JONATHAN KIMMELMAN, Ph.D.

Biomedical Ethics Unit
Department of Social Studies of Medicine
McGill University, Faculty of Medicine
3647 Peel St., Montreal, QC H3A 1X1, Canada

Phone: (514) 398-3306
Fax: (514) 398-8349
Email: jonathan.kimmelman@mcgill.ca
Web: www.translationalethics.com
http://www.mcgill.ca/biomedicalethicsunit/faculty/kimmelman/

EDUCATION

1999	Ph.D. Molecular Biophysics and Biochemistry, Yale University. *The Activating Threonine of KIN28 in Saccharomyces cerevisiae*
1990	B.Sc. Chemistry, Duke University, *cum laude*

ACADEMIC APPOINTMENTS

2015-present	Interim Director, Biomedical Ethics Unit, McGill University
2010-present	Associate Professor, Dept. Social Studies of Medicine / Biomedical Ethics Unit, McGill University
2013-present	Associate Appointment, Epidemiology and Biostatistics
2010-present	Associate Appointment, Dept. Human Genetics
2009-present	Associate Appointment, Experimental Medicine
2014- 2015	Visiting Professor, Neurology Dept., Charité-Mitte, Berlin GER
2005-2010	Assistant Professor, Dept. Social Studies of Medicine / Biomedical Ethics Unit
2004-2005	Research Associate, McGill Biomedical Ethics Unit
2002-2004	Postdoctoral Fellow, McGill Biomedical Ethics Unit
2000-2001	Associate, U. Manitoba, Centre for Professional and Applied Ethics
1999-2000	Lecturer, Yale, Dept. Political Science
1990-1992	Research Associate, Natural Resources Defense Council, NY

BOOKS

Kimmelman J. *Gene Transfer and the Ethics of First-in-Human Experiments: Lost in Translation*. New York: Cambridge University Press, 2010.

REFEREED PUBLICATIONS

(* = Corresponding author; † = received commissioned commentary)

1. Kimmelman J,* Carlisle B, Gönen M. Drug Development at the Portfolio Level Is Important for Policy, Care Decisions, and Human Protections. *JAMA* 2017 (in press).
2. Benjamin D, Mandel DR, Kimmelman J*. Can Cancer Researchers Accurately Judge Whether Preclinical Reports will Reproduce? *PLoS Biology* 2017; 15: e2002212.
3. Hakala A, Fergusson D, Kimmelman J*. Nonpublication of Trial Results for New Neurological Drugs: A Systematic Review. *Annals of Neurol* 2017; 81: 782-89.
4. Benjamin D, Kimmelman J*. Does the Unrealistic Optimist in Research Have a Defense? *Perspect Biol Med* 2017; 59: 491-506.
5. Neumann K, Grittner U, Piper SK, Rex A, Florez-Vargas O, Karystianis G, Schneider A, Wellwood I, Siegerink B, Ioannidis JP, Kimmelman J, Dirnagl U. Increasing efficiency of preclinical research by group sequential designs. *PLoS Biol*. 2017 Mar 10;15(3):e2001307
6. Federico C, Kimmelman J*. First in Human Drug Testing: Higher Standards Required. *Nature* 2017; 542: 25-7.
7. Mattina J, Carlisle B, Hachem Y, Fergusson D, Kimmelman J*. Inefficiencies and Patient Burdens in the Development of the Targeted Cancer Drug Sorafenib: A Systematic Review. *PLoS Biology* 2017; 15: e2000487.
8. Kimmelman J*, Resnik DB, Peppercorn J, Ratain MJ. Burdensome Research Procedures in Trials: Why Less is More. *JNCI* 2017; 109: djw315.†
9. Kimmelman J*, Kesselheim AS. Translational Research and the U.S. Federal Elections. *Sci Trans Med* 2016; 8: 361ed13.
10. Kimmelman J.* Are Phase 1 Cancer Trials *Really* Therapeutic? *J Clin Oncol* 2017; 35: 135-8.†
11. London AJ, Kimmelman J.* Accelerated Approval and Health Inequality. *JAMA Intern Med* 2016; 176: 883-4.
12. Barsanti-Innes B, Hey SP, Kimmelman J.* "The Challenges of Validating in Precision Medicine: The Case of ERCC1 Diagnostic Testing." *The Oncologist* 2017: 22: 89-96.
13. Mattina J, MacKinnon N, Henderson VC, Fergusson D, Kimmelman J.* Design and Reporting of Targeted Anti-Cancer Preclinical Studies: A Meta-Analysis of Animal Studies Investigating Sorafenib Antitumour Efficacy. *Canc Res* 2016. Pii: canres.3455.2016.
14. Kimmelman J,* Hyun I, Benvenisty N, Caulfield T, Heslop HE, Murry CE, Sipp D, Studer L, Sugarman J, Daley GQ. Global Standards for Stem Cell Research. *Nature*. 2016; 533(7603): 311-3.
15. Kimmelman J,* Heslop HE, Sugarman J, Studer L, Benvenisty N, Caulfield T, Hyun I, Murry CE, Sipp D Daley GQ. The New ISSCR Guidelines: Clinical Translation of Stem Cell Research. *Lancet* 2016; 387(10032): 1979-81.
16. Caulfield T, Sipp D, Murry CE, Daley GQ, Kimmelman J. Confronting Stem Cell Hype. *Science* 2016; 352(6287): 776-7.

17. Daley GQ, Hyun I, Apperly JF, … Kimmelman J,*. Setting Global Standards for Stem Cell Research and Clinical Translation: The 2016 ISSCR Guidelines. *Stem Cell Reports* 2016; S2213-6711.
18. Grankvist H, Kimmelman J.* How do Researchers Decide Early Clinical Trials? *Med Health Care Philos* 2016.
19. Franck C, Filion KB, Kimmelman J, Grad R, Eisenberg MJ. Ethical considerations of e-cigarette use for tobacco harm reduction. *Respir Res* 2016; 17: 53
20. Hey S, Kimmelman J*. Do We Know Whether Researchers and Reviewers Are Estimating Risk and Benefit Accurately? *Bioethics* 2016; 30: 609-17.
21. Holman C, Piper SK, Grittner U, Diamantaras AA, Kimmelman J, Siegerink B, Dirnagl U. Where Have All the Rodents Gone? The Effects of Attrition in Experimental Research on Cancer and Stroke. *PLoS Biology* 2016; 14: e1002331.
22. London AJ, Kimmelman J*. Why Clinical Translation Cannot Succeed Without Failure. *eLife* 2015; 4: e12844.
23. Henderson V, Demko N, Hakala A, Fergusson D, Kimmelman J*. A Meta-analysis of Sunitinib Preclinical Studies. *eLife* 2015; 4 doi: 10.7554.
24. Kimmelman J,* Henderson V. Assessing Risk/Benefit for Trials Using Preclinical Evidence. *J Med Ethics* 2016; 42:50-3
25. Tuttle AH, Tohyama S, Ramsay T, Kimmelman J, Schweinhardt P, Bennett GJ, Mogil J. Increasing placebo responses over time in U.S. clinical trials of neuropathic pain. *Pain* 2015; 156:2616-26.
26. Wenner D, Kimmelman J*, London AJ. Patient-Funded Trials: Opportunity or Liability? *Cell Stem Cell* 2015; 17: 1-3.
27. Carlisle B, Demko N, Freeman G, Hakala A, MacKinnon N, Ramsay T, Hey S, London AJ, Kimmelman J.* Benefit, Risk and Outcome in Drug Development: A Systematic Review of Sunitinib. *J Natl Canc Inst* 2015; 108(1) Print 2016.
28. Hakala A, Kimmelman J,* Carlisle B, Fergusson D. Accessibility of Trial Reports for Drugs Stalling in Clinical Development. *BMJ* 2015; 350: h1116.
29. Brehaut JC, Carroll K, Elwyn G, Saginur R, Kimmelman J, Shojania K, Syrowatka A, Nguyen T, Fergusson D. Elements of Informed Consent and Decision Quality Were Poorly Correlated in Informed Consent Documents. *J Clin Epid* 2015; S0895-4356(15)00120-1 [Epub]
30. Kimmelman J, London AJ. The Structure of Clinical Translation: Efficiency, Information, and Ethics. *Hastings Cent Rep* 2015; 45:27-39.†
31. Hey SH, Kimmelman J*. Are Outcome Adaptive Allocation Clinical Trials Ethical? *Clin Trials* 2015; 12: 102-6.†
32. Carlisle B, Kimmelman J*, Ramsay T, MacKinnon N. Unsuccessful Trial Accrual and Human Subjects Protections: An Empirical Analysis of Recently Closed Trials. *Clin Trials* 2015; 12: 77-83.
33. Federico C, Kimmelman J*, Carlisle B, Fergusson DA. Late, Never or Nonexistent: The Inaccessibility of Preclinical Evidence for New Drugs. *Br J Pharmacol* 2014; 171: 4247-54.
34. Kimmelman J,* Mogil J, Dirnagl U. Distinguishing Between Exploratory and Confirmatory Preclinical Research will Improve Translation. *PLoS Biology* 2014; 12: e1001863.

