2006) NK105, a paclitaxel-incorporating micellar nanoparticle, is a more potent radiosensitising agent compared to free paclitaxel. *British Journal of Cancer* 95(5) 601-606. doi:10.1038/sj.bjc.6603311

Nektar | R&D Pipeline | Products in Development | Oncology | NKTR-102. (nd) Retrieved September 26, 2010.

Newman MS. (1999) Comparative pharmacokinetics, tissue distribution, and therapeutic effectiveness of cisplatin encapsulated in long-circulating, pegylated liposomes (SPI-077) in tumor-bearing mice. *Cancer Chemotherapy and Pharmacology* 43(1) 1.

Ocean NanoTech LLC. (nd) Retrieved September 26, 2010.

OHagan DT. (2007) MF59 is a safe and potent vaccine adjuvant that enhances protection against influenza virus infection. *Expert Review of Vaccines* 6(5) 699.

Oncologic and Triton BioSystems Merge to Form Aduro BioTech. (nd) Retrieved September 26, 2010.

OsSatura.pdf. (nd).

Pannu J, Ciotti S, Eisma R, Ma L, Sutcliffe J. (2009) In vitro susceptibility of propionibacterium acnes and skin permeation of NB-00X formulations. In Society for Investigative Dermatology, 69th Annual Meeting.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Park J. (2002) Liposome-based drug delivery in breast cancer treatment. *Breast cancer research*, 4(3), 95-99.

Paul A, Vicent MJ, Duncan R. (2007) Using small-angle neutron scattering to study the solution conformation of (2-hydroxypropyl)methacrylamide copolymer—doxorubicin conjugates. *Biomacromolecules* 8(5) 1573-1579. doi:10.1021/bm060925s

Plasmachem | Nanomaterials NanoDiamonds. (nd) Retrieved September 26, 2010.

Platypus Technologies | Optically Transparent Polyurethane Substrates. (nd) Retrieved September 26, 2010.

Qdot® Nanocrystal Technology Overview. (2010) Retrieved.

Qi X, Chu Z, Mahller YY, Stringer KF, Witte DP, Cripe TP. (2009) Cancer-selective targeting and cytotoxicity by liposomal-coupled lysosomal saposin c protein. *Clinical Cancer Research* 15(18) 5840 - 5851. doi:10.1158/1078-0432.CCR-08-3285

Ratner ML. (2006) Mersana Therapeutics Inc. Start-up: Windhover's review of emerging medical ventures.

Rauschmann MA. (2005) Nanocrystalline hydroxyapatite and calcium sulphate as biodegradable composite carrier material for local delivery of antibiotics in bone infections. *Biomaterials* 26(15) 2677.

Rossi JJ. (2006) RNAi therapeutics: SNALPing siRNAs in vivo. *Gene Therapy* 13(7) 583.

Roszek B. Nanotechnology in medical devices. Presentation: Centre for Biological Medicines and Medical Technology, National Institute for Public Health and the Environment (RIVM) Bilthoven, The Netherlands. (nd).

Rudin CM. (2004) Delivery of a liposomal c-raf-1 antisense oligonucleotide by weekly bolus dosing in patients with advanced solid tumors. *Clinical Cancer Research* 10(21) 7244.

Saladax Biomedical | Product Pipeline Assays. (nd) Retrieved September 26, 2010.

Sankhala KK, Mita AC, Adinin R, Wood L, Beeram M, Bullock S, Yamagata N, et al. (2009) A phase I pharmacokinetic (PK) study of MBP-426, a novel liposome encapsulated oxaliplatin. *J. Clin. Oncol* 27 15s.

Satchi-Fainaro R, Mamluk R, Wang L, Short SM, Nagy JA, Feng D, Dvorak AM, et al. (2005) Inhibition of vessel permeability by TNP-470 and its polymer conjugate, caplostatin. *Cancer Cell* 7(3) 251–261.

Sato M, Sambito M, Aslani A, Kalkhoran NM, Slamovich EB, Webster TJ. (2006) Increased osteoblast functions on undoped and yttrium-doped nanocrystalline hydroxyapatite coatings on titanium. *Biomaterials* 27(11) 2358–2369.

Schettini DA. (2006) Improved targeting of antimony to the bone marrow of dogs using liposomes of reduced size. *International Journal of Pharmaceutics* 315(1-2) 140.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Schluep T, Cheng J, Khin KT, Davis ME. (2005) Pharmacokinetics and biodistribution of the camptothecin–polymer conjugate IT-101 in rats and tumor-bearing mice. *Cancer Chemotherapy and Pharmacology* 57(5) 654-662. doi:10.1007/s00280-005-0091-7

Schluep T, Hwang J, Hildebrandt IJ, Czernin J, Choi CH, Alabi CA, Mack B. C, et al. (2009) Pharmacokinetics and tumor dynamics of the nanoparticle IT-101 from PET imaging and tumor histological measurements. *Proceedings of the National Academy of Sciences* 106(27) 11394.

