SOUTH JERSEY

MEDICAL REPORT™

Clinical Trials

More than 450 clinical trials, including national trials, are currently underway at Cooper University Health Care, addressing a wide-range of the latest pharmacologic, surgical and device-related therapeutic options. Cooper's robust research program offers clinicians and their patients access to some of the most novel therapies and innovative trials in the region.

The following list represents some of the clinical trials currently enrolling patients at Cooper.

Spring/Summer 2015

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Anesthesia Post Operative Cognition	Ronak Desai, DO	Robyn T. or Ashley S. 856.968.7333	Drug Study	Examines memory before and after surgery requiring general anesthesia using a computerized testing system.	**1.** Must be 65 years and older. **2.** Having non-cardiac surgery requiring general anesthesia.
Anesthesia Post Operative Pediatric	Bharathi Gourkanti, MD	Robyn T. or Ashley S. 856.968.7333	Treatment Study	Evaluates the safety and efficacy of a drug therapy for relieving acute pain after pediatric surgery.	**1.** Must be aged 3-6 years old. **2.** Having adenoids, tonsils, or myringotomy tube surgery.
Anesthesia/Psychiatry Post Traumatic Stress Disorder	Basant K. Pradhan, MD	Robyn T. or Ashley S. 856.968.7333	Treatment Study	This study is to compare the safety and efficacy of study drug vs. placebo for the treatment of posttraumatic stress disorder in outpatients.	**1.** Must be over 18 years old. **2.** Must have diagnosed PTSD. **3.** Must be seen in psychiatry at Cooper prior to enrollment.
Cardiology Atrial Fibrillation	Andrea M. Russo, MD	Julie F. 856.968.7032	Treatment Study	International study that will compare treating AFib with medication vs. treatment with a procedure called Ablation and decide which treatment is best or preferred.	**1.** Must be ≥ 18 years old. **2.** Must have over the preceding 6 months electrocardiographic documentation of either > 2 paroxysmal AF episodes lasting > 1 hour in duration, or 1 persistent AF episode, or 1 longstanding persistent AF episode. **3.** Must warrant active therapy (within the past 3 months) beyond simple ongoing observation.
Cardiology Atrial Fibrillation	Andrea M. Russo, MD	Dawn S. 856.342.3088	Registry Study	To investigate the patient characteristics influencing the choice of antithrombotic treatment for prevention of stroke in non-valvular AF patients.	**1.** Must be ≥ 18 years old. **2.** Must have CHA2DS2-VASc score of at least 1. **3.** Must be newly diagnosed with non-valvular AF (< 3 months prior to baseline visit) with documentation by 12 lead ECG, ECG rhythm strip, pacemaker/ICD electrogram or halter ECG of AF of at least 30 seconds.
Cardiology Central Sleep Apnea	Fredric L. Ginsberg, MD	Amanda L. 856.968.7615	Device Study	Evaluates the safety and effectiveness of therapy delivered by the study system in subjects with moderate to severe central sleep apnea (CSA) and optimal medical management.	**1.** At least 18 years of age. **2.** Central Sleep Apnea confirmed by core lab analysis of PSG with EEG. **3.** Medically stable for 30 days prior to all baseline testing (including PSG), i.e., no hospitalizations for illness, no breathing mask-based therapy, and on stable medications and therapies.
