Department of Surgery
Division of Clinical Research

Current Protocols
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Abdominal Aortic Aneurysms

810068  Zenith® Fenestrated AAA Endovascular Graft Clinical Study (continued access)

PI: Ronald Fairman, MD
Contact: Linda Mark, RN (215) 662-4305
Recruiting at HUP

Key Inclusion Criteria:
(one of the following)
• Aortic or aortoiliac aneurysm with diameter ≥ 5 cm.
• Aortic or aortoiliac aneurysm with a history of growth ≥ 0.5 cm per year
• Clinical indications for AAA repair

Aortic Stenosis

806493  Stroke and Cognitive Dysfunction in Surgical Aortic Stenosis

PI: Michael A. Acker, MD
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Brandon Ciaudelli at (215) 662-4293
Scott Welden at (215) 662-4291
Recruiting at HUP, PPMC

Key Inclusion Criteria:
• Adults 65 years or older
• Diagnosis of moderate to critical Aortic Stenosis (with or without Coronary Artery Disease) –& recommended for Aortic Valve Replacement
• Diagnosis of stable moderate to severe Aortic Stenosis (with or without Coronary Artery Disease) - No surgery planned
• Diagnosis of stable Coronary Artery Disease with no more than mild Aortic Stenosis- No surgery planned
• Must be able to undergo an MRI (no pacemakers or MRI-incompatible implants or devices, not claustrophobic)
Carotid Artery Disease

811017 Carotid Stenting for High Surgical-Risk Patients; Outcomes Through The Collection of Clinical Evidence (CHOICE)

PI: Ronald Fairman, MD
Contact: Linda Mark, RN (215) 662-4305
Recruiting at HUP

Key Inclusion Criteria:
Patient is considered at high risk for carotid endarterectomy (CEA).

High Risk Patients
- Patients at high risk for CEA have significant co-morbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon.

Examples of significant co-morbid conditions and anatomical risk factors include, but are not limited to:
- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) < 30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis;
- recurrent stenosis and/or previous radical neck dissection;
- prior radiation treatment to the neck; and
- other conditions that were used to determine patients at high risk for CEA in the prior CAS trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II

1. Patient requires percutaneous carotid angioplasty and stenting for carotid artery disease. Patients with neurological symptoms and ≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram,
OR
2. Patients without neurological symptoms and ≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram.
Coronary Artery Disease

808756  Autologous Endothelial Progenitor Cells as Therapy for Ischemic Heart Disease

PI: Joseph Woo, MD
Contact: Jessica Howard (215) 615-3265
Recruiting at HUP

Key Inclusion Criteria:
- Requires at least coronary bypass graft x2
- Ejection Fraction less than or equal to 49%

Heart Failure

808277  Levitronix® CentriMag® VAS-Failure-to-Wean from Cardiopulmonary Bypass Trial

PI: Michael Acker, MD
Contact: Jessica Howard (215) 615-3265
Recruiting at HUP

Key Inclusion Criteria:
- Cardiac dysfunction due to failure-to-wean from cardiopulmonary bypass
- Hemodynamic instability indicated by specific parameters measured

809304  Evaluation of the HeartWare® LVAD System for the Treatment of Advanced Heart Failure

PI: Michael Acker, MD
Contact: Kim Breuer (215) 662-4806
Recruiting at HUP

Key Inclusion Criteria:
- Patient listed status 1A or 1B for cardiac transplantation
- HeartWare LVAD is intended as Bridge-to-Transplant
- Patient is NYHA Class IV
A Prospective, Randomized, Controlled, Un-blinded, Multi-Center Clinical Trial to Evaluate the HeartWare® Ventricular Assist System for Destination Therapy of Advanced Heart Failure

PI: Michael Acker, MD
Contact: Kim Breuer (215) 662-4806
Recruiting at HUP

Key Inclusion Criteria:
- LVAD implant is intended as destination therapy
- Left ventricular ejection fraction < 25%
- Patients with advanced heart failure symptoms (Class IIIB or IV) who meet one of the following:
  o On optimal medical management, including dietary salt restriction and diuretics, for at least 45 out of the last 60 days and are failing to respond; or
  o In Class III or Class IV heart failure for at least 14 days, and dependent on intra aortic balloon pump (IABP) for 7 days and/or inotropes for at least 14 days

Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)

PI: Joseph Woo, MD
Contact: Joe Donnelly (215) 615-4667
Recruiting at HUP

Key Inclusion Criteria:
- Patient receives a durable mechanical circulatory support device (MCSD) which is FDA approved
- Implanted on or after March 1, 2006

SynCardia Freedom Driver System Study

PI: Michael Acker, MD
Contact: Kim Breuer (215) 662-4806
Recruiting at HUP

Key Inclusion Criteria:
- Implanted with temporary Total Artificial Heart (TAH-t)
- Off any IV medications
- Ambulatory
The SynCardia temporary Total Artificial Heart (TAH-t)
Postmarket Surveillance Study

PI: Michael Acker, MD
Contact: Kim Breuer (215) 662-4806
Joe Donnelly (215) 615-4667
Recruiting at HUP

Key Inclusion Criteria:
• Patient has received or is scheduled to received the TAH-t
• The patient is cardiac transplant eligible
• The patient is at risk of imminent death from biventricular heart failure.

