

MedRIST Presents:

**CONSCIOUS COUPLING:**  
**Governance and Oversight Between**  
**the Institution & IRBs/REBs**



LUNCHEON DATE: Monday, November 14, 2016 | 13:00PM - 14:00PM

TOPICS TO BE DISCUSSED

o Institutional authorization: an emerging model

AER Conference Delegates will have the opportunity to participate and contribute to a dynamic discussion on Institutional Authorization as an emerging model required to initiate research involving humans within institutions.

Participants will have the opportunity to learn about how this emerging model contributes to increased efficiencies in the review and approval of proposed human research studies. The model provides enhanced communication and transparency among departments reviewing and approving research and enables improved adherence to research ethics and integrity guidelines and compliance to regulations.

The model allows members of the research community to better understand the interplay of institutional requirements and responsibilities to sponsors and regulators in an increasingly complex regulatory environment.



KEYNOTE SPEAKER



**Elyse I. Summers, J.D.**  
**President and CEO**  
**Association for the**  
**Accreditation of Human**  
**Research Protection**  
**Programs, Inc.**  
**(AAHRPP)**

Ms. Summers is AAHRPP's second President and CEO. She provides strategic and substantive leadership and oversight on all aspects of AAHRPP's operations and is looking forward to leading AAHRPP well into the 21st century as the indispensable global organization for the accreditation of human research protection programs.

Ms. Summers was most recently the Director of the Division of Education and Development at the Office for Human Research Protections, a position she had held since January 2008.

Ms Summers began working for OHRP and its predecessor, the Office for Protection Research Risks (OPRR), in 1998 in the Division of Compliance Oversight before moving to the Division of Education. Prior to joining OPRR/OHRP, Ms Summers practiced law pertaining to food, drugs, and other medical products. She offered guidance and counseling on Federal regulations and ethical issues related to the conduct of biomedical research. Ms. Summers spent five years before that time in the Office of the Commissioner at FDA, as Special Assistant to the Deputy Commissioner for External Affairs, and later as an original staff member of FDA's Office of Women's Health.

Ms. Summers has spoken extensively and published several articles and book chapters on biomedical and behavioral research and human research protections. She has also practiced the law of tax-exempt organizations, and has spoken and written on that topic as well. At the start of her professional career, Ms. Summers represented research universities at the Association of American Universities. She earned a J.D. from the George Washington University National Law Center and a B.A. from the University of Michigan. She is a member of the Bar of the District of Columbia and of the Commonwealth of Pennsylvania.