Executive Summary

Title	**NEU-ME (New England Urogynecologic Mesh Registry)**
Goal	The NEU-ME Registry aims to establish an accurate regional surgical database which represents all uses of synthetic vaginal mesh for the treatment of pelvic floor disorders, related complications and surgical outcomes.
Main Clinical Outcome Measures	• Establishment of a comprehensive database of vaginal surgical cases using mesh, designed to describe mesh efficacy and safety • Describe regional mesh utilization for pelvic floor disorders • Subjective and objective outcomes assessment
Design	NEU-ME is a regional multi-centered prospective observational surgeon-generated registry of all surgical cases utilizing mesh performed for the correction of female urinary incontinence and/or pelvic organ prolapse.
Method of Data Collection	The method of data collection will be prospective and will include clinical, surgical and subjective data entered by participating surgeons, trained registry personnel and patients.
Population	All patients undergoing surgical treatment for urinary incontinence and/or pelvic organ prolapse in which mesh is utilized will be included in the registry. Active surveillance will be achieved by utilizing operating room records and the hospital surgical log of implantable devices to ensure full reporting by participating surgeons.
Duration	• Minimum of 3 years
Participating Sites	• Physicians in New England performing surgeries for pelvic organ prolapse or incontinence (currently 25 surgeons interested) • First site: University of Massachusetts Memorial Medical Center • Early enrollment sites: Women & Infants Hospital of Rhode Island (Brown), Providence, RI Hartford Hospital, Hartford, CT Massachusetts General Hospital, Boston, MA • Additional sites will be enrolled in order of approval
Main Data Collected	**Surgeon Enrollment Form:** Participating surgeons will complete a Surgeon Enrollment Form which will collect information about their training, surgical case load and the hospitals they serve. This form

Data collected, Cont'd	will also serve as a contract between the participating surgeon and the NEU-ME Registry. **Operative Case Report Form:** An Operative Case Report Form (O-CRF) will document the following information for eligible patients enrolled in the study: • Demographic and biometric information • Medical history • Pre-operative clinical information • Operative Information – Pre-operative diagnoses – Procedure(s) performed – Sutures and devices/implants used – Antibiotics – Intra-operative Complications **Outpatient Encounter Form:** A Routine POF will document clinical information collected during the post-operative period and will be submitted by the surgeon. **Quality of Life & Patient Satisfaction Survey:** Patients will be invited to complete validated subjective outcomes surveys (PFDI, PFIQ, PISQ) at 6, 12 and 24 months post-operatively.
Statistical Analysis	Registry data will be available for query by future IRB-approved study protocols. Investigators may either contract the COR or another statistician of their choice.
Timelines	Patient enrollment will begin following IRB approval. UMASS – IRB Approved 3-27-2009 - Active enrollment in progress