Thoracic Aortic Disease

International Registry of Acute Aortic Dissection

PI: Reed E. Pyeritz, MD, PhD
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Recruiting at HUP

Key Inclusion Criteria:
• Acute aortic dissection and/or intramural hematoma ("acute" is defined as presentation to a primary or referral center within 14 days of symptom onset)
• Latrogenic dissections are eligible if the cause of the dissection occurred within 14 days of diagnosis

Key Exclusion Criteria:
• Acute aortic dissection due to traumatic injury
• Presentation over 14 days since symptom onset or an unknown date of symptom onset
An Evaluation of the GORE Conformable TAG Thoracic Endoprosthesis for the Primary Treatment of Aneurysm of the Descending Thoracic Aortic (CTAG 08-03)

PI: Joseph Bavaria, MD
Contact: Danh Vuong (215) 349-5752
Lauren Solometo at PPMC (215) 776-6761
Recruiting at HUP, PPMC

Key Inclusion Criteria:
- Presence of DTA aneurysm deemed to warrant surgical repair
- Fusiform (≥ 50 mm), or
- Saccular (no diameter criteria)
- Proximal and distal landing zone length ≥ 2.0 cm
- Landing zones must be in native aorta
- Landing zone may include left subclavian artery, if necessary
- All proximal and distal landing zone inner diameters are between 16-42 mm
- Diameter assessed by flow lumen and thrombus, if present; calcium excluded

Key Exclusion Criteria:
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements (sizing guide) for a single endoprosthesis diameter and the inability to use devices of different diameters (in adherence to the sizing guide) to compensate for the taper.
- Tortuous or stenotic iliac and/or femoral arteries and inability to use a conduit for vascular access
- Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s)
- Mycotic aneurysm
- Hemodynamically unstable aneurysm rupture
- Aortic dissection
- Planned coverage of left carotid or celiac arteries with the CTAG Device
- Known degenerative connective tissue disease
- ASA risk classification = V
- NYHA class IV
- Participating in another investigational device or drug study within 1 year of treatment
- Known sensitivities or allergies to the device materials
- Systemic infection and may be at increased risk of endovascular graft infection
Zenith TX2® TAA Endovascular Graft Post-market Approval Study (08-005-02)

PI: Joseph Bavaria, MD
Contact: Danh Vuong (215) 349-5752
Lauren Solometo at Presby (215) 776-6761
Recruiting at HUP, PPMC

Key Inclusion Criteria:
Patient has at least one the following:
- Descending thoracic aneurysm with diameter $\geq 5.0$ cm
- Descending thoracic aneurysm with a history of growth $\geq 0.5$ cm within the previous 12 months
- Descending thoracic degenerative or atherosclerotic ulcers $\geq 10$ mm in depth and $20$ mm in diameter.

Patients must be excluded if any of the following are true:
- Receiving home oxygen therapy
- FEV1 < 1 liter
- Left ventricular ejection fraction < 20%
- New York Heart Association Classification 4
- Myocardial infarction or stroke within the last 3 months
- Diagnosed or suspected congenital degenerative collagen disease (no Marfan’s or Ehlers-Danlos syndrome)
- Systemic infection (e.g., sepsis)
- Bleeding diathesis, uncorrectable coagulopathy or refuses blood transfusion
- Allergy to stainless steel, polyester, solder (tin, silver), polypropylene, nitinol, or gold
- Untreatable reaction to contrast, which in the opinion of the investigator, cannot be adequately premedicated
- Symptomatic carotid disease warranting intervention, which will not be performed prior to TAA repair
- Mycotic aneurysm, leaking/ruptured aneurysm, impending rupture, aortobronchial fistula, aortoesophageal fistula, dissection or traumatic injury
- Surgical or endovascular AAA repair within 30 days before or after TAA repair
- Previous placement of a thoracic endovascular graft
- Aortic dissection
- Prior open repair involving descending thoracic aorta including supra-renal aorta and/or arch (except prior elephant trunk procedure is acceptable if $> 30$ days post-procedure)
- Interventional and/or open surgical procedures (unrelated to TAA repair) within 30 days before or after TAA repair
Evaluation of the GORE Conformable TAG Thoracic Endoprosthesis for Treatment of Traumatic Transection of the Descending Thoracic Aorta (CTAG 08-02)

PI: Nimesh Desai, MD
Contact: Danh Vuong (215) 349-5752
Recruiting at HUP

Key Inclusion Criteria:
- Traumatic transection of the DTA that requires repair, determined by the treating physician
- Traumatic aortic transection location between, but does not include, the left subclavian artery and celiac artery
- Endovascular repair with the GORE Conformable TAG® Device performed < 14 days after aortic injury
- Proximal and distal landing zone length ≥ 2.0 cm
  - Landing zones must be in native aorta
  - Landing zone may include left subclavian artery, if necessary
- All proximal and distal landing zone inner diameters are between 16-42 mm
- Diameter assessed by flow lumen and thrombus, if present; calcium excluded

Key Exclusion Criteria:
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements (sizing guide) for a single endoprosthesis diameter and the inability to use devices of different diameters (in adherence to the sizing guide) to compensate for the taper
- Tortuous or stenotic iliac and/or femoral arteries and inability to use a conduit for vascular access
- Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s)
- Infected aorta
- Subject has a systemic infection and may be at increased risk of endovascular graft infection
- Planned coverage of left carotid or celiac arteries with the CTAG Device
- Known degenerative connective tissue disease, e.g., Marfan or Ehler-Danlos Syndrome
Evaluation of the GORE Conformable TAG Thoracic Endoprosthesis for the Treatment of Acute Complicated Type B Aortic Dissection (CTAG 08-01)

**PI:** Alberto Pochettino, MD  
**Contact:** Danh Vuong (215) 349-5752  
**Recruiting at HUP**

**Key Inclusion Criteria:**

- Presence of acute complicated type B aortic dissection:
  - Dissection is acute: Time from symptom onset to dissection diagnosis \( \leq 14 \) days
  - Dissection is complicated: Subject must present with at least one of the following:
    - Clinical evidence of organ or leg malperfusion
    - Contained rupture of the DTA
  - Dissection is type B: Entire dissection is distal to the left subclavian artery
  - Primary Treatment Indication is Class 1 Aortic Dissection 10: Classical aortic dissection with intimal flap between true and false lumen with double barrel flow in thoracic aorta
  - Subjects with multiple entry tears are allowed to be enrolled in the study

