

## SHARONA HOFFMAN

Case Western Reserve University School of Law  
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### LAW SCHOOL FACULTY POSITIONS

- 1999-Present **Case Western Reserve University School of Law**, Cleveland, OH  
**Assistant Professor 1999-2003, Associate Professor 2003-2005, Professor 2005-present**  
**Associate Dean for Academic Affairs, 2006-2007; Senior Associate Dean 2007-2009**  
Co-Director, Law-Medicine Center 2006-present, Associate Director 2005-06  
Secondary appointment: Professor of Bioethics, School of Medicine  
Courses: Civil Procedure; Employment Discrimination; Health Care and the Courts Seminar; Health Care and Human Rights Seminar; Religion, Ethics, and Law Seminar, Health Matrix Notes Seminar, Perspectives on Law and Biomedicine
- 2003 **Senior Fellow: University of Melbourne**, Melbourne, Australia  
Course: "Health Care and Human Rights," July 2003

### EDUCATION

#### Wellesley College

B.A. with Honors in English Literature, *Magna Cum Laude*, 1985  
Phi Beta Kappa  
Wellesley College Trustee Scholarship  
Margaret Freeman Bowers Fellowship  
Youngren Award in Critical Reading

#### Harvard Law School

J.D., *Cum Laude*, 1988

#### University of Houston Law Center

LL.M. in Health Law, 1999  
American Association of University Women Career Development Grant, 1998-99  
Winner of 1999 Epstein, Becker & Green Health Law Writing Competition

### SIGNIFICANT PROFESSIONAL APPOINTMENTS

- 2007 **Guest Researcher: Centers for Disease Control and Prevention (CDC)**, Atlanta, GA  
Worked with the Public Health Law Program, January – April 2007 (unpaid position during sabbatical).
- 2007 **Committee Member: Institute of Medicine**  
Served on the Committee on Research Priorities in Emergency Preparedness and Response for the Public Health System. The Committee was responsible for identifying short-term (3-5

year) research priorities for public health schools, designed to improve public health emergency preparedness.

2008 **Member: Board of Scientific Counselors for CDC Coordinating Office for Terrorism Preparedness and Emergency Response.**

Appointed by Secretary of Health and Human Services Michael Leavitt for the term 2008-2012

## **ADDITIONAL EMPLOYMENT EXPERIENCE**

1992-98 **Senior Trial Attorney: Equal Employment Opportunity Commission, Houston, TX**

Litigated civil rights employment discrimination cases (including trials) involving claims under the Americans with Disabilities Act, Title VII of the Civil Rights Act, Age Discrimination in Employment Act, and Equal Pay Act.

1989-92 **Associate: O'Melveny & Myers, Los Angeles, CA**

Member of the litigation section. Assignments included drafting motions, court appearances, attending depositions, and responding to discovery. Drafted portions of two briefs filed in the United States Supreme Court. Assigned to civil and criminal aspects of the Exxon Valdez oil spill case. Conducted extensive trial preparation including discovery and witness interviews.

1988-89 **Judicial Law Clerk: Chief Judge Douglas W. Hillman, United States District Court for the Western District of Michigan, Grand Rapids, Michigan**

Drafted bench memoranda, opinions, and findings of fact and conclusions of law. Advised and assisted judge in court during motion hearings, civil and criminal trials, jury charge conferences, and sentencing hearings.

## **AWARDS AND HONORS**

2000-2001 Case Western Reserve University Glennan Fellowship

2002 Recipient of National Endowment for Humanities grant to participate in summer seminar on "Justice, Equality, and the Challenge of Disability"

2004 Recipient of grant to participate in the Case Learning Fellows Program, Case Western Reserve University

2005 Case Western Reserve University Spotlight Series Prize for Women's Scholarship

## **MAJOR ACADEMIC PUBLICATIONS**

“E-Health Hazards: Provider Liability and Electronic Health Record Systems,” *Berkeley Technology Law Journal* (with Andy Podgurski forthcoming 2010).

“Preparing for Disaster: Protecting the Most Vulnerable in Emergencies,” 42 *UC Davis Law Review* 1491 (2009)

“Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems” 22 *Harvard Journal of Law & Technology* 103 (2008) (with Andy Podgurski). Reprinted in 9 *Telehealth Law* 53 (June 2009).

