

Seema K. Shah

Faculty, Department of Bioethics, National Institutes of Health
10 Center Dr., 10/1C118
Bethesda, MD 20892
(301)435-8711
shahse@mail.nih.gov

ACADEMIC EMPLOYMENT HISTORY

Faculty Bioethicist, Department of Bioethics, National Institutes of Health (NIH) 3/09 – present
Joint Appointment at Division of AIDS,
National Institute of Allergy & Infectious Diseases (NIAID)
Head of Unit on International Research Ethics
Bethesda, Maryland

Contractor, Bioethicist 12/06 – 3/09
Henry M. Jackson Foundation
Liaison Office at Division of AIDS, NIAID
NIH
Bethesda, Maryland

EDUCATION

STANFORD LAW SCHOOL, J.D. 2002 – 2005
Pro bono distinction
Co-President, Asian Pacific Islander Law Students Association
Vice-President, Stanford Biolaw
Member Editor, *Stanford Technology Law Review*

STANFORD UNIVERSITY, A.B., Human Biology 1996 – 2000
Honors in Ethics & Society
Thesis on acceptance of parental responsibility following surrogate motherhood
Teaching assistant for Thinking About Religion(s) & Bioethics courses

PROFESSIONAL EMPLOYMENT HISTORY

Judicial Law Clerk The Chambers of the Honorable William B. Shubb U.S. District Court for the Eastern District of California Sacramento, California	2005 – 2006
Summer Associate Perkins Coie, L.L.P. Menlo Park, California	7/2004-8/2004
Summer Associate Morrison & Foerster, L.L.P. San Diego, California	6/2004-7/2004
Judicial Extern Chambers of the Honorable Irma Gonzalez San Diego, California	6/2003-8/2003
Predoctoral Fellow Department of Bioethics, NIH Bethesda, Maryland	2000-2002

PUBLICATIONS

S.K. Shah, Kenneth Kasper, Franklin G. Miller, A Narrative Review of the Empirical Evidence on Public Attitudes on Brain Death and Vital Organ Transplantation: The Need for Better Data to Inform Policy, *Journal Medical Ethics*, *forthcoming*.

D.S. Wendler, **S.K. Shah**, Involving Communities in Deciding What Benefits They Receive in Multinational Research, *Journal Medicine & Philosophy* 2014, *forthcoming*.

S.K. Shah, Experimental Execution, *Washington Law Review*, *forthcoming*.

S.K. Shah, Piercing the Veil: The Limits of Brain Death as a Legal Fiction, *University of Michigan Journal of Law Reform*, *forthcoming*.

S.K. Shah, Deborah Persaud, David S. Wendler, Holly A. Taylor, Hannah Gay, Mariana Kruger, Christine Grady, Research on Functional Cure for HIV in Neonates: The need for ethical foresight, *Lancet Infectious Diseases* 14 (9):893–898 (2014).

L. Bekker, C. Slack, S. Lee, **S.K. Shah**, B. Kapogiannis, Ethical Issues in Adolescent HIV Research in Resource-Limited Countries, *J Acquir Immune Defic Syndr* 65(1):S24-S28 (2014).

S.K. Shah, Does Research with Children Violate the Best Interests Standard? An Empirical and Conceptual Analysis, *8 Northwestern Journal of Law & Social Policy* 8:121-173 (2013).

S.K. Shah, Outsourcing Ethical Obligations: Should the Revised Common Rule Address the Responsibilities of Investigators and Sponsors? *Journal of Law, Medicine & Ethics* 41:397-410 (2013).

S.K. Shah, R. Wolitz, E. Emanuel, Refocusing the Responsiveness Requirement, *Bioethics* 27(3):151-9 (2013).

J.C. Lindsey, **S.K. Shah**, G.K. Siberry, P. Jean-Philippe, M.J. Levin, Ethical Tradeoffs in Trial Design: Case Study of an HPV Vaccine Trial in HIV-infected Adolescent Girls in Lower Income settings. *Developing World Bioethics* 13(2):95-104 (2013).

S.K. Shah, S.C. Hull, M.A. Spinner, B.E. Berkman, L.A. Sanchez, R. Abdul-Karim, A.P. Hsu, R. Claypool, S.M. Holland. What Does the Duty to Warn Require? *American Journal of Bioethics* 2013; 13(10):62-63.

Shah SK, Lie RK, Aiming at a Moving Target: Research Ethics in the Context of Evolving Standards of Care and Prevention, *Journal of Medical Ethics* 39:699-702 (2013).

