Need a research contact?
Looking for studies by practice area?

RESEARCH TEAM CONTACT LISTS
(click practice area to find team list):

- Valve / Structural Heart Team
- Interventional / Endovascular / Imaging / CCAD Team
- HF / Regenerative Therapies Team
- EP / Prevention Team

STUDY LISTS
(click practice area to find study list):

- Valve / Structural Heart Studies
- Interventional / Endovascular / Imaging / CCAD Studies
- HF / Regenerative Therapies Studies
- EP / Prevention Studies

Bookmark this web link to access a list of current, open featured studies: mplsheart.org/studies
MHIF Practice Areas
(click links below to access study and team contact lists)

- Valve / Structural Heart
- Interventional / Endovascular / Imaging / CCAD Science Center
- HF / Regenerative Therapies
- EP / Prevention

Bookmark this web link to access a list of current, open featured studies: mplsheart.org/studies
MHIF Featured Studies
Valve/Structural Heart

MHIF RESEARCH CONTACTS FOR: Valve / Structural Heart

- **Accurate IDE** for Symptomatic Severe Aortic Stenosis (AS)
- **Alflo** for Symptomatic clinically significant heart failure and elevated atrial pressures
- **Early TAVR** for asymptomatic, severe, calcific Aortic Stenosis (AS)
- **Evolut Low-Risk** for severe aortic valve stenosis in low surgical risk patients
- **HighLife** for symptomatic mitral regurgitation
- **Portico NG** for symptomatic severe aortic stenosis (AS)
- **REPAIR MR** for severe primary MR who are at moderate surgical risk
- **TRILUMINATE Pivotal** for severe tricuspid regurgitation

Bookmark this web link to access a list of current, open featured studies: mplsheart.org/studies
MHIF Featured Studies:
Interventional/Endovascular/Imaging/CCAD Science Center

MHIF RESEARCH CONTACTS FOR: Interventional / Endovascular / Imaging / CCAD

- **Disrupt CAD III** for calcified coronary artery disease
- **ECLIPSE** for Coronary Artery Disease
- **MINT** for Myocardial Ischemia and Transfusion
- **Radiance II** for hypertension
- **Radiance HTN** for hypertension
- **Spyral HTN** for hypertension

Bookmark this web link to access a list of current, open featured studies: [mplsheart.org/studies](http://mplsheart.org/studies)
MHIF Featured Studies: HF/Regenerative Therapies

MHIF RESEARCH CONTACTS FOR: HF / Regenerative Therapies

- **CORCINCH-HFrEF** – ACCUCINCH 5017 ventricular repair system in patient with reduced EF
- **Guide HF** for heart failure
- **Heart EXPAND CAP** for heart failure/transplant
- **Heart FID** Heart failure with iron deficiency anemia
- **HITSOVA** for Heparin-Induced Thrombocytopenia
- **Reduce LAP-HF RCT II** for heart failure

Bookmark this web link to access a list of current, open featured studies: [mplsheart.org/studies](http://mplsheart.org/studies)
MHIF Featured Studies: EP/Prevention

MHIF RESEARCH CONTACTS FOR: EP / Prevention

• AEGIS 2 for acute coronary syndrome
• AKI for Preventing AKI post OHS
• Artesia for sub-clinical atrial fibrillation (SCAF) detected by PPM, ICD, or ICM
• Cascade FH Registry for familial hypercholesterolemia
• Prominent for high triglycerides, low HDL, T2DM, secondary cardiovascular prevention
• QDOT for paroxysmal atrial fibrillation
• Rhapsody for pericarditis
• Vesalius for high cardiovascular risk without prior myocardial infarction or stroke
• VISITAG SURPOINT for atrial fibrillation
• WARRIOR for non-obstructive CAD in Women

Bookmark this web link to access a list of current, open featured studies: mplsheart.org/studies
VALVE AND STRUCTURAL STUDIES
MHIF FEATURED STUDY: ACURATE IDE

OPEN AND ENROLLING: EPIC message to “Research MHIF Patient Referral”

DESCRIPTION:
To evaluate safety and effectiveness of the ACURATE neo 2™ Transfemoral Aortic Valve System for transcatheter aortic valve replacement (TAVR) in symptomatic subjects with severe aortic stenosis who are considered at intermediate or greater risk for surgical valve replacement. Prospective, multicenter, 1:1 randomization to any commercially available TAVR device.