“Responders’ Responsibility: Liability and Immunity in Public Health Emergencies,” 96 *Georgetown Law Journal* 1913 (2008)

“Settling the Matter: Does Title I of the ADA Work?” 59 *Alabama Law Review* 305 (2008)

“Securing the HIPAA Security Rule,” 10 *Journal of Internet Law* 1 (February 2007) (with Andy Podgurski)

“In Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information,” 48 *Boston College Law Review* 331 (2007) (with Andy Podgurski)

“‘Racially-Tailored’ Medicine Unraveled” 55 *American University Law Review* 395 (2005)

“The Suitability of IRB Liability,” 67 *University of Pittsburgh Law Review* 365 (2005) (with Jessica Wilen Berg)

“Is There A Place for Race As A Legal Concept?” 36 *Arizona State University Law Journal* 1093 (2004) (lead article)

“Birth After Death: Perpetuities & The New Reproductive Technologies,” 38 *Georgia Law Review* 575 (2004) (with Andrew P. Morriss)

“Corrective Justice and Title I of the ADA,” 52 *American University Law Review* 1213 (2003)

“Unmanaged Care: Towards Moral Fairness in Health Care Coverage,” 78 *Indiana Law Journal* 659 (2003)

“AIDS Caps, Contraceptive Coverage, and the Law: An Analysis of the Federal Anti-Discrimination Statutes’ Applicability to Health Insurance,” 23 *Cardozo Law Review* 1315 (2002)

“Continued Concern: Human Subject Protection, the IRB, and Continuing Review,” 68 *Tennessee Law Review* 725 (2001) (lead article)

“Preplacement Examinations and Job-Relatedness: How to Enhance Privacy and Diminish Discrimination in the Workplace,” 49 *Kansas Law Review* 517 (2001)

“The Use of Placebos in Clinical Trials: Responsible Research or Unethical Practice?” 33 *Connecticut Law Review* 449 (2001)

“Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials,” 33 *Indiana Law Review* 475 (2000)

“A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments,” 78 *Oregon Law Review* 203 (1999)

“Genetic Testing, Genetic Medicine, and Managed Care,” 34 *Wake Forest Law Review* 849 (1999) (with Mark A. Rothstein)

“Pre-Employment Examinations and the Americans with Disabilities Act: How Best to Avoid Liability under Federal Law,” 8 *Journal of Occupational Rehabilitation* 255 (1998) (with Glenn Pransky)

“First, Do No Harm: Why Doctors Are Not Omnipotent Under the Americans With Disabilities Act,” 14 *Hofstra Labor Law Journal* 151 (1996)

“Mandatory Arbitration: Alternative Dispute Resolution or Coercive Dispute Suppression?” 17 *Berkeley Journal of Employment and Labor Law* 131 (1996)

“The After-Acquired Evidence Rule: The Best of All Possible Worlds?” 22 *Employee Relations Law Journal* 79 (1996)

“Criminal Sanctions in Accidental Oil Spill Cases - Punishment Without A Crime,” 71 *Nebraska Law Review* 1033 (1992). Reprinted in 2 *Environmental Law Anthology* (1992-1993)

## **BOOK CHAPTERS**

“Electronic Health Information Security and Privacy,” HARBORING DATA: INFORMATION SECURITY, LAW AND THE CORPORATION, (Stanford University Press, forthcoming September 2009) (with Andy Podgurski)

“Health Care in the United States: A Matter of Right or Privilege?” HEALTH CAPITAL AND SUSTAINABLE SOCIOECONOMIC DEVELOPMENT (Taylor & Francis 2008)

## **OTHER**

“Why Electronic Health Record Systems Require Safety Regulation,” *Bioethics Forum*, (3/20/09) (with Andy Podgurski) available at <http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=3284>

“Law, Liability, and Public Health Emergencies” 3 *Disaster Medicine and Public Health Preparedness* 117 (2009) (with Richard Goodman and Daniel Stier)

“Title I of the ADA: What We Know and Don’t Know About Its Impact in the Workplace,” 33 *Administrative Law News* (Summer 2008)

Letter to the Editor, 38 *The Hastings Center Report* 8 (Jan-Feb 2008) (discussing the HIPAA Privacy Rule)

“Assessing Competencies for Public Health Emergency Legal Preparedness,” special supplement to

36:1 *Journal Law Medicine & Ethics* 28 (2008) (with others).

