KINDRA L. COOPER, JD, MPA, MA, CIP

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PERSONAL STATEMENT

I am a regulatory and life sciences attorney currently serving as the IRB Director for Creighton University in Omaha, Nebraska, where I also hold an appointment as an Assistant Clinical Professor in the Department of Medical Humanities. I previously served as an IRB Chairperson for Advarra and as Senior Regulatory Counsel for Quorum Review IRB. I am a Certified IRB Professional (CIP), site visitor (in training) on behalf of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), and a member of the Consortium to Advance Effective Research Oversight (AEREO). My areas of expertise include regulation of medical devices including mobile apps and in-vitro diagnostic devices, eConsent, and the use of End User License Agreements in human subjects research. My research interests include regulation of medical devices, the history of human subjects research protections, research ethics, bioethics, and end-of-life narrative. I am licensed to practice law in the state of Washington.

PROFESSIONAL EXPERIENCE

LAW AND COMPLIANCE

Associate Clinical Professor, Medical Humanities, Creighton University, Omaha, Nebraska, 09/2022 – Present
Prepare course material and teach research ethics courses to graduate and pre-med students.

Institutional Review Board (IRB) Director, Creighton University, Omaha, Nebraska, 08/2021 – Present
Provide senior level guidance to all operational aspects of the University's Institutional Review Board (two separate panels). Conduct annual evaluations of IRB Chairs and Board members. Oversee and/or approve all submissions to determine appropriate level of review (exempt, expedited and full board). Develop, analyze, and implement Creighton University Human Research Protection Policies and Procedures as federal regulations evolve. Monitor federal regulatory websites and other research-related resources to stay current with regulatory changes in human research protections. Manage the Office of Human Subjects Research's electronic database. Audit protocol submissions for accuracy. Maintain and uphold AAHRRP Accreditation. Responsible for complex application processes, metrics of HRPP performance, strategic planning of site visits by accreditors that include preparation and education to university researchers. Maintain Creighton University's Federal Wide Assurance (FWA). Oversee the quality assurance monitoring of the HRPP, including research protocols and investigation of matters of non-compliance. Ensure implementation of corrective action, as needed, in accordance with Creighton IRB policies and procedures as well as external audits conducted by agencies. Provide ongoing education for incoming faculty and students. Develop and present monthly topics and educational outreach for study coordinators (CURE Meetings) and IRB Chairs and members. Facilitate Human Subjects Research training and workshops on a university wide as needed basis.

Institutional Review Board (IRB) Chairperson, Advarra, Seattle, Washington, 03/2019 – 08/2021
Applied knowledge of federal regulations, guidance, and ethical frameworks in order to ensure continuous Review Board compliance with all applicable regulations and AAHRPP accreditation standards. Pre-reviewed new research submissions to assess the appropriate level of review (exempt, expedited, full board) and proactively identify errors, omissions, and potential regulatory concerns. Chaired two IRB meetings per week. Reviewed exempt and expedited research. Reviewed and presented to the board on new protocols, protocol modifications, research misconduct, corrective action plans, and the regulatory status of investigational products. Served as a resource for IRB staff and board members on issues of regulatory compliance, ethics, efficient IRB review, and IRB policy. Consulted with investigators, sponsors, and sponsors' representatives

regarding IRB review and regulatory issues. Interpreted federal regulations and guidance in order to draft internal guidance documents. Remained current with federal regulations and guidance on human research protections. Conducted board member training on complex areas of IRB review. Contributed to thought leadership through publications, webinars, and conference presentations. Provided expert consultation on questions pertaining to IRB review of medical devices under 21 CFR 812.

Senior Regulatory Attorney, Quorum Review IRB, Seattle, Washington, 10/2018-3/2019*
*Note: Advarra IRB purchased Quorum Review IRB on 3/1/2019.
Provided regulatory counsel to the IRB and organization to ensure compliance with federal regulations and AAHRPP accreditation standards. Provided guidance to staff, board members, and clients regarding the application and interpretation of laws, guidance, and ethical frameworks related to human research protections. Collaborated on operational initiatives including implementation of the Revised Common Rule. Developed and implemented changes to IRB policies, guidelines, and standard operating procedures. Assessed research submissions to identify appropriate level of review (exempt, expedited, full board) and potential regulatory issues prior to board review. Monitored changes in applicable laws, guidance, and accreditation standards. Developed and delivered monthly training to the board on evolving regulatory guidance, investigator misconduct, FDA and sponsor audits, and changes to IRB policy. Managed and approved sensitive correspondence to investigators and sponsors. Authored and submitted correspondence to FDA and other regulatory bodies. Interacted with sponsors, CROs, sites, investigators, institutions, agencies, and other organizations on behalf of the company. Provided content for white papers, webinars, blogs, and presentations.