- Primary treatment is endovascular treatment with the CTAG device. Adjunctive treatments may include left subclavian artery revascularization, percutaneous fenestration, aortic stenting, peripheral vessel stenting, surgical fenestration, and/or peripheral artery bypass
  - Proximal landing zone characteristics include:
    - Proximal extent of intended proximal landing zone cannot be dissected
    - Length \( \geq 2.0 \) cm proximal to the primary entry tear
    - Trans-aortic diameters between 16-42 mm (diameter assessed by flow lumen
      - and thrombus, if present; calcium excluded)
    - Cannot be aneurysmal, heavily calcified, or have excessive intraluminal thrombus
    - Must be native aorta
    - May include left subclavian artery, if necessary
A Phase II Clinical Study of the Safety and Efficacy of the Relay™ Thoracic Stent-Graft in Patients with Thoracic Aortic Pathologies

PI: Wilson Szeto, MD
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Lauren Solometo at Presby (215) 776-6761
Recruiting at HUP, PPMC

Key Inclusion Criteria:
- The subject must meet at least one of the following:
  - Descending thoracic fusiform aneurysm, 5 cm in diameter or greater
  - Descending thoracic aneurysm that is 4 cm or more in diameter that has increased in size by 0.5 cm in last 6 months
  - Descending thoracic aneurysm with a maximum diameter that exceeds two times the diameter of the non-aneurysmal, adjacent aorta
  - Saccular aneurysm in the descending thoracic aorta or Penetrating Atherosclerotic Ulcers (PAUs)
  - Subject must have proximal and distal aortic neck suitable for stent-graft placement, with diameter ranging between 18 mm and 42 mm.
  - Subject must have a proximal attachment zone distal to the left common carotid and a distal attachment zone proximal to the origin of the celiac artery. The length of the attachment zones will depend on the intended stent graft diameter. The proximal attachment zone should be 15 mm for 22 – 28 mm grafts, 20 mm for 30 – 38 mm grafts, and 25 mm for 40 – 46 mm grafts. The distal attachment zone should be 25 mm for 22 – 38 mm grafts and 30 mm for 40 – 46 mm grafts. Note that coverage of the left subclavian artery is permitted. Additionally, coverage of the celiac artery is permitted but only if this artery is already occluded at the time of the procedure.
  - Subject’s vascular dimensions (e.g., aortic diameters, length from left subclavian to celiac artery) must be in the range that can be safely treated with the Relay Delivery Systems.
  - Subject has adequate vascular access (e.g., patent iliac or femoral arteries) for introduction of the delivery system (26 Fr maximum outer diameter [8.7 mm]). Alternatively, subject may have femoral or iliac arteries that can be extended via an access conduit.

Continued on next page
Key Exclusion Criteria:
- Subject has any of the following conditions in his/her descending thoracic aorta:
  - Dissections – acute or chronic, in ascending or descending aorta
  - Intramural Hematoma (current or previous)
  - Acute Transection or Acute Traumatic Injury
  - Pseudoaneurysm (false aneurysm)
  - Symptomatic Aneurysm, including ruptured lesions

Evaluation of the clinical performance of the Valiant Thoracic Stent Graft with Captivia Delivery System for the treatment of acute, complicated Type B aortic dissections

**PI:** Wilson Szeto, MD
**Contact:** Danh Vuong (215) 349-5752
**Recruiting at HUP**

Key Inclusion Criteria:
- Subject must be considered a candidate for elective surgical repair of the TAA (i.e., low-to-moderate risk [categories 0, 1, and 2] per the modified SVS/AAVS scoring system at the time of implant). See Appendix B: Modified SVS/AAVS Medical Co-Morbidity Grading System
- Subject has a DTA that is:
  - A fusiform aneurysm with a maximum diameter of ≥ 5 cm OR is > 2 times the diameter of the non-aneurysmal thoracic aorta; AND/OR Saccular aneurysm (penetrating atherosclerotic ulcer)
- Subject’s anatomy must meet all of the following anatomical criteria:
  - Subject’s TAA must be ≥ 20 mm distal to the origin of the left common carotid artery
  - and must be ≥ 20 mm proximal to the celiac artery;
  - Proximal and distal non-aneurysmal neck diameter measurements must be between 20 mm and 42 mm;
  - Proximal and distal non-aneurysmal neck must be ≥ 20 mm in length.
- Thoracic aortic lesion is confirmed, at a minimum, by diagnostic contrast enhanced computerized tomography (CT) with optional 3-D reconstruction, and/or contrast enhanced Magnetic Resonance Angiogram obtained within four (4) months prior to the implant procedure.

**Continued on next page**
• Subject has patent iliac or femoral arteries or can tolerate a vascular conduit that allows endovascular access to the aneurysmal site with the delivery system of the appropriate size device chosen for treatment.

Key Exclusion Criteria:

• Planned placement of the COVERED portion of the stent graft over the left carotid artery, or the celiac trunk.
• Subject has systemic infection.
• Subject has a history of Marfan syndrome or other connective tissue disorder.
• Subject is pregnant.
• Subject has received a previous stent or stent graft or previous surgical repair in the DTA.
• Subject has had a cerebral vascular accident (CVA) within 2 months.
• Subject has a history of bleeding diathesis, coagulopathy, or refuses blood transfusion.
• Subject is currently participating in an investigational drug or device clinical trial which would interfere with the endpoints and follow-ups of this study.
• Subject has a known allergy or intolerance to the device components.
• Subject has a known hypersensitivity or contraindication to anticoagulants or contrast media, which is not amenable to pre-treatment.
• Subject has a co-morbidity causing expected survival to be less than 1 year.
Valve Disease

**812272** Post-Approval Study Protocol of the St. Jude Medical Biocor and Biocor Supra Valves

*PI: Joseph Woo, MD*

*Contact: Jessica Howard (215) 615-3265*

*Recruiting at HUP*

**Key Inclusion Criteria:**
- Requires aortic or mitral valve replacement

**808782** Surgical Interventions for Moderate Ischemic Mitral Regurgitation

*PI: Michael Acker, MD / Joseph Woo, MD*

*Contact: Mary Lou Mayer, RN (215) 662-7981*

*Dorothy Kliniewski, RN (215) 615-0518*

*Recruiting at HUP, PAH, PPMC*

**Key Inclusion Criteria:**
- Moderate MR by TTE, using an integrative method.
- CAD amenable to coronary artery bypass grafting and a clinical indications for revascularization