“Addressing Privacy Concerns Through the Health Insurance Portability and Accountability Act Privacy Rule,” 7 *American Journal of Bioethics* 48 (March 2007)

“Review of Sofia Gruskin, Michael A. Grodin, George J. Annas, and Stephen P. Marks (eds.), *Perspectives on Health and Human Rights*,” 7 *American Journal of Bioethics* 90 (March-April 2007)

“Health Insecurity: The Vulnerability of Electronic Personal Health Information,” 32 *Administrative Law & Regulatory News* 7 (Spring 2007) (with Andy Podgurski)

“Unmanaged Care: Should there be a Right to Health Care in the United States?” 15 *Legal Medicine Perspectives* 35, May/June 2006

“Protect intent of donor,” opinion piece, *The National Law Journal*, September 6, 2004, reprinted in the *New Jersey Law Journal*, September 13, 2004

“New Reproductive Technologies and the Inheritance Rights of Unborn Children,” 31 *The Journal of Law, Medicine & Ethics* 721 (2003) (with Andrew P. Morriss)

“Intrinsic Conflicts of Interest in Clinical Research,” 13 *Kennedy Institute of Ethics Journal* 83 (2003) (with others)

“Regulating Clinical Research: Informed Consent, Privacy, and IRBs,” 31 *Capital University Law Review* 71 (2003) (solicited symposium piece)

“Actuarial Fairness vs. Moral Fairness in Health Insurance,” *Law and Bioethics Report*, published by the Institute for Bioethics, Health Policy and Law of the University of Louisville, June 2002

“Legislation and Genetic Discrimination,” 16 *Journal of Law and Health* 47 (2001-2002)

“ADA Obligations of Employers,” 42 *South Texas Law Review* 59 (2000) (solicited symposium piece).

“DNA Databanks,” *Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology* 413, eds. Maxwell J. Mehlman & Thomas H. Murray (John Wiley & Sons 2000) (with Paul Giannelli and Wendy Wagner)

“Prisoner Participation in Biomedical Research,” *Health Law News*, June 2000, at 7

“AIDS: Insurance Coverage and the Americans with Disabilities Act,” *The Houston Lawyer*, July/August 1994, at 27, (with Guy Kidd)

“Employer-Mandated Dispute Resolution: Taking a Stand on Coercive Policies,” *Inside Employee Rights Litigation*, November 1996, at 4

## **PRINCIPAL SPEAKING ENGAGEMENTS**

“Establishing Standards of Care for Use in Disaster Situations,” Institute of Medicine, Washington, DC, September 1, 2009.

“2009 Update on Anti-Discrimination Legislation”

- Health Law Professors Conference, June 5, 2009, Cleveland, Ohio
  - AALS Mid-Year Workshop on Work Law, June 11, 2009, Long Beach, California
- “Electronic Health Information Security and Privacy,” Information Security Best Practices 2009 conference, Wharton School, University of Pennsylvania, Philadelphia, PA, January 29, 2009

“Preparing for Disaster: Individuals with Disabilities in Emergencies,”

- Emory School of Public Health, August 12, 2009, Atlanta, Georgia
- Association of American Law Schools 2009 Annual Meeting, San Diego, California, January 9, 2009

“The Impact of Electronic Health Record Systems on Health Disparities,” Association of American Law Schools 2009 Annual Meeting, San Diego, California, January 7, 2009

“HIPAA – What Primary Care Physicians Need to Know,” American College of Legal Medicine Conference, Chicago, IL, September 27, 2008

“Is There Privacy in the American Workplace?” Twenty Fifth Annual Carl A. Warns Jr. Labor & Employment Law Institute, University of Louisville Brandeis School of Law, May 29, 2008

Panelist, “Liability Constraints, Concerns, and Unknowns,” Medical Countermeasures Dispensing: Forum on Medical and Public Health Preparedness for Catastrophic Events, Institute of Medicine, March 4, 2008, Washington, DC

“Is There A Place for Race in Jewish Thought?”

