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.

Fall/Winter 2016

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Anesthesiology Abdominal Surgery	Robert A. Hirsh, MD	Bill T. 856.968.7333	Treatment Study	This study is to compare the safety and efficacy of an IV analgesic in patients undergoing abdominal surgery.	1. Must be scheduled for laparoscopically-assisted, robotic, or open abdominal surgery. 2. Must be 21 or older at time of screening.
Anesthesiology Hip Fracture	Kelly A. Bolkus, MD	Bill T. 856.968.7333	Treatment Study	This study is evaluating two types of anesthesia to promote independence after hip fracture.	1. Must be 50 years or older. 2. Must have a hip fracture requiring surgical treatment. 3. Must have had the ability to walk without assistance before fracture.
Cardiology Arrhythmia/Implantable Defibrillator	Andrea M. Russo, MD	Claire F. Beeper 856.253.2361 Julie F. 856.669.8847	ICD Programming Study	The primary purpose of this study is to evaluate a subcutaneous ICD at specifically programmed settings.	1. Patient ≥ 21 years of age. 2. New patients undergoing a Subcutaneous ICD System (S-ICD) for primary prevention. 3. Patients without spontaneous sustained VT or VF.
Cardiology Arrhythmia/Implantable Defibrillator	John A. Andruilli, DO	Claire F. Beeper 856.253.2361 Leana A. 856.342.2648	Device Study	Patients who are scheduled to undergo a de novo pacemaker or ICD implant, generator exchange, device, lead, or pocket revision, or re-implantation after a recent CIED infection will be screened for entry into the study.	1. Age ≥18 years old. 2. At least two risk factors for infection.
Cardiology Arrhythmia/Implantable Defibrillator	Andrea M. Russo, MD	Claire F. Beeper 856.253.2361 Julie F. 856.669.8847	ICD Education Study	The purpose of this study is to provide patients with information about an implantable cardioverter defibrillator device (ICD) that prevents Sudden Cardiac Death (SCD), to learn more about what kind of information is helpful to patients in making treatment decisions with their doctors.	1. Age >21. 2. Eligible for an implantable cardioverter defibrillator (ICD) for the primary prevention of sudden cardiac death. 3. Non-hospitalized patients with ejection fraction ≤35%.
Cardiology Structural Heart Disease	Janah Aji, MD	Leana A. 856.342.2648	Device Study	The purpose of this trial is to evaluate the safety and effectiveness of transcatheter aortic valve implantation (TAVI) in patients with severe, symptomatic Aortic Stenosis (AS) at intermediate surgical risk with TAVI.	1. Must be 18 years of age or older. 2. Must require aortic valve replacement. 3. Must be symptomatic from his/her aortic valve stenosis, as demonstrated by New York Heart Association (NYHA) Functional Class II or greater."
Cardiology Structural Heart Disease	Sajjad A. Sabir, MD	Leana A. 856.342.2648	Device Study	This study is to compare the safety and efficacy of the percutaneous device for the treatment of moderate to severe symptomatic mitral regurgitation.	1. Must be 18 years of age or older. 2. Must have moderate to severe symptomatic mitral regurgitation and be considered high risk for surgical treatment. 3. Must be able to be randomized to device vs. medical therapy for moderate to severe mitral regurgitation.
Critical Care Septic Shock	R. Phillip Dellinger, MD	Christa S. 856.968.7493	Treatment Study	A double-blind randomized, placebo-controlled study investigating the efficacy and safety of Selepressin as treatment for patients with vasopressor-dependent septic shock.	1. Must be 18 years of age or older. 2. Proven or suspected infection. 3. Septic shock defined as hypotension requiring vasopressors despite adequate fluid resuscitation.
Hematology/Oncology Breast Cancer	Pallav K. Mehta, MD	Kim K. 856.735.6237	Treatment Study	This study is comparing standard treatment to standard treatment plus a non-steroidal antiandrogen in subjects with Advanced Triple Negative Breast Cancer who have received 0 or one prior treatment.	1. Must be 18 years of age or older. 2. Must have confirmed diagnosis of Advanced/Metastatic Triple Negative Breast Cancer (TNBC). 3. Must have had either 0 or one prior treatment for advanced/metastatic TNBC.
Hematology/Oncology Breast Cancer Surgery	Kristin L. Brill, MD	Kim K. 856.735.6237	Surgical/ Registry Study	This is a registry study for subjects who have axillary nodal metastases identified during ultrasound staging for Breast Cancer.	1. Must be 18 years of age or older. 2. Must have histologically confirmed Breast Cancer. 3. Must have axillary lymph node metastases.
Hematology/Oncology Non-Small Cell Lung Cancer	Polina Khrizman, MD	Kim K. 856.735.6237	Treatment Study	This study is comparing standard treatment to standard treatment plus anti Pd-L1 immunotherapy in subjects with previously untreated Non-Small Cell Lung cancer.	1. Must be 18 years of age or older. 2. Must have confirmed diagnosis of Stage IV Non-Small Cell Lung Cancer (NSCLC). 3. Must not have received prior treatment for Stage IV NSCLC.
Hematology/Oncology Ovarian, Fallopian Tube or Primary Peritoneal Cancer	David P. Warshal, MD	Kim K. 856.735.6237	Treatment Study	This study is looking at adding a new anti-cancer drug to standard treatment in women with relapsed Ovarian, Fallopian Tube or Primary Peritoneal Cancer that have previously responded to platinum therapy.	1. Must be 18 years of age or older. 2. Must have confirmed diagnosis of Advanced Ovarian, Fallopian Tube or Primary Peritoneal Cancer. 3. Must have received and responded to first-line platinum therapy.

