# Amy C. Waltz, JD, CIP



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**Professional Experience**

**Areas of Experience**

* Research misconduct regulations and proceedings (42 CFR 93, 45 CFR 689)
* Human subjects protections (45 CFR 46)
* FDA regulations (21 CFR 50, 56, 312 and 812)
* HIPAA/HITECH
* Conflicts of interest (45 CFR 50 and 94)
* Indiana state healthcare laws and regulations
* Contract drafting and negotiating
* Knowledge of several additional areas including, among others: Stark Law, ADA, E-Verify, FERPA, FMLA, Export Controls, Animal Welfare Act

**Research Integrity Office** March 2019 – present

**Indiana University Office of Research Compliance**

***Deputy Research Integrity Officer & Associate Director***

* Receive and track allegations of research misconduct
* Evaluate allegations of research misconduct to determine when allegations warrant inquiries, and sequester evidence when required
* Coordinate, facilitate, and oversee confidential inquiries and investigations into research misconduct allegations in accordance with federal laws and Indiana University policy
* Draft reports to the Vice President for Research detailing research misconduct inquiry and investigation activities, findings, and reasoning on behalf of inquiry and investigation committees
* Provide education to the IU research community regarding identification and reporting of potential research misconduct, as well as strategies for avoiding instances of research misconduct
* Manage daily operations for the Research Integrity Office, including ensuring timely response to allegations, tracking metrics and trends, and reporting to internal stakeholders
* Administer, revise, and implement the Indiana University Policy on Research Misconduct

**Indiana University Robert H. McKinney School of Law** November 2011 – Present ***Adjunct Faculty Member***

* + - Co-instructor for health law course analyzing the issues arising out of life sciences compliance, including conflicts of interest, historical and regulatory background and ethical considerations of human research protection, HIPAA requirements, FDA regulations, and contractual considerations
* Coordinating with several alumni to propose and implement a health care compliance program for the Hall Center for Law & Health and School of Public Health; implementation in progress

**Human Research Protection Program** September 2008 – February 2019

**Indiana University Office of Research Compliance**

***Associate Director****, August 2011 – February 2019*

* Led implementation of revised Federal Policy for the Protection of Human Subjects (Common Rule, effective July 2018) for all Indiana University campuses and its affiliates, including three major hospital systems
	+ Conducted and coordinated analysis of revised Common Rule, including determining potential impacts on investigators, human research protection program staff, KC IRB electronic system, and policies and procedures
	+ Drafted and revised IU Human Research Protection Program (HRPP) policies and procedures
	+ Created and implemented strategic plan for implementation, including strategic decision-making, communication and education to research community, revision of KC IRB electronic system, and revision of policies and procedures
	+ Created and coordinated two advisory committees throughout 2017 and 2018 which provided input into strategic planning
	+ Provided project management to multiple teams of HRPP staff
	+ Facilitated monthly calls throughout 2017 with Big10 Academic Alliance IRB Administrators Group, including a targeted conversation with federal agency representatives
* Oversaw and facilitated IRB reliance collaborations with external institutions
	+ Created and implemented reliance program, including reliance policy, compliance plan, and internal procedures
	+ Oversaw full time staff member in processing and reviewing IRB reliance requests, including providing final approval for reliance arrangements
	+ Drafted and reviewed IRB reliance agreements
	+ Participated in and provided local support for IU’s participation in multiple national consortiums
* Assisted with strategic planning and implementation of the research compliance program for IU and its affiliates
	+ Detected and recognized compliance concerns and vulnerabilities in the conduct of research, then created and implemented strategic plans for addressing concerns, considering relevant regulations and guidance, expectations of federal agencies, and logistical issues
	+ Collaborated with auditors from regulatory agencies such as FDA and the Office of Human Research Protections to coordinate investigations of IRB processes and procedures
	+ Responded to and investigated concerns raised by investigators, staff, and/or regulatory agencies such as FDA and the Office of Human Research Protections
	+ Created, implemented, and managed policies and procedures for ongoing compliance with local and federal laws and guidance, and accreditation standards, including a full review and rewrite of all IU HRPP Policies in 2018
	+ Led and facilitated working groups for consideration of complicated compliance issues, including research with biospecimens (2013-2015), research with individuals lacking consent capacity (2016-2018), community engaged research (2017), informed consent (2018), and return of research results (2019)
	+ Provided regulatory direction and support to the ongoing development and implementation of KC IRB electronic IRB submission and submission management system
	+ Led staff in an implementation of major office reorganization in fall 2011 to address concerns regarding effectiveness and efficiency
* Advised and counseled university and hospital leadership, staff members, research personnel, and faculty members about research compliance and regulatory requirements
	+ Coordinated and provided education on all areas of research compliance to human research protection program staff members, investigators and research community members, and affiliate partners through in-person collaboration, one-on-one counseling, and group presentations

***Assistant Director****, January 2010 – August 2011*

* Provided guidance to research personnel regarding FDA regulations, specifically compliance with human subject protection regulations and determining when/if new drug applications and investigational device exemptions are necessary
* Counseled research personnel regarding study design for compliance with human subject protection regulations
* Coordinated and attended IRB and related committee meetings to provide guidance, direction, and expertise relative to the review of research protocols
* Provided direction, guidance, and assistance to a functional team of 8-10 staff members devoted to the support and review of human subjects research through direct management and oversight