CRITERIA LIST/QUALIFICATIONS:

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Severe native aortic stenosis defined as initial AVA ≤1.0 cm² (or AVA index ≤0.6 cm²/m²) AND a mean pressure gradient ≥40 mm Hg OR maximal aortic valve velocity ≥4.0 m/s OR Doppler velocity index ≤0.25 as measured by echocardiography and/or invasive hemodynamics</td>
<td>1. Unicuspid or bicuspid aortic valve.</td>
</tr>
<tr>
<td>2. Aortic annulus size of ≥21 mm and ≤27 mm</td>
<td>2. Previous acute myocardial infarction within 30 days prior to the index procedure</td>
</tr>
<tr>
<td>3. Symptomatic aortic valve stenosis per IC1 definition above with NYHA Functional Class ≥ II</td>
<td>3. Subject has severe aortic, tricuspid, or mitral regurgitation</td>
</tr>
</tbody>
</table>
MHIF FEATURED STUDY: ALTFLO

CONDITION:
Symptomatic clinically significant heart failure and elevated atrial pressures

PI:
Paul Sorajja, MD

RESEARCH CONTACT:
Karen Meyer, RN
Karen.meyer2@allina.com | 612-863-5855

SPONSOR:
Edwards LifeScience

DESCRIPTION:
Multi-center, prospective, early feasibility study to evaluate initial clinical safety, device functionality and effectiveness of the Edwards Transcatheter Atrial Shunt System.

CRITERIA LIST/QUALIFICATIONS:

Inclusion
1. Chronic symptomatic Heart Failure (HF)
2. Stable Guideline Directed Medical Therapy (GDMT) for heart failure management
3. Elevated LA (or PCWP) pressure of >15 mmHg at rest or >25 mmHg during supine ergometer exercise stress test.

Exclusion
1. Severe HF
   1. ACC/AHA/ESC Stage D, non ambulatory NYHA IV
   2. Cardiac index <2.0L/min/m²
   3. Inotropic infusion
   4. Listed for cardiac transplant
   5. LVEF <20%
2. Presence of significant valve disease (>3+MR, > 2+TR, >2+ AR or > moderate AS)

OPEN AND ENROLLING:
EPIC message to “Research MHIF Patient Referral”
**MHIF FEATURED STUDY:**
Early TAVR Trial

**DESCRIPTION:**
Prospective, multicenter study, randomized 1:1 with the SAPIEN 3 valve or clinical surveillance. Patients must have suitable anatomy for transfemoral Transcatheter Aortic Valve Replacement (TAVR). 75 sites in the U.S. and 1109 patients will be enrolled.

**PARTIAL CRITERIA LIST/QUALIFICATIONS:**

**Inclusion**
- Aortic valve area (AVA) ≤ 1.0 \(\text{cm}^2\) or AVA index ≤ 0.6 \(\text{cm}^2/m^2\)
- Peak jet velocity ≥ 4.0 m/s or Mean gradient ≥ 40 mmHg
- Negative treadmill stress test
- EF ≥ 50%

**CONDITION:**
Asymptomatic, severe, calcific Aortic Stenosis (AS)

**PI:**
Santiago Garcia, MD

**RESEARCH CONTACT:**
Aisha Ahmed
Aisha.Ahmed@allina.com | 612-863-9362

**SPONSOR:**
Edwards Lifesciences

**ACTION:**
Do you see patients with severe aortic stenosis but remain asymptomatic?

If so, please contact Dr. Garcia or Aisha Ahmed (Study Coordinator)
aisha.ahmed@allina.com

**OPEN AND ENROLLING:**
EPIC message to “Research MHIF Patient Referral”
MHIF FEATURED STUDY:
EVOLUT Low-Risk

<table>
<thead>
<tr>
<th>CONDITION:</th>
<th>Severe aortic valve stenosis in low surgical risk patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI:</td>
<td>Paul Sorajja, MD</td>
</tr>
<tr>
<td>RESEARCH CONTACT:</td>
<td>Karen Meyer, RN</td>
</tr>
<tr>
<td>SPONSOR:</td>
<td>Medtronic</td>
</tr>
</tbody>
</table>

**DESCRIPTION:**
Transcatheter aortic valve replacement (TAVR) with FDA approved Medtronic Evolut TAVR system for patients at low surgical risk for surgical aortic valve replacement (SAVR). Subjects are randomized 1:1 to either TAVR or SAVR. This study is comparing SAVR to TAVR in a new patient population for this approved device.

**CRITERIA LIST/ QUALIFICATIONS:**

- **Inclusion**
  - Severe aortic stenosis, either symptomatic or asymptomatic (no bicuspid valves)
  - Documented heart team agreement that the subject is considered low surgical risk (predicted risk of mortality for SAVR < 3% at 30 days)
  - Follow-up is for 10 years

**STATUS:**
In Follow-Up
MHIF FEATURED STUDY: HighLife

DESCRIPTION:

Purpose: to evaluate the safety and efficacy of the HighLife trans-septal access 28mm Transcatheter Mitral valve and its delivery system (transfemoral venous access and interatrial puncture) in patients with moderate-severe or severe mitral regurgitation who are at a high risk for surgical treatment.