**Key Exclusion Criteria:**
- Any evidence of structural (chordal or leaflet) MV disease. Prior surgical or percutaneous mitral valve intervention

**809901** Surgical Ablation versus no Surgical Ablation for Patients with Persistent or Longstanding Persistent Atrial Fibrillation Undergoing Mitral Valve Surgery

*PI: Michael Acker, MD / Joseph Woo, MD*

*Contact: Mary Lou Mayer, RN (215) 662-7981*

*Recruiting at HUP, PAH, PPMC*

**Key Inclusion Criteria:**
- Clinical indications for MV Surgery
- Persistent AF or Longstanding Persistent AF

**Key Exclusion Criteria:**
- AF w/o MV surgery.
- AF is paroxysmal.
- Evidence of left atrial thrombus by intra-operative TEE and active infection
Evaluation of Outcomes Following Mitral Valve Repair/Replacement in Severe Chronic Ischemic Mitral Regurgitation

PI: Michael Acker, MD / Joseph Woo, MD
Contact: Mary Lou Mayer, RN (215) 662-7981
Dorothy Kliniewski, RN (215) 615-0518
Recruiting at HUP, PAH, PPMC

Key Inclusion Criteria:
• Chronic severe ischemic MR by TTE using an integrative method, CAD with or without the need for coronary revascularization.
• Eligible for surgical repair and replacement of mitral valve

Key Exclusion Criteria:
• Any evidence of structural (chordal or leaflet) MV disease. Prior surgical or percutaneous mitral valve intervention

The PARTNER Trial: Placement of aortic transcatheter valves

PI: Joseph Bavaria, MD
Contact: Lisa Walsh (215) 662-4289
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Lauren Roche (215) 662-4228
Alice Carlin at Presby (215) 662-9548
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Recruiting at HUP, PPMC

Key Inclusion Criteria:
Critical AS AVA mean gradient > 40 mmHg or jet velocity greater than 4.0 m/s or an initial aortic valve area (AVA) of < 0.8 cm² (indexed EOA < 0.5 cm²/m²).
• Cohort A: Patients must have co-morbidities such that the surgeon and cardiologist Co-PIs concur that the predicted risk of operative mortality is ≥15% and/or a minimum STS score of 10
• Cohort B: Patients, after formal consults by a cardiologist and two cardiovascular surgeons agree that medical factors preclude operation, based on a conclusion that the probability of death or serious, irreversible morbidity exceeds the probability of meaningful improvement.

Key Exclusion Criteria:
• Non-operable without femoral access
• Creatinine > 3.0
The PARTNER II Trial: Placement of Aortic Transcatheter Valves

PI: Joseph Bavaria, MD
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Lauren Roche (215) 662-4228
Alice Carlin at Presby (215) 662-9548
Lauren Solometo at Presby (215) 776-6761
Recruiting at HUP, PPMC

Key Inclusion Criteria:
- Critical AS AVA mean gradient >40mmHg or jet velocity > 4.0 m/s
  and and initial AVA < 0.8cm² or indexed EOA , 0.5cm²/m²
- Deemed non-operable by 2 cardiovascular surgeons and 1 cardiac interventionist

Key Exclusion Criteria:
- Congenital Unicuspid or Bicuspid Aortic Valve
- Chronic renal insufficiency with a creatinine >3.0
- Need for emergency surgery

806983 Clinical Investigation of the Sorin Memo 3D™ Annuloplasty Ring for Mitral Valve Repair

PI: W. Clark Hargrove, III, MD
Contact: Lauren Solometo at Presby (215) 776-6761
Recruiting at PPMC

Key Inclusion Criteria:
- Annuloplasty ring indicated for reinforcement of dysfunctional or diseased native mitral valve.

810725 Post Approval Clinical Study for ATS 3f® Aortic Bioprosthesis Model 1000

PI: W. Clark Hargrove, III, MD
Contact: Lauren Solometo at Presby (215) 776-6761
Recruiting at PPMC

Key Inclusion Criteria:
- ≤ 60 years of age
- Tricuspid aortic valve requiring replacement
- With or without CABG or another valve repair, but not replacement
A Randomized Study to Compare Sizing, Implant Techniques and Hemodynamic Performance between the Mitroflow and the Carpentier-Edwards Magna Pericardial Tissue Valves in the Aortic Position

PI: Joseph Bavaria, MD
Contact: Marcus Pochettino (215) 349-5752
Recruiting at HUP

Key Inclusion Criteria:
- Patients eligible for screening are those indicated for implant with a bioprosthetic valve in the aortic position according to the current practice for valve selection at the center. Patients with any of the following exclusion criteria should not be enrolled:
  - Less than 18 years of age
  - Emergency surgery
  - Pre-existing valve prosthesis in the aortic position
  - Aortic root replacements or enlargements
  - Active endocarditis
A Randomized, Prospective, Multi-centered Study Comparing Clinical Outcomes of the Ligation of Intersphincteric Fistula Tract (LIFT) Procedure versus Use of an Anal Fistula Plug (AFP) in the Surgical Repair of Trans-sphincteric Anal Fistulae of Cryptoglandular Origin

PI: Joshua Bleier, MD
Contact: Robyn Broach (215) 776-8609
Recruiting at HUP, PPMC

Key Inclusion Criteria
- Has a documented diagnosis, confirmed by physical exam and/or Endorectal Ultrasound (if available), of a trans-sphincteric fistula tract determined to be of cryptoglandular origin. Fistula may be primary or recurrent

Key Exclusion Criteria
- History or suspicion of Inflammatory Bowel Disease (Crohn’s or Ulcerative Colitis)
- History of connective tissue disease
- Rectovaginal fistula
- Presence of horseshoe fistula
- History of immunosuppression therapy / treatment within previous six months
- Presents with a proximal diversion and refractory fistula
- Any physical condition, disease or disorder that would exclude subject from being a candidate for elective surgery
- Known history of allergy to pork or pork products
A Randomized Double-Blind Study of 2% Chlorhexidine Gluconate / 70% Isopropyl Alcohol vs Iodine Povacrylex [0.7% available Iodine] / 74% Isopropyl Alcohol for Perioperative Skin Preparation in Open Elective Colorectal Surgery

