



Ethics, Regulatory Knowledge, & Support (ERKS)

The **Ethics, Regulatory Knowledge, & Support (ERKS)** program provides ethics and regulatory knowledge infrastructure and support for clinical and translational investigators within the ACTSI. The program has helped to centralize and consolidate research support infrastructure program-wide at Emory University, Morehouse School of Medicine (MSM), and Georgia Institute of Technology (Georgia Tech), including broadening of the Emory Clinical Trials Office to form an Office of Clinical Research and Research Compliance. In addition, a research ethics resource is available within Emory, titled the Section on Ethics in Research and Participant Advocacy (SERPA).

Available ERKS Resources

ERKS provides support to ACTSI investigators on major regulatory issues through its integration with the **Emory Offices of Clinical Research** and **MSM Office of Sponsored Research Administration**, which provides the infrastructure to integrate and broaden the scope of regulatory support and training, assist the academic growth of clinical investigations, and support the highest level of ethically conducted clinical and translational investigation across institutions.



ERKS resources include:

- Investigator and protocol support for regulatory affairs
- Investigator and institutional conflict of interest assistance
- Complex Internal Review Board issue resolution
- Coordination of multiple committee approvals
- Intellectual property issues
- Competing or conflicting institutional policies
- Safety surveillance and support
- Financial and research compliance
- Quality assurance
- Adverse event database
- IRB reciprocity, Memorandums of Understanding, and Material Transfer Agreements with ACTSI partner institutions
- Training and education programs for investigative teams

ERKS offers **research ethics consultative service**, research, and support to ACTSI investigators by the members of SERPA. The **Ethical Dilemmas in Scientific Research and Professional Integrity** website (www.actsi.org/ethics) also presents case scenarios involving responsible conduct in research. Each case is followed by a brief, expert opinion that suggests strategies for resolution. The cases include issues on:

- Animal Use
- Authorship
- Confidentiality
- Conflict of Interest
- Data Interpretation and Management
- Drug Trials
- Informed Consent
- Intellectual Property
- Mentoring
- Misconduct
- Participant Recruitment



These cases can provide useful teaching materials for college or university faculty who present lectures on responsible conduct in research.

To learn more about the Ethics, Regulatory Knowledge, & Support (ERKS) program visit www.actsi.org/erks.