Schmid G, Bäumle M, Geerkens M, Heim I, Osemann C, Sawitowski T. (1999) Current and future applications of nanoclusters. *Chemical Society Reviews* 28(3) 179–185.

Schwartz JA. (2009) Feasibility study of particle-assisted laser ablation of brain tumors in orthotopic canine model. *Cancer Research* 69(4) 1659.

Senior Staff Writer. (2009) Endo, SkyePharma cease propofol IDD-D agreement.

Seymour LW, Ferry DR, Anderson D, Hesslewood S, Julyan PJ, Poyner R, Doran J, et al. (2002) Hepatic drug targeting: Phase I evaluation of polymer-bound doxorubicin. *Journal of Clinical Oncology* 20(6) 1668.

Silence Therapeutics. (nd) Retrieved September 26, 2010.

SilvaGard™: Antimicrobial Silver Nanotechnology Treatment for Medical Devices. (2005) Retrieved.

Spies CKG. (2009) The efficacy of Biobon™ and Ostim™ within metaphyseal defects using the Göttinger Minipig. *Archives of Orthopaedic and Trauma Surgery* 129(7) 979.

St John JV, Callahan EH. (2009) Calculation, measurement and optimization of pressure decrease through capillary forces at a powder wound dressing-wound interface. In 2009 Diabetic Limb Salvage Meeting.

Supratek Pharma Inc. (nd) Retrieved September 26, 2010.

T2 Biosystems – NanoDx Nanoparticles. (nd) Retrieved September 26, 2010.

Tetric Evo Ceram (Ivoclar Vivadent North America) Project #07-015. (2008) Retrieved.

Thurston G, McLean JW, Rizen M, Baluk P, Haskell A, Murphy TJ, Hanahan D, et al. (1998) Cationic liposomes target angiogenic endothelial cells in tumors and chronic inflammation in mice. *Journal of Clinical Investigation* 101(7) 1401.

Trop M. (2006) Silver-coated dressing acticoat caused raised liver enzymes and argyria-like symptoms in burn patient. *The Journal of Trauma* 60(3) 648.

Veridex LLC a Johnson, Johnson company in vitro diagnostics oncology. (nd) Retrieved September 26, 2010.

Welcome to Bexion Pharmaceuticals(nd) Retrieved September 26, 2010.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

- Wiedenmann N. (2007) 130-nm albumin-bound paclitaxel enhances tumor radiocurability and therapeutic gain. *Clinical Cancer Research* 13(6) 1868.
- Xie X. (2007) Targeted expression of BikDD eradicates pancreatic tumors in noninvasive imaging models. *Cancer Cell* 12(1) 52.
- Yu JJ. (2007) Bio-distribution and anti-tumor efficacy of PEG/PLA nano particles loaded doxorubicin. *Journal of Drug Targeting* 15(4) 279.
- Zamboni WC. (2008) Concept and clinical evaluation of carrier-mediated anticancer agents. *The Oncologist* 13(3) 248.
- Zhang JA. (2004) Development and characterization of a novel liposome-based formulation of SN-38. *International Journal of Pharmaceutics* 270(1-2) 93.
- Zhang JA. (2005) Development and characterization of a novel Cremophor® EL free liposome-based paclitaxel (LEP-ETU) formulation. *European Journal of Pharmaceutics and Biopharmaceutics* 59(1) 177.
- Zhang X, Bowen C, Gareua P, Rutt B. (2001) Quantitative analysis of SPIO and USPIO uptake rate by macrophages: Effects of particle size, concentration, and labeling time, 9.
- Zhang Z, Dunn MF, Xiao TD, Tomsia AP, Saiz E, CT ICF. (2001) Nanostructured hydroxyapatite coatings for improved adhesion and corrosion resistance for medical implants.

### Nanomedicine Products & Applications

- Bandak S. (2010) Novavax Inc. Unpublished manuscript.
- Bao A. (2003) Direct <sup>99m</sup>Tc labeling of pegylated liposomal doxorubicin (doxil) for pharmacokinetic and non-invasive imaging studies. *The Journal of Pharmacology and Experimental Therapeutics*. 308(2): 419.
- Booser DJ. (2002) Phase II study of liposomal annamycin in the treatment of doxorubicin-resistant breast cancer. *Cancer Chemotherapy and Pharmacology* 50(1): 6.
- Boulikas T. (2007) Designing platinum compounds in cancer: Structures and mechanisms. *Cancer Therapy* 5: 537.
- Buxton DB. (2009) Current status of nanotechnology approaches for cardiovascular disease: A personal perspective. *Wiley Interdisciplinary Reviews (WIREs): Nanomedicine and Nanobiotechnology* 1(2): 149.
- Ceram-X: Nano ceramic restorative. DENTSPLY DeTrey GmbH. Unpublished manuscript.
- Chang S. (2009) A novel vaccine adjuvant for recombinant flu antigens. *Biologicals* 37(3): 141.



Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Chaudhury P. (2006) Malaria—the cause of heartburn among scientists and funding agencies alike. *Current Science* 91(11): 1441.

Christensen D. (2009) CAF01 liposomes as a mucosal vaccine adjuvant: In vitro and in vivo investigations. *International Journal of Pharmaceutics*.

Chu TC. (2002) Biodegradable calcium phosphate nanoparticles as a new vehicle for delivery of a potential ocular hypotensive agent. *Journal of Ocular Pharmacology and Therapeutics* 18(6): 507.

Constantinides PP. (2007) Advances in the use of lipid-based systems for parenteral drug delivery. PowerPoint presentation.

Davis ME, et al. (2008) Nanoparticle therapeutics: an emerging treatment modality for cancer. *Nature Reviews Drug Discovery* 7(9):771–782.

de Araujo DR. (2008) Pharmacological and local toxicity studies of a liposomal formulation for the novel local anaesthetic ropivacaine. *Journal of Pharmacy and Pharmacology* 60(11): 1449.

Debbage P, Jaschke W. (2008) Molecular imaging with nanoparticles: giant roles for dwarf actors. *Histochemistry and Cell Biology* 130 (5), 845-875. doi:10.1007/s00418-008-0511-y

Dobson MG. (2007) Emerging technologies for point-of-care genetic testing. *Expert Review of Molecular Diagnostics* 7(4): 359.

Elamanchili P, Diwan M, Cao M, Samuel J. (2004) Characterization of poly (d,l-lactic-co-glycolic acid) based nanoparticulate system for enhanced delivery of antigens to dendritic cells. *Vaccine* 22(19): 2406-2412.

Filtek™ supreme plus universal restorative: A true nanocomposite. (2005) 3M ESPE. Unpublished manuscript.

García-Gallont R. (2004) Impact of C2 measurement on cyclosporine neoral dosing in a latin-american transplant program: The guatemalan experience. *Transplantation Proceedings* 36(2): S451.

Gelmon KA. (1999) Phase I study of liposomal vincristine. *Journal of Clinical Oncology* 17(2): 697.

Gil PR. (2010) Nanopharmacy: Inorganic nanoscale devices as vectors and active compounds. *Pharmacological Research*.

Griese N. (2002) Determination of free and liposome-associated daunorubicin and daunorubicinol in plasma by capillary electrophoresis. *Journal of Chromatography A* 979(1-2): 379.

Guggenbichler JP. (2003) Central venous catheter associated infections pathophysiology incidence clinical diagnosis and prevention-a review. *Materialwissenschaft Und Werkstofftechnik* 34(12): 1145.

Han J. (2001) Physical properties and stability of two emulsion formulations of propofol. *International Journal of Pharmaceutics* 215(1-2): 207.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