Primary Feasibility endpoint: technical success

Safety: all cause mortality at 30 days

Performance: total MR reduction to 1+ or less as assessed by core lab

CRITERIA LIST/QUALIFICATIONS:

Inclusion: moderate-severe or severe mitral regurgitation; NYHA class II, III; or ambulatory class IV

Exclusion: mitral stenosis; Flail Leaflet or prolapse; severe calcification; prior mitral intervention; mitral annulus <30 mm & >45 mm; Aortic prosthesis; LVEF<30%; PAS >70mmHg; TR requiring intervention

CONDITION: Symptomatic mitral regurgitation

PI: Paul Sorajja, MD

RESEARCH CONTACT: Jane Fox

JANE.FOX@ALLINA.COM | 612-863-6289

SPONSOR: HighLife Medical, Inc.

OPEN AND ENROLLING: EPIC message: Research MHIF Patient Referral
DESCRIPTION:
Prospective, single-arm study of the Portico™ NG transcatheter aortic valve in patients with symptomatic, severe aortic stenosis at high to extreme risk for surgical aortic valve replacement

ACTION:
Is your patient experiencing symptomatic severe AS and at high to extreme risk for SAVR?

Contact Dr. Sorajja or Jennifer Nguyen (Study Coordinator; Jennifer.Nguyen@allina.com)
DESCRIPTION:

Purpose: to compare the clinical outcome of MitraClip™ device versus open surgical repair in patients with severe primary MR who are at moderate surgical risk.

Primary endpoint: survival, free of stroke and any cardiovascular hospitalization at 2 years; MR ≤ mild at 30 days; QOL improvement of at least 5 points at 2 years compared to baseline; hospital length of stay; rate of mitral valve replacement at index procedure.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion: severe primary MR (Grade III or greater mitral regurgitation mixed etiology is acceptable if principal mechanism is a degenerative mitral valve); symptomatic NYHA class II, III, or asymptomatic with EF < 60%, PAS >50 mm HG, or LVESD >40 mm; 75 years or if < 75 years subject with STS predicted risk of mortality repair score >2%, or presence of comorbidities

Exclusion: ischemic or non-ischemic secondary MR; EF <30%; severe TR; severe annular calcification; valve anatomy which would preclude reducing MR to mild or less
MHIF FEATURED STUDY: TRILUMINATE Pivotal

DESCRIPTION:
Prospective, randomized, multicenter trial of TriClip™ device in symptomatic patients with severe tricuspid regurgitation (TR) who have been determined to be at intermediate or greater estimated risk for mortality with tricuspid valve surgery.

PARTIAL CRITERIA LIST/QUALIFICATIONS:

Inclusion
• Symptomatic severe TR despite optimal medical therapies (drug and/or device)
• Adequately treated per applicable standards and stable for 30 days
• Intermediate or greater surgical risk of mortality with tricuspid valve surgery

Exclusion
• Systolic pulmonary artery pressure (sPAP) >70 mmHg
• Severe uncontrolled hypertension Systolic Blood Pressure (SBP) ≥180 mmHg and/or Diastolic Blood Pressure (DBP) ≥110 mmHg
• Pacemaker or ICD leads that would prevent appropriate placement of TriClip
• Left Ventricular Ejection Fraction (LVEF) ≤ 20%
STUDIES FOR:
Interventional
Endovascular
Imaging
CCAD Science Center
MHIF FEATURED STUDY: 
DISRUPT CAD III

DESCRIPTION:
Phase III study to assess the safety and effectiveness of the Shockwave Coronary Intravascular Lithotripsy (IVL) System to treat de novo, calcified, stenotic, coronary lesions prior to stenting.

PARTIAL CRITERIA LIST/ QUALIFICATIONS:
Inclusion
Untreated severely calcified lesion in a coronary artery
Vessel size 2.5mm to 4.0mm
70-99% stenosis

Exclusion
STEMI
Previous stented target lesion

CONDITION: 
Calcified Coronary Artery Disease

PI: 
Nicholas Burke, MD

RESEARCH CONTACT: 
Jo Anne Goldman, RT
JoAnne.Goldman@allina.com | 612-863-3793

SPONSOR: 
Shockwave Medical

OPEN AND ENROLLING: 
EPIC message to “Research MHIF Patient Referral”

ACTION: Are the patients you are referring for coronary angiography appropriate for this trial?
Contact Dr. Burke or Jo Anne Goldman, RT (Study Coordinator) joanne.goldman@allina.com
MHIF FEATURED STUDY: ECLIPSE

DESCRIPTION:
Prospective, randomized 1:1 (stratified by site single lesion vs multiple lesion) multicenter trial to evaluate Orbital Atherectomy compared to conventional balloon angioplasty technique for the treatment of severely calcified lesions prior to implantation of drug-eluding stents.

PARTIAL CRITERIA LIST/QUALIFICATIONS:
Inclusion
Present with stable ischemic heart disease, NSTEMI or USA, or stabilized recent STEMI > 48hr with severe calcification
Excludes patients with previous PCI within 12 months
Excludes patients unable to take DAPT for min. of 6 months

CONDITION: Coronary Artery Disease
PI: Ivan Chavez, MD
RESEARCH CONTACT: Amy McMeans
amy.mcmeans@allina.com | 612-863-3895
SPONSOR: Cardiovascular Systems, Inc.

