Office of Research Services (ORS)

Developed in response to the needs of Mount Sinai’s ever growing research community, the Office of Research Services (ORS) has been established to facilitate the conduct of clinical research through a centralized infrastructure supported by Conduits – The Institutes for Translational Sciences. Our staff provides researchers with resources, information, and expertise in clinical research in order to foster the clinical and translational research enterprise within Mount Sinai, its affiliates, and the broader community. Our project management team supports the following services for investigator initiated single center and/or multi-center clinical trials:

- **Assistance with Grant Development and Submissions:**
  - Confidential preliminary review of grant proposals
- **Regulatory Coordination:**
  - Preparation of internal and external regulatory documents
  - Investigational New Drug Application and Investigational Device Exemption (IND/IDE) submissions & progress reports to the FDA
  - Data and safety monitoring boards (DSMB) and plans
  - Guidance on posting research to ClinicalTrials.gov
  - Site activation
  - Central Patient Registration
  - Liaison with Investigation Drug Service and Data Coordinating Center
- **Clinical Trials Management Systems:**
  - Electronic Regulatory Document Management
  - Regulatory Approval Tracking and Reminders
  - Participant Enrollment, Management, and Scheduling
  - Adverse Event Reporting
  - Research Billing Compliance
  - Sponsor Invoicing and Payment Tracking
  - Multi-Site Studies
  - Metrics Reporting
- **Clinical Research Monitoring Services:**
  - Development of Case Report Forms (CRF) with Research IT
  - Site initiation visits
  - Study monitoring plans and services to assure GCP compliance
  - Onsite and Offsite study monitoring for multicenter clinical trials
  - Protocol specific clinical research trainings
- **Outreach Coordination:**
  - Patient recruitment and retention strategies
  - Development of brochures, newsletters, media and marketing materials
  - Access to ResearchMatch.org a national web-based recruitment registry that will help ‘match’ researchers with willing volunteers all over the country who may wish to participate in research studies. This recruitment tool was developed through the collaborative spirit of the Clinical and Translations Science Award (CTSA) Consortium
  - Volunteer call center

For more information:
Visit: http://www.mssm.edu/research/resources/office-of-clinical-research