



New York State SOCRA Chapter Clinical Research Program
Monday, November 2, 2026, 8:00 a.m. – 4:00 p.m.
The Lodge Skaneateles, 4355 State Street Rd, Skaneateles Falls, NY

Agenda

8:30 Sign in/Welcome & Intro

8:45-9:45 Regulatory Pathways & Study Start-Up Requirements

Overview of IND vs. IDE pathways, IRB roles, and essential approvals required to initiate a clinical study. - Nikki Mason

9:45-10:45 “Commercialization: Concept to Clinical Trial to Market for Medical Devices”- Kathi Durdon

10:45-11:00: Beverage Break

11:00-12:00 ICF- Informed Consent & Protection of Human Subjects

Key regulatory and ethical requirements, including considerations for vulnerable populations and foundational principles (Belmont Report, Declaration of Helsinki).- **Dr. Quincy Byrdsong**

12:00-1:00 Lunch and Networking

1:00-2:00 Adverse Event Reporting & Safety Oversight

Identification, documentation, and reporting requirements for AEs, SAEs, and unanticipated events, including regulatory timelines and MedWatch reporting.- **Dr. Disha Jain**

2:00-3:00 Essential Documents & Inspection Readiness

Development, maintenance, and audit readiness of regulatory binders, source documentation, and required investigator/site documentation. - **Kelly Unsworth**

3:00-4:00 Clinical Trial Compliance & Ongoing Regulatory Obligations:

Maintaining compliance throughout study execution, including protocol adherence, amendments, continuing review, and [ClinicalTrials.gov](https://clinicaltrials.gov) requirements.- **Tanisha LaVeck, MS, CPCP, CPC**