S.K. Shah, L. Dawson, D.O. Dixon, R. Lie, Should Sponsors and DSMBs Share Interim Results Across Trials? *Journal of AIDS* 58(5):433-435 (2011).

S.K. Shah, R.D. Truog, F.G. Miller, Death and Legal Fictions, *Journal of Medicine and Ethics* (based on Can We Handle the Truth? Legal Fictions in the Determination of Death, above), 37(12):719-722 (2011).

S.K. Shah, Commentary: The Dangers of Using a Relative Standard for Minimal Risk, *American Journal of Bioethics* 11(6): 22-23 (2011).

S.K. Shah, Franklin G. Miller, Can We Handle the Truth? Legal Fictions in the Determination of Death, *American Journal of Law and Medicine* 36:540-585 (2010).

S.K. Shah, Patricia Zettler, From a Constitutional Right to a Policy of Exceptions: Abigail Alliance and the Future of Access to Experimental Therapy, *Yale Journal of Health Policy, Law, and Ethics* 10(1):135-196 (2010).

S.K. Shah, D. Wendler, Interpretation of the Subjects' Condition Requirement: A Legal Perspective, *Journal of Law, Medicine, and Ethics* 38(2):365-373 (2010).

S. Shah, S. Elmer, C. Grady, Planning for Posttrial Access to Antiretroviral Treatment for Research Participants in Developing Countries, *American Journal of Public Health* 99(9): 1-6 (2009).

R. Wolitz, E. Emanuel, **S. Shah**, Rethinking the Responsiveness Requirement for International Research, *Lancet* 374(9692):847-9 (2009).

S.K. Shah, How Lethal Injection Reform Constitutes Impermissible Research on Prisoners, *American Criminal Law Review* 45:1101-47 (2008) (cited in Matt McCarthy, What's the Best Way to Execute Someone? *Slate Magazine* (March 27, 2014)).

S. Shah, Beyond Barriers: A Surprising Lesson about the Complexity of Culture, Organizational Ethics: Healthcare, Business, and Policy, 3(1) (2006).

D. Wendler, **S. Shah**, How Can Medical Training and Informed Consent be Reconciled with Volume-Outcome Data? Journal of Clinical Ethics 17:149 (2006).

A. Whittle, **S. Shah**, B. Wilfond, G. Gensler, D. Wendler, Institutional Review Board Practices Regarding Assent in Pediatric Research, Pediatrics 113(1747) (2004).

S. Shah, A. Whittle, B. Wilfond, G. Gensler, D. Wendler, How Do Institutional Review Boards Apply the Risk and Benefit Standards for Pediatric Research? JAMA 291(476) (2004).

D. Wendler, **S. Shah**, Should Children Decide Whether they are Enrolled in Non-Beneficial Research?, American Journal of Bioethics 3(4): 1-7 (2004).

D. Wendler, **S. Shah**, A. Whittle, B. Wilfond, Non-Beneficial Research with Individuals Who Cannot Consent: Is it Ethically Better to Enroll Healthy or Affected Individuals?, IRB 25(1) (2003).

S. Shah, The “Subject’s Condition Requirement”: Unjustified Exceptionalism in the Federal Regulations, The Legal Brief, American Society for Bioethics and Humanities Exchange 6(5) (2003).

S. Shah, Transplantation Ethics Book Review, Progress in Transplantation 11(298) (2001).

H. Forster, **S. Shah**, Legal Trends in Bioethics, Journal of Clinical Ethics 12(319) (2001).

M. Forzley, H. Forster, **S. Shah**, E. Howe, International Health Law, International Law 35(713) (2001).

BOOKS

M. Danis, E. Largent, D. Wendler, S.C. Hull, **S.K. Shah**, J. Millum, B. Berkman, C. Grady, Research Ethics Consultation: A casebook, New York: Oxford University Press, 2012.

BOOK CHAPTERS

S.K. Shah, Outsourcing Ethical Obligations: Should the Revised Common Rule Address the Responsibilities of Investigators and Sponsors?, Chapter 8 (based on Outsourcing Ethical Obligations: Should the Revised Common Rule Address the Responsibilities of Investigators and Sponsors? J. Law, Medicine and Ethics 2013, above) in Human Subjects Research Regulation: Perspectives on the Future, I. Glenn Cohen and Holly F. Lynch, eds., MIT Press, 127-142 (2014).

S.K. Shah, F.G. Miller, R.D. Truog, Legal Fictions Approach to Organ Donation, Chapter 7 (based on Can We Handle the Truth? Legal Fictions in the Determination of Death, above) in Death, Dying, and Organ Transplantation: Reconstructing Medical Ethics at the End of Life, New York: Oxford University Press, 153-171 (2011).

