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.

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Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Anesthesia	Kingsuk Ganguly, MD	Brian M. 856.968.7333	Drug Study	Single-blind evaluation of Exparel vs bupivacaine in robotic thoracic surgery.	**1.** Age ≥ 18 years. **2.** Robotic wedge resection or lobectomy. **3.** Weight ≥ 155 lbs.
Anesthesia	Angelo A. Andonakakis, DO	Brian M. 856.968.7333	Device Study	This study seeks to determine if the depth of propofol sedation in gastrointestinal endoscopy assessed by SedLine® brain function monitoring influences the incidence of postoperative delirium and postoperative cognitive dysfunction.	**1.** Age ≥ 65. **2.** BMI ≤ 40. **3.** Not taking benzodiazepine medications.
Cardiology Arrhythmia	Andrea M. Russo, MD	Claire F. Beeper: 856.253.2361	Treatment Study	Medication study for the reduction of thromboembolism in patients with device-detected subclinical atrial fibrillation.	**1.** Device detected episode of SCAF ≥ 6 min but < 24 hr. **2.** At least one stroke risk factor.
Cardiology Arrhythmia/ Implantable Defibrillator	Andrea M. Russo, MD	Julie F. 856.669.8847	Device Education Study	Patient education study about an implantable cardioverter defibrillator device (ICD) for the prevention of sudden cardiac death (SCD) and what kind of information is helpful to patients in making treatment decisions with their doctors.	**1.** Age > 21 years. **2.** Eligible for an implantable cardioverter defibrillator (ICD) for primary prevention of sudden cardiac death. **3.** Nonhospitalized patients with ejection fraction ≤ 35%.
Cardiology Structural Heart	Sajjad A. Sabir, MD	Emerson C. 856.342.2000 ext. 100.6169	Device Study	Trial of patients with atrial fibrillation comparing left atrial appendage occlusion therapy with non-vitamin K antagonist oral anticoagulants.	**1.** Documented paroxysmal, persistent, or permanent nonvalvular AF. **2.** High risk of stroke or systemic embolism, defined as a CHA2DS2-VASc score of ≥ 3. **3.** Eligible for long-term NOAC therapy.
OB/GYN	Lioudmila Lipetskaia, MD	Julie F. 856.669.8847	Prospective Cohort	To implement a screening process among gynecologic oncology patients to identify symptoms of pelvic floor dysfunction and implement an early intervention program to streamline patients' access to care for pelvic floor diseases.	**1.** Age ≥ 18 years. **2.** New patients presenting for treatment of a gynecologic cancer.
OB/GYN	Peter J. Chen, MD	Jeff B. 856.968.7547	Drug Study	Trial to evaluate the efficacy and safety of a respiratory syncytial virus (RSV) vaccine in infants born to women vaccinated during pregnancy.	**1.** Women ≥ 18 and ≤ 49 years of age and ≥ 24 and ≤ 36 weeks of gestation at vaccination day. **2.** Single pregnancy. **3.** Fetal ultrasound at ≥ 18 weeks of pregnancy, with no significant fetal abnormalities observed.
OB/GYN	Meena Khandelwal, MD	Jeff B. 856.968.7547	Device Study	This study aims to assess the prevalence of sleep disordered breathing in pregnant women with a singleton gestation who have hypertensive disorder of pregnancy (HDP) compared with women without HDP.	**1.** Age ≥ 18 years. **2.** Women with diagnosis of a hypertensive disorder of pregnancy. **3.** Greater than 20 weeks of pregnancy.
OB/GYN	Saiffudin T. Mama, MD	Jeff B. 856.968.7547	Drug Study	Investigational oral drug in combination with combined oral contraceptive to assess dysmenorrhea response in women with endometriosis and associated moderate to severe pain.	**1.** Documented surgical confirmation of endometriosis and associated moderate to severe pain. **2.** Must agree to use dual nonhormonal methods of contraception consistently during washout (if applicable), screening, and 3-month double-blind, placebo-controlled treatment periods of the study. **3.** Must be an appropriate candidate to receive combined oral contraceptives (COCs).