35. Hey SH, Kimmelman J*. The Risk Escalation Model: A Principled Design Strategy for Early Phase Trials. *Kennedy Inst. Ethics J*. 2014; 24: 121-39.
36. Hey SH, Kimmelman J*. The Questionable Use of Unequal Randomization in Confirmatory Trials. *Neurology* 2014; 82: 77-9.
37. Abadie R, Kimmelman J*, Lafleur J, Lemmens T. Recall of Consent to Invasive Research Procedures: A Pilot Investigation. *IRB* 2014; 36(3): 9-15.
38. Freeman GA, Kimmelman J*, Dancey J, Monzon JG. Reporting Practices of Pharmacodynamic Studies Involving Invasive Research Procedures in Cancer Trials. *Br J Cancer* 2013; 109: 897-908.
39. Henderson VH, Kimmelman J*, Fergusson D, Grimshaw JM, Hackam DG. Threats to Validity in the Design and Conduct of Preclinical Efficacy Studies: A Systematic Review of Guidelines for In Vivo Animal Experiments. *PLoS Med* 2013; e1001489†
40. Hey SH, Kimmelman J*. Ethics, Error, and Initial Trials of Efficacy. *Sci Trans Med* 2013; 5: 184-6.
41. Taljaard M, Weijer C, Grimshaw JM et al. Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials: Precis for Researchers and Research Communities. *BMJ* 2013; 346: f2838
42. Kimmelman J*, Lemmens T, Kim SY. Analysis of Consent Validity for Invasive, Nondiagnostic Research Procedures. *IRB* 2012; 34: 1-7. PMID=23072039
43. Haimes E, Skene L, Ballantyne AJ, Caulfield T, Goldstein LS, Hyun I, Kimmelman J, Robert JS, Roxland BE, Scott CT, Solbakk JH, Sugarman J, Taylor PL, Testa G; ISSCR Position statement on the provision and procurement of human eggs for stem cell research. *Cell Stem Cell*. 2013 Mar 7;12(3):285-91
44. Kato K, Kimmelman J, Robert J, Sipp D, Sugarman J. Ethical and policy issues in the clinical translation of stem cells: report of a focus session at the ISSCR Tenth Annual Meeting. *Cell Stem Cell* 2012; 765-7. PMID=23217422
45. Kimmelman J*. Beyond Human Subjects: Risk, Ethics, and Clinical Development of Nanomedicines. *J Law Med Ethics* 2012; 40: 841-7. PMID=23289686
46. Weijer C et al. Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials. *PLoS Med* 2012; 9: e1001346 [member of consensus group] PMID=23185138
47. Kimmelman J*. A Theoretical Framework for Early Human Studies: Uncertainty, Intervention Ensembles, and Boundaries. *Trials* 2012; 13: 173-8. PMID= 22999017
48. Freeman GA, Kimmelman J*. Publication and Reporting Conduct for Pharmacodynamic Analyses of Tumor Tissue in Early Phase Oncology Trials. *Clin Canc Res* 2012; 18(23). PMID=22912391†
49. London AJ, Kimmelman J*. Carlisle B. Rethinking Research Ethics: The Case of Postmarketing Trials. *Science* 2012; 336: 544-5. PMID=22556237
50. Kimmelman J*. Anderson JA. Should Preclinical Studies be Registered? *Nat Biotechnol* 2012; 30: 488-9. PMID=22678379
51. Anderson JA, Kimmelman J*. Are Phase 1 Trials Therapeutic? Risk, Ethics, and Division of Labor. *Bioethics* 2012: 138-46 PMID=22681632
52. Brehaut JC, Carroll K, Elwyn G, Saginur R, Kimmelman J, Shojania K, Syrowatka A, Nguyen T, Hoe E, Fergusson D. Informed consent documents do not

encourage good-quality decision making. *J Clin Epidemiol* 2012; 65: 708-24. PMID=22537428
53. Kimmelman J*, Duckworth K, Ramsay T, Voss T, Ravina B, Emborg ME. Risk of Surgical Delivery to Deep Nuclei: A Meta-analysis. *Mov Disord* 2011; 26: 1415-21. PMID=21574186†
54. Racine E, Northoff G, Menon RS, Kimmelman J, Illes J. A Canadian Perspective on Ethics and Neuroimaging: Tensions and Solutions. *Can J Neurol Sci* 2011; 38: 572-9. PMID=21672697
55. Kimmelman J, London AJ. Predicting Harms and Benefits in Translational Trials: Ethics, Evidence, and Uncertainty. *PLoS Medicine* 2011; 8:e1001010. PMID=21423344†
56. Kimmelman J*. Ethics, Ambiguity Aversion, and the Review of Complex Translational Trials. *Bioethics* 2012; 26: 242-50. PMID=21241343
57. London AJ, Kimmelman J*, Emborg ME. Beyond Protection vs. Inclusion in Trials of Innovative Therapies. *Science* 2010; 328: 829-30. PMID=20466907
58. Braude H, Kimmelman J*. The Ethics of Manipulating Affective and Emotional States to Improve Informed Consent: Autonomy, Comprehension, and Voluntariness. *Bioethics* 2012; 26: 149-56. PMID=21039686
59. Brehaut JC, Fergusson DA, Kimmelman J, Shojania KG, Saginur R, Elwyn G. Using decision aids may improve informed consent for research. *Contemp Clin Trials* 2010; 31: 18-20. PMID=20156597
60. Anderson JA, Kimmelman J*. Extending Clinical Equipoise to Phase 1 Trials: Unresolved Problems. *Kennedy Institute of Ethics Journal* 2010; 20: 75-98. PMID=20506695
61. Kimmelman J*, London AJ, Ravina B, Ramsay T, Bernstein M, Stahnnisch FW, Emborg ME. Launching Invasive, First-in-Human Trials Against Parkinson's Disease: Ethical Considerations. *Movement Disorders* 2009; 24: 1893-901. PMID=19672990
62. London AJ, Kimmelman J*. Justice in Translation: From Bench to Bedside in the Developing World. *Lancet* 2008; 372: 82-5. PMID=18603162†
63. Kimmelman J*. The Ethics of Human Gene Transfer. *Nature Reviews—Genetics* 2008; 9: 239-44. PMID=18278058
64. Kimmelman J*. Staunch Protections: The Ethics of Haemophilia Gene Transfer Research. *Haemophilia* 2007; 14: 5-14. PMID=18005150
65. Lipsman N, Skanda A, Kimmelman J, Bernstein M. The Attitudes of Brain Cancer Patients and their Caregivers Towards Death and Dying: A Qualitative Study. *BMC Palliative Care* 2007 6: 7. PMID=17996072
66. Kimmelman J*. The Therapeutic Misconception at 25: Research, Treatment, and Confusion" *Hastings Center Report* 2007; 37(6): 36-42. PMID=18179103
67. Kimmelman J*. Missing the Forest: Further Thoughts on Bystander Risk in Medical Research. *Cambridge Quarterly Healthcare Ethics* 2007; 16: 483-90. PMID=18018930
68. Kimmelman J*. Stable Ethics: Enrolling Non-Treatment Refractory Volunteers in Novel Gene Transfer Trials. *Molecular Therapy* 2007; 15: 1904-6. PMID=17948045