***Research Compliance Coordinator****, September 2008 – January 2010*

* Conducted review of human subjects research and worked directly with investigators and research community staff to facilitate IRB review and approval
* Coordinated and attended IRB and related committee meetings to provide guidance, direction, and expertise relative to the review of research protocols
* Provided support to the Methodist IRB and coordinated its full integration into the IU IRB system

**Walker Information** May 2003 – July 2005

 ***Marketing Communications Coordinator***

* Designed and drafted a comprehensive crisis communications plan which was presented to and adopted by executive leadership
* Secured coverage in national publications through weekly story ideas and regular cooperation with both national and local media through press releases and media advisories
* Designed and copyedited collateral materials and newsletter articles

## Education & Certifications

RIO Boot Camp, University of Tennessee, Knoxville, March 11 – 13, 2019

* Hosted by the Office of Research Integrity, Department of Health and Human Services
* Intensive program of training in handling investigations of misconduct in research for Research Integrity Officers and their legal counsel

The Institute for Supervising Excellence, completed December 2016

* Presented by Indiana University Human Resources Administration
* 12-month program designed to further management skills, including: accurate self-awareness, leading change, managing conflict, managing performance, providing timely and effective communication, managing and building relationships, demonstrating care for others, creating an inclusive environment and responding resourcefully to situations

Certified IRB Professional (CIP), April 2009 – June 2021

## Indiana University Robert H. McKinney School of Law

##  Juris Doctor with health law concentration, May 2008

* Civil mediation certified: completed 40-hour civil mediation training, January 2008
* Advocate, National Health Law Moot Court Competition, November 2007
* Order of the Barristers, Kime Stork Best Brief Award, Honorable Robert H. Staton Moot Court Competition, April 2007
* Indiana Health Law Review, *2007 Executive Notes Editor, 2006 Note Candidate*
	+ Organized and supervised joint writing competition for law review membership
	+ Reviewed submissions for membership and selected new members
	+ Supervised note writing process for note candidates and reviewed final note submissions for publication

## Franklin College, Franklin, IN

Bachelor of Science, Journalism/Business Marketing, May 2005

**Publications, Presentations & Honors**

Jones, Marta, Waltz, Amy. “Full Board Review.” *Institutional Review Board: Management and Function*, Third Edition. Ed. Public Responsibility in Medicine & Research (PRIM&R) et al. Jones & Bartlett Learning, 2021. (ISBN 978-1284181159). 3-21. Print.

Presenter, “Relying on Someone Else’s IRB: Why, When, and How for Hospitals and Academic Medical Centers” presented at Health Care Compliance Association (HCCA) Research Compliance Conference. Orlando, FL. June 9-12, 2019.

Kelly Anderson, CIP; Ashley Meyers; Jill Wallace, CIP; Amy Waltz, JD, CIP; “Going Visual: Adopting Creative Alternatives for the Concise Summary.” Poster session presented at: Association for the Accreditation of Human Research Protection Programs (AAHRPP) Annual Conference. New Orleans, LA. May 21-23, 2019.

Hartsock JA, Schwartz PH, Waltz AC, Ott MA. Anticipatory Waivers of Consent for Pediatric Biobanking. *Ethics Hum Res*. 2019;41(2):14-21.

Presenter, “Let’s Review a Protocol: Reviewing Research that Requires Expedited or Full Board Review” presented at Public Responsibility in Medicine & Research (PRIM&R) 2018 Advancing Ethical Research Conference. San Diego, CA. November 14-17, 2018.

Poster Presenter: Public Responsibility in Medicine & Research (PRIM&R) 2018 Advancing Ethical Research Conference. “Erasing Silos: Enhancing HRPP Collaborations for NIH Single IRB Proposals.” Ryan Ballard; John Bauman, PhD; Bethany Johnson, CIP; Amy Waltz, CIP. San Diego, CA. November 14-17, 2018.

Waltz, Amy. The Changing Landscape of Human Subjects Research.” *SOCRA SOURCE*, August 2018, pp. 52-55.

Presenter, “Research with Individuals Lacking Consent Capacity” presented at 2018 Association for the Accreditation of Human Research Protection Programs (AAHRPP) Annual Conference. Denver, Co. April 20-22, 2018.

Poster Presenter: 2018 Association for the Accreditation of Human Research Protection Programs (AAHRPP) Annual Conference. “Erasing Silos: Enhancing HRPP Collaborations for NIH Single IRB Proposals.” Ryan Ballard; John Baumann, PhD; Bethany Johnson, CIP; Amy Waltz, CIP. Denver, Co. April 20-22, 2018.

Presenter, “Conducting Research with Individuals Lacking Capacity to Consent” presented at Public Responsibility in Medicine & Research (PRIM&R) 2017 Advancing Ethical Research Conference. San Antonio, TX. November 5-8, 2017.