- Hayman ML. (2009) The emerging product and patent landscape for nanosilver-containing medical devices. *Nanotechnology Law & Business* 148: 148-158.
- Hosokawa T. (2002) Formulation development of a filter-sterilizable lipid emulsion for lipophilic KW-3902 a newly synthesized adenosine A 1-receptor antagonist. *Chemical Pharmaceutical Bulletin* 50(1): 87.
- Huang Z. & HUANG. (2008) Development and evaluation of lipid nanoparticles for camptothecin delivery: A comparison of solid lipid nanoparticles nanostructured lipid carriers and lipid emulsion. *Acta Pharmacologica Sinica (Monthly)* 29(9): 1094.
- Huckriede A. (2005) The virosome concept for influenza vaccines. *Vaccine* 23: S26.
- Ito I. (2004) Liposomal vector mediated delivery of the 3p FUS1 gene demonstrates potent antitumor activity against human lung cancer in vivo. *Cancer Gene Therapy* 11(11): 733.
- Jain K. (2008) The handbook of nanomedicine. Springer, March 3. (no pdf available)
- Jain V, Vyas SP, Kohli DV. (2009) Well-defined and potent liposomal hepatitis B vaccines adjuvanted with lipophilic MDP derivatives. *Nanomedicine* 5(3): 334.
- Jamil H. (2004) Liposomes: The next generation. *Modern Drug Discovery* 7: 36.
- Kanaoka E. (2001) A novel and simple type of liposome carrier for recombinant interleukin-2. *Journal of Pharmacy and Pharmacology* 53(3): 295.
- Kim BYS, Rutka JT, Chan WCW. (2010) Nanomedicine. *New England Journal of Medicine* 363(25):2434–2443.
- Knight V. (2006) 9-nitrocamptothecin liposome aerosol treatment of human cancer subcutaneous xenografts and pulmonary cancer metastases in mice. *Annals of the New York Academy of Sciences* 922(The camptothecins: unfolding their anticancer potential): 151.
- Koizumi F. (2006) Novel SN-38-incorporating polymeric micelles NK012 eradicate vascular endothelial growth factor-secreting bulky tumors. *Cancer Research* 66(20): 10048.
- Kulshreshtha AK, Singh ON, Wall GM, eds. (2010) *Pharmaceutical Suspensions*. New York, NY: Springer New York. Available at <http://www.springerlink.com/content/j74851g93h573402/>.
- Lammers T, Hennink WE, Storm G. (2008) Tumour-targeted nanomedicines: principles and practice. *British Journal of Cancer* 99(3): 392–397.
- Lasic D, Papahadjopoulos D (eds). *Medical Applications of Liposomes* Amsterdam: Elsevier Science BV, 1998.
- Leary SP, Liu CY, Apuzzo MLJ. (2006) Toward the emergence of nanoneurosurgery: Part II- Nanomedicine: Diagnostics and imaging at the nanoscale level. *Neurosurgery* 58(5):805-823.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

- Leary SP, Liu CY, Apuzzo MLJ. (2006) Toward the emergence of nanoneurosurgery: Part III- Nanomedicine: Targeted nanotherapy, nanosurgery, and progress toward the realization of nanoneurosurgery. *Neurosurgery* 58(6):1009-1026.
- Li W. (2007) Lower extremity deep venous thrombosis: Evaluation with ferumoxytol-enhanced MR imaging and dual-contrast mechanism—preliminary experience1. *Radiology* 242(3): 873.
- Li Z. (2008) Characterization of nebulized liposomal amikacin (arikace™) as a function of droplet size. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* 21(3): 245.
- Lindner L. H. (2008) Dual role of hexadecylphosphocholine (miltefosine) in thermosensitive liposomes: Active ingredient and mediator of drug release. *Journal of Controlled Release* 125(2): 112.
- Liversidge G, Merisko-Liversidge E, Ruddy S, Callana D. (2009) Will Nanoparticles Deliver? *Drug Discovery & Development* 12(5):30-34.
- Lu S, Gao W, Gu HY. (2008) Construction application and biosafety of silver nanocrystalline chitosan wound dressing. *Burns* 34(5): 623-628.
- Mayer LD. (2007) Optimizing combination chemotherapy by controlling drug ratios. *Molecular Interventions* 7(4): 216.
- Mischler R. (2002) Inflexal® V a trivalent virosome subunit influenza vaccine: Production. *Vaccine* 20: B17.
- Mozafari MR. (2007) *Nanomaterials and Nanosystems for Biomedical Applications*. Springer, December 6.
- Muggia FM. (2001) Liposomal encapsulated anthracyclines: New therapeutic horizons. *Current Oncology Reports* 3(2): 156.
- Newman MS. (1999) Comparative pharmacokinetics tissue distribution and therapeutic effectiveness of cisplatin encapsulated in long-circulating pegylated liposomes (SPI-077) in tumor-bearing mice. *Cancer Chemotherapy and Pharmacology* 43(1): 1.
- O'Hagan DT. (2007) MF59 is a safe and potent vaccine adjuvant that enhances protection against influenza virus infection. *Expert Review of Vaccines* 6(5): 699.
- Pannu J, Ciotti S, Eisma R, Ma L, et al. (2009) In vitro susceptibility of propionibacterium acnes and skin permeation of NB-00X formulations. Society for Investigative Dermatology 69th Annual Meeting Montreal Canada.
- Paradise J, Diliberto G, Tisdale A, Kokkoli E. (2008) Exploring emerging nanobiotechnology drugs and medical devices. *Food & Drug Law Journal* 63(2):407–420.
- Park J. (2002) Liposome-based drug delivery in breast cancer treatment. *Breast Cancer Research* 4(3): 95-99.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides. Appendix A: Nano-Silver Products Inventory. Petition. International Center for Technology Assessment.

Qdot® nanocrystal technology overview. 2010.

Ratner ML. (2006) Mersana therapeutics inc. START-UP: *Windhover's Review of Emerging Medical Ventures*.

Rauschmann MA. (2005) Nanocrystalline hydroxyapatite and calcium sulphate as biodegradable composite carrier material for local delivery of antibiotics in bone infections. *Biomaterials* 26(15): 2677.

