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David Gordon Holt, J.D., CIP

Work Experience

 Director

 2003– 2013 Research Subject Protection Office (RSPO) Portland, OR

 Kaiser Permanente, Northwest Region

 Center for Health Research

* Provides region-wide leadership on all issues pertaining to inclusion and protection of KPNW membership related to research
* Directs and leads Human Research Subject Protection Program
* Develops and implements compliance policies and procedures
* Manages RSPO staff and compliance program
* Member of Center for Health Research Leadership Team (Senior Management)
* Member of Center for Health Research Compliance Committee
* Advises the Vice President for Compliance, research investigators and project managers on bioethics, research subject protection, regulatory compliance and research subject design
* Maintains effective collaborative working relationships with key stakeholders, departmental directors, government officials, employees, and researchers
* Headed project team and implemented web-based, automated research study review process
* Chaired Kaiser Permanente NW, Center for Health Research Diversity Committee

 Chair

2004 – current State of Oregon/Multnomah County Portland, OR

Institutional Review Board

 Oregon Health Authority

* Reviews all human research projects under the auspices of the Oregon Health Authority and the Multnomah County Health Department

 Member

 2003-2005 Oregon Governor’s Advisory Committee Portland, OR

 on Genetic Privacy and Research (ACGPR)

* Gave testimony to Oregon State Senate Committee on Genetic Privacy (2005)
* Contributed to committee recommendations for Oregon Genetic Privacy Law

 Director

 2001 – 2003 Office of Human Research Protection Sacramento, CA

 University of California, Davis

 Office of the Vice Chancellor for Research

* Directed all aspects of UC Davis Human Subjects Protection Program
* Liaised with federal government concerning regulatory issues
* Advised IRB, Vice Chancellor for Research, and other institutional

officials on legal, regulatory and ethical aspects of research

* Coordinated with other UC campuses regarding Human Research Protection policies
* Administered Office of Human Research Protection

Compliance Officer

 1999 - 2001 Institutional Review Board Columbia, MO

 University of Missouri Health Sciences Division

* Counseled investigators on legal, ethical, and regulatory aspects of

 biomedical research

* Monitored developments in case law and legislation
* Drafted policy and regulatory documents
* Reviewed and approved selected categories of research
* Managed and administered Institutional Review Board Office

Law Clerk

 1998 Office of State Public Defender Columbia, MO

* Prepared legal briefs for appellate actions
* Performed specialized legal research on constitutional issues
* Drafted various motions, pleadings, and responding memoranda
* Interviewed witnesses and assisted in investigations

Law Clerk

 1997 Steven Faber & Associates Columbia, MO

* Prepared documents involving litigation process
* Drafted legal correspondence with clients
* Performed filing, copying, word processing, and administrative tasks
* Acted as liaison between courts and law office

Managing Director

 1985 - 1994 Holt Stationers, PTY. LTD. Melbourne, Australia

* Managed finances for operation with net turnover of over

 $5 million per year

* Negotiated and executed multiple vendor contracts
* Managed complete staff of 25
* Supervised sales team of 5 full-time sales representatives
* Directed marketing operations
* Managed customer service and warehouse distribution

Education

 Juris Doctor

 1996 - 1999 University of Missouri School of Law Columbia, MO

* International Law Society
* Missouri Equal Justice Foundation

Bachelor of Arts, History

 1994 - 1995 University of Memphis Memphis, TN

* Graduated Cum Laude
* Journalist, University of Memphis newspaper

Bachelor of Arts, Political Science

 1982 - 1985 Swinburne University Melbourne, Australia

* Editor, Swinburne University newspaper

Presentations

And Educational

Seminars

* Conflict of Interest in Research, Kaiser Permanente NW IRB - Seminar, 2012
* Coercion and Undue Influence in Research, Kaiser Permanente NW IRB -Seminar , 2012
* Creating a Research Compliance Program and Feedback Loop

Kaiser Permanente National IRB Conference, San Francisco, CA 2011

* Speaker , American Thoracic Society at North American Annual Convention, Toronto, Canada 2006
* Issues in Human Subject Research, New Faculty Orientation Group,

 UC Davis School of Medicine, October 2002

* Human Subject Research and the IRB Process, Department of Epidemiology, UC Davis, School of Medicine, September 2001
* Human Subjects Protections, the IRB Process, and Informed Consent,

 all research staff - UMC, September 2000

* The Informed Consent Process, Department of Community and Family Medicine - UMC, June 2000
* IRB Review Process and Ethical Problems, Department of Community

 and Family Medicine – UMC, May 2000

* Issues in Research Ethics, Missouri Institute of Mental Health - St. Louis,

 UMC, May 2000

* IRB Review Process and Informed Consent, UMC Health Sciences

 Center Staff, March 2000

* IRB Fundamentals, Department of Obstetrics and Gynecology - UMC,

 January 2000

Professional Memberships and Affiliations

* PRIM&R Certified IRB Professional (CIP) current
* Public Responsibility in Medicine & Research, (PRIM&R)
* Applied Research Ethics National Association, (ARENA)
* Clinical Research Oversight Committee, UC Davis School of Medicine
* HIPAA Compliance Oversight Committee, UC Davis School of Medicine
* Task Force on Research Injuries Compensation Policies, University of California, Office of the President

Professional

Development And Continuing Education

* Kaiser Foundation Research Institute Annual National Conference, 2003 -2012
* PRIM&R/ARENA National Convention, November 2000 - 2010
* Portland State University, Project Management Series - 2008
* University of California System-wide Conference on Human Subject

 Protections, UCLA, August 2002

* Advanced Investigative Techniques Workshop, Federal Office of Research

 Integrity, NIH Campus at Bethesda, March 2002

* University of California System-wide Conference on Human Subject

 Protections, UC Irvine, July 2001

* NIH Conference on Conflict of Interest, NIH Campus at Bethesda,

 August 2000

* NCI Conference on Central IRB Pilot Project, National Cancer Institute,

 May 2000

* Human Subjects Research and IRB’s Under Fire, Temple

 University/Western Pennsylvania Hospital, April 2000

* Balancing the Belmont, Michigan State University/OPRR, November 1999

Professional

Achievements

* Headed project and implemented inter-regional national expansion of web-based review process (2012)
* Headed project team and implemented web-based, automated research study review process (2010)
* Recipient, Kaiser Permanente National Diversity Award (2008)
* Chair, Center for Health Research Diversity Committee (2003 – 2008)
* Coordinated successful grant application for NIH Educational Enhancement Grant, October 2002
* Facilitation of favorable FDA Audit, July 2002
* Implemented comprehensive database for Office of Human Research Protections, June 2002
* Facilitation of favorable FDA Audit, August 2000
* Recruitment for and creation of two separate Institutional Review Boards, UMC, March 2000
* Facilitation of merger between Columbia Regional Hospital IRB and UMC Health Sciences IRB, January 2000
* Negotiation of New Multiple Project Assurance, July 1999