Cardiology Ventricular Tachycardia/ Fibrillation	Andrea M. Russo, MD	Dawn S. 856.342.3088	Drug Study	To determine whether ranolazine administration will decrease the likelihood of a composite arrhythmia endpoint consisting of ventricular tachycardia or ventricular fibrillation requiring antitachycardia pacing, ICD shocks, or death.	**1.** Must be ≥ 21 years old. **2.** Must meet current guidelines for ICD or CRT-D device therapy. **3.** Must be primary or secondary prevention patients with ischemic or nonischemic cardiomyopathy.
Critical Care Sepsis	R. Phillip Dellinger MD	Christa S. 856.968.7493	Device Study	Evaluating the use of Polymyxin B Hemoperfusion in a randomized controlled trial of adults treated for endoxemia and septic shock.	**1.** Septic shock. **2.** Endotoxin Activity Assay of ≥ 0.60 EAA units. **3.** Evidence of new onset organ dysfunction.
Critical Care Sepsis	R. Phillip Dellinger MD	Christa S. 856.968.7493	Drug Study	A randomized, double-blind, placebo controlled phase 3 study to assess the safety and efficacy of investigational drug in subjects with severe sepsis and coagulopathy.	**1.** Sepsis induced organ dysfunction requiring vasopressor support and/or mechanical ventilation. **2.** INR > 1.4. **3.** Admitted to an ICU setting.
Critical Care Sepsis	Stephen W. Trzeciak, MD	Lisa P. 856.968.7203	Treatment Study	To test the safety and efficacy of the study drug, a 12 hour IV infusion.	**1.** Must be over 18 years old. **2.** Must be vasopressor dependent for less than 24 hours. **3.** Must have most recent blood lactic acid value of more than 2.0mMol/L.
Gynecologic Oncology Endometrial Cancer	David P. Warshal, MD	Maria D. 856.325.6733	Treatment Study	Compares standard treatment with standard treatment plus metformin for endometrial cancer.	**1.** Primary disease-must have measurable disease for stage III or IVA-no measurable disease needed for stage IVB or recurrent disease. **2.** No previous chemo or targeted therapy. **3.** Must not be taking metformin now or in the past 6 months.
Gynecologic Oncology Ovarian Cancer	David P. Warshal, MD	Maria D. 856.325.6733	Treatment Study	Compares safety and effectiveness of a parp-inhibitor vs. standard chemotherapy in patients with platinum sensitive relapsed ovarian cancer carrying germline BRCA 1-2 mutations.	**1.** Must have relapsed high grade serous or high grade endometrioid ovarian, primary peritoneal or fallopian tube cancer. **2.** Must have measurable disease. **3.** Must have received at least 2 previous regimens of chemotherapy. **4.** Must not be a poor medical risk due to a serious, uncontrolled medical disorder; non-malignant system disease or active; uncontrolled infection."
Gynecologic Oncology Ovarian Primary/Peritoneal Fallopian Tube Cancer	David P. Warshal, MD	Maria D. 856.325.6733	Non-Treatment	To see if women who recently completed primary treatment for ovarian, primary peritoneal and fallopian tube cancer and who are in complete remission when randomized to and comply with a healthy lifestyle intervention will have significant increased progression-free survival compared to similar women who are randomized to a usual care comparison group.	**1.** Must have recently completed chemotherapy & must be in complete remission (normal CT scans & normal CA 125). **2.** Must not be currently enrolled in an ongoing medically prescribed diet or physical activity regimen. **3.** Must not have any chronic disease such as heart problems, chronic hepatitis, rheumatoid disease, insulin dependent diabetes, recent leg fracture, arthritis, degenerative neurological conditions, etc.