Rossi JJ. (2006) RNAi therapeutics: SNALPing siRNAs in vivo. *Gene Therapy* 13(7): 583.

Rudin CM. (2004) Delivery of a liposomal c-raf-1 antisense oligonucleotide by weekly bolus dosing in patients with advanced solid tumors. *Clinical Cancer Research* 10(21): 7244.

Schettini DA. (2006) Improved targeting of antimony to the bone marrow of dogs using liposomes of reduced size. *International Journal of Pharmaceutics* 315(1-2): 140.

Schwartz JA. (2009) Feasibility study of particle-assisted laser ablation of brain tumors in orthotopic canine model. *Cancer Research* 69(4): 1659.

Senior Staff Writer. (2009) Endo SkyePharma cease propofol IDD-D agreement.

Shah P. (2010) Nanoemulsion: A pharmaceutical review. *Systematic Reviews in Pharmacy* 1(1): 24.

SilvaGard™: Antimicrobial silver nanotechnology treatment for medical devices. (2005) Inc AcryMed. Unpublished manuscript.

Spies CKG. (2009) The efficacy of biobon™ and ostim™ within metaphyseal defects using the Göttinger minipig. *Archives of Orthopaedic and Trauma Surgery* 129(7): 979.

St. John JV, Callahan EH. (2009) Calculation measurement and optimization of pressure decrease through capillary forces at a powder wound dressing-wound interface. 2009 Diabetic Limb Salvage Meeting.

Tetric evo ceram (ivoclar vivadent north america) (project #07-015) (2008) USAF Dental Evaluation & Consultation Service. Unpublished manuscript.

Trommelmans L, Selling J, Dierickx K. (2009) An exploratory survey on the views of European tissue engineers concerning the ethical issues of tissue engineering research. *Tissue Engineering: Part B* 15(3):241-247.

Trop M. (2006) Silver-coated dressing acticoat caused raised liver enzymes and argyria-like symptoms in burn patient. *The Journal of Trauma* 60(3): 648.

Wang YX, Hussain S, Krestin G. (2001) Superparamagnetic iron oxide contrast agents: physicochemical characteristics and applications in MR imaging. *European Radiology* 11(11): 2319-2331.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

Wiedenmann N. (2007) 130-nm Albumin-bound paclitaxel enhances tumor radiocurability and therapeutic gain. *Clinical Cancer Research* 13(6): 1868.

Wong YWH, Yuen CWM, Leung MYS, Ku SKA, Lam HLI. (2006) Selected applications of nanotechnology in textiles. *AUTEX Research Journal* 6(1).

Xie X. (2007) Targeted expression of BikDD eradicates pancreatic tumors in noninvasive imaging models. *Cancer Cell* 12(1): 52.

Yu JJ. (2007) Bio-distribution and anti-tumor efficacy of PEG/PLA nano particles loaded doxorubicin. *Journal of Drug Targeting* 15(4): 279.

Zamboni WC. (2008) Concept and clinical evaluation of carrier-mediated anticancer agents. *The Oncologist* 13(3): 248.

Zhang JA. (2004) Development and characterization of a novel liposome-based formulation of SN-38. *International Journal of Pharmaceutics* 270(1-2): 93.

Zhang JA. (2005) Development and characterization of a novel cremophor® EL free liposome-based paclitaxel (LEP-ETU) formulation. *European Journal of Pharmaceutics and Biopharmaceutics* 59(1): 177.

Zuo L. (2007) New technology and clinical applications of nanomedicine. *Medical Clinics of North America* 91(5): 845.

### Nanomedicine Reviews

Anon. (2010) Reflection paper on nanotechnology-based medicinal products for human use. Reflection Paper. London, England: European Medicines Agency.

Boegedal M, Gleiche M, Guibert JC, Hoffschulz H, Locatelli S, Malsch I, Morrison M, Nicollet C, Wagner V. (2003) Nanotechnology and its implications for the health of the EU citizens. *NanoForum.org - European Nanotechnology Gateway*.

Brewer M, Zhang T, Dong W, Rutherford M, Tian ZR. (2007) Future approaches of nanomedicine in clinical science. *Medical Clinics of North America* 91(5):963–1016.

Buxton DB. (2009) Current status of nanotechnology approaches for cardiovascular disease: a personal perspective. *Wiley interdisciplinary reviews (WIREs): Nanomedicine and nanobiotechnology* 1(2):149-155.

Caruthers SD, Wickline SA, Lanza GM. (2007) Nanotechnological applications in medicine. *Current opinion in biotechnology* 18(1):26–30.

