Study Staff

Pre-Study
- Consent Development
- Coordinator Training
- Good Clinical Practice
- Pre-Study Budgeting
- Recruitment Strategy
- ResearchConnect
- WebIRB Submissions

Regulatory
- 21 CFR Part 11
- Clinicaltrials.gov
- Data & Safety Monitoring
- IND Development
- IDE Development
- Regulatory Binder
- Safety Reporting
- SOPs

Study Management
- Data Management
- Research Billing
- Specimen Management
- Study Management
- Subject Enrollment Logs
- Accountability Logs
Quality Management

Regulatory Binder Logs

Last updated: 15 Nov 2016

• Group 1
  ◦ Clinical Research Information Systems
  ◦ Clinical Research Business Partners
• Group 2
  ◦ Office of Research Administration
  ◦ Jonsson Comprehensive Cancer Center
• Group 3
  ◦ Office of Human Subjects Protection
  ◦ CareConnect Website

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