A. Rid, **S. Shah**. Fernando Meirelles' The Constant Gardener: Introducing the ethics of international research, in The Picture of Health: Medical Ethics and the Movies, Henri Colt et al. (eds.), New York: Oxford University Press (2011).

CORRESPONDENCE

S.K. Shah, Deborah Persaud, David S. Wendler, Holly A. Taylor, Hannah Gay, Mariana Kruger, Christine Grady, Research on very early ART in neonates at risk of HIV infection, *Lancet Infectious Diseases* 14 (9):797 (2014).

S.K. Shah, C. Grady, When to Start ART in Africa, *New England Journal of Medicine* 2013;368:2238.

S.K. Shah, C. Grady, Shah and Grady Respond, *American Journal of Public Health* 100(6): 967 (June 2010).

TEACHING INTERESTS

Bioethics, International Research Ethics, Health Care Law, Global Health

AWARDS AND HONORS

National Institutes of Health Clinical Center Director's Award for Teaching and Training	2013
Finalist, Mark S. Ehrenreich Prize in Healthcare Ethics Research	2012
<i>Pro bono</i> distinction from Stanford Law School	2005
Outstanding Witness Award, Mock Trial competition	2000

BOARDS AND MEMBERSHIPS

Current

Ethics Consultant, Clinical Sciences Review Committee
Attending, Bioethics Consult Service, Clinical Center, NIH
Member, Clinical Center Ethics Committee
Member, American Society of Bioethics and Humanities
Member, American Bar Association
Member, International Association of Bioethics

Past

Member, International Bioethics Subcommittee, Extramural Scientific Program Management Committee, NIH

BAR ADMISSION

2005 Admitted to California State Bar

SELECTED PRESENTATIONS

- June 2014 American Society of Law, Medicine, and Ethics Health Law Professors' Conference, U.C. Hastings College of Law, San Francisco, CA—"Brain Death and the Limits of Legal Fictions."
- June 2014 International Association of Bioethics (IAB) Conference, Mexico City—"Responsiveness & Social Value," in Symposium on *The Social Value of Research: Conflicts between Science, Society, and Individuals*.
- December 2013 International Symposium on Brain Death and Disorders of Consciousness, Definition of Death Network of IAB, Havana, Cuba—"A legal fictions approach to organ transplantation from brain dead donors."
- November 2013 Pan American Health Organization, World Health Organization, Washington, DC, USA—"Ethical trade-offs in trial design."
- May 2013 NIAID, Workshop on Tuberculosis in Children and Pregnant Women, Bethesda, MD—"Towards Earlier Ethical Involvement of Children in Trials of New Tuberculosis Drugs."
- May 2013 International Maternal Pediatric Adolescent Clinical Trials Network Annual Meeting, Washington, DC—"An ethical path to curing HIV in children?"
- June 2012 IAB Meeting, Rotterdam, Netherlands—"Is Pediatric Research Legally Unsound?"
- June 2012 IAB Meeting, Rotterdam, Netherlands—"The Future Targets of Bioethics: Institutions in Research Ethics?"
- December 2011 Post-Trial Access to Trial Drugs: Legal, ethical, and practical issues, Brocher Foundation, Geneva, Switzerland—"The Responsible Termination of Research."
- October 2011 American Society of Bioethics and Humanities Meeting, Minneapolis, MN—"Data on Compensation for Research Related Injury: How much will it cost?"
- June 2011 Bowie State University, Bowie, MD—"The Ethics of Pediatric Research."
- July 2010 Fogarty Scholars' Meeting, Bethesda, MD—"The Responsiveness Requirement."

- June 2010 IAB Meeting, Singapore—"The Responsiveness Requirement."
- June 2009 FDA Center for Drug Evaluation and Research, Annual Meeting, Bethesda, MD—"A Legal or Ethical Right to Access Unapproved Therapy?"

WORKSHOPS/TRAINING ACTIVITIES

- 2007-present Organize, moderate, and present at "Advanced Research Ethics Workshop" at Annual Professional Responsibility in Medicine & Research (PRIM&R) conference.
- 2006-present Teach individual classes and lead training sessions at the National Institutes of Health, including: Clinical Center Ethical & Regulatory Aspects of Human Subjects Research, Department of Bioethics Seminar on Introductory Bioethics, and Division of AIDS ethics workshops.
- 2006-present International workshops on research ethics for health researchers, ethics committee members, and government officials in countries including China, Mali, Vietnam, Philippines, Singapore, Peru, Indonesia, Japan.