

Compliance Today – December 2019 Meet Linda Coleman

An interview by Joan Podleski

Linda Coleman, JD, CIP, CHC, CHRC, CCEP-I, Director, Human Research Protection Program, Yale University

This interview with Linda Coleman (linda.coleman@yale.edu) was conducted in September 2019 by Joan Podleski (Joan.Podleski@childrens.com), Chief Privacy Officer–Senior Director, Children’s Health, Dallas.

JP: Tell me a little about yourself and what your areas of responsibility include.

LC: I am the director of the Yale Human Research Protection Program (HRPP) and have held this position since 2016. In my role, I assist the university in meeting its ethical and regulatory obligations for the protection of human participants in research. Some of the duties include assisting with audits and inquiries from regulatory agencies and accreditation bodies; assessing HRPP policies and practices for operational efficiency and compliance with applicable human research standards; and working with other offices and departments across the university to improve the research process and ensure compliance with human research standards and organizational policy.

Before joining Yale, I held several positions at a company that provided independent [institutional review board] IRB and regulatory and technology consulting services for institutional, independent, and international sites. These positions included, Vice President of Regulatory & Legal Affairs in 2016, Director of Regulatory Affairs & General Counsel from 2011–2015, and Director of Regulatory Affairs from 2007–2010. From 2003–2007, I was an attorney at a law firm specializing in health law. Outside of work, I am involved in professional organizations and committees focused on human research matters and global bioethics. I am also very involved in education access for students pursuing higher education.

JP: You started your career in a health law firm before moving to a company that provided independent IRB and consulting services. What piece of advice did you get while working at the law firm and how did that advice shape how you approached your work after moving in-house and in your current role?

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