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Hematology/Oncology Quality of Life and Behavioral	Evelyn Robles-Rodriguez, RN, MSN, APN, AOCN	Kim K. 856.735.6237	Quality of Life Study	This study is comparing two different psychological interventions for the treatment of insomnia in subjects who have non-metastatic Breast, Gynecologic, Lung, Colon or Prostate Cancers.	1. Must be 18 years old or over. 2. Must have a confirmed diagnosis of non-metastatic Breast, Gynecologic, Lung, Colon, or Prostate Cancer. 3. Must have self-reported and untreated insomnia.
Neurology TIA or Minor Stroke	Thomas R. Mirsen, MD	Andrew M. 856.342.2460	Drug Study	This study evaluates the safety and efficacy of a drug therapy for prevention of reoccurring ischemic event.	1. Males or Females 18 years of age and older. 2. High risk TIA; or 3. Minor ischemic stroke.
Neurology Huntington's Disease	Amy Colcher, MD	Andrew M. 856.342.2460	Drug Study	This study evaluates the safety and efficacy of drug therapy for Huntington's Disease.	1. Males or Females 18 years of age and older. 2. Huntington's Disease Stage I or II. 3. Ambulatory patients.
Neurosurgery Acute Spinal Cord Injury	Steven S. Yocom, DO	Andrew M. 856.342.2460	Device Study	This study evaluates the safety and efficacy of a surgical device implanted in those with spinal cord injury.	1. Males or Females between 16 and 70 years of age. 2. AIS A classification of traumatic spinal cord injury at spinal cord level T2 to T12/L1. 3. Non-penetrating SCI that is approximately 4 mm in diameter or greater.
Neurosurgery Acute Spinal Cord Injury	Steven S. Yocom, DO	Andrew M. 856.342.2460	Drug Study	This study evaluates the safety and efficacy of drug therapy injections in adults with spinal cord injury.	1. Males or Female between 14 and 75 years of age. 2. Acute traumatic cervical SCI, motor level of C4, C5, or C6 on each side. 3. AIS grade A or AIS grade B.
Orthopaedics Osteoarthritis	Lawrence S. Miller, MD	Justin F. 856.682.2501	Treatment Study	This study is to compare the safety and efficacy of using SVF cells derived from autologous adipose tissue to treat osteoarthritis of the knee.	1. Male or Female between ages of 40-75. 2. Must have grades II or III knee OA from KL-grade scale. 3. Having already tried two or more conservative therapies for relief: oral pain medications, physical therapy, corticosteroid injection of the knee, viscosupplementation injection of the knee.
Trauma Surgery Necrotizing Infections	Ju-Lin Wang, MD	Lisa C-W 856.361.1324	Drug Study	This study evaluates treatment and outcomes for patients with surgery for necrotizing soft tissue infections.	1. Males or Females 18 years of age and older. 2. Clinical diagnosis of necrotizing soft tissue infections AND requires surgery for treatment.
Vascular Surgery AAA	Jose L. Trani, 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 abdominal aortic aneurysms (AAA).	1. Age > 18 years. 2. Must have an aneurysm/ulcer of the abdominal aorta.

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

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