Debbage P, Jaschke W. (2008) Molecular imaging with nanoparticles: giant roles for dwarf actors. *Histochemistry and Cell Biology* 130 (5), 845-875. doi:10.1007/s00418-008-0511-y.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

de Groot R, Sutter JLU. (2006) Roadmap Report Concerning the Use of Nanomaterials in the Medical & Health Sector. The project was funded by the European Community under the "Sixth Framework" Programme (Contract No NMP4-CT-2004-505857).

Dobrovolskaia MA, McNeil SE. (2007) Immunological properties of engineered nanomaterials. *Nat Nano* 2 (8), 469-478. doi:10.1038/nnano.2007.223

Dobson MG. (2007) Emerging technologies for point-of-care genetic testing. *Expert Review of Molecular Diagnostics* 7 (4), 359.

Dobson MG, Galvin P, Barton DE. (2007) Emerging technologies for point-of-care genetic testing. *Expert Review of Molecular Diagnostics* 7 (4), 359-370. doi:10.1586/14737159.7.4.359.

Emerich DF, Thanos CG. (2007) Targeted nanoparticle-based drug delivery and diagnosis. *Journal of Drug Targeting* 15 (3), 163-183. doi:10.1080/10611860701231810.

Ferrari M, Philibert MA, Sanhai WR. (2009) Nanomedicine and Society. *Clinical Pharmacology & Therapeutics* 85(5):466-467.

Fukumori Y, Ichikawa H. (2006) Nanoparticles for cancer therapy and diagnosis. *Advanced Powder Technology* 17(1):1-28.

Gil PR. (2010) Nanopharmacy: Inorganic nanoscale devices as vectors and active compounds. *Pharmacological research*. Retrieved from [http://www.sciencedirect.com/science?\\_ob=MIimg&\\_imagekey=B6WP9-4Y7P4MJ-1-3&\\_cdi=6985&\\_user=616288&\\_pii=S104366181000023X&\\_orig=search&\\_coverDate=01%2F25%2F2010&\\_sk=999999999&view=c&wchp=dGLzVtb-zSkWA&md5=e1a7b4a57e189ee42e3594be817382d8&ie=/sdarticle.pdf](http://www.sciencedirect.com/science?_ob=MIimg&_imagekey=B6WP9-4Y7P4MJ-1-3&_cdi=6985&_user=616288&_pii=S104366181000023X&_orig=search&_coverDate=01%2F25%2F2010&_sk=999999999&view=c&wchp=dGLzVtb-zSkWA&md5=e1a7b4a57e189ee42e3594be817382d8&ie=/sdarticle.pdf).

Hauptman A, Sharan Y. (2005) Envisioned Developments in Nanobiotechnology. *Expert Survey*. Tel-Aviv.

Hayman ML. (2009) Emerging Product and Patent Landscape for Nanosilver-Containing Medical Devices, The. *Nanotech L & Bus* 6, 148.

Jamil H, Sheikh S, Ahmad I. (2004) Liposomes: the next generation. *Modern Drug Discovery* 7, 36-39.

Kelly B. (2010) Nanomedicines: regulatory challenges and risks ahead. *Regulatory Affairs Pharma* October 2010:14-17.

Khemtong C, Kessinger CW, Gao J. (2009) Polymeric nanomedicine for cancer MR imaging and drug delivery. *Chemical Communications* (24), 3497. doi:10.1039/b821865j.

Lasic DD, Papahadjopoulos D. (1998) Medical applications of liposomes. *Elsevier*.

Matsumura Y. (2007) Preclinical and clinical studies of anticancer drug-incorporated polymeric micelles. *Journal of Drug Targeting* 15 (7-8), 507-517. doi:10.1080/10611860701499888.

Bibliography for NIH, NHGRI project on  
“**Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,**”  
Grant award #1RC1HG005338  
Last updated 9/2011