Compliance Officer, LightHeart Psychological Associates, Redmond, Washington, 10/2017 — 10/2018
Developed and implemented privacy and security policies for a multi-location psychotherapy practice. Created guidance materials on Safe Harbor rules, data de-identification, sentinel/adverse events, and HIPAA-appropriate social media. Conducted compliance training for staff and clinicians, annual risk assessments, and audits. Reviewed and drafted Business Associate Agreements. Investigated security incidents. Developed corrective action plans. Served as a resource for staff, clinicians, and graduate students on compliance issues.

Contract Attorney, Law Offices of Jan G. Zager, Mercer Island, Washington, 5/2017 — 11/2017
Law Clerk, Law Offices of Jan G. Zager, Mercer Island, Washington, 12/2015 — 5/2017
Research and litigation support for an elder law, estate planning, and guardianship practice. Advised clients on end-of-life planning and health care decision-making, advance directives, durable and health care powers of attorney and ethical wills. Drafted estate planning documents. Reviewed insurance, medical, law enforcement, and Department of Social and Health Services records. Drafted Special Guardian Ad Litem Reports.

Rule 9 Attorney, UWLS Child and Youth Advocacy Clinic (CYAC), Seattle, Washington, 9/2003 — 6/2004
Represented a caseload of teenage dependency clients. Assisted clients to access social and health services. Authored “Psychotropics 101: What Dependency Practitioners Should Know.” Conducted quarterly staff training on dependency law topics. Authored a clinic manual on immigration law for dependency counsel.

EDUCATION

Master of Arts, Bioethics & Health Policy, Loyola University of Chicago, Chicago, Illinois. 8/2018
Partial tuition scholarship. Coursework in Research Ethics, Pediatric Research Ethics, Biomedical Ethics and the Law, Justice and Healthcare, Bioethics in the Social Sciences, History of Medicine, and Bioethics.

Juris Doctor, University of Washington School of Law, Seattle, Washington. 6/2004.
Winner, Client Counseling Competition. Second-Place Best Speaker, 1L Appellate Advocacy Competition.

Master of Public Administration, The George Washington University, Washington, District of Columbia. 5/2002.
Full tuition scholarship. Pi Alpha Alpha, National Public Administration Honor Society.

Bachelor of Arts, Political Science/Society & Justice, University of Washington, Seattle, Washington. 6/1998.
Full tuition scholarship. Alpha Phi Sigma, National Criminal Justice Honor Society. Cum laude graduate.

PUBLICATIONS

- eConsent (book chapter), IRB Management and Function (3rd edition), Public Responsibility in Medicine and Research (PRIM&R), 02/2021 (first author)
- Mobile Apps and Human Subjects Research (online training module), Collaborative Institutional Training Initiative (CITI), 1/2020 (co-author)
- *Psychotropics 101: What Dependency Practitioners Need to Know*, published by the UW CYAC and taught by the UW School of Social Work, 6/2004.
- *The Lewis and Clark Bicentennial Sourcebook: Federal, State, and Philanthropic Assistance for State and Community Projects*, published by the United States Department of the Interior, 6/2000.
- *Reflecting the Public-Private Divide: Workplace Violence and the United States Forest Service*, Journal of Policy Perspectives, Fall 1999.

INVITED PRESENTATIONS

- *IRB Review of Products with Emergency Use Authorization*. 2022 University of Nebraska Medical Center (UNMC) Protection of Human Subjects Conference, October 28, 2022.
- *Your Guide to sIRB Mandates*. Advarra Live Webinar, September 20, 2022.
- *Remote Technology in Clinical Trials, IRB Considerations*. Northwest Association for Biomedical Research (NWABR) Regional IRB Conference, July 28, 2022.
- *How Do I Consent Thee? Let Me Count the Ways (Documentation of Remote Informed Consent).* Public Responsibility in Medicine and Research (PRIM&R) National Conference, November 17, 2021.
- *Thorny Issues in Medical Device Research*. Advarra Live Webinar, July 2021.
- *IRB Myths: Busted*. Northwest Association for Biomedical Research (NWABR) Regional IRB Conference, May 15, 2019

PROFESSIONAL MEMBERSHIPS & ASSOCIATIONS

- Site Visitor, Association for the Accreditation of Human Research Protection Programs (HRPP)
- Member, Consortium to Advance Effective Research Oversight (AEREO).