

Cardiothoracic and Vascular Surgeons Clinical Research Department

### SITE CURRICULUM VITAE

At CTVS we are dedicated to providing access to the most advanced, state-of-the-art surgical care for our patients and participating in the scientific advancement of surgical medicine with a commitment to excellence in medical care.

#### **RESEARCH SITE LOCATIONS:**

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#### **RESEARCH HOSPITAL AFFILIATIONS:**

The Heart Hospital of Austin 3801 North Lamar Austin, TX 78756

St. David's South Austin Medical Center 901 W Ben White Blvd. Austin, TX 78704

St. David's Medical Center 919 E 32nd St. Austin, TX 78705

### **RESEARCH COMMITTEE:**

Faraz Kerendi, MD - Chair Stephen Dewan, MD Brannon Hyde, MD Jonathan Yang, MD Daniel Fortes, MD Jeffrey Apple, MD

### **DEPARTMENT MANAGERS:**

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Isaiah Knight Clinical Research Coordinator

Kathlyne Brown, DO, CCRP Clinical Research Assistant

# **RESEARCH STUDIES:**

# Current Research Studies:

<u>VERNACULAR</u> - The BARD® VENOVO <sup>™</sup> Venous Stent Study – A Prospective, Non-Randomized, Multi-Center, Single-Arm Study of the Treatment of Iliofemoral Occlusive Disease – an Assessment for Effectiveness and Safety Sponsor: Bard Peripheral Vascular, Inc., Principal Investigator: Jeffrey Apple, MD, 9/16

<u>RECON Study</u> – A Post Market Observational Study to Obtain Additional Information on the Use of CorMatrix ECM for Pericardial Reconstruction. Sponsor: CorMatrix Cardiovascular Inc., Prinicipal Investigator: Faraz Kerendi, MD, 2/17

<u>TBE Device</u> - Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in the Treatment of Lesions of the Aortic Arch and Descending Thoracic Aorta. Sponsor: W. L. Gore & Associates, Principal Investigator: Mark Felger, MD, 2/17

<u>MYPRO RETRO</u> - Myocardial Protection in Adult Cardiac Surgery Utilizing del Nido Cardioplegia- A Retrospective Review. Sponsor: Cardiothoracic and Vascular Surgeons, Principal Investigator: William C. Conner, MD 5/16

<u>ROADSTER 2</u> – Registry of Transcarotid Artery Revascularization in Patients with Significant Carotid Artery Disease. The ROADSTER2 Registry. Sponsor: Silk Road Medical, Principal Investigator: Mazin Foteh, MD, 11/15

<u>ENDURANT EVO</u> – Endurant Evo US Clinical Trial. Sponsor: Medtronic Endovascular Principal Investigator: Stephen Settle, MD, 8/15

<u>PATENCY 2</u> - Multicenter, Double Blind, Placebo Controlled Study of Vonapanitase (PRT- 201) Administered Immediately After Radiocephalic Arteriovenous Fistula Creation in Patients With Chronic Kidney Disease. Sponsor: Proteon Therapeutics, Principal Investigator: Stephen Settle, MD, 6/15

<u>LEOPARD</u> - Multicenter, Post-Market Study to Assess Outcomes of Patients Treated With the AFX System Compared to Other EVAR Devices for Endovascular Abdominal Aortic Aneurysm Repair. Sponsor: Endologix, Principal Investigator: Jeffrey Apple, MD, 11/15

<u>CREST-2</u> – Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial. Sponsor: National Institutes of Health, Principal Investigator: Mazin Foteh, MD, 4/15

<u>LIBERTY 360°</u> – Prospective, Observational, Multi-Center Clinical Study to Evaluate Acute and Long Term Clinical and Economic Outcomes of Endovascular Device Intervention in Patients with Distal Outflow Peripheral Arterial Disease (PAD). Sponsor: Cardiovascular Systems, Inc, Principal Investigator: Mazin Foteh, MD, 3/15

