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For my primary position, I manage the Johns Hopkins University's Office of Human Subjects Research (the IRB) Compliance Monitoring Program, for which I utilize my experience in clinical research and training in regulatory compliance. In particular, I supervise on-site, routine monitoring and for-cause/directed audits of our human subjects research protocols. In this role I apply my knowledge of Federal regulations, Institutional requirements, and GCP Guidelines, to assess compliance at all applicable levels. Further, I work with investigators to identify deficiencies in regulatory compliance and a protocol's procedural conduct, in addition to generating corrective action mechanisms to maximize attention to a culture of safety whereby the rights, well-being, and safety of research subjects are safeguarded. Finally, I develop and present educational and training sessions for the JHU research community regarding Human Subjects Research compliance and best-practices. These programs are offered at the JHU Schools of Medicine, Public Health, and Nursing.

For my second position, my effort is supported by the JHU Institute for Clinical and Translational Research (ICTR), a CTSA funded center. My position is the Research Participant Advocate for the Johns Hopkins Bayview Medical Center Clinical Research Unit. My responsibility is to serve as an objective resource or ombudsman for all research participants, and also for the community at large, from which many of our studies draw participants. Second, I function as a regulatory resource for the JHU researchers and B-CRU research staff. In addition, I review protocols for attention to human subject safety in both their design and conduct, focusing on the quality and adequacy of a given study's Data Safety Monitoring Plans. To this end, I also serve in an educational and consultative capacity to assist the client investigators and study-teams utilizing our Unit. Within this role, I have also developed and currently direct the JHU ICTR's Data Safety Monitoring Service, whereby I assist and guide investigators across the JHU community with the development of Data Safety Monitoring Plans and with the assembly of Data Safety Monitoring Boards (DSMBs), along with writing DSMB Charters, if necessary.