69. Kimmelman J*. Ethics at Phase 0: Clarifying the Issues. *Journal of Law, Medicine and Ethics* 2007; 35(4): 727-33. PMID=18076522
70. Kimmelman J*. Clinical Trials and SCID Row: The Ethics of Phase 1 Trials in the Developing World. *Developing World Bioethics* 2007; 7(3): 483-90. PMID=18021117
71. Kimmelman J*, Nalbantoglu J. Faithful Companions: A Proposal for Neurooncology in Pet Dogs. *Cancer Research* 2007; 67: 4451-4. PMID=17510377
72. Kimmelman J*. Inventors as Investigators: Patents, Clinical Research, and Conflict of Interest. *Academic Medicine* 2007; 82: 24-31. PMID=17198287
73. Kimmelman J*. The Post-Human Genome Project Mindset: Race, Reliability, and Healthcare. *Clinical Genetics* 2006; 70: 427-32. PMID=17026628
74. Dimichele D, Chuansumrit A, London AJ, Thompson AR, Cooper CG, Killian RM, Ross LF, Lillicrap D, and Kimmelman J. Ethical issues in haemophilia. *Haemophilia* 2006; 12 (Suppl. 3): 30-5. PMID=16683994
75. Kimmelman J*, Baylis F, and Glass, KC. Stem Cell Trials: Lessons from Gene Transfer Research. *Hastings Center Report* 2006; 36(1): 23-6. PMID=16544835
76. Kimmelman J*. Medical Research, Risk and Bystanders. *IRB: Ethics and Human Research* 2005; 27(4): 1-6. PMID=16220627
77. Kimmelman J*, Levenstadt A. Elements of Style: Consent Form Language and the Therapeutic Misconception in Trials of Gene Therapy. *Human Gene Therapy* 2005; 16(4): 502-8. PMID=15871681
78. Kimmelman J*. Recent developments in gene transfer: risk and ethics. *BMJ* 2005 330(7482): 79-82. PMID=15637370
79. Kimmelman J*, and Palmour N. Therapeutic Optimism in the Consent Forms of Phase 1 Gene Transfer Trials: An Empirical Analysis. *Journal of Medical Ethics* 2005; 31(4): 209-14. PMID=15800361
80. Kimmelman J*. Valuing Risk: The Ethical Review of Clinical Trial Safety. *Kennedy Institute of Ethics Journal* 2004; 14(4): 369-393. PMID=15812985
81. Kimmelman J*. Protection at the Cutting Edge: The Case for Central Review of Human Gene Transfer Research. *CMAJ* 2003; 169(8): 781-2. PMID=14557316
82. Kimmelman J*. Risking Ethical Insolvency: A Survey of Trends in Criminal DNA Databanking in 50 States. *J Law, Medicine and Ethics* 2000; 28(4): 209-23. PMID=11210371†
83. Kimmelman J, Kaldis P, Hengartner CJ, Laff GM, Koh SS, Young RA. and Solomon, MJ. Activating Phosphorylation of the Kin28p Subunit of Yeast TFIIH by Cak1p. *Mol Cell Biol* 1999; 19(7): 4774-87. PMID=10373527
84. Ziegler A, Jonason AS, Leffell DJ, Simon JA, Sharma HW, Kimmelman J, Remington L, Jacks T, and Brash DE. Sunburn and p53 in the onset of skin cancer. *Nature* 1994; 372(6508): 773-6. PMID=7997263

BOOK CHAPTERS

1. Kimmelman J. Ethics and Cancer Gene Transfer Research. In *Gene Therapy of Cancer*. W. Walther, U. Stein, eds. Humana Press: Totowa, NJ (2015).

2. Hey SH, Kimmelman J. Ensemble Space and the Ethics of Clinical Development. In: *Research Ethics Forum*. Strech D, Mertz M, eds Springer (2015). Pp137-152.
3. Hey S, Kimmelman J. Clinical Translation in Central Nervous System Diseases: Ethical and Social Challenges. In: *Handbook of Neuroethics*. Clausen J, Levy N. Springer (2013).
4. Hyun I, Kimmelman J. Ethical Issues in Early Phase Translation of Cancer Gene Transfer Strategies. In: *Gene Therapy of Cancer: Translational Approaches from Preclinical Studies to Clinical Implementation*. 3rd Edition. Lattime EC, Gerson S, eds. Elsevier: (2013).
5. Kimmelman J. "Biologics, Ethics and the Human Brain." In: *Neuroethics in Practice*. Farah M, Chatterjee A, eds. New York: Oxford University Press (2012). Pp 249-61.
6. Kimmelman J. "Ethics in Clinical Trials Involving the Central Nervous System: Risk, Benefit, Justice, and Integrity." In: *Clinical Trials in Neurology: Design, Conduct, Analysis*. Ravina B, Cummings J, McDermott M, Poole RM, eds. New York: Cambridge University Press (2012). Pp 173-86.
7. Anderson JA, Kimmelman J. "Ethics and Uncertainty: Considerations for the Design and Review of Translational Trials Involving Stem Cells." In: *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Embryo*. Hug K, Hermerén G, eds. New York: Springer (2010). Pp403-18.
8. Kimmelman J. "Ethics of Cancer Gene Transfer Clinical Research." In W. Walther, U. Stein, eds. *Gene Therapy of Cancer*. Humana Press: Totowa, NJ (2008). Pp 423-45.

OTHER REFEREED PUBLICATIONS

Kimmelman J. (2008). Research Ethics Review. Royal College of Physicians and Surgeons of Canada, Bioethics Education Project.
http://www.rcpsc.medical.org/ethics/bep_index.php

NONREFEREED PUBLICATIONS AND INVITED COMMENTS

1. Kimmelman J. The Secret Realm of Phase I Trials in Healthy Volunteers. *BMJ* 2015; 350: h3444.
2. Kimmelman J, Hey S. Rejoinder. *Clinical Trials* 2015; 12: 125-7.
3. Kimmelman J. The Social Function of Clinical Equipoise. *Clin Trials* 2012; 9(5): 630-1.
4. Kimmelman J. Tomorrow, Interrupted: Risk, Ethics, and Medical Advance in Gene Transfer. *Molecular Therapy* 2009; 17: 1938-9.
5. Kimmelman J. Battling a Thousand Points of Might. *Hastings Cent Rep* 2009; 39: 3.
6. Kimmelman J, Weijer C, Meslin EM. Helsinki Discords: FDA, Ethics, and International Drug Trials. *Lancet* 2009; 373: 13-4.
7. Brehaut JC, Lott A, Fergusson DA, Shojania KG, Kimmelman J, Saginur R.Can patient decision aids help people make good decisions about participating in clinical trials? A study protocol. *Implement Sci*. 2008; 3:38.
8. Kimmelman J. Putting the Shoe on the Wrong Foot: Response to Ponder and Srivastava. *Haemophilia* 2008; 14: 1112-4.