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Hematology/Oncology Hodgkin Lymphoma	Tulin Budak-Alpdogan, MD	Kristine M. 856.735.6249	Drug Study	Immunotherapy (nivolumab or brentuximab vedotin) plus combination chemotherapy in treating patients with newly diagnosed Stage III-IV classic Hodgkin lymphoma.	**1.** Confirmed newly diagnosed, previously untreated Stage III or IV classical Hodgkin lymphoma. **2.** Must have measurable disease, with at least one lesion ≥ 1.5 cm.
Hematology/Oncology Lung	Young Ki Hong, MD	Kristine M. 856.735.6249	Treatment Study	This study evaluates adoptive cell therapy with tumor-infiltrating lymphocytes (TIL) as a single therapy.	**1.** Confirmed diagnosis of non-small cell lung cancer. **2.** Must have been previously treated and progressed on chemotherapy and CPI concurrently. **3.** At least one resectable lesion ≥ 1.5 cm in diameter.
Hematology/Oncology Pancreatic	Jamin C. Morrison, MD	Kristine M. 856.735.6249	Treatment Study	Comparative study of subjects receiving IA vs IV chemotherapy with locally advanced unresectable pancreatic adenocarcinoma.	**1.** Confirmed pancreatic ademocarcinoma initially diagnosed within 6 weeks of consent. **2.** Locally advanced, unresectable disease. **3.** No previous treatment for pancreatic cancer.* **Exceptions may be granted.*
Orthopaedics	Catherine J. Fedorka, MD	Pietro G. 856.968.7079	Treatment Study	Single-blinded study evaluating the effect of liposomal bupivacaine nerve block on postoperative pain after rotator cuff repair or shoulder arthroscopy.	**1.** Age ≥ 18 years. **2.** Undergoing rotator cuff surgery or shoulder arthroscopy with an interscalene block.
Orthopaedics	Catherine J. Fedorka, MD	Pietro G. 856.968.7079	Registry Study	Registry of clinical and microbiological outcomes in patients undergoing revision shoulder arthroplasty.	**1.** Age ≥ 18 years. **2.** Undergoing or have previously undergone revision shoulder arthroplasty at Cooper University Hospital after August 2016.
Orthopaedics	Catherine J. Fedorka, MD	Pietro G. 856.968.7079	Treatment Study	This study compares 4-week continuous postoperative sling use vs. sling for comfort only in subjects who undergo reverse total shoulder arthroplasty for fracture.	**1.** Age ≥ 60 years. **2.** Must have a displaced proximal humerus fracture that requires reverse total shoulder arthroplasty.
Orthopaedics	David A. Fuller, MD	Pietro G. 856.968.7079	Treatment Study	Postoperative antibiotic delivery in treating upper extremity abscesses in patients without sepsis.	**1.** Must have undergone I&D of a single cutaneous abscess of the upper extremity at Cooper.
Orthopaedics	David A. Fuller, MD	Pietro G. 856.968.7079	Treatment Study	A prospective study comparing early mobilization vs. traditional methods for tendon injury.	**1.** Isolated zone V injuries without other tendon involvement (such as concomitant extensor tendon laceration or multiple zones of laceration). **2.** No contraindication to immediate postoperative mobilization.
Orthopaedics	Christina J. Gutowski, MD	Pietro G. 856.968.7079	Drug Study	Can a nonopioid analgesic option decrease postoperative narcotic use after benign soft tissue tumor resection?	**1.** Previous surgical treatment by orthopaedic oncology surgeon Dr. Gutowski or Dr. Tae Won Kim. **2.** Diagnosis of benign soft tissue tumor.
Orthopaedics	Christina J. Gutowski, MD	Pietro G. 856.968.7079	Device Study	A prospective observational study assessing the role of oxygen saturation levels in tissue and postoperative surgical wound complications in patients undergoing soft tissue tumor resection.	**1.** Age ≥ 18 years. **2.** Undergoing surgery for soft tissue tumor resection (benign or malignant).
Pulmonary	Wissam Abouzgheib, MD	Chris R. 856.342.3024	Device Study	Treatment of moderate to severe COPD with chronic bronchitis.	**1.** Age > 40 to < 80 years. **2.** Diagnosis of chronic bronchitis and COPD for a minimum of 2 years. **3.** Smoking history of at least 10 years.
Vascular Surgery AAA	Joseph V. Lombardi, MD	Jonelle O. 856.342.2150	Device Study	This study evaluates the safety and efficacy of a polymer and endovascular graft combination in the treatment of complex abdominal aortic aneurysms (AAA).	**1.** Age ≥ 18 years. **2.** Must have an aneurysm/ulcer of the abdominal aorta.
Vascular Surgery AAA	Joseph V. Lombardi, MD	Jonelle O. 856.342.2150	Device Study	This study evaluates a thoracic branch device in the treatment of aneurysms of the aortic arch and descending thoracic aorta.	**1.** Age > 18 years. **2.** Must have an aneurysm/ulcer of the thoracic aorta.
Vascular Surgery	Philip M. Batista, MD	Jonelle O. 856.342.2150	Biologics Study	This study evaluates the safety and tolerability of a human acelluar vessel in patients with vascular trauma who undergo surgery for vascular replacement and reconstruction.	**1.** Age > 18 years. **2.** Must have limb-threating injury to an artery that requires replacement or reconstruction.

Cooper University Health Care

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