

PAUL WILLIAM NEWTON, JD, CIP

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EDUCATION AND PROFESSIONAL TRAINING

Certified IRB Professional (CIP) ☐ Certification: 2006, 2012 and 2015

Licensed Attorney in Oregon ☐ 1989

Santa Clara University School of Law, Santa Clara, CA ☐ 1987 Juris Doctor

Portland State University, Portland, OR ☐ 1982 Bachelor of Science in History

PROFESSIONAL EXPERIENCE

New England IRB: Needham, MA ☐ **Board Member** ☐ **July 2018 to present**

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

Innovations for Poverty Action (IPA) IRB: New Haven, CT ☐ **Board Member** ☐ **June 2017 to present**

Board Member and Prisoner Representative for human subject research for medical and behavioral research for private researchers and institutional clients.

Yale IRB: New Haven, CT ☐ **Consultant** ☐ **December 2016 to present; IRB Member 2018 to present**

Regulatory, ethics and compliance consultant regarding human subject research for Yale University IRB.

Hummingbird IRB: Cambridge, MA ☐ **Board Member** ☐ **February 2016 to present**

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

IPSL, LLC IRB: Portland, OR ☐ **Board Member** ☐ **2013 to present**

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

IPSL, LLC IRB: Portland, OR ☐ **General Counsel** ☐ **2013 to present**

General Counsel/Compliance Officer for international service-learning company, specializing in international programs for students and researchers, research, contracts, program development.

Legacy Research Institute: Portland, OR ☐ **Research Regulatory Specialist Sr.** ☐ **2014 to present**

Regulatory, Ethics and Compliance specialist for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

Oregon Health & Science University IRB: Portland, OR ☐ **Board Member** ☐ **2014 to present**

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

Portland State University IRB: Portland, OR ☐ **Board Member** ☐ **2014 to 2017**

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

Western Institutional Review Board: Olympia, WA ☐ **Regulatory Counsel/IRB Chair** ☐ **2005 to 2014**

Regulatory, Ethics and Compliance counsel for human subject research for medical and pharmaceutical research, private industry, Department of Defense, and institutional clients.

Legacy Research Institute: Portland, OR □ Board Member □ 2004 to 2005

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

Oregon Health & Science University IRB: Portland, OR □ Board Member □ 2001 to 2005

Board Member, Expedited Reviewer and Prisoner Representative for human subject research for medical, pharmaceutical and behavioral research for private researchers and institutional clients.

Oregon Health Division Institutional Review Board □ IRB Chair □ 1997 to 2005

IRB Chair for review of county/state-wide research involving populations of prisoners, juveniles involved in court, persons in treatment through probation and parole programs, and persons involved in domestic violence relationships.

Metropolitan Public Defender Inc: Portland, OR □ Staff/Supervising Attorney □ 1990 to 2005

Staff attorney/Legal representation of indigent litigants charged with misdemeanor and felony crimes, court and jury trials, legal research and writing, and appeals. Management positions include management of office, staff supervision and evaluations, recommendations for rotations, discipline, and promotion.

Presiding Court/Multnomah County Courthouse: Portland, OR □ Administrative/Judicial Law Clerk □ 1988 to 1990

Administrative Management of Presiding Court Chambers, case management and problem-solving of court dockets, use of court database, legal research and writing, processing of legal orders and documentation, development and implementation of Presiding Court policy and procedures; periodic review and revision of local court rules.

Joint Enterprise for Aerospace Research and Technology Transfer: Santa Clara, CA. □ Law Clerk □ March 1987 to June 1987

Law Clerk and Administrative Assistant to Enterprise Director, contract development and administration, legal research and writing; emphasis upon high technology joint enterprise projects between NASA-Ames Research Center, universities and industry.

NASA-Ames Research Center: Moffett Field, CA □ Research Law Clerk □ 1985-1986

Legal research and writing, drafting documents, assisting litigation counsel; emphasis upon technology transfer, government contracts, torts, internal compliance with NASA regulations and procedures, and litigation support.

LEADERSHIP POSITIONS

Oregon Health Division Institutional Review Board □ IRB Chair, 2003-2005

- IRB Chair for review of county/state-wide research involving populations of prisoners, juveniles involved in court, persons in treatment through probation and parole programs, and persons involved in domestic violence relationships.

IPSL International IRB □ Consultant, 2013-Present

- Regulatory, ethics and compliance consultant regarding human subject research for institutional IRB within IPSL, an international service-learning and advocacy organization.

SKILLS

Law Experience: I have over 20 years of experience in law and litigation, investigation, trials, and appeals.

Compliance and Regulatory: I have extensive experience in regulatory affairs, ethics and compliance, bio-ethics, institutional review board oversight, protection of rights of individuals of human subjects in research, I have special expertise related to client and employee conflicts of interest, protection of privacy and

confidentiality, other issues relating to institutional integrity ethics, honesty and compliance. I also have substantial experience in conducting training for internal staff and for outside presentations at conferences, accreditation classes, and as a guest speaker regarding compliance, regulations, and ethics.

Management and Training: I have over fifteen years of management experience, including supervising attorneys, paralegals, investigators, and compliance specialists. I have had ongoing supervision and training of other professionals (including lawyers, international fellows and institutional review board members).