PI: Najjia Mahmoud, MD
Contact: Robyn Broach (215) 776-8609
Recruiting at HUP, PAH, PPMC

Key Inclusion Criteria
- Undergoing any large bowel procedure with an incision greater than or equal to 7 cm (including) ileostomy closure and Hartman’s colostomy reversals).
- A clean-contaminated preoperative classification.
- Patient must have decision-making capacity and undergo appropriate informed consent process.
- Non-pregnant or post menopausal or surgically sterilized females. If of childbearing age, patients must have a negative (serum or urine) pregnancy test prior to surgery.

Key Exclusion Criteria
- Antibiotics taken within 5 days prior to surgery.
- Infected wound classification.
- Preoperative evaluation that may preclude full closure of the skin.
- Incisions less than 7 cm.
- Ongoing radiation or chemotherapy treatment.
- Refusal to accept medically indicated blood products.
- Current abdominal wall infection or surgical site infection from previous laparotomy / laparoscopy.
- History of laparotomy within the last 60 days.
- Known allergy to iodine or to chlorhexidine gluconate.
- Participating in a preoperative antibiotic trial.
- Participating in a skin antiseptic trial
- Participating in Ulcerative colitis trial conflicting with this trial.
807010 A Randomized Trial of HER-2/neu Pulsed DC1 Vaccine for Patients with DCIS

PI: Brian Czerniecki, MD, PhD
Contact: Jeanne Schueller (215) 349-8399
Recruiting at HUP

Key Inclusion Criteria:
- Subjects with biopsy-proven DCIS, DCIS with microinvasion, or Paget’s disease of the nipple (DCIS of the nipple) who have not yet received definitive treatment.
- HER-2/neu positive tumor as determined by >5% of tumor population expressing this marker by immunohistochemical staining 2+ using anti-HER-2/neu verified by Dr. Paul Zhang in the Department of Pathology

705888 Development of DC Vaccines

PI: Brian Czerniecki, MD, PhD
Contact: Jeanne Schueller (215) 349-8399
Recruiting at HUP

Key Inclusion Criteria:
- Healthy non-pregnant volunteers over 18 years of age
Inamed Corporation Style 410 Silicone-Filled Breast Implant Continued Access Reconstruction/Revision Expansion (CARE) Clinical Study

PI: Joseph Serletti, MD
Contact: Nancy Folsom (215) 662-4150
Recruiting at HUP

Key Inclusion Criteria:
Patient presents with one or more of the following conditions:

- Primary breast reconstruction (i.e., no previous breast implant surgery other than implantation of tissue expanders or contralateral augmentation for asymmetry) indicated for the following:

  For affected breast(s):
  - Mastectomy for cancer
  - Prophylactic mastectomy
  - Breast trauma (resulting in mastectomy)

  For the unaffected (contralateral) breast:
  - Contralateral asymmetry (may be performed on the date of the mastectomy or the date when permanent implants are placed in the reconstructed breast).

Breast implant revision surgery (i.e., removal and replacement of breast implants) indicated for the following:

- Previous augmentation or reconstruction with silicone-filled or saline-filled breast implants.
- Adequate tissue available to cover implants.
- Patients at MRI designated sites must be willing to undergo MRI at their 2, 5 and 10 year follow-up visits (serial MRI). The patient must be eligible for MRI (for example, no implanted metal or metal devices and no history of severe claustrophobia that may make her ineligible for MRI).
Plastic Surgery

Key Exclusion Criteria:

- Advanced fibrocystic disease considered to be premalignant without accompanying subcutaneous mastectomy.
- Existing carcinoma of the breast, without mastectomy.
- Abscess or infection in the body at the time of enrollment.
- Pregnant or nursing.
- Have any disease, including uncontrolled diabetes (e.g., Hb A1c > 8%), that is clinically known to impact wound healing ability.
- Show tissue characteristics that are clinically incompatible with mammaplasty, such as tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration.
- Have, or under treatment for, any condition that may constitute an unwarranted surgical risk (e.g., unstable cardiac or pulmonary problems).
- Show psychological characteristics that may be incompatible with the surgical procedure and the prosthesis, such as inappropriate attitude or motivation (e.g., body dysmorphic disorder).
- Are not willing to undergo further surgery for revision, if medically required.
807056 A double-blind, randomized, placebo-controlled Phase III study to assess the efficacy of recMAGE-A3 + AS15 Antigen-Specific Cancer Immunotherapeutic as adjuvant therapy in patients with resectable MAGE-A3-positive Non-Small Cell Lung Cancer (NSCLC)

PI: John Kucharczuk, MD
Contact: Marie Kromplewski (215) 615-4117
Janet Riggs 215-615-4368
Recruiting at HUP

Key Inclusion Criteria:
- Patients with completely resected, stage IB,II or IIIA NSCLC (non small cell lung cancer)
- Surgical technique is at least a lobectomy or sleeve lobectomy
- Tumor to be tested for MAGE-A3 expression (must be positive to enroll onto the vaccine trial)
- Adequate bone marrow reserve

812341 An open-label, Phase I dose-escalation study to assess the safety and immunogenicity of recPRAME + AS15 Antigen-Specific Cancer Immunotherapeutic as adjuvant therapy in patients with resectable PRAME-positive Non-Small Cell Lung Cancer

PI: John Kucharczuk, MD
Contact: Marie Kromplewski (215) 615-4117
Janet Riggs 215-615-4368
Recruiting at HUP