<u>PERIGON</u> - Medtronic PERIcardial SurGical AOrtic Valve ReplacemeNt Pivotal Trial A Multi-center, Nonrandomized Trial to Determine the Safety and Effectiveness of the Model 400 Aortic Valve Bioprosthesis in Patients With Aortic Valve Disease. Sponsor: Medtronic Cardiovascular, Principal Investigator: Faraz Kerendi, MD, 2/15

<u>VIVO</u> - Evaluation of the Zilver Vena Venous Stent in the Treatment of Symptomatic Iliofemoral Venous Outflow Obstruction. Sponsor: Cook Incorporated, Principal Investigator: Jeffrey Apple, MD, 5/14

<u>GREAT</u> - "GREAT" Global Registry for Endovascular Aortic Treatment Outcomes Evaluation. Sponsor: W.L. Gore & Associates, Principal Investigator: Stephen Settle, MD 5/14 CTVS Clinical Research Site Curriculum Vitae Page 3 of 4

<u>CONVERGE</u> - Convergence Of Epicardial And Endocardial Radiofrequency (RF) Ablation For The Treatment Of Symptomatic Persistent AF. Sponsor: nContact Surgical Inc. Principal Investigator: Faraz Kerendi, MD, 12/13

<u>PARTNER II</u> - SAPIEN XT<sup>TM</sup> Transcatheter Heart Valve with NovaFlex and Ascendra delivery systems in Intermediate and High Risk for Aortic Valve Surgery and Patients Who Cannot Undergo Surgery. The PARTNER II Trial "Placement of AoRTic TraNscathetER" Valves Trial". Sponsor: Edwards Lifesciences, Principal Investigator: Faraz Kerendi, MD, 2/13

<u>PARTNER 3 Trial</u> - A Prospective, Randomized, Controlled, Multi-Center Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients Requiring Aortic Valve Replacement who have Severe, Calcific, Symptomatic Aortic Stenosis. Sponsor: Edwards Lifesciences, Principal Investigator: Faraz Kerendi, MD, 8/16

<u>ALCHEMIST</u> - Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial Sponsor: National Cancer Institute (NCI), Investigator: Daniel Fortes, MD, 10/15

<u>CONVERGENT</u> – Retrospective Study of Outcomes of the Convergent Procedure for the Treatment of Persistent and Longstanding Persistent Atrial, Sponsors Include: Austin Heart PLLC, Principal Investigator: Faraz Kerendi, MD, 8/14

<u>CONVERGE</u> – nContact EPI-Sense AF Guided Coagulation System with VisiTrax for the treatment of symptomatic persistent AF. Sponsor: nContact, Principal Investigator: Faraz Kerendi, MD 5/14

<u>TEVAR B</u> – SVS PSO Type B Thoracic Aortic Dissection Quality Improvement Project. Sponsor: Society for Vascular Surgery Patient Saftey Organization, Principal Investigator: Mazin Foteh, MD 5/14

<u>COAPT</u> Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation. Sponsor: Evalve, Investigator: William Kessler, MD, 8/12

<u>PORTICO</u> – Transcatheter heart valve therapy vs. commercially available trans-catheter valve (CAV) in patients with symptomatic severe native aortic stenosis, who are considered high or extreme surgical risk. Principal Investigator: Faraz Kerendi, MD Sponsor: St. Jude Medical, 9/14

## **Completed Research Studies:**

C2R - CREST2 Registry. Sponsor: National Institutes of Health, Principal Investigator: Mazin Foteh, MD, 4/15

<u>CONTEGRA</u> - Use of Contegra Pulmonary Valve Conduit Designated as Humanitarian Use Device. Sponsor: Medtronic, Principal Investigator: Kenneth Fox, MD 1/11

<u>RETRO-OP</u> - Retrospective Study of Outcomes of Pain Management using Liposomal Bupivacaine following Surgical Procedure, Principal Investigator: Brannon Hyde, MD, 4/15