- Park Synagogue, January 29, 2008, Cleveland, Ohio
- Jewish Secular community, October 19, 2007, Cleveland, Ohio
- Beth El – The Heights Synagogue, May 12, 2007, Cleveland, Ohio

“Protecting Data, Protecting Privacy?” Joint Program of Sections on Defamation and Privacy, and Law and Computers, Association of American Law Schools, January 4, 2008, New York, New York.

Panelist, “Back to the Future? The Re-emergence of a Biological Conceptualization of Race,” Toward a Transformative Agenda around Race Conference, Ohio State University, December 2, 2007, Columbus, Ohio

“Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems,”

- Public Affairs Discussion Group, Case Western Reserve University, September 7, 2007
- Health Law Professors Conference, June 7, 2008, Philadelphia, PA
- Annual Meeting of the American Society for Bioethics and Humanities, Cleveland, October 26, 2008
- St. Louis Area Health Law Association, St. Louis, Missouri, September 11, 2009

“Public Health Law and Ethics: Liability and Immunity,” AMA/CDC Second National Congress on Health system Readiness, July 19, 2007, Washington D.C.

“In Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information”

- Health Law Professors Conference, June 1, 2007, Boston, Massachusetts
- University of Florida Levin College of Law, February 22, 2007, Gainesville, Florida

- Computers, Freedom, Privacy Conference, May 23, 2008, New Haven, Connecticut

“Responders Responsibility: Liability and Immunity in Public Health Emergencies,”

- Cities Readiness Initiative Regional Meeting, May 1, 2007, Dallas, Texas
- Kentucky Department for Public Health, May 30, 2008, Frankfort, Kentucky

Panelist, “Clinical Decision Making When Resources Are Scarce: Ethical and Legal Challenges,” sponsored by the University of Virginia and others, Charlottesville, Virginia, April 18, 2007

“Law, Liability, and Public Health Emergencies,” Centers for Disease Control and Prevention, Public Health Law Symposium, April 9, 2007 Atlanta, Georgia

“Racially-Tailored Medicine: Troubled History, Current Controversy,” Georgia State University College of Law public talk, March 14, 2007, Atlanta, Georgia

“HIPAA Security Rule for Electronically Stored Information,” annual conference of the American College of Legal Medicine, March 2, 2007, Orlando, Florida

“‘Racially-Tailored’ Medicine Unraveled”

- Georgia State University College of Law faculty workshop, February 12, 2007, Atlanta, Georgia
- Cleveland Clinic monthly Bioethics Seminar, November 7, 2006, Cleveland, Ohio
- American Society for Bioethics and Humanities Annual Meeting, October 28, 2006, Denver Colorado
- ASLME Health Law Teachers Conference, June 3, 2006, Baltimore, Maryland
- Mather Spotlight Series on Women’s Scholarship Presentation, February 23, 2006, Cleveland, Ohio

“Settling the Matter: Does Title I of the ADA Work?”

- Emory Law School, February 5, 2007, Atlanta, Georgia
- Employment Law Colloquium, Northwestern University School of Law, April 2, 2009

“Privacy Rights and the Electronic Storage of Personal Health Information,” VI World Computer Law Conference, Edinburgh, Scotland, September 7, 2006.

“Essential Health Care Services As A Constitutional Right,” annual conference of the American College of Legal Medicine, March 4, 2006, Las Vegas, Nevada

“New Reproductive Technologies and New Legal Challenges,” ASLME Health Law Teachers Conference, June 4, 2005, Houston, Texas

“Is There A Place for Race As A Medical Concept?” CWRU Department of Genetics and Center for Human Genetics Clinical Genetics Rounds, May 13, 2005, Cleveland, Ohio

“Unmanaged Care: Towards Moral Fairness in Health Care Coverage”

- University of North Dakota, Department of Religion and Philosophy Colloquium Series, Grand Forks, North Dakota, April 28, 2005
- keynote speaker, The Role of Health Care Providers in America, conference sponsored by the Ethics Center of Oklahoma State University, March 13, 2004, Tulsa, Oklahoma

- Association for Practical and Professional Ethics Twelfth Annual Meeting, February 28, 2003, Charlotte, North Carolina
- American Society for Bioethics and Humanities Annual Meeting, October 24, 2002, Baltimore, Maryland
- Health Law Teachers Conference, June 7, 2002, Indianapolis, Indiana
- Michigan State University-Detroit College of Law, March 28, 2002, East Lansing, Michigan

“Is There A Place for Race As A Legal Concept?”