Presenter, “Let’s Review a Protocol: Identifying and Applying Federal Regulations to the Review of Research that Requires Expedited or Full Board Review” presented at Public Responsibility in Medicine & Research (PRIM&R) 2017 Advancing Ethical Research Conference. San Antonio, TX. November 5-8, 2017.

Presenter, plenary session “The Changing Landscape of Human Subjects Research” presented at the Society of Clinical Research Associates (SOCRA) 2017 Annual Conference. Orlando, FL. October 8, 2017.

McGregor, Kyle A., Hensel, Devon J., Waltz, Amy C., Molnar, Elizabeth E., and Ott, Mary A. (2017). “Adolescent Sexual Behavior Research: Perspectives of Investigators, IRB Members, and IRB Staff about Risk Categorization and IRB Approval.” *IRB: Ethics & Human Research, Volume 39*(4).

Presenter, “Operationalizing Collaborative IRB Review” presented at Public Responsibility in Medicine & Research (PRIM&R) 2016 Advancing Ethical Research Conference. Anaheim, CA. November 13-16, 2016.

Presenter, “The Changing Landscape of Human Subjects Research” presented at the Indiana University Health 41st Annual Nursing Research Conference, Engaging Direct Care Nurses in Research Activities: Creating New Knowledge and Innovative Practices, December 4, 2015.

Baumann, John R., Heather Mullins-Owens, David Russell, and Amy Waltz. “Human Subjects Research Protections.” *Research Regulatory Compliance.* Ed. Mark A. Suckow and Bill Yates. Elsevier, 2015. ISBN 978-0-12-420058-6. 1-20. Print.

Presenter, “Panel: Special Ethical Issues in Vulnerable Populations” presented at the American Medical Writers Association, Indiana chapter conference, June 6, 2014.

Poster Presenter: Public Responsibility in Medicine & Research (PRIM&R) 2012 Advancing Ethical Research Conference. “Beyond the Presentation Approach: New Outreach Practices at a Large Medical Center.” Shawn Axe, John Baumann, Sara Benken, Amy Waltz. San Diego, CA. December 4-6, 2012.

Poster Presenter: Public Responsibility in Medicine & Research (PRIM&R) 2012 Advancing Ethical Research Conference. “IRB Member, Staff, and Investigator Assessments of IRB Competence to Review Adolescent Protocols.” Mary A. Ott, MD, MA; Elizabeth E. Molnar, BA; Devon J. Hensel; PhD; Amy C. Waltz, JD, CIP. San Diego, CA. December 4-6, 2012.

Poster Presenter: Public Responsibility in Medicine & Research (PRIM&R) 2012 Advancing Ethical Research Conference. “IRB Review and Vulnerable Populations: Investigator, IRB Member and Staff Capacity and Perceptions of Protocol Review for Cognitively Impaired Adults.” Amy Waltz, JD, CIP; Elizabeth A. Molnar, BA; Devon J. Hensel, PhD; Alexia M. Torke, MD, MS; Mary A. Ott, MD, MA. San Diego, CA. December 4-6, 2012.

Poster Presenter: Indiana Clinical and Translational Sciences Institute (CTSI) Fourth Annual Meeting. “Emerging From Crisis: Changing HRPP Policies and Processes.” John Bauman, Shawn Axe, Sara Benken, Amy Waltz. Indianapolis, IN. August 31, 2012.

Presenter: “Maintaining Data Confidentiality: How IRBs and Investigators Can Avoid the Crisis, and Deal with It Afterward”presented at the Association for the Accreditation of Human Research Protection Programs (AAHRPP) 2012 conference, April 2012.

Waltz, Amy C. (2008). Closing the Deal: Making the Right Congressional Decision about Patent Settlement Agreements. *Indiana Health Law Review*, *Volume 5*(1).

**Grants**

*Vulnerability in Medical Research.* Funded by Indiana University Health Values Fund for the Integration of Spiritual and Religious Dimensions in Health Care. Mary A. Ott, MD – Principal Investigator. Participating as co-investigator on grant to enhance the ethical review of medical research with vulnerable populations at IU Health and beyond, including examination of beliefs and attitudes of investigators and IRB staff and members. 6/1/2010 – 5/31/2012.

**Professional Organizations and Community Involvement**

* Association of Research Integrity Officers (ARIO), member, 2019 – present; ARIO annual meeting program committee, 2022 - 2023
* Hall Center Mentor Board, Hall Center for Law & Health, IU McKinney School of Law, 2021 - present
* Community member, Ascension St. Vincent Institutional Review Board, 2019 - present
* Membership Advisor, Zeta Tau Alpha Fraternity, Beta Theta Chapter (Franklin College, IN), 2011 – present
* Single IRB Working Group 1: Assess Processes for Initial Evaluation of Protocol Documents and Protocol Modifications, and Tolerance for Process Standardization - INFORMED CONSENT, facilitated by New York University, 2018
* SMART IRB Harmonization Subcommittee: Institutional and Local/State Responsibilities, 2017 – 2018
* Big10 Academic Alliance, IRB Administrators Group, 2014 – 2018
* Public Responsibility in Medicine and Research (PRIM&R), 2012 – 2018