Key Inclusion Criteria:
- Patients with completely resected, stage IB,II or IIIA NSCLC (non small cell lung cancer)
- Surgical technique is at least a lobectomy or sleeve lobectomy
- Tumor to be tested for PRAME expression (must be positive to enroll onto the vaccine trial)
- Adequate bone marrow reserve, renal and hepatic function
Z4051: A Phase II Study of Neoadjuvant Therapy with Cisplatin, Docetaxel, Panitumumab Plus Radiation Therapy Followed by Surgery in Patients with Locally Advanced Adenocarcinoma of the Distal Esophagus—; ACOSOG Z4051

PI: John Kucharczuk, MD
Contact: Marie Kromplewski (215) 615-4117
Janet Riggs 215-615-4368
Recruiting at HUP

Key Inclusion Criteria:
- Biopsy-proven resectable primary (nonrecurrent) adenocarcinoma of the distal esophagus or GE junction (Siewert Type I or II).
  Siewert Type definitions:
  - Siewert Type I: adenocarcinoma of the distal esophagus
  - Siewert Type II: adenocarcinoma of the esophago-gastric junction/real cardia
- Pre-registration EUS, CT of chest and upper abdomen, and PET must support a clinical stage of T3N0M0, T2-3N1M0 or T2-3N0-1M1a (celiac adenopathy must be ≤ 2 cm by EUS). Clinically staged T1 tumors and T2N0M0 tumors are not eligible. N1 does not require biopsy/FNA.
- No definitive radiological evidence of distant metastases.
- No pre-existing grade 2 or greater peripheral neuropathy of any etiology.
- Adequate bone marrow, hepatic and renal function prior to registration.
A2ALL-2 Adult to Adult Living Donor Transplant Cohort Study

PI: Kim Olthoff, MD
Contact: Kim Olthoff, MD (215) 662-6136
Mary Shaw (215) 614-0528

Key Inclusion Criteria:
- Must be receiving a live donor liver transplant

Effect of Thymoglobulin versus Basiliximab on Regulatory T Cell Function in Live Donor Kidney Transplant Recipient

PI: Matthew Levine, MD, Ph.D.
Emerg. Contact: Kidney Transplant Fellow (215) 662-4000
Recruiting at HUP

Key Inclusion Criteria:
- Live Donor Kidney Transplant
- No HCV, HIV or pregnancy
- May not be African American

AAV (adeno-associated virus) Reactivation during the Immune Suppression of Organ Transplantation

PI: Abraham Shaked, PhD
Emerg. Contact: Mary Shaw (215) 614-0528
Recruiting at HUP

Key Inclusion Criteria:
- 1st kidney or liver transplant
803167  AWISH (Immunosuppression Withdrawal in Liver Transplant Recipients TN030ST)

PI: Abraham Shaked, MD, PhD
Emerg. Contact: Mary Shaw (215) 614-0528
Recruiting at HUP

Key Inclusion Criteria:
- Non Hepatitis C
- 1st liver transplant
- Availability of donor specimens

704851  GRITS – Gene Expression and Regeneration Study

PI: Kim Olthoff, MD
Emerg. Contact: Mary Shaw (215) 614-0528
Recruiting at HUP

Key Inclusion Criteria:
- Any liver transplant

810787  TREG (Pilot study of Calcineurin Inhibitor Use on Regulatory T Cells (Tregs) in Adults Liver Transplant Recipients)

PI: Matthew Levine, MD, PhD
Emerg. Contact: Mary Shaw (215) 614-0528
Recruiting at HUP

Key Inclusion Criteria:
- Liver transplant
**Sapphire AST-111 / Evaluation of Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury**

**PI:** Pat Kim, MD  
**Contact:** Joy Steele, BSN (267) 971-0021  
**Recruiting at HUP**

**Key Inclusion Criteria:**
- SICU admission with urinary catheter admitted to unit within 24 hours
- Need for indwelling urinary catheter minimum 48 hours after enrollment

**Key Exclusion Criteria:**
- Previous renal transplant
- Known moderate to severe acute kidney injury
- HIV acute or chronic active hepatitis
- Hgb < 7 g/dL
- Active bleeding with anticipated need for > 4 units PRBCs
- Acute or chronic dialysis or imminent need of dialysis

**An open-label, randomized, multicenter, Phase IIIB study to assess the efficacy, safety, and tolerance of Beriplex® P/N compared with plasma for rapid reversal of coagulopathy induced by vitamin K antagonists in subjects requiring an urgent surgical procedure.**

**PI:** Pat Kim, MD  
**Contact:** Joy Steele, BSN (267) 971-0021  
**Recruiting at HUP**

**Key Inclusion Criteria**
- Subjects currently on oral VKA therapy,
- An urgent surgical procedure is required within 24 hours of the start of IMP,
- Due to the nature of the procedure, withdrawal of oral VKA therapy and infusion of plasma are also indicated to reverse the VKA effect,
- INR ≥ 2 within 3 hours before start of IMP
A pilot, single institutional, prospective, non-blinded, three-phase, three-arm open label study to compare two single-agent osmotherapies (20% mannitol or 5% NaCl (hypertonic saline) to standard of care crossover therapy in subjects who have traumatic brain injury and refractory intracranial hypertension requiring osmotherapy

Key Inclusion Criteria:
- Presence of ICP monitor (add or pending placement)
- measured ICP < 20 mm Hg for > 5 minutes unrelated to procedural pain, patient manipulation
- Not more than one dose of mannitol given emergently prior to arrival in ICU
- GCS < 8
- Osmol gap < 20

Key Exclusion Criteria:
- Known chronic hyponatremia
- Known or current renal failure, serum creatinine > 1.5, CHF, cardiogenic pulmonary edema
- Previous traumatic brain injury requiring hospitalization > 1 day
- Hx of stroke, neurosurgery or brain tumors
A randomized, double-blind, placebo-controlled, dose-escalation study to assess the anti-inflammatory activity, efficacy, and safety of intravenous SB-681323 in subjects at risk for development of acute lung injury or ARDS

PI: Jason Christie, MD
Investigator: Pat Kim
Contact: Joy Steele, BSN (267) 971-0021
Recruiting at HUP