- Medina C, Santos-Martinez MJ, Radomski A, Corrigan OI, Radomski MW. (2007) Nanoparticles: pharmacological and toxicological significance. *British Journal of Pharmacology* 150(5):552–558.
- Peters R. (2006) Nanoscopic medicine: the next frontier. *Small* 2(4):452–456.
- Powers M. (2006) Special report details rapid growth of nanomedicines, diagnostics pipeline. *NanoBiotech News Jan. 4, 2006* 4(1):1-4.
- Riehemann K, Schneider SW, Luger TA, Godin B, Ferrari M, Fuchs H. (2009) Nanomedicine—echallenge and perspectives. *Angewandte Chemie International Edition* 48(5):872–897.
- Roszek B, Jong WH, Geertsma RE. (2005) Nanotechnology in medical applications: state-of-the-art in materials and devices.
- Salamanca-Buentello F, Persad DL et al. (2005) Nanotechnology and the developing world. *PLoS Medicine* 2(5):383-386.
- Schrand AM, Hens SAC, Shenderova OA. (2009) Nanodiamond particles: properties and perspectives for bioapplications. *Critical Reviews in Solid State and Materials Sciences* 34(1):18–74.
- Shah P, Bhalodia D, Shelat P. (2010) Nanoemulsion: A pharmaceutical review. *Systematic Reviews in Pharmacy* 1 (1), 24.
- Shah P. (2010) Nanoemulsion: A pharmaceutical review. *Systematic Reviews in Pharmacy* 1 (1), 24.
- Tomellini R, Faure U, Panzer O.(2005) Vision Paper and Basis for a Strategic Research Agenda for NanMedicine. Vision Paper. *European Technology Platform on NanoMedicine–Nanotechnology for Health*.
- Wagner V, Dullaart A, Bock AK, Zweck A. (2006) The emerging nanomedicine landscape. *Nature Biotechnology*, 24 (10) 1211–1218.
- Wagner V, Hüsing B, Gaisser S, Bock AK. (nd) Nanomedicine: Drivers for development and possible impacts. *JRC-IPTS, EUR 23494*
- Wolbring G. (2007) Nanomedicine. E-Newsletter. *Innovation Watch*. Also available at <http://innovationwatch-archive.com/choiceisyours/choiceisyours-2007-03-30.htm>.
- Wong YWH, Yuen CWM, Leung MYS, Ku SKA, Lam HLI. (2006) Selected applications of nanotechnology in textiles. *AUTEX Research Journal* 6 (1), 1–8.
- Wong YWH, Yuen CWM, Leung MYS, Ku SKA, Lam HLI. (2006) Selected Applications of Nanotechnology in Textiles. *AUTEX Research Journal* 6 (1) . Retrieved from [http://www.freewebs.com/jayaram-co/doc/Selected\\_Appz\\_of\\_Nanotechnology\\_in\\_Textiles.pdf](http://www.freewebs.com/jayaram-co/doc/Selected_Appz_of_Nanotechnology_in_Textiles.pdf).
- Yih TC, Al-Fandi M.(2006) Engineered nanoparticles as precise drug delivery systems. *Journal of Cellular Biochemistry* 97(6):1184–1190.

Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Zamboni WC. (2008) Concept and Clinical Evaluation of Carrier-Mediated Anticancer Agents. *Oncologist* 13 (3), 248-260. doi:10.1634/theoncologist.2007-0180.

Zuo L. (2007) New technology and clinical applications of nanomedicine. *Medical clinics of North America* 91 (5), 845.

### Nanotoxicology Reviews

Adisheshaiah PP. (2010) Nanomaterial standards for efficacy and toxicity assessment. *Wiley interdisciplinary reviews (WIREs): Nanomedicine and nanobiotechnology* 2(1), 99.

Aggarwal P. (2009) Nanoparticle interaction with plasma proteins as it relates to particle biodistribution, biocompatibility and therapeutic efficacy. *Advanced Drug Delivery Reviews* 61(6), 428.

Bhogal N, Seabra R. (2010) Why animal studies cannot suitably assess nanomedicines. *PharmaTech.com*

Buzea C, Pacheco II, Robbie K. (2007) Nanomaterials and nanoparticles: Sources and toxicity. *Biointerphases* 2(4):MR17-MR172.

Chithrani BD, Ghazani AA, Chan WCW. (2006) Determining the size and shape dependence of gold nanoparticle uptake into mammalian cells. *Nano Lett* 6(4): 662–668.

Dobrovolskaia MA. (2007) Immunological properties of engineered nanomaterials. *Nature Nanotechnology* 2(8), 469.

Dobrovolskaia MA. (2008) Preclinical studies to understand nanoparticle interaction with the immune system and its potential effects on nanoparticle biodistribution. *Molecular pharmacology* 5(4), 487.

Dobrovolskaia MA. (2009) Evaluation of nanoparticle immunotoxicity. *Nat Nano* 4(7), 411.

Dobrovolskaia MA, McNeil SE. (2007) Immunological properties of engineered nanomaterials. *Nat Nano* 2(8), 469-478.

Fischer HC. (2007) Nanotoxicity: The growing need for in vivo study. *Current opinion in biotechnology* 18(6), 565.

Gessner A. (2000) Nanoparticles with decreasing surface hydrophobicities: Influence on plasma protein adsorption. *International journal of pharmaceutics* 196(2), 245.

Jiang W, Kim BYW, Rutka JT, Chan WCW. (2008) Nanoparticle-mediated cellular response is size-dependent. *Nature Nanotechnology* 3(3):14.