OPEN AND ENROLLING: EPIC message to “Research MHIF Patient Referral”
MHIF FEATURED STUDY: MINT

**DESCRIPTION:**
MINT is a multicenter randomized clinical trial comparing red blood cell transfusion strategies for patients who have had a myocardial infarction and are anemic (positive troponins and a hemoglobin of less than 10 g/dL).

The trial will enroll 3,500 hospitalized patients diagnosed with myocardial infarction who are anemic (have blood counts less than 10 g/dL) to receive either a liberal or a restrictive transfusion strategy. Patients will be followed for 6 months to assess how well they are recovering from their heart attack.

**CRITERIA LIST/QUALIFICATIONS:**
- Inclusion
- Positive Troponin and a hemoglobin of less than 10 g/dL

Evidence suggests it is safe to wait to give a blood transfusion; however, for those who have suffered a heart attack, there is a lack of high-quality evidence to guide transfusions. **The study’s results will influence transfusion practice worldwide.**
MHIF FEATURED STUDY: RADIANCE II Study

OPEN AND ENROLLING:
EPIC message to “Research MHIF Patient Referral”

DESCRIPTION:
Designed to assess potential therapeutic benefits of catheter directed renal denervation in managing essential and resistant hypertension. The study objective is to demonstrate the effectiveness and safety of the Paradise System in subjects with Stage 2 hypertension on 0-2 medications at time of consent. Prior to randomization, subjects will be hypertensive in the absence of hypertension medication.

CRITERIA LIST/QUALIFICATIONS:

Inclusion
- Age 18-75 years at time of consent (reduces potential that hypertension is due entirely to stiff arteries)
- History of being “treated” with antihypertensive medications
- Uncontrolled at screening visit (average seated office BP ≥ 140/90 mmHg and < 180/120 mmHg) on no more than 2 antihypertensive medications
- Must remain uncontrolled (daytime ABP ≥ 135/85 mmHg and < 170/105 mmHg) after a 4-week washout/run-in period
- Must have an eligible renal anatomy documented by MRA or CTA and confirmed by renal angiogram at procedure (where applicable)

Exclusion
- Lacks appropriate renal artery anatomy for treatment; known, uncorrected causes of secondary hypertension other than sleep apnea
- Type I diabetes mellitus or uncontrolled Type II diabetes; eGFR of <40; Brachial circumference ≥ 42 cm
- History of cerebrovascular event or severe cardiovascular event, or history of stable or unstable angina within 12 months; Repeat (>1) hospitalization for hypertensive crisis

CONDITION:
Hypertension

PI:
Yale Wang, MD

RESEARCH CONTACT:
Rose Peterson
Rose.Peterson@allina.com | 612-863-6051

SPONSOR:
ReCor
RADIANCE-HTN

- **CONDITION**: Hypertension; Vascular Diseases
- **CONTACT INFO**: Rose Peterson, RN | Rose.Peterson@allina.com | 612-863-6051
- **DESCRIPTION**: Hypertension, or high blood pressure, affects over 1 billion people. Left untreated, high blood pressure can increase your risk of serious health problems such as heart attack, stroke, and kidney failure. Yet nearly 1 in 3 individuals with hypertension struggle to control their blood pressure despite being on medication.

If you and your physician have been unable to control your blood pressure, or are interested in an alternative to daily medications, you may be a candidate for the RADIANCE-HTN Clinical Study. The study is evaluating an investigative minimally-invasive, catheter-based procedure (the Paradise® Renal Denervation System) which may lower your blood pressure and reduce your need for blood pressure medications.

- **CRITERIA LIST/QUALIFICATIONS**: Complete [this questionnaire](#) to see if you qualify to participate in the Radiance-HTN Study.
- **INVESTIGATORS**: Yale Wang, MD
- **SPONSORS**: ReCor Medical
- **STATUS**: Open/Enrolling
MHIF FEATURED STUDY:
SPYRAL-HTN

DESCRIPTION:
The aim of the study is to test the hypothesis that renal denervation is safe and reduces systolic blood pressure (SBP) in patients with uncontrolled hypertension compared to a sham controlled population, in the absence of antihypertensive medications (OFF MED) or uncontrolled hypertension on one, two, or three standard antihypertensive medications (ON-MED).