9. Kimmelman J. Response to Miller, Appelbaum, and Lidz. *Hastings Cent Rep* 2008; 38(2): 4-5.
10. Kimmelman J. Cheap Shots and pricey propositions: evidence, disclosure, and treatment of age-related macular degeneration. *Retina* 2007; 27: 1166-7.
11. Kimmelman J. Toward a Global Human Embryonic Stem Cell Bank: Differential Termination. *Am J Bioethics* 2007; 7: 52-3.
12. Kimmelman J. Book Review: *Belmont Revisited: Ethical Principles for Research with Human Subjects* (J. Childress, E. Meslin, and H. Shapiro, eds.; Georgetown University Press). *JAMA Aug* 2006; 296(5): 589-90.
13. Kimmelman J. Book Review: *What Price Better Health: Hazards of the Research Imperative* (Daniel Callahan, University of California Press). *JAMA Aug* 2004; 292 (6): 744-5.
14. Kimmelman J. Book Review: *Owning the Genome: A Moral Analysis of DNA Patenting*. (David B. Resnik, State University of New York Press). *Biotechnology Focus* Dec 2004; 7(12): 30.
15. Kimmelman J. "Laboratories of democracy" *The Nation* 2002; Oct 28: 38-42.
16. Kimmelman J. "The Promise and Perils of Criminal DNA Databanking." *Nature Biotechnol* 2000; 18(7): 695-6.

ABSTRACTS (selected)

1. Benjamin, D., Mandel, D.R., Kimmelman, J., Can cancer researchers accurately judge whether preclinical reports will reproduce?, Economics and Computation Workshop on Forecasting; paper presentation. Cambridge MA. Jun 27, 2017
2. Hakala A, Fergusson D, Kimmelman J. Accessibility of Trial Evidence for Novel Neurological Drugs. Evidence Live 2016: Oxford, UK. Jun 26, 2016
3. Waligora M, Bala MM, Koperny M, Jaeschke RR, Kargul A, Piasecki J, Sliwka A, Mitus JW, Nowis D, Kimmelman J. Risk and benefits of pediatric phase I trial in oncology, 2004 through 2014: a systematic review. Cochrane Colloquium. Vienna, AUS, Oct 5, 2015 (poster)
4. Carlisle B, Kimmelman J*, Ramsay T, MacKinnon N. Trial Accrual and Ethics: An Empirical Analysis. ." Society of Clinical Trials Annual Meeting, Philadelphia, May 19, 2014 (oral)
5. Henderson VC, Demko N, Hakala A… Kimmelman J*. Addressing Threats to Clinical Generalizability in Preclinical Experiments: A Feasibility Study of Sunitinib." Society of Clinical Trials Annual Meeting, Philadelphia, May 20, 2014 (oral)
6. Federico CA, Carlisle B, Kimmelman J*, Fergusson DA. Late, Never, or Nonexistent: The Inaccessibility of Preclinical Evidence for New Drugs. Society for Clinical Trials. Philadelphia, PA. May 21, 2014. (oral)
7. Federico CA, Kimmelman J*, Fergusson D, Grimshaw J, Hackam DG. The Publication of Preclinical Evidence Supporting Translation of New Drugs: An Empirical Analysis. 33rd Society for Clinical Trials. Miami, FL. May 23, 2012. (oral)
8. Kimmelman J*, Henderson VC, Fergusson D, Grimshaw J, Hackam DG. Validity threats and preclinical research: a systematic analysis. Systematic Reviews in Laboratory Animal Science. Nijmegen, the Netherlands. Feb 9-10, 2012. (poster)

9. Kimmelman J*, Duckworth K, Ramsay T, Voss T, Emborg ME. Delivery Co-interventions in Gene Transfer and Cell Transplantation: A Meta-analysis of Surgical Risk for Trials Involving Inoculation to Deep Brain Structures. American Society of Gene and Cell Therapy, Washington DC, May 22, 2010. (poster)
10. Kimmelman J*. When to Begin Human Testing: The Principle of Modest Translational Distance. American Society of Bioethics and Humanities, Washington DC, Oct 21, 2007. (oral)
11. Kimmelman J*. Human Studies as Basic Investigations: Patterns of Citation for Gene Transfer Phase I Clinical Trials in Glioblastoma. American Society of Gene Therapy. Seattle, WA June 1, 2007. (poster)
12. Durell KL, Kimmelman J, Nalbantoglu J, Gold ER. Patent Inventorship of Principal Investigators in Phase 1 Gene Transfer Clinical Trials: An Empirical Analysis. American Society of Gene Therapy. Seattle, WA June 2, 2007. (poster)
13. Kimmelman J. Description of Benefit in Trials of Novel Agents: An Empirical Analysis. Stem Cell Network, Annual General Meeting. Vancouver, BC Sept 18, 2003. (poster)
14. Peterson T, Glass KC, Kimmelman J. "Shortcut to germline modification: gene transfer into human embryos." Stem Cell Network, Annual General Meeting. Vancouver, BC Sept 18, 2003. (poster)

OTHER WRITINGS (selected)

1. Kimmelman J. In Search of Genomic Incentives (Op-Ed). *Globe and Mail*, December 19, 2012, A19.
2. Kimmelman J, London AJ. Clinical Testing and the Common Good: Trials of Innovative Therapies are More than a Private Affair. Science Progress. Center for American Progress. June 2010. See: http://www.scienceprogress.org/2010/06/clinical-trials-and-the-common-good/
3. Kimmelman J., *Lost in Translation*. Blog on translational clinical research ethics. Occasional entries monthly since Feb 8, 2008. See: http://lostintranslationethics.blogspot.com/
4. Kimmelman J., "Licensing life: Free the Harvard mouse" (Op-Ed) *The Globe and Mail* Dec 4, 2002: A19.
5. Kimmelman J., "Unlimited license: An analysis of the CBAC's report on patenting higher life forms" *Canadian Centre for Policy Alternatives* (www.policyalternatives.ca/publications/unlimitedlicense.html) 2002.
6. Kimmelman, J. "Just a Needle Stick Away" *The Nation* 2000; 271(Nov. 27): 17-21.

INVITED PLENARY / KEYNOTE TALKS

1. "How Efficient is Clinical Translation in Neurology." Presidential Symposium. American Society for Neural Therapy and Repair. Clearwater, FL. April 29, 2017

