CTSC Informational Sessions

Data Management Series

Session	Title	Description
Basic 1	**It's a System!**	Talking through the critical questions, the march of science, systems and diagrams. Start here to understand the entire process.
Basic 2	**Research Plan**	Learn the elements of a well-developed Research Plan including an Introduction, Background, Goals, Clinical Plan, Data management Plan, Statistical Analysis Plan, Regulatory Considerations Human Subject Protections.
Basic 3	**Building a Data Management Plan**	Outline the basic data management process and data flow. Examine the elements of a data management plan. Define individual roles, responsibilities, and access privileges.
Basic 4	**Data Entry and Quality Control (including CRF design)**	Ensure the CRF reflects the protocol's main points. Develop clear unambiguous questions. Discuss the development of CRF instructions. Address common design challenges and design the CRF to record data that can be used in the final study report. Develop methods to track CRFs.
Advanced 1	**The Regulations: HIPAA for Research**	Ensure data collection and management complies with HIPAA privacy laws. Review PHI and identifiers. Common Rule vs. Privacy Rule.
Advanced 2	**The Regulations: 21 CFR Part 11**	Scope and application guidance, electronic records, electronic signatures, and validation.
Advanced 3	**Data Safety Monitoring Board**	A system for the oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data. The data and safety monitoring functions and oversight of study activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB).
Advanced 4	**Study Infrastructure Template**	A template to help organize the entire study.