PARTIAL CRITERIA LIST/QUALIFICATIONS:
Inclusion
• Office systolic blood pressure (SBP) ≥150mmHg and <180mmHg and an office diastolic blood pressure (DBP) ≥90mm Hg with or without meds

Exclusion:
• Main renal artery < 3 mm or > 8 mm ; eGFR <45 ml/min
*Screen failure if OSBP > or = 180 mm Hg
HEART FAILURE/REGENERATIVE STUDIES
**MHIF FEATURED STUDY:**  
**CORCINCH-HFrEF**  
(aka ACCUCINCH 5017)

| ACCUCINCH ventricular repair system in patient with reduced EF | PI: Peter Eckman, MD | RESEARCH CONTACT: Jake Jensen  
Jacob.jensen@allina.com | SPONSOR: Ancora Heart |
|---|---|---|---|

**DESCRIPTION:**  
The objective of this trial is to evaluate the safety and performance of the AccuCinch system in patients with HFrEF.

**CRITERIA LIST / QUALIFICATIONS:**

**Inclusion**  
Dilated Ischemic Cardiomyopathy or Non Ischemic Cardiomyopathy; NYHA III-Iva; LVEF ≥ 20 and ≤ 40%

**Exclusion**  
No mod-severe MR, AR, or AS; TAPSE >14, severe TR; no AV prosthesis; LVEDD must be ≥ 55 mm  
> 3m from CRT or > 1m from ICD implant or revision (LBBB and QRS >150 required to have CRT)

~6.5 million Americans and ~25 million people worldwide have HF.  
Projections show that the prevalence of HF will increase 46% from 2012 to 2030, resulting in >8 million people ≥18 years of age with heart failure.
MHIF Featured Study: Guide HF

CONDITION: Heart Failure

DESCRIPTION:
Study comparing CardioMEMS sensor to standard of care heart failure treatment. There are 1.2+ MILLION hospitalizations for decompensation of heart failure annually.

The CardioMEMS sensor is a wireless PA pressure monitoring system which enables providers to proactively treat heart failure and reduce the likelihood of hospitalization.

REFER PATIENTS!

PI: Mosi Bennett, MD

CONTACT: Sarah Schwager 612-863-6257
Kari Thomas, 612.863.7493

SPONSOR: Abbott Vascular

CONTACT:
Sarah Schwager 612-863-6257
Kari Thomas, 612.863.7493

PI: Mosi Bennett, MD

PARTIAL CRITERIA LIST / QUALIFICATIONS:

**Inclusion**
All heart failure patients (NYHA Class II-IV)
Patients with and without a prior heart failure hospitalization

**Exclusion**
Received or are likely to receive an LVAD or heart transplant
**MHIF FEATURED STUDY:**
**Heart EXPAND CAP**

**DESCRIPTION:** A single-arm study evaluating the OCS™ Heart System and extended criteria donor hearts (those that are currently not transplanted or are seldom transplanted in the US)

**CRITERIA LIST/QUALIFICATIONS:**

**Donor Heart Inclusion**
- Expected total cross-clamp time of ≥4 hours; OR expected total cross-clamp time of ≥2 hours PLUS one of the following risk factors:
  - Donor age 45-55 years, inclusive, with no coronary catheterization data
  - Donor age ≥55 years
  - Left ventricular septal or posterior wall thickness of >12 mm, but ≤16 mm
  - Reported down time of ≥20 min, with stable hemodynamics at time of final assessment
  - Left heart ejection fraction (EF) ≥40%, but ≤50% at time of acceptance of offer
  - Donor angiogram with luminal irregularities with no significant CAD (≤50%)
  - History of carbon monoxide poisoning with good cardiac function at time of donor assessment
  - Social history of alcoholism with good cardiac function at time of donor assessment
  - History of diabetes without significant CAD on angiogram (≤50%)

**CONDITION:** Heart Failure/Transplant

**PI:** Karl Mudy, MD

**RESEARCH CONTACTS:**
- Kari Thomas - Kari.M.Thomas@allina.com | 612-863-7493
- Kari Williams - Kari.Williams@allina.com | 612-863-0027

**SPONSOR:** TransMedics, Inc.

**OPEN AND ENROLLING:**
EPIC message to “Research MHIF Patient Referral”
Heart-FID

OPEN AND ENROLLING:
EPIC message to “Research MHIF Patient Referral”

• CONDITION: Heart failure with iron deficiency anemia
• PI: Peter Eckman, MD
• CONTACT INFO: Stephanie Ebnet, RN | stephanie.ebnet@allina.com | 612-863-6286
  Sarah Schwager, RN | sarah.schwager@allina.com | 612-863-6257

DESCRIPTION: This is a randomized, double blind, placebo-controlled study to investigate the efficacy and safety of Injectafer® (ferric carboxymaltose) as treatment for heart failure with iron deficiency. Study drug administration will occur as two intravenous doses every six months for duration of study.