2. "How Many Patients Does it Take to Develop a Cancer Drug?" Tom Weinburger and Leslie Vermut endowed lectureship; UCLA. Los Angeles, CA: November 15, 2016.
3. "Can We Predict the Future of Genetics in Medicine"? Tom Weinburger and Leslie Vermut endowed lectureship; Cedars Sinai Hospital. Los Angeles, CA: November 16, 2016
4. "Into the Unknown: The Ethics of Phase 1 Clinical Trials. CAREB Annual Meeting, Toronto, ON. May 28, 2016.
5. "Sunitinib: A Story of Drug Development and Research Inefficiencies." Distinguished Lecture Series, Jewish General Hospital, Montreal QC. Feb 22, 2016
6. "Risk / Benefit Evaluation in First in Human Trials: Implications for Gene Editing in Human Embryos." International Summit on Human Gene Editing: A Global Discussion. U.S. National Academy of Sciences / U.S. Academy of Medicine / Chinese Academy of Medicine. Washington, DC. December 2, 2015.
7. "Gene Transfer, Clinical Research, and Ethics." OMICRON Visiting Professorship, Jagellonian University, Krakow, Poland. October 28, 2014.
8. "How to Think (Ethically) About Early Phase Trials." Canadian Association of Research Ethics Boards Annual Meeting, Montreal, QC. April 26, 2014
9. "Threats to Validity in Preclinical Research: Problems and Solutions." Forum on Preclinical Cardiovascular Studies. Wake Forest Innovations, Winston Salem, NC October 30, 2013
10. "How to Think About Early Phase Research." Hannover Medical School, Hannover, GER. August 27, 2013
11. "Pediatric Trials and Biosecurity." Workshop on Pediatric Development of Medical Countermeasures: Ethical and Regulatory Considerations. FDA. Rockville, MD. February 15, 2012.
12. "Access to Experimental Therapies: Benefits, Harm, and Evidence." PRIM&R Annual Meeting. Washington, DC. December 4, 2011.
13. "Access Denied: Medicine, Trust, and Experimental Treatments." Science and its Publics National Lecture Series. Toronto. March 14, 2011.
14. "Of Mice but not Quite Humans: Ethics, Evidence, and Preclinical Research" Ottawa Hospital Research Institute. Research Day. Ottawa. November 18, 2010.
15. "Ethics of Gene Transfer and Risk Management." CONSERT / The Ethics of Gene Therapy of Inherited Diseases. Brugge, Belgium. November 13, 2008.

INVITED LECTURES AND WORKSHOPS (selected)

External

1. "Reproducibility, Ethics and Clinical Research." Consequential and Reproducible Clinical Research: Charting the Course for Continuous Improvement Conference. U.S. National Library of Medicine, NIH. Bethesda, MD: June 15, 2017
2. Debate: Should Bystanders Be Protected in Human Research? Yes. Harvard Medical School. Boston: June 13, 2017.
3. "How Many Patients Does (and Should) It Take to Develop a New Drug?" Ste Justine Rounds. Montreal, QC: May 19, 2017.

4. "Regulation of Unproven Stem Cell-Based Interventions: The ISSCR Guidelines." International Society of Cell Therapy. London, UK. May 3, 2017.
5. "My Foray into Figure 4A." U.S. National Institutes of Health Rounds, Bioethics. April 5, 2017.
6. "How Many Patients Does (and Should) It Take to Develop a New Cancer Drug?" Center for Bioethics, Harvard Medical School. Boston, MA: March 30, 2017.
7. "How to Succeed With Failure in Clinical Development." University of Wisconsin, Madison, WI: November 25, 2016.
8. "Ethics and the Efficiency of Drug Development in Cancer." University of Wisconsin, Madison, WI: November 25, 2016.
9. "Ethics of Early Phase Trials in Early Phase Neurological Drug Development." Workshop on Therapeutic Development for Nervous System Disorders. U.S. National Academies of Sciences. Washington, DC. September 13, 2016
10. "Regulation of Unproven Stem Cell-Based Interventions: The ISSCR Guidelines." FDA Workshop: Scientific Evidence in Development of HCT/Ps Subject to Premarket Approval U.S. FDA. Silver Spring, MD. September 8, 2016.
11. "Terms of Cooperation: Stem Cell Research and the ISSCR Guidelines." MHH, Hannover, GER August 10, 2016
12. "How Well Can Researchers Predict the Outcomes of Cancer Trials?" Summit for Cancer Immunotherapy, Halifax, NS. June 28, 2016.
13. "How to Be Less Vacuous When Assessing Risk in Novel Settings." CRISPR Technology: Responsible Dialog about Science and Bioethics Symposium, UC Davis. Davis, CA. May 26, 2016.
14. "Ethics and Gene Editing in Human Embryos: ISSCR Policy." California Institute of Regenerative Medicine. Los Angeles, CA Feb 4, 2016.
15. "The Role of Patients in Design and Conduct of Trials." NECTAR conference. Lund, SWE. December 10, 2015.
16. "Validity Threats in Preclinical Research: Concepts and Solutions." Treat NMD Biannual Conference. Cosmos Club, Washington DC. December 6, 2015
17. "Addressing Validity Threats in Biomedical Research: Policy, Practice and a Proposal." Metrics. Stanford University. November 20, 2015.
18. "Animals Containing Human Cells: Ethics and ISSCR Guidelines." NIH Workshop on Animals Containing Human Cells, Bethesda, MD. November 6, 2015.
19. "How to use Failure to Succeed in Stem Cell Research." Till and McCulloch Annual Meeting, Toronto ON. October 28, 2015.
20. "Are Interventions that are in Early Stages of Developments Therapeutic? Till and McCulloch Annual Meeting, Toronto ON. October 28, 2015.
21. "Clinical Equipoise and the Ethics of Randomization." Strengthening Causal Inference in Obesity Behavioral Research. Birmingham, University of Alabama. July 21, 2015.
22. "Why Translation Cannot Succeed Without Failing." Charité Entrepreneurship Summit. Berlin, GER, May 29, 2015

23. "Clinical Translation, Efficiency, and Natural Limits. Linköping University, Dept. Thematic Studies- Technology and Social Change seminar series. Linköping SWE. April 15, 2015
24. "Prospective Registration of Animal Studies." NC3R. Publication Bias Workshop. London, UK. February 24, 2015.
25. "Validity Threats in Preclinical Drug Development: Science, Policy and Ethics." Instituto de Biologia Molecular e Cellular. Porto, PGL. Feb 13, 2015
26. "Clinical Trials and Efficiency: Scientific and Moral Dimensions." Berlin Centrum Schlaganfallforschung Berlin, GER. January 20, 2015
27. "A Structured Approach for Reviewing Risk/Benefit for Preclinical and Early Phase Human Studies." 9th Annual Congress on Alternatives and Animal Use in the Life Sciences. Prague, CZE. August 26, 2014
28. "Anatomy of Clinical Development in Neurology." Charité Neuroscience Colloquia. Berlin, GER. July 26, 2014
29. "Reproducibility of Preclinical Research: Activities and Opportunities." U.S. Institute of Medicine- ILAR. Washington DC. June 4, 2014.
30. "Review of Preclinical Evidence Supporting Clinical Trials." Canadian Association of Research Ethics Boards / Animal Care Workshop. Montreal QC. April 24, 2014.
31. "Anatomy of Clinical Translation." Rotman Institute of Philosophy, University of Western Ontario. London ON. March 21, 2014.
32. "Ethics and Clinical Development of Novel Interventions." Ottawa Hospital Research Institute. Ottawa ON. February 11, 2014
33. "Ethical Issues in Design of ALS Stem Cell Trials." University of California Davis. Stem Cell Research and Neurological Disorders Symposium. Davis, CA. January 30, 2014.
34. "Gene Transfer and the Ethics of Phase 1 Research." Current Challenges in Preclinical, Clinical, and Public Health Research. Hannover, GER. Aug 27, 2013.
35. "ALS Cell Therapy Translation: Criteria for Initiating Trials". San Diego-CIRM ALS Stem Cell Therapy Consensus Conference. Sanford Burnham Center for Regenerative Medicine. La Jolla, CA. May 6, 2013
36. "Patient Preferences and Translation: Epistemic and Ethical Issues." Expert Workshop: Values in Clinical Translation. Enschede, NETH. November 23, 2012.
37. "Ethical Evaluation of Risk in Clinical Research." Ottawa Hospital Research Institute Clinical Research Training Course. Ottawa, ON. Oct 17, 2012.
38. "Ethics, Trials, and Neurological Disorders: An Introduction." Clinical Trials Methods Course in Neurology (NINDS). Vale, CO. July 24, 2012.
39. "Sham Comparators in Stem Cell Trials." ISSCR Ethics Focus Session. Yokohama, JPN. June 13, 2012.
40. "Missing Information, Risk, and Drug Development." The Uses and Abuses of Evidence Conference. Banff, AB. June 1, 2012.
41. "Medical Countermeasures Risk Communication: An Ethical Appraisal." FDA Workshop on Pediatric Development of Medical Countermeasures: Ethical and Regulatory Considerations. Rockville, MD. Feb 16, 2012.