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Infectious Diseases HIV	John D. Baxter, MD	Yolanda S. 856.968.8651	Drug Study	This study is being conducted to establish if human immunodeficiency virus type 1 (HIV-1) infected adult subjects with current virologic suppression on a integrase inhibitor (INI)-based antiretroviral (ARV) regimen remain suppressed upon switching to a two drug regimen with dolutegravir (DTG) + rilpivirine (RPV).	**1.** HIV-1 infected men or women > 18 years of age on a current regimen whether first or second line (ART) for at least 6 months prior to screening. **2.** Within the last 6 months prior to screening, at least one documented plasma HIV-1-RNA measurements < 50 c/mL. **3.** Plasma HIV-1 RNA < 50 c/mL at screening.
Infectious Diseases HIV	Rosalie Pepe, MD	Yolanda S. 856.968.8651	Drug Study	To determine the effects of pitavastatin as a primary prevention strategy for major adverse cardiovascular events (MACE) in HIV.	**1.** HIV-1 infected men and women age ≥ 40 and ≤ 75 years of age on combination antiretroviral therapy (ART) for at least 180 days prior to study entry. **2.** Fasting LDL cholesterol < 190 mg/dL, fasting triglycerides < 500 mg/dL. **3.** CD4+ cell count > 100 cells/mm3 obtained from standard of care within 180 days prior to study entry.
Nephrology Diabetic Nephropathy	Christopher B. McFadden, MD	Trisha N. 856.968.7269	Treatment Study	Study the effects of Atrasenten on renal outcomes in subjects with type 2 diabetes and nephropathy.	**1.** Age 18-85 years. **2.** Type 2 diabetes with proteinuria.
Neurology Epilepsy Epilepsia Partialis Continua	Melissa A. Carran, MD	Cory H 856.324.2460	Drug Study	To evaluate whether an investigational medication is more effective as an adjunctive or monotherapy in terminating Epilepsia Partialis Continua (EPC) than either lorazepam and/or clonazepam.	**1.** Males or Females 18 years of age or older. **2.** Diagnosis of EPC by a neurologist.
Neurology Parkinson's Disease	Amy Colcher, MD	Cory H. 856.324.2460	Drug Study	This study is evaluating the safety and efficacy of an investigational medication for the treatment of OFF episodes in Parkinson's disease patients.	**1.** Males or Females between 30 and 80 years of age. **2.** Have a medical diagnosis of Parkinson's disease and experience a minimum of 2 hours of OFF episodes per day (excluding early morning OFF time). **3.** Be taking oral levodopa at least 4 times during the waking day, and on a stable levodopa regimen for at least 2 weeks prior to the study.
Ob/Gyn General Obstetrics	Richard L. Fischer, MD	Gunda S. 856.968.7547	Treatment Study	The purpose of this study is to assess the effectiveness of preventative antidepressants in women at increased risk for postpartum depression.	**1.** History of depression or postpartum depression. **2.** Singleton pregnancy (must be available for screening in the third trimester). **3.** Delivery at Cooper, after 34 weeks of pregnancy. **4.** No active signs of depression.
Ob/Gyn Maternal-Fetal Medicine	Meena Khandelwal, MD	Gunda S. 856.968.7547	Diagnostics Study	The purpose of this study is to develop a noninvasive prenatal test (NIPT) for fetal chromosomal abnormalities.	**1.** Female over 18 years of age. **2.** Between 8 and 26 weeks of pregnancy. **3.** At increased risk for fetal chromosomal abnormality based on age, screening, or previous or family history.
Pediatrics Phenylketonuria	Caroline Eggerding, MD	Sandie C. 856.968.7366	Treatment Study	This study is assessing the effectiveness of a dose regimen of a medication in patients not previously treated with it.	**1.** Must be between 18 and 70 years old. **2.** Documented history of PKU. **3.** Willing to maintain current diet throughout the study, including medical formula.
Pulmonary Emphysema	Wissam Abouzgheib, MD	Trisha N. 856.968.7269	Device Study	Evaluate the safety and effectiveness of the valve system for the single-lobe treatment of severe emphysema.	**1.** Age 40 years and older. **2.** Severe emphysema.
Trauma Surgery	Joshua P. Hazelton, DO	Lisa C.-W. 856.361.1324	Device Study	Evaluates a device to assist in anticoagulation in patients that cannot receive anticoagulation drug therapy.	**1.** Males or Females 18 years of age and older. **2.** Patient cannot receive anticoagulation via drug therapy due to injury.
Trauma Surgery Acute Bleeding Injury	Salina Wydo, MD	Lisa C.-W. 856.361.1324	Drug Study	Evaluates the safety and efficacy of drug therapy in patients taking anticoagulation medication.	**1.** Males or Females 18 years of age and older. **2.** Require reversal of anticoagulation therapy.
Trauma Surgery Behavioral Health	Nicole M. Fox, MD	Lisa C.-W. 856.361.1324	Intervention Study	Evaluates outcomes of patients with trauma injuries.	**1.** Males or Females 18 years of age and older. **2.** Patient involved in a traumatic event.
Urogynecology Female Pelvic Medicine and Reconstructive Surgery	Adam S. Holzberg, DO Ricardo Caraballo, MD Karolyn T. Echols, MD	Gunda S. 856.968.7547	Device Study	FDA/industry-sponsored studies are being conducted to assess the long-term safety and efficacy of surgical repair of pelvic organ prolapse.	**1.** Female over 18 years of age. **2.** Have pelvic organ prolapse and be seeking surgical repair.
Urology Premature Ejaculation	Allen D. Seftel, MD	Sandie C. 856.968.7366	Treatment Study	To assess the effectiveness of a new drug on patients with lifelong premature ejaculation.	**1.** Must be 18-60 years of age. **2.** Life-long history of premature ejaculation. **3.** Must not have erectile dysfunction.
Vascular Surgery AAA	Francis J. Caputo, MD	Jonelle O. 856.342.2150	Device Study	Evaluates the safety and efficacy of a low profile endovascular graft in the treatment of abdominal aortic aneurysms (AAA).	**1.** Age > 18 years. **2.** Must have an aneurysm/ulcer of the abdominal aorta.
Vascular Surgery AAA	Jose L. Trani, MD	Jonelle O. 856.342.2150	Device Study	Evaluates the safety and efficacy of a polymer and endovascular graft combination in the treatment of abdominal aortic aneurysms (AAA).	**1.** Age > 18 years. **2.** Must have an aneurysm/ulcer of the abdominal aorta.

Cooper University Health Care

For more information about clinical trials at Cooper, please contact:
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