MEMBERSHIPS AND ACTIVITIES

Bioethicist for DAINIPPON SUMITOMO PHARMA SERB Committee 2007-2012

Member of Providence Medical Ethics Committee 2009-2014

Oregon State Bar Health Law Section 1998-2013

Oregon State Bar Animal Law Section 2012-Present

Oregon Health Division IRB for Multnomah County 1997-2005

Oregon Health Sciences University IRB III 2001-2005; 2014-Present

Legacy Health System Institutional Review Board 2004-2005; 2014-Present

Western Institutional Review Board 2005-2014

Advisory Committee on Genetic Privacy and Research 2004-2005; 2014-Present

Oregon Criminal Defense Lawyers Association 1990-2006

Portland Animal Welfare (PAW) Team Board Member 2013-2015

IPSL, LLC IRB 2014-Present

Portland State University Institutional Review Board 2014-2017

Hummingbird IRB 2016-Present

Yale IRB 2016-Present

IPA IRB 2017-Present

New England IRB 2018-Present

TRAINING ACTIVITIES

- “In’s & Out’s of County Procedures” Motions Practice Seminar, OCDLA Conference, Sept 2000
- “What IRBs Worry About the Most” NW Health Conference Summer 2004
- “Mandatory Reporting Issues for Scientific Research” OHD IRB Summer 2004
- “Confidential Information & Breaches” OHD IRB Summer 2004
- “Triggering Certificates of Confidentiality” WIRB Spring Conference Spring 2006
- “Inventors, Institutions, and Interests: Is there a Conflict?” FDA Device Conference Summer 2006
- “The Role of the IRB in the Life Cycle of a Clinical Study” UW Biomed Regulatory Fall 2006, 2007
- “The Ethics of “Finding” Lost Subjects – Subject Locator Services”, WIRB In-House Training, 2008
- CIP Course Training (Various topics), WIRB In-House Training, 2006-2012
- WIRB International Fellows Training (Various topics), 2007-2012
- “Encouraging Advocacy Research: Resolving Practical Problems for the Student Researcher” IPSL London Conference Speaker November 2013
- Middleton Foundation for Ethical Studies – International Fellows Training (Various topics), Fall 2014
- Middleton Foundation for Ethical Studies – International Fellows Training (Various topics), Spring/Fall 2015
- “Federal Regulations and Proposed Changes in NPRM”, Legacy Research Institute, CRSS Unit, January 2016
- “New Ethics -- Germline Editing”, Legacy IRB, March 2016
- Middleton Foundation for Ethical Studies – International Fellows Training (Various topics), Spring 2016
- “Criteria for IRB Approval of Research”, Legacy IRB, March 2016
- “Consent Process Evaluation”, Legacy IRB, May 2016

- “Deception in Research”, Legacy IRB, June 2016
- “Consent Processes”, Legacy Research Institute, CRSS Unit, July 2016
- “Medical Devices”, Hummingbird IRB, July 2016
- “Medical Devices”, Legacy IRB, July 2016
- “Drugs”, Legacy IRB, August 2016
- “Waiver of Consent”, Legacy IRB, August 2016
- “Vulnerable Populations”, Legacy IRB, September 2016
- “Prisoners in Research”, Hummingbird IRB, October 2016
- “IRB Radicalism in a New Age”, Portland NWABR Conference – Crossing the I’s, November 2016
- “Ethics of Enhancements”, Legacy IRB, January 2017
- “Access to Treatment:”, Legacy IRB, February 2017
- “Therapeutic Misconception/Equipose”, Legacy IRB, February 2017
- “Assent of Minors”, Legacy IRB, March 2017
- “Social-Behavioral Research”, Legacy IRB, March 2017
- Middleton Foundation for Ethical Studies – International Fellows Training (Various topics), Spring 2017
- “Oregon Law regarding Research”, Legacy IRB, May 2017
- “Mandatory Reporting”, Legacy IRB May, 2017
- “Data Protection Issues”, Legacy IRB June 2017
- “Types of Research”, Legacy IRB September 2017
- “Risks and Benefits of Research”, Legacy IRB September 2017

MISCELLANEOUS ACTIVITIES

- “*A Balancing Act*”, Guest Editor -- The Human-Animal Relationship website, October 10, 2013
- “*The Evolution of Animal Law*”, Guest Editor -- The Human-Animal Relationship website
- “*What would you do? Personal and Community ethics during a disease outbreak*” Co-Facilitator, NWABR Community Conversations, Portland, Oregon February 24, 2015.
- “*From Therapeutic Drug Development to Bike Helmets - The Technology Transfer Pathway at Legacy, OHSU and Providence*”, Conference Panelist, Oregon Bio 2016: The Bioscience Landscape, October 20, 2016
- “*IRB Radicalism in a New Age*”, Speaker, Portland NWABR Conference – Crossing the I’s, November 2016
- “*Progressive Consent and Specimen Accrual Models to Address Sustainability: A Decade’s Experience at an Oregon Biorepository*”, John A. Ost, Paul W. Newton, Duncan R. Neilson, Joseph Cioffi, P. Ashley Wackym, R. Serene Perkins, Legacy Research Institute, Legacy Health, Portland, Oregon USA.; Biopreservation and Biobanking, Volume 15, Number 1, 2017
- “*In the Weeds of Ethics: Legal and Ethical Tensions in Treating Patients with Medical Marijuana*”, Speaker, Legacy Health Spring Ethics Conference: Marijuana Use – Ethical Considerations, Legacy Health, May, 2018
- “*Research Ethics*”, Speaker, Legacy Health Fellowship Ethics Training, Fall, 2018