42. "Stem Cell Trials and a Theory of Centralized Ethical Review." ISSCR Workshop on Stem Cell Ethics. Brocher Foundation. Geneva, Switzerland. December 1, 2011.
43. "Comment on Gatekeepers / Vulnerable Populations." Cluster Randomized Trials Consensus Workshop. Ottawa, ON. Nov 28, 2011.
44. "Research Ethics, Transactions, and Others." University of Minnesota, Nanomedicine Research Ethics Meeting. Minneapolis, MN. Sept 26, 2011.
45. "Expectation, Stem Cells, and the Integrity Thesis." ISSCR Ethics Focus Session. Toronto, ON. June 15, 2011.
46. "Animals, Humans, and the Continuity of Evidence: A Study in Clinical Translation." Society of Clinical Trials. Vancouver, BC. May 17, 2011.
47. "What is Research Ethics For? From Nuremberg to TCPS" Society of Clinical Trials. Vancouver, BC. May 16, 2011.
48. "Subjects in Early Phase Trials of Novel CNS Agents: Guinea Pigs or Patients?" Brain Matters 2. Montréal, QC. May 27, 2011.
49. "Identifying Genetic Markers of Cancer in Early Phase Trials: Ethical Challenges." 4th Annual Canadian Human Genetics Conference. Banff, AB. Apr 28, 2011.
50. "Ethics and Gene Transfer Clinical Research." Clinigene. Paris, FR. Apr 8, 2011.
51. "A Typology of Preclinical Validity." Institute de Researche Clinique de Montréal. Montréal, QC. Jan 17, 2011.
52. "Better Mousetraps: Ethics, Evidence, and Preclinical Research." Canadian Association of Immunization Research and Evaluation. Quebec City, QC. Dec 5, 2010.
53. "Uncertainty, Ethics, and Translation of Nanomedicines." University of Minnesota, Nanomedicine Research Ethics Meeting. June 22, 2010. Minneapolis, MN
54. "Knowledge Value in Sham Surgery." National Institute of Neurological Diseases / NIH. Sham Neurosurgical Procedures in Clinical Trials for Neurodegenerative Diseases: Scientific and Ethical Considerations. June 28, 2010. Washington, DC
55. "Clinical Trials, Ethics, and Information Technologies: Emerging Capabilities for Autonomy, Risk Assessment, and Reporting." Polish Academy of Sciences. Transparency and Open Access in Science. Warsaw, POL. May 7, 2010.
56. World Medical Association. Placebo Conference. Sao Paulo, BRA. Feb 1-3, 2010
57. Canadian Institutes of Health Research. Biomarkers for Precision in Medicine Initiative Workshop. Toronto, ON. Nov 19-20, 2009.
58. "Phase 1 Clinical Trials and Informed Consent." Ottawa Hospital Research Institute. Ottawa, ON. Oct 26, 2009
59. Canadian Network for the Governance of Ethical Health Research Involving Humans. Organized through University of British Columbia. Jul 26-30, 2009. Vancouver, BC
60. "Translational Clinical Trials: Ethics, Ends, and Evidence." Ottawa Hospital Research Institute Ottawa, ON. May 8, 2009

61. Canadian Network for the Governance of Ethical Health Research Involving Humans. University of British Columbia. Victoria, BC. Jul 27-31, 2008.
62. "Just Research, Or Just Plain Exploitation? Translational Clinical Trials and the Developing World." Université de Montréal. Forum de Group en Bioéthique. Montreal, QC. Nov 22, 2007
63. "Phase 1 Gene Transfer Trials and Informed Consent." Society of Clinical Research Associates. Denver, CO. Sep 26, 2007.
64. "Justice, Subject Selection and Gene Transfer." American Society of Gene Therapy. Seattle, WA. June 1, 2007
65. CIHR- Institute of Genetics. Genetic Diversity and Science Communication Workshop. Toronto, ON. Apr 27-29, 2006
66. "Ethics of Research Trials and Implementation of Novel Therapies Targeted a the Youngest Generation of Haemophilia Patients: An Ethicist's View." World Hemophilia Federation. Annual Meeting, Vancouver, BC. May 24, 2006
67. University of North Carolina. Social Studies of Medicine. Therapeutic Misconception Workshop. Chapel Hill, NC. Sep 8, 2005
68. "Gene Transfer, Risk and Ethics." Clinical Epidemiology and Community Medicine Rounds. Ottawa Hospital Research Institute. Ottawa, ON. June 4, 2004
69. "Therapeutic optimism in the consent forms of phase 1 gene transfer trials: an empirical analysis." 6ième colloque de l'Association de thérapie génique du Québec, Institutue for Research on Biotechnology. Montreal, QC. Oct 24, 2003

<u>Internal</u>

1. Clinical Epidemiology Seminar Series. "Into Thin Air: The Loss of Evidence in Drug Development." Jewish General Hospital; Montreal, QC. November 4, 2015
2. McGill University Epidemiology /Biostatistics Seminar Series. "Moral Efficiency in Clinical Translation." Seminar Series. Nov 25, 2013. Montreal, QC
3. Training Program for Applied Oral Health Research "The Ethics of Gene Transfer for Dentistry and Oral Health." Faculty of Dentistry, July 26, 2007
4. Rounds, McGill Dept of Psychology. "Gene Transfer Applications to Psychology and Human Behavior: Science, History, and Ethics." Apr 10, 2007
5. McGill REB Day. "The Ethics of Phase I research." McGill / McGill University Health Complex, May 16, 2007
6. McGill Pharmacology Research Day. McGill University. "Gene Transfer, Stem Cells, and Ethics." May 19, 2005.
7. McGill Bioethics Conference. McGill Univ. "Genes and Society." Oct 1, 2004
8. Human Genetic Sciences Symposium. McGill University, Montreal, QB. "Risky Business: Drugs, Genes and Individuals." Apr 22, 2004
9. Department of Zoology, University of Manitoba, Winnipeg, MB: "Reflections on the Past and Future of Medical Biotechnology," Jan 11, 2001.
10. Centre for Professional and Applied Ethics, University of Manitoba, Winnipeg, MB: "Medical Biotechnology: The Political Machine," Nov 3, 2000.

11. Yale Bioethics Society, New Haven, CT: "The Social Implications of Criminal DNA Databanking," Mar 28, 2000.
12. The Hastings Center, Garrison, NY: "From Refrigerators to Recombinant DNA," Nov 22, 1999.

AWARDS AND HONORS

2014 Friedrich Wilhelm Bessel Research Award (Humboldt Foundation, Germany); €45,000

2013 Nominee, World Technology Award, World Technology Network, New York City. Ethics Category

2006 Maud Menten New Principal Investigator Prize (CIHR Institute of Genetics); $30,000

2008-2013 Principal Investigator. Ethics in Translational Research: Navigating the Interface Between the Bench and Clinic. CIHR New Investigator Salary Award; $300,000.

FUNDING

2016-2020 Principal Investigator, "Ethics, Efficiency and Patient Burden in Drug Development" CIHR Project Grant. $366,000

2016- 2019 Principal Investigator, "Improving the Quality of Judgment in Cancer Therapeutics Development. BioCanRx / CIHR Network Grant. $535K.