- Public Affairs Discussion Group, Case Western Reserve University, April 1, 2005, Cleveland, Ohio
- Annual Law and Society Conference, May 29, 2004, Chicago, Illinois

“How to Write An Effective Informed Consent Form,” MetroHealth Hospital, November 10, 2004, Cleveland, Ohio

“Suing Institutional Review Boards: A New Way to Protect Subjects?” American Society for Bioethics and Humanities Annual Meeting, October 30, 2004, Philadelphia, Pennsylvania

“The Regulation of Clinical Research and the Role of the IRB” and “Discrimination in Insurance and Employment,” American College of Legal Medicine Cancer and the Law Conference, October 2, 2004, New Orleans, Louisiana

“Current Issues Under the ADA,” Carl A. Warns Jr., Labor and Employment Law Institute, Louis D. Brandeis School of Law, June 11, 2004, Louisville, Kentucky

“IRB Liability,” Health Law Teachers Conference, June 5, 2004, Newark, New Jersey

“Institutional Review Board (IRB) Liability Issues,” American College of Legal Medicine Annual Conference, March 7, 2004, Las Vegas, Nevada

“Institutional Review Boards and You,” AALS Annual Meeting, January 5, 2004, Atlanta, Georgia

“Americans with Disabilities Act and Medical Practice,” Cleveland Bar Association Health Law Section, October 15, 2003, Cleveland, Ohio

“Moral Fairness in Health Care Coverage,” Gheens Bioethics Lecture, University of Louisville School of Medicine Institute for Bioethics, Health Policy, and Law, October 3, 2003, Louisville, Kentucky

“How to Successfully Pursue an ADA Claim,” Cleveland Employment Lawyers Association seminar, September 19, 2003, Cleveland, Ohio

“Corrective Justice and Title I of the ADA,” Annual Health Law Teachers Conference, June 7, 2003, Wilmington, Delaware

“Disability Rights in the Workplace: Are They Really Protected?” CWRU Alumni Weekend Law-Medicine Symposium, May 31, 2003, Cleveland, Ohio

“The ADA: What Works and What Doesn’t,” Case Western Reserve University Public Affairs Forum,

November 1, 2002, Cleveland, Ohio

“The Use of Placebos in Clinical Trials: Responsible Research or Unethical Practice?”

- Conference on Value Inquiry, April 6, 2002, Milwaukee, Wisconsin
- American College of Legal Medicine Annual Conference, March 10, 2001, Atlanta, Georgia
- ASLME Annual Health Law Teachers Conference, June 8, 2000, Cleveland, Ohio
- Case Western Reserve University Center for Biomedical Ethics Conversations in Bioethics Presentation, February 3, 2000, Cleveland, Ohio

“Remember that You Were Slaves in Egypt: Employment Relations in Jewish and American Law,” Congregation Beth El - The Heights, February 9, 2002, Cleveland, Ohio

“Americans with Disabilities Act, How Does It Affect Your Practice?” Hillcrest Hospital Grand Rounds Forum, January 29, 2002, Cleveland Ohio

“Laws Addressing Genetic Discrimination,” Is there a Pink Slip in Your Genes: Genetic Discrimination in Employment and in Health Insurance, Cleveland-Marshall College of Law, December 7, 2001, Cleveland, Ohio

“Regulating Research: Informed Consent, Privacy, and the IRB,” Sullivan Lecture Bioethics Symposium, Capital Law School, October 19, 2001, Columbus, Ohio

“Continuing Concern: IRBs and Continuing Review,” American Society of Law, Medicine & Ethics Annual Health Law Teachers Conference, June 1, 2001, Boston, Massachusetts

“ADA Obligations of Legal Employers,” The Learning Disabled Lawyer: An Examination of the Implications for the Law Student, the Law School, the Legal Employer, the Client, and the Legal Profession, South Texas Law Review Symposium, September 8, 2000, Houston, Texas

“Religion in the Workplace,” Cleveland College of Jewish Studies Midrasha Program, May 15, 2000, Cleveland, Ohio

“Prisoner Participation in Clinical Trials” and “Genetic Discrimination,” University of Texas Health Science Center Conference on Privacy and Confidentiality in Clinical and Social Science Research, February 10, 2000, Houston, Texas. Served on the planning committee for this conference.