<u>ROADSTER</u> – Investigation of flow altered, short transcervical carotid artery stenting in patient with significant carotidartery disease with filter. Sponsor: Silk Road Medical, Principal Investigator: Mazin Foteh, MD 5/13

<u>PERCEVAL</u> - Clinical Investigation of the Perceval S Sutureless Heart Valve. Sponsor: Sorin Group USA, Inc., Principal Investigator: William Kessler, MD 4/13

<u>EXCEL</u> - Evaluation of XIENCE PRIME or XIENCE V versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization. Sponsor: Abbott Vascular. Principal Investigator: John Oswalt, MD 2/12

<u>CRYOVALVE</u> - CryoValve SG Pulmonary Valve, Post Clearance Study. Sponsor: CryoLife, Inc, Principal Investigator: John Oswalt, MD 1/10

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<u>TRIFECTA</u> - An Observational, Prospective Evaluation of the Trifecta<sup>TM</sup> Valve. Sponsor: St. Jude Medical, Principal Investigator: John Oswalt, MD 11/07

<u>TRIFECTA</u> - An Observational, Prospective Evaluation of the Trifecta<sup>™</sup> Valve Sponsor: St. Jude Medical, Inc, Principal Investigator: Stephen Dewan, MD 08/08

<u>BIOCOR</u> – Post-Approval Study Protocol of the St. Jude Medical Biocor and Biocor Supra Valves. Sponsor: St. Jude Medical, Inc, Principal Investigator: Mark Felger, MD 08/08

<u>GRAFTCATH</u> - GRAFTcath Vascular Access System (GVAS) Clinical Study Protocol. Sponsor: GRAFTcath, Principal Investigator: Stephen Settle, MD 10/05

<u>PRIMO-CABII</u> - A Multicenter, Randomized, Double-Blind, Parallel-group, Placebo-Controlled Study of 2 mg/kg Bolus Plus 24-hour 0.5 mg/kg/hr Infusion Pexelizumab in Patients Undergoing Coronary Artery Bypass Grafting with Cardiopulmonary Bypass. Sponsor: Procter & Gamble/Alexion Pharmaceuticals, Principal Investigator: Andrew Hume, MD 02/05

<u>EPIC</u> - An Observational Prospective Evaluation of the SJM Epic<sup>™</sup> Valve. Sponsor: St. Jude Medical, Inc, Principal Investigator: John D. Oswalt, MD 05/04

<u>PREVENT-IV</u> - A Phase III ,Multi-Center Randomized, Double-Blind, Placebo-Controlled Trial of the Ex Vivo Treatment with CGT003 of Coronary Vein Grafts in Patients Undergoing Coronary Artery Bypass Graft Procedures. Sponsor: Corgentech, Principal Investigator: Mark Felger, MD 02/03

<u>BI-LINX</u> - An Observational Prospective Evaluation of the SJM Toronto Bioprosthesis with BiLinx<sup>TM</sup>, Sponsor: St. Jude Medical, Inc, Principal Investigator: John D. Oswalt, MD 10/02

<u>ON-X</u> - A Multicenter, Prospective Clinical Trial to Investigate the On-X Prosthetic Heart Valve Aortic and Mitral Models 100 and 200 Safety and Effectiveness in Replacement of Diseased Aortic or Mitral Valves. Sponsor: Procter & Gamble/Alexion Pharmaceuticals, Principal Investigator: Emery Dilling, MD 10/99

<u>SALUS</u> - SALUS Trial TranScatheter Aortic Valve RepLacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Tanscatheter Aortic Valve System. Sponsor: Direct Flow Medical, Inc, Principal Investigator: Stephen Dewan, MD, 12/15

## **PRESENTATIONS:**

A Novel Pain Management Approach to Pericardial Pain Post Convergent Ablation for Atrial Fibrillation. Brannon Hyde, MD, Daniel Berson, DO, Faraz Kerendi, MD, Mannling Ho, PharmD, and Bonnie B. Punske, PhD, South Texas Chapter of the American College of Surgeons, San Antonio, Texas, Feb 25-27, 2016.