CRITERIA LIST/QUALIFICATIONS:

  Inclusion:
  - Ejection fraction ≤35%
  - Stable heart failure (NYHA II-IV) on maximally tolerated background therapy
  - Hemoglobin 9.0-13.5 g/dL (females) or <15.0 g/dL (males), serum ferritin <100 ng/mL or 100-300 ng/mL with TSAT <20%

  Exclusion:
  - Current or planned LVAD or heart transplantation, history of recent cardiovascular events, and significant co-morbidities

SPONSOR: Luitpold Pharmaceuticals, Inc.
**MHIF FEATURED STUDY:**
**HITSOVA**

**CONDITION:**
Heparin Induced Thrombocytopenia

**PI:**
Nedaa Skeik, MD

**RESEARCH CONTACTS:**
Carina Benson: carina.benson@allina.com | 612-863-4393 | pager: 612-654-5542
Jane Fox: jane.fox@allina.com | 612-863-6289

**SPONSOR:**
Aspen Global, Inc.

**DESCRIPTION:**
Open-Label, Randomized, Active Controlled, Multi-Centre Phase 3 Study to Evaluate the Safety and Efficacy of Danaparoid vs Argatroban in Treatment of Subjects with Acute HIT (HITSOVA study)

**CRITERIA LIST / QUALIFICATIONS:**

<table>
<thead>
<tr>
<th><strong>Inclusion</strong></th>
<th><strong>Exclusion</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Males or females aged ≥2 weeks</td>
<td>Life expectancy less than study duration of 44 days</td>
</tr>
<tr>
<td>Subjects with suspected HIT by 4Ts of &gt;3 and with reduction of platelet count of ≥ 30% at either:</td>
<td>Lumbar puncture or spinal/epidural catheter placement within past 48 hrs</td>
</tr>
<tr>
<td>a) Between Day 4 and 14 of the start of heparin exposure OR</td>
<td>Severe hepatic impairment (Child-Pugh Class C)</td>
</tr>
<tr>
<td>b) At Day 1 of heparin exposure with pre-treatment with heparin within the last 30 days</td>
<td>Active bleeding</td>
</tr>
<tr>
<td>Have adequate renal function: Glomerular filtration rate ≥ 15 mL/min/1.73 m²</td>
<td>Hemorrhagic cerebrovascular accident within previous 3 mos.</td>
</tr>
<tr>
<td></td>
<td>Severe, uncontrolled hypertension defined as blood pressure &gt;180/110 mmHg</td>
</tr>
<tr>
<td></td>
<td>Diabetic retinopathy</td>
</tr>
</tbody>
</table>

**OPEN AND ENROLLING:**
EPIC message to “Research MHIF Patient Referral”
MHIF FEATURED STUDY: REDUCE LAP-HF RCT II

DESCRIPTION:
A study to evaluate the Corvia Medical, Inc. IASD® System II to REDUCE Elevated Left Atrial Pressure in Patients with Heart Failure

CRITERIA LIST/QUALIFICATIONS:

**Inclusion**
- Age ≥ 40 years – GDMT for 4 weeks
- HF requiring current treatment w/ diuretics for ≥ 30 days AND NYHA class II if a prior history of > NYHA class II, to ambulatory NYHA class IV
- IV diuretics or need for intensification of oral diuresis for HF 12 months prior; OR an NT-pro BNP value > 150 pg./ml in normal sinus rhythm, > 450 pg./ml in AFIB, or a BNP value > 50 in NSR or, > 150 in AFIB within past 6 months
- EF ≥ 40% within the past 6 months, without EF <30% in the past 5 years
- End-expiratory PCWP during supine ergometer exercise ≥ 25mm Hg, and > RAP by ≥ 5 mm Hg.

**Exclusion**
- Inability to perform 6-minute walk test (distance < 50 m), OR 6-minute walk test > 600m
- Resting RAP > 14 mmHg
- MI and/or percutaneous cardiac intervention within past 3 months; CABG in past 3 months, or current indication for coronary revascularization; AVR (surgical AVR or TAVR) within past 12 months
- Significant PH with PVR > 3.5 Woods units at rest or at peak exercise

CONDITION: Heart Failure
PI: Michael Samara, MD
RESEARCH CONTACT: Jane Fox
jane.fox@allina.com | 612-863-6289
SPONSOR: Corvia Medical Inc.
EP/PREVENTION STUDIES
MHIF FEATURED STUDY:
AEGIS 2

DESCRIPTION:
CSL112 is being developed for use in patients with ACS (diagnosed with either STEMI or NSTEMI and exclusive of unstable angina) to reduce the risk of CV death, MI, and stroke upon delivery of CSL112. Evidence from the Apo-I Event Reducing in Ischemic Syndromes-I (AEGIS-I) study has demonstrated that administration of apoA-I increases cholesterol efflux in MI patients.