Karlsson HL. (2008) Copper oxide nanoparticles are highly toxic: A comparison between metal oxide nanoparticles and carbon nanotubes. *Chemical research in toxicology* 21(9), 1726.

Kim D. (2005) Interaction of plga nanoparticles with human blood constituents. *Colloids and Surfaces B: Biointerfaces* 40(2), 83.



Bibliography for NIH, NHGRI project on  
“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”  
Grant award #1RC1HG005338  
Last updated 9/2011

Lasagna-Reeves C, et al. (2010) Bioaccumulation and Toxicity of Gold Nanoparticles after Repeated Administration in Mice. *Biochemical and Biophysical Research Communications* 393: 649-655.

Marnett LJ. (2009) Nanotoxicology—a new frontier. *Chemical research in toxicology* 22(9), 1491.

McNeil SE. (2009) Nanomaterial safety. *Bulletin of the Atomic Scientists* 65(1), 56.

Muller J. (2008) Structural defects play a major role in the acute lung toxicity of multiwall carbon nanotubes: Toxicological aspects. *Chemical research in toxicology* 21(9), 1698.

Oberdörster G. (2010) Safety assessment for nanotechnology and nanomedicine: Concepts of nanotoxicology. *Journal of internal medicine* 267(1), 89.

Ostrowski AD. (2009) Nanotoxicology: Characterizing the scientific literature, 2000—2007. *Journal of nanoparticle research* 11(2), 251.

Petushkov A. (2009) Effect of crystal size and surface functionalization on the cytotoxicity of silicalite-1 nanoparticles. *Chemical research in toxicology* 22(7), 1359.

Qu G, et al. (2009) The Effect of Multiwalled Carbon Nanotube Agglomeration On Their Accumulation In and Damage to Organs In Mice. *Carbon* 47: 2060-2069.

Stern ST. (2007) Nanotechnology safety concerns revisited. *Toxicological Sciences* 101(1), 4.

Stern ST. (2010) Translational considerations for cancer nanomedicine. *Journal of Controlled Release*.

Zolnik BS. (2010) Nanoparticles and the immune system. *Endocrinology* 151(2), 458.

## University Clinical Trials Guidance Documents

Case Western Reserve University. Chemical Hygiene and Safety Plan.

Case Western Reserve University Department of Occupational & Environmental Safety (DOES) Safety Service Operations Annual report 2008-2009.

Cornell University. Nanoparticle Health and Safety.

Duke University. Laboratory Safety Manual.

Duke University. Standard Operating Procedures.

Duke University. Working safely with Nanomaterials in the laboratory.

Duke University. Safe Use of Nanomaterials.

Georgia Tech. R&D policy in the United States: The Promotion of Nanotechnology R & D.

Bibliography for NIH, NHGRI project on  
**“Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,”**  
Grant award #1RC1HG005338  
Last updated 9/2011

NIST. Reporting Guidelines For The Preparation Of Aqueous Nanoparticle Dispersions From Dry Materials. July 8, 2010.

Northwestern University. Safety guidelines for research with engineered nanomaterials.

University of Arizona. Micro/Nano Fabrication Center Safety Manual.

University of California- Berkeley. Health & Environmental Effects.

University of California- Berkeley. Local Disclosure Ordinance as Regulatory Catalyst: Early Insights from the Berkeley, California Manufactured Nanoscale Materials Health and Safety Disclosure Ordinance the 21st Century.

University of California- Berkeley. Nanotechnology: Guidelines for Safe Research Practices.

University of California- Berkeley. The Berkeley City Ordinance on Nanotechnology: Shortcomings, improvements, and implications for risk governance.

University of California-Davis. FACT SHEET. Nanotechnology: Guidelines for Safe Research Practices.

University of California- Los Angeles. University of California Center for Environmental Implications of Nanotechnology (UC CEIN).

University of California- San Diego. Nanotechnology: Guidelines for Safe Research Practices. September 1, 2010.

University of California- San Francisco. A Nanotechnology Policy Framework For California: Policy Recommendations For Addressing Potential Health Risks From Nanomaterials.

University of Illinois at Urbana-Champaign. Micro and Nanotechnology Laboratory.

University of Indiana. Selected Resources in Nanotechnology and the Environment.

University of Minnesota. The Nanotechnology-Biology Interface: Exploring Models for Oversight. September 15, 2005.

University of Minnesota. U of MN Nanofabrication Center: Laboratory Safety Plan. 2007.

University of North Carolina. Lab Safety Manual.

University of North Carolina- Chapel Hill. Nanotechnology Safety.

University of Washington. Nanoethics on the World Wide Web.

Virginia Commonwealth University. Nanotechnology and Nanoparticles. July 17, 2009.

Washington University St. Louis. Nano Resources.