Key Inclusion Criteria
- ISS > 16 to < 70
- Major trauma, admitted to ICU
- Randomization with 24 hours of trauma, not admission

A Prospective Study Examining Change in Stroke Volume During Passive Leg Raise as a Predictor of Volume Challenge Response Measured by an Arterial Pulse Pressure Cardiac Output Monitor

PI: John Gallagher, MD

Key Inclusion Criteria:
- 18 yoa or older admitted to SICU anticipated to receive fluid or bolus

Key Exclusion Criteria:
- Intervention to lower extremities or pelvis preventing manipulation of lower extremity, increased intracranial pressure preventing supine positioning
A Phase II Study to Evaluate: Delay in Intravaginal Ejaculatory Latency Time (IELT), Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Two Oral Doses of GSK557296 in a Randomized, Double Blind, Placebo-Controlled, Parallel Group Study in Men with Premature Ejaculation

PI: Andrew Axilrod, MD
Contact: Sylvia Salazar, MD (215) 615-3780
Recruiting at HUP

Key Inclusion Criteria:
- Diagnosed with PE
- 18-55 years old
- No conmeds except for seasonal allergies treatment, stable asthma medication, and multivitamins

Key Exclusion Criteria:
- Erectile Dysfunction
- liver or heart disease
- Primary Hipoactive Sexual Disorder
- Active peptic ulceration

Labs will be drawn including for HIV, Hepatitis, and Nicotine
Genitourinary Tumor Tissue and Biospecimen Bank (GUTTAB)

Genitourinary Tumor Tissue and Biospecimen Bank (GUTTAB)

PI: David I. Lee, MD
Contact: Sylvia Salazar, MD (215) 615-3780
Mary Walicki, RN (215) 662-9633
Recruiting at HUP

Key Inclusion Criteria:
- Male or female over 18 years of age
- Cancer genitourinary surgery through UPHS

Key Exclusion Criteria:
- Not able to sign consent
A Prospective Study of Quality of Life and Functional Outcomes in Patients with Urologic Malignancies

**PI:** Thomas Guzzo, MD  
**Contact:** Sylvia Salazar, MD (215) 615-3780  
**Recruiting at HUP**

**Key Inclusion Criteria:**
- Male  
- Diagnosis of bladder cancer  
- Treatment of BCG

**Key Exclusion Criteria:**
- Previous BCG treatments (booster)  
- Unable to consent

A Single-Masked, Randomized, Multi-Center, 2-Arm Parallel Study Comparing the Safety and Effectiveness of Bulkamid® and Contigen® as Bulking Agents for the Treatment of Stress Urinary Incontinence in Female

**PI:** William Jaffe, MD  
**Contact:** Sylvia Salazar, MD (215) 615-3780  
Mary Walicki, RN (215) 662-9633  
**Recruiting at HUP, PPMC**

**Key Inclusion Criteria:**
- Female over 18 years old  
- Bladder Diary incontinence episodes  
- Diagnosis of mainly stress Urinary incontinence

**Key Exclusion Criteria:**
- detrusor overactivity  
- previous surgical treatment for UI  
- Investigator and Medical Monitor UDS parameter approval
A Prospective Multi-Institutional Robotic Genitourinary Surgery Registry

PI: David I. Lee, MD
Contact: Sylvia Salazar, MD (215) 615-3780
Mary Walicki, RN (215) 662-9633

Key Inclusion Criteria:
- Male or female over 18 years of age
- Robotic surgery
- Multi-site

Key Exclusion Criteria:
- Not to have had robotic surgery

A Prospective Laparoscopic Genitourinary Surgery Registry

PI: David I. Lee, MD
Contact: Sylvia Salazar, MD (215) 615-3780
Mary Walicki, RN (215) 662-9633

Key Inclusion Criteria:
- Male or female over 18 years of age
- Robotic surgery
- Penn subjects only

Key Exclusion Criteria:
- Not to have had robotic surgery
Translating Unique Learning for Incontinence Prevention
(The TULIP Project)

PI: Diane Newman, CRNP
Contact: Sylvia Salazar, MD (215) 615-3780

Key Inclusion Criteria:
- Female over 55 years of age
- Negative for demonstrable UI

Key Exclusion Criteria:
- Pelvic pain
- Actively taking UI medication
- Evidence of UTI (by urine dipstick for leukocytes +1 and/or hematuria +1) Patients can be re-screened after 10 days of treatment on antibiotics or if the work up for an UTI is negative
- History of > 2 recurrent UTI’s in the past year and no more than one UTI within 6 months
- Post void residual > 150 cc
Zenith® Fenestrated AAA Endovascular Graft Clinical Study
(continued access)

PI: Ronald Fairman, MD
Contact: Linda Mark, RN (215) 662-4305
Recruiting at HUP

Key Inclusion Criteria: (one of the following)
• Aortic or aortoiliac aneurysm with diameter ≥ 5 cm
• Aortic or aortoiliac aneurysm with a history of growth ≥ 0.5 cm per year
• Clinical indications for AAA repair

Zenith Iliac Branch System Clinical Study (05-625-05)

PI: Edward Woo, MD
Contact: Linda Mark, RN (215) 662-4305

Key Inclusion Criteria:
• An aortoiliac or iliac aneurysm
• An unsuitable distal sealing site for a traditional Zenith iliac leg graft within common iliac artery on intended side of Branch Graft implantation (e.g., fixation/seal length < 10 mm or diameter > 20 mm)

Key Exclusion Criteria:
• Proximal neck < 15 mm in length
• Proximal neck, measured outer wall to outer wall on a sectional image (CT), > 32 mm in diameter or < 18 mm in diameter
• Inadequate common iliac fixation site or occluded internal iliac artery on side opposite of intended implantation of the Zenith Branch Endovascular Graft-Iliac Bifurcation
• Proximal neck angulated more than 60 degrees relative to the long axis of the aneurysm
• Immediately suprarenal neck angulated more than 45 degrees relative to the immediate infrarenal neck
• Proximal neck inverted funnel shape
• Proximal neck with circumferential thrombus/atheroma
• Severe occlusive disease, tortuosity, or calcification of the iliac arteries
• Iliac artery diameter on either side, measured inner wall to inner wall on a sectional image (CT), < 7.5 mm (prior to deployment)
• Indispensable inferior mesenteric artery (IMA)
• Renal artery stenosis > 80%
• Unsuitable arterial anatomy
Carotid Stenting for High Surgical-Risk Patients; Outcomes Through The Collection of Clinical Evidence (CHOICE)

PI: Ronald Fairman, MD
Contact: Linda Mark, RN (215) 662-4305
Recruiting at HUP

Key Inclusion Criteria:
Patient is considered at high risk for carotid endarterectomy (CEA).