CRITERIA LIST/QUALIFICATIONS:

Inclusion
Positive Troponin with at least 50% stenosis on > 1 epicardial artery or prior cath with at least 50% stenosis on > 1 epicardial artery or prior CABG
Additional risk factor: DM, > 65 y.o., prior hx of MI or PAD

Exclusion
- EF < 30%
- ALT > 3 x ULN
- GFR< 30

Body weight < 50 kg
Allergy to soy beans or peanuts
Plan for CABG

CONDITION:
Acute Coronary Syndrome

PI:
Thomas Knickelbine, MD

RESEARCH CONTACT:
Stephanie Ebnet
Stephanie.ebnet@allina.com | 612-863-6286

SPONSOR:
CSL Behring

OPEN AND ENROLLING:
Please Refer Patients to Steph!
MHIF FEATURED STUDY:
AKI

DESCRIPTION: To evaluate the efficacy of post-surgery treatment with ASP1128 (investigational medication) in subjects at risk for acute kidney injury (AKI) following coronary artery bypass graft (CABG) and/or valve surgery. ASP1128 is a potent and highly selective PPARδ modulator, that is believed to have protective effects on kidney cells that are under cellular stress as a result of ischemia, inflammation and oxidative stress following coronary artery bypass graft and/or valve (CABG/V) surgery. In addition, ASP1128 will reduce inflammatory responses and increased oxidative stress systemically which is expected to reduce the immediate consequences of stress responses following CABG/V surgery.

CRITERIA LIST/QUALIFICATIONS:

Inclusion
• Subject undergoing non-emergent open chest cardiovascular surgery with use of CPB (i.e., CABG and/or valve surgery [including aortic root and ascending aorta surgery, without circulatory arrest])
• Subject has moderate/high risk of developing AKI following surgery (must have 2 risk factors):
  • Risk factors: age > 70, eGFR < 60, CHF, DM, proteinuria/albuminuria

Exclusion
• On another investigational medication
• GFR < 30
• Prior kidney transplant
• Known or suspected glomerulonephritis
• Endocarditis or active infection
• Surgery off pump
• IV Drug abuse
• Chronic liver disorder
• LVAD

CONDITION: Preventing AKI post OHS
PI: Dr. Shukrallah
RESEARCH CONTACT: Steph Ebnet
Stephanie.ebnet@allina.com | 612-863-6286
SPONSOR: Astellas Pharma Inc. (API)

Coming soon:
Please Refer Patients!
ARTESIA

CONDITION: Sub-clinical atrial fibrillation (SCAF) detected by PPM, ICD, or ICM.

PI: JoEllyn Moore, MD

CONTACT INFO: Jacob Cohen, MS | jacob.cohen@allina.com | 612-863-4022

DESCRIPTION: Prospective, randomized, parallel group, double-blind trial to determine if the use of apixaban in patients with SCAF will reduce the incidence of stroke and systemic embolism compared to aspirin. The experimental part of being in this study is being randomized to either aspirin or apixaban.

CRITERIA LIST/QUALIFICATIONS:

Inclusion:
- Permanent pacemaker or defibrillator (with or without resynchronization) or insertable cardiac monitor capable of detecting SCAF
- At least one episode of device-detected SCAF ≥ 6 minutes in duration but no single episode > 24 hours in duration at any time prior to enrollment. Any atrial high rate episode with average > 175 beats/min will be considered as SCAF. No distinction will be made between atrial fibrillation and atrial flutter.
- Age ≥ 55 years
- Risk Factor(s) for Stroke:
  - Previous stroke, TIA or systemic arterial embolism OR Age at least 75 OR Age 65-74 with at least 2 other risk factors OR Age 55-64 with at least 3 other risk factors

Exclusion:
- Clinical atrial fibrillation documented by surface ECG (12 lead ECG, Telemetry, Holter) lasting ≥ 6 minutes, with or without clinical symptoms

SPONSOR: Hamilton Health Sciences Corporation through the Population Health Research Institute (PHRI)
Cascade FH Registry

**CONDITION:** Familial Hypercholesterolemia (FH), a genetic condition marked by dramatically high levels of LDL-C that are not related to diet or lifestyle.

**PI:** Thomas Knickelbine, MD

**CONTACT INFO:** Christine Majeski, RN | christine.majeski@allina.com | 612-863-3546

**DESCRIPTION:** A national registry tracking the longitudinal treatment, clinical outcomes and patient reported outcomes of FH with the aim of increasing awareness and family screening of FH.

**CRITERIA LIST/ QUALIFICATIONS:**

**Inclusion:**
- Patient with existing diagnosis of FH using one of the three diagnostic tools:
  - US MedPed Program Criteria
  - Simon Broome Register Criteria with a diagnosis of “probable”
  - Dutch Lipid Clinic Network Diagnostic Criteria with a diagnosis of “probable”
- Patients with FH genetic mutation

**Exclusion:**
- Patients with a known medical condition other than FH thought to contribute to hyperlipidemia (i.e. untreated hyperthyroidism, nephrotic syndrome, cholestasis hypopituitarism)

**SPONSOR:** FH Foundation
### MHIF FEATURED STUDY: PROMINENT

**DESCRIPTION:**

Placebo controlled trial of a potent fibrate, pemafibrate, to prevent MI, ischemic stroke, unstable angina requiring revascularization, and CV death in adults with T2DM.