2016-2018 Co-Investigator. G3LS Network in Genomics and Personalized Health. Genome Canada. Principal Investigators: B Knoppers, C McCabe, F Rousseau. $18K

2015-2019 Consultant. "HIV Cure Studies: Risk, Risk Perception, and Ethics." U.S. NIAID Operating Grant 1RO1A|114617-01A1. Principal Investigator: Nir Eyal. $3.1M

2014-2015 Co-investigator. "The Clinical, Regulatory, and Ethical Implications of Electronic Cigarettes: a Knowledge Synthesis Grant." CIHR Knowledge Synthesis Grant. Principal Investigator: Mark Eisenberg. $100K

2014-2018. Co-investigator, Theme Co-Leader. "Vascular Health Network." CIHR Emerging Network Grant. Principal Investigator: Duncan Stewart. $7.2M

2013-2016 Principal Investigator. "Can Researchers Accurately Predict Trial Outcomes? An Empirical Investigation." CIHR Operating Grant. $280,007.

2013-2017 Principal Investigator. "PACE-'Omics: Personalized, Accessible, Cost-Effective applications of 'Omics technologies." Genome Canada. PACEOMICS Lead Principal Investigator: Chris McCabe and Tania Bubela. $4.5M (my portion:

$573,571)

2012-2015 Principal Investigator. Signal, Safety, and Success: An Analysis of Risk, Benefit, and Translation after Detection of Clinical Activity in Drug Development (MOP119574). CIHR Operating Grant. $320,000

2011-2014 Principal Investigator. Animals, Humans, and the Continuity of Evidence: A Study of Clinical Translation (EOG 111391). CIHR Operating Grant. $273,952

2010-2013 Co-investigator. Molecular Profiling of Drug-Resistant Triple Negative Breast Cancer. Genome Quebec; General Stream. Principal Investigator: Mark Basik; $500,000

2010-2013 Co-investigator. Ethical, Legal, and Social Issues, "Therapeutic Opportunities to Target Tumor Initiating Cells in Solid Tumors" California Institute of Regenerative Medicine / CIHR. Principal Investigator: Trudo Lemmens,; $500,000

2010-2013 Principal Investigator. Justifying Translational Clinical Trials: An Ethical Analysis of Risk, Design, and Prediction (EOG 102823). CIHR; Operating Grant; $183,119.

2008- 2011 Co-investigator. Informing the Decision to Participate in a Clinical Trial: Can Decision Aids Improve the Quality of Trial Participation Decisions? CIHR. Principal Investigator: Jamie Brehaut; Operating Grant; $349,557.

2006-2011 Co-investigator. States of Mind: Emerging Issues in Neuroethics. CIHR. New Emerging Teams Program; Principal Investigator: Françoise Baylis; $1,376,500.

2006-2008 Principal Investigator. Investigators as Inventors: An Empirical Study of Patent Holding and Ethics in Human Gene Transfer Research. CIHR; Operating Grant; $104,826

2006-2007 Co-investigator. Advancing the Ethics of Clinical Trials: Enhancing Participant Protection and Scientific Rigour. CIHR; Operating Grant; Principal Investigator: Kathleen Glass; $251,205

2005-2008 Co-investigator. Therapeutic Hopes and Ethical Concerns: Clinical Research in the Neurosciences. CIHR; Operating Grant; Principal Investigator: Françoise Baylis. $472,348.

COMMITTEES AND AFFILIATIONS

External

2017 - External Advisory Committee, Orphan Disease Center. University of Pennsylvania (Philadelphia)

2016-2017 Member, NAM of the U.S. National Academy of Sciences. Issues in Organ Donor Intervention Research (Washington, DC).
2016-2017 Member, Writing Group, The Ethics of Zika Challenge Clinical Trials. NIAID (NIH, US).
2016- Data Safety Monitoring Board, Dimension Therapeutics.
2015- Affiliate, METRICS (Stanford University)
2015-2016 Member, IOM of the National Academy of Sciences. Committee on Ethical and Social Policy Aspects of Novel Techniques for the Prevention of Maternal Transmission of Mitochondrial DNA Diseases
(Washington, DC).
2013-2014 Member, IOM of the National Academy of Sciences. Committee on Ethics Principles and Guidelines for Long Duration and Exploration Space Flights. (Washington, DC).
2014-2016 Chair, Task Force for Revision of Guidelines for Stem Cell Research and Clinical Translation. International Society for Stem Cell Research. (Deerfield, IL)
2010-Pres. Member, Ethics Committee, International Society for Stem Cell Research. (Deerfield, IL); Chair, 2013 – Present; Annual Meeting Program Committee Member, 2013-14; Legislative Educational Initiative, 2013-Pres.
2011-2013 Trial of the Year Committee, Society for Clinical Trials (Philadelphia, PA)
2010-2011 Program Committee (Annual Meeting), Society for Clinical Trials (Philadelphia, PA)
2010-2012 Stem Cell Oversight Committee, Canadian Institutes of Health Research
2007-2014 Protocol Review Committee, Cardiovascular Cell Therapy Research Network, NHLBI (Bethesda, MD)
2006-2009. Institute of Genetics Ethical, Legal and Social Issues Priority and Planning Committee, Canadian Institutes of Health Research (Toronto, ON)
2006-Pres. Data Safety Monitoring Board. NHLBI Gene and Cell Therapy Group (Bethesda, MD)
2005-2010 Ethics Committee, American Society of Gene and Cell Therapy; Chair of Committee 2008-2010 (Milwaukee, WI)

<u>Internal (selected)</u>
2007-2008 Jewish General Hospital Research Ethics Board 'B'
2007 Benjamin Freedman Memorial Symposium organizing committee
2005-2008 Chair: REB-day Organizing Committee
2006 Hiring Committee, Biomedical Ethics Unit
2005-2007 Montreal General Hospital Research Ethics Board
2005-2008 Physicianship Curriculum Coordinating Committee

EDITORIAL
2016- Editorial Board, *PLoS Biology*
2016- Deputy Editor, *Clinical Trials*

2013- Associate Editor, *Clinical Trials*
2011-2014 Associate Editor, *Trials*
2011- Associate Editor, Springer (Research Ethics Series)

SERVICE, CONSULTING AND REVIEWING ACTIVITIES (selected)
Manuscript Reviewer: *Arch Int Med*, *Bioethics, Blood, BMJ*, *Can Bull Med Hist, Clinical Trials*, *CMAJ*, Croatian *Medical Journal, Ethical Theory and Moral Practice, Future Med, Hastings Center Report, IRB*, *JAMA, JAMA- Internal Medicine, J Law Med Ethics, J Med Ethics*, *Kennedy Inst Ethics J, Lancet, National Cancer Institute, Nature, Nature Biotechnology*, *Nature Medicine*, *Nature Reviews-Oncology*, *NEJM*, *Philosophy of Science*, *Molecular Therapy*, *Open Medicine, PLoS Biology, PLoS Medicine*, *Regenerative Medicine, Science, Social Studies Med, Trials, Sociology of Health and Illness, Stem Cell Reviews, Wellcome Trust*

2016 CIHR Doctoral Fellowships Competition
2015 CIHR Doctoral Fellowships Competition
2015 Reviewer, Bundesministeriums für Bildung und Forschung, Ethics competition.
2013-2014 Ethical, Social and Cultural Program for Global Health, Sandra Rotman Centre, University of Toronto
2013 CIHR Reviewer, Postdoctoral Fellowship Competition
2013 U.S. NCI, External Reviewer, Pediatric Preclinical Testing Program
2011, 2006 Invitee Member, Peer Review Committee, Ethics, Law and Humanities CIHR
2009- 2010 Advisory Committee Member, "Therapeutic Expectation and Phase 1 Trials" (NCI-funded project; Kevin Weinfurt, Neil Meropol, PIs)
2009- 2010 Advisory Committee Member, "Do Research Participants Give Informed Consent," (St. Mary's Hospital, Montreal; Zita Kruszewski, PI)
2007 Chair, Workshop: The Ethics of Initiating Invasive, First-in-Human Clinical Trials involving Parkinson's Disease." November 9; Montreal, QC
2006 Co-chair, Ethical Issues in Haemophilia, World Haemophilia Federation annual meeting (Vancouver, May 22)
2006 Chair, Ethics Symposium. Gene Transfer and Biosecurity. ASGT annual meeting (Baltimore, June 2)
2003 Grant Referee, SSHRC, Ottawa, Canada
2002 Canadian Centre for Policy Alternatives. Response to Canadian Biotechnology Advisory Council patent report
2001 SoundVision Productions, National Public Radio, U.S. "The DNA Files"
1991-'92 Expert witness, "Detroit Audubon Society et al v. City of Detroit et al."