High Risk Patients:
- Patients at high risk for CEA have significant co-morbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon.

Examples of significant co-morbid conditions and anatomical risk factors include, but are not limited to:
- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) <30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis;
- recurrent stenosis and/or previous radical neck dissection;
- prior radiation treatment to the neck; and
- other conditions that were used to determine patients at high risk for CEA in the prior CAS trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II

1. Patient requires percutaneous carotid angioplasty and stenting for carotid artery disease. Patients with neurological symptoms and ≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram,
OR
2. Patients without neurological symptoms and ≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram.
Zenith Low Profile AAA Endovascular Graft Study
Continued Access (08-013-04)

PI: Edward Woo, MD
Contact: Linda Mark, RN (215) 662-4305

Key Inclusion Criteria:
At least one of the following AND is suitable for treatment with the Zenith Low Profile AAA Endovascular Graft and 16 Fr H&L-B One-Shot Introduction System:

- Aortic or aortoiliac aneurysm with a diameter $\geq 5.0$ cm for males or $\geq 4.5$ cm for females
- Iliac aneurysm with a diameter $\geq 3.0$ cm
- Aneurysm with a history of growth $\geq 0.5$ cm per year

Key Exclusion Criteria:

- Significant occlusive disease, tortuosity or calcification
- Proximal neck $< 15$ mm in length
- Proximal neck, measured outer wall to outer wall on a sectional image (CT) $> 28$ mm in diameter or $< 18$ mm in diameter
- Proximal neck angulated more than 60 degrees relative to the long axis of the aneurysm
- Immediate suprarenal neck angulated more than 45 degrees relative to the immediate infrarenal neck
- Proximal seal site with inverted funnel shape (change in neck diameter $> 10\%$ over the first 15 mm of proximal neck length)
- Proximal seal site with circumferential thrombus/atheroma
- Aortic diameter, measured inner wall to inner wall on a sectional image (CT), $< 20$ mm at the bifurcation
- Iliac/femoral anatomy that is unsuitable for access with the 16 Fr (6 mm nominal sheath O.D.) introduction system
- Iliac artery diameter, measured outer wall to outer wall on a sectional image (CT), $> 20$ mm or $< 8$ mm at distal fixation site
- Iliac artery distal fixation site $< 10$ mm in length
- Indispensable inferior mesenteric artery (IMA)
- Inability to maintain at least one patent hypogastric artery
- Renal artery stenosis $> 80\%$ (and serum creatinine $> 2.0$ mg/dl)
- Unsuitable arterial anatomy
Zenith TX2 Low Profile TAA Endovascular Graft

**Key Inclusion Criteria:**
At least one of the following AND is suitable for treatment with the Zenith TX2 Low Profile TAA Endovascular Graft and 16 Fr or 18 Fr Z-Trask Plus Introduction System:
- Descending thoracic aneurysm with diameter $\geq 5.0$ cm
- Descending thoracic aneurysm with a history of growth $\geq 0.5$ cm per year
- Descending thoracic degenerative or atherosclerotic ulcer $\geq 10$ mm in depth and 20 mm in diameter

**Key Exclusion Criteria:**
- Treatment length (i.e., aneurysm/ulcer length including fixation sites) along greater curvature:
  - a. $> 127$ mm for 18 to 24 mm diameter grafts
  - b. $> 149$ mm for 26 mm diameter grafts
  - c. $> 355$ mm for 28 to 32 mm diameter grafts (straight and tapered)
  - d. $> 324$ mm for 34 and 36 mm diameter grafts (straight)
  - e. $> 363$ mm for 34 to 36 mm diameter grafts (tapered)
  - f. $> 339$ mm for 38 mm diameter grafts (straight)
  - g. $> 332$ mm for 38 mm diameter grafts (tapered)
- Proximal neck length measuring $< 20$ mm between the left common carotid artery and aneurysm (covering the subclavian artery is acceptable except in patients with LIMA bypass, anomalous vertebral artery off of the arch in the region of the subclavian artery, or dominant vertebral artery off of the subclavian artery)
- Distal neck length measuring $< 20$ mm between the celiac artery and the aneurysm
- Aortic arch radius $< 20$ mm (if device is deployed in arch)
- Proximal neck diameter, measured outer wall to outer wall on a sectional image or multiplanar reconstruction (CT), $< 15$ mm or $> 34$ mm
- Distal neck diameter, measured outer wall to outer-wall on a sectional image or multiplanar reconstruction (CT), $< 15$ mm or $> 34$ mm (estimate from more proximal segment if diaphragm makes identification of the outer wall difficult)
• Tortuosity, calcification, occlusive disease, or arterial diameter, measured inner wall to inner wall on a sectional image, that is not conducive to placement of the introducer sheath (16 Fr for 18 to 30 mm diameter grafts or 18 Fr for 32 to 38 mm diameter grafts) – use of an access conduit is acceptable
• Prohibitive calcification, occlusive disease, or tortuosity of intended fixation sites
• Circumferential thrombus in region of intended fixation sites
• Inverted funnel-shaped proximal neck with > 10% increase in diameter over length of neck
• Funnel-shaped distal neck with > 10% increase in diameter over length of neck
• Inability to preserve the left common carotid artery and celiac artery
• Aneurysm or angulation in the distal thoracic aorta that would preclude advancement of the introduction system