“Insurance Coverage for Experimental and Investigational Treatments,” Cleveland Clinic Foundation Bioethics Grand Rounds Presentation, December 13, 1999, Cleveland, Ohio

“Your Employee Rights: What Patients & Survivors Need to Know,” MD Anderson Cancer Center Living Fully with Cancer patient conference, September 25, 1999, Houston, Texas

“The Economics of Modern Health Care - Genetics Factor,” National Conference of State Legislatures Genetics Seminar, May 27, 1999, Lake Tahoe, Nevada

## **BAR ADMISSIONS**

State Bar of California – 1988 (inactive)  
District of Columbia - 1990  
U. S. Court of Appeals - Ninth Circuit - 1990  
U. S. District Court - Southern District of Texas - 1992  
U.S. District Court - Central District of California -1989

## **LAW SCHOOL SERVICE**

Curriculum Committee, 2006-present  
Honor Code Revision Committee, 2007-08  
Graduate & Foreign Legal Studies Committee, 2007-08  
*Chair, Dean Search Committee, 2005-06*  
Building Committee, 2003-2004, 2004-05  
Library & Computers Committee, 2003-04, 2004-05  
Rankings Advisory Committee, 2003-2004  
Faculty Advisor to Health Matrix: Journal of Law Medicine, 2003-04, 2007-08  
Sponsoring Faculty of the Health Law Concentration, Spring 2004  
Guest Editor, Health Matrix, Volume 11, Issue 2.  
Appointments Committee, 2000-2001  
Admissions Committee, 2001-2003  
Law School Community Committee, 1999-2000, 2002-2003

## **UNIVERSITY SERVICE**

Deans' Council Member, 2006-present  
University-wide Women's Faculty Committee, 2003-2006, Chair, 2004-2006  
UCITE Advisory Committee, 2004-present  
MetroHealth Institutional Review Board, member, 2000-2006  
Review proposed research protocols to ascertain compliance with federal regulations and safeguard the welfare of human subjects.  
University Hospitals Ethics Committee, member, 2003-present  
Case Western Reserve University Center for AIDS Research Working Group, Member 1999-present  
The Center for Child Health and Policy at Rainbow Babies & Children's Hospital, Member 2008-present

## **COMMUNITY SERVICE AND ORGANIZATION MEMBERSHIPS**

Member, Board of Directors, Public Health Law Association, 2009-2010  
Chair, ad hoc workgroup to review fiscal allocation process for CDC Coordinating Office for Terrorism Preparedness and Emergency Response, February 25-27, 2009.  
Peer reviewer of grant proposals, for CDC program entitled: "Preparedness and Emergency Response Research Centers: A Public Health Systems Approach," July 7-9, 2008.  
Health Law Scholars Selection Committee – 2002-2008  
Association of American Law Schools, Employment Discrimination Section Executive Committee – 2003-2006  
American Society for Bioethics and Humanities, Member – 2002-present  
Employment and Recruitment Task Force – 2004-2005  
Anti-Defamation League, Board Member, 1996-2006; Regional Vice Chair, 2002-2005  
Cleveland Hillel Foundation, Trustee, 2001-2004; Executive Committee Member, 2002-2003  
American Bar Association, Member - 1999-present

American Society of Law, Medicine & Ethics, Member - 1999-present

Houston Bar Association

Labor and Employment Law Section

Council Member - 1995-98

Treasurer - 1996-97

Secretary - 1997-98

Editorial Board, *Inside Employee Rights Litigation*, published monthly by John Wiley & Sons, Inc., 1996-98

A.A. White American Inn of Court, University of Houston, Barrister Member, 1997-98

University of Texas Health Science Center Committee for Protection of Human Subjects, 1998-99

Reviewed proposed research protocols to ascertain compliance with federal regulations and safeguard the welfare of human subjects