STUDENTS SUPERVISED

Postdoctoral Fellows:
1. Michael Yu, 2017- Present. "Forecasting in Early Phase Drug Development."

2. Adelaide Doussau: 2016-2017 “Forecast and Feedback in Clinical Research.”
3. Daniel Benjamin: 2015- “Forecast Skill in Clinical Research”
4. Hannah Grankvist: 2013-15 “How Researchers Decide to Initiate Clinical Development in Novel Research Arenas: A Qualitative Study.” Current position: Research Fellow, Lindköping University, Dept. Thematic Studies.
5. Spencer Hey: 2013- 2015. “Navigating the Phase 2 / Phase 3 Transition: Ethics and Policy.” Current Position: Faculty, Harvard Center for Bioethics,
6. Roberto Abadie: 2012. “Consent to Tumor Biopsy.” Current Position: Assistant Professor, Anthropology, University of Nebraska-Lincoln
7. James Anderson: 2010-11. “Ethical Justification of Risk in Phase 1 Trials.” Current Position: Assistant Professor, Joint Center for Bioethics, University of Toronto.
8. Hillel Braude: 2009-10. “Management of Affect in Informed Consent.”

Doctoral Students:

1. Amanda Hakala MD/PhD (expected 2020). “Risk/Benefit and Translation Trajectories for Novel Neurological Drugs.”
2. Benjamin Carlisle: PhD (expected 2018). “Risk/Benefit and Knowledge Accrual Across the Translation Trajectory.”
3. Carole Federico: MS / PhD (expected 2018). “Systematic Review of Pain Preclinical Studies.”

Master’s Students:

1. Holly Sarvas (2017-). “Ethics of Precision Medicine Drug Development Trajectories in Cancer”
2. Vince Madai (2016). “Reproducibility in Stroke Preclinical Studies”
3. Amanda Hakala (2016). “Translational Trajectory for Neurological Drugs.”
4. Nadine Demko (2017). “Design and Reporting of Preclinical Studies for New Cancer Drugs: A Systematic Review.”
5. Effy Koukoulas (2012). “Ethics and Policy of Pharmacovigilence.”
6. Georgina Freeman (2012). “Publication Bias and Quality of Reporting of Pharmacodynamic Studies Utilizing Invasive Research Procedures within Early Phase Cancer Trials.”
7. Benjamin Carlisle (2011). “A Critique of Phase IV Studies on the Basis of a Non-Paternalistic Justification for Subject Protections in Human Research.”
8. Clarissa Allen (2011). “Intellectual Property and Biotechnology: Theoretical Arguments and Evidence.”
9. Katherine Duckworth (2010). “Surgical Risk of Delivery of Experimental Agents to Deep Nuclei.”
10. David McLaughlin (2009). “Exploitation and Biomedical Research in the Developing World.”

Undergraduates:

1. Xuhan (Sean) Zhang (2017-Present)
2. Aden Feustel (2016-Present)
3. Sandy Wong (2016-Present)

4. Michael Pratte (2016-Present)
5. Kara Smith (2016- Present)
6. Sylvia Ganeshamoorthy (2016-Present)
7. Taiji Wang (2014- Present)
8. Yasmina Hachem (2014-16)
9. Nathalie MacKinnon (2013-14)
10. Nadia Demko (2013-14
11. Amanda Hakala (2013-14)
12. James Mattina (2014)
13. Tiger Zheng (2014)
14. Andrew Chung (2014)
15. Aaron Levenstadt (2007)

Visiting Students

1. Sara Boers (Medical Student from University of Utrecht); 2017
2. Peter Grabitz (Medical Student from Charité) 2017
3. Gaëlle LeMoine (Master's Student from Paris) 2017
4. Vince Madai (Postdoctoral Student from Charité) 2016

TEACHING (selected)

2006-Pres.	PHIL 543: Ethics of Human Experimentation (13 weeks Masters course)
2006-Pres.	BOM. Medicine and Society. Small group leader (6 sessions)
2013	Lectures: NSCI 300, HGEN696, BIOT505, BMDE505
2012	Lectures: MMIM387, BIOL215, BIOT505, HGEN696, EPIB660, BMDE505, NSCI 300
2011	Lectures: BIOL215, BIOT505, HGEN696, EPIB660, BMDE505, NSCI 300
2010	Lectures: BIOT505, EPIB660, NSCI 300
2005-2010	Unit Organizer: Unit 1, Basis of Medicine (1 session, 14 groups) PHP-1, Ethics Module organizer (3 sessions) and small group leader (1 session)
2008	Lectures: EPIB603, EPIB677, BMDE 505, HGEN660B, BIOT505 Small Group Leader, (Capacity; Resource Allocation) Unit Organizer: Unit 1, Basis of Medicine (1 session, 14 groups) PHP-1, Ethics Module organizer (3 sessions) and small group leader (1 session)
2007	Lectures: BMDE 505 Unit Organizer: Unit 1, Basis of Medicine (1 session, 14 groups) PHP-1, Ethics Module organizer (3 sessions) and small group leader (1 session)
2006	Unit Organizer: Unit 1, Basis of Medicine (1 session, 14 groups) PHP-1, Ethics Module organizer (3 sessions) and small group leader (1 session) ICM, Ethics and Health Law Module. co-organizer (5 small groups + 5 lectures)

Lectures: MIMM 387

2005 ICM, Ethics and Health Law Module. co-organizer (5 small groups + 5 lectures)
Lectures: HGEN 660B

MEDIA APPEARANCES (selected)
All Things Considered (NPR): Jul 4, 2017
BMJ: Oct 15, 2015
CBC News: Jul 13, 2013
Chicago Tribute: Nov 8, 2012
Chronicle of Higher Education: Jul 16, 2013
CMAJ: Jul 12, 2016
CNN: Jan 30, 2017
The Current (CBC National): Aug 14, 2015
Le Devoir: Sep 24, 2016, Aug 31, 2015
Globe and Mail: Mar 12, 2015, Aug 28, 2014
The Guardian (UK): Oct 13, 2015
Maclean's: May 12, 2016
MIT Technology Review: Jan 13, 2017
Nature: Oct 13, 2015, Apr 17, 2015
National Post: Aug 12, 2015,
New York Times: Mar 13, 2015, Sep 9, 2013
New Scientist: Jul 24, 2012
Neurology Today: Dec 8, 2016
La Presse: Jan 30, 2017
Reuters: June 29, 2017, Nov 8, 2012
Science: Jul 18, 2014
The Scientist: June 30, 2017, May 5, 2017, Mar 8, 2011
Second Opinion (CBC National): Feb 2, 2017
STAT News: Jan 31, 2017
Vermont Public Radio, Oct 12, 2015
Wall Street Journal: Jan 6, 2015
Washington Post: Oct 25, 2012

MEMBERSHIPS
International Society of Stem Cell Research
Society of Clinical Trials