**CONDITION:**

High triglycerides, low HDL, T2DM, secondary cardiovascular prevention

<table>
<thead>
<tr>
<th>PI:</th>
<th>Dr. Matthew Chu</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUB I'S:</td>
<td>Marc Newell, MD</td>
</tr>
<tr>
<td></td>
<td>Thomas Knickelbine, MD</td>
</tr>
<tr>
<td></td>
<td>Amy Cooley, CNP</td>
</tr>
</tbody>
</table>

**CRITERIA LIST / QUALIFICATIONS:**

**Inclusion**

- TG > 200, HDL < 40, T2DM, LDL<70 or high dose statin or statin intolerant

**Exclusion**

- Type 1 diabetes, HbA1c > 9.5%, NYHA Class IV HF, significant liver disease

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**RESEARCH CONTACT:**

Ezi Ebere  
Ezi.Ebere@allina.com | 612-863-4393

**SPONSOR:**

Kowa Research Institute

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**TRIGLYCERIDES MATTER – AND THIS STUDY IS HELPING ADDRESS THEM!**

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**OPEN AND ENROLLING:**

EPIC message to “Research MHIF Patient Referral”
MHIF FEATURED STUDY: QDOT

DESCRIPTION:
Prospective, non-randomized, pre-market clinical evaluation of the QDOT MICRO™ catheter for pulmonary vein isolation (PVI) in the treatment of subjects with paroxysmal atrial fibrillation.

PARTIAL CRITERIA LIST/QUALIFICATIONS:

Inclusion
Symptomatic paroxysmal AF with one electrocardiographically documented AF episode within 6 months prior to enrollment and a physician’s note indicating recurrent self-terminating AF within 7 days

Failed at least one (1) antiarrhythmic drug (AAD) (class I or III) as evidenced by recurrent symptomatic AF, contraindicated or intolerable to the AAD

Exclusion
Previous surgical or catheter ablation for atrial fibrillation
Patient on amiodarone at any time during his past 3 months prior to enrollment
Previously diagnosed with persistent or long-standing persistent AF and/or continuous AF lasting > 7 days

OPEN AND ENROLLING:
Please Refer Patients!

CONDITION: Proxysmal Atrial Fibrillation (PAF)
PI: Daniel Melby, MD
RESEARCH CONTACT: Jacob Cohen
Jacob.Cohen@allina.com | 612-863-4022
SPONSOR: Biosense Webster

ACTION: Are the patients you are referring for EP consultation and ablation appropriate for this trial?

If so, please contact Dr. Melby or Jacob Cohen, MS (Study Coordinator) jacob.cohen@allina.com
MHIF FEATURED STUDY:  
Rhapsody

DESCRIPTION:
First multinational, phase 3, double-blinded, placebo-controlled, randomized withdrawal, study assessing the efficacy of rilonacept, an interleukin 1 alpha and beta receptor decoy, in the treatment of recurrent pericarditis.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion
Diagnosis of recurrent pericarditis

Exclusion
- Pericarditis secondary to specific prohibited etiologies, including tuberculosis (TB); neoplastic, purulent, or radiation etiologies
- Post-thoracic blunt trauma (e.g., motor vehicle accident)
- Myocarditis
- Systemic autoimmune diseases with exception of Still’s disease, pregnancy, hx HIV, prednisone > 60 mg/day, positive Hep B or C, serious infection

MHIF was first in the world to enroll in this trial and has 4 subjects enrolled out of the 9 in the world. Pericarditis patients are experiencing significant benefits and most often have no chest pain after starting this medication.

CONDITION:  
Pericarditis

PI:
David Lin, MD

RESEARCH CONTACT:
Christine Majeski
Christine.Majeski@allina.com | 612-863-3546

SPONSOR:
Kiniksa Pharmaceuticals

STATUS:
In Follow-Up
**MHIF FEATURED STUDY: Vesalius**

**DESCRIPTION:**
The purpose of this trial is to evaluate the effect Evolocumab has in reducing the risk of coronary heart disease (CHD) death, MI, stroke, and ischemia-driven arterial revascularization in adults at high risk of cardiovascular events without prior MI or stroke.

**CRITERIA LIST/QUALIFICATIONS:**

**Inclusion**
- ≥ 50 years (men); or ≥ 55 years (women) to < 80 years of age (either sex)
- LDL-C ≥ 100 mg/dL (≥ 2.6 mmol/L) or HDL-C ≥ 130 mg/dL (≥ 3.4 mmol/L) on maximal tolerated therapy
- CAD w revasc
- High calcium score (≥100)
- TIA, carotid revasc, PVD
- DM with microvascular disease
- **PLUS** one high risk criteria: polyvascular disease, metabolic syndrome, Lp(a)>125, LDL ≥130, known FH, fam hx premature CAD, CRP ≥3, current tobacco, ≥ 65 yrs, eGFR < 45

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**CONDITION:**
High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke

**PI:**
Thomas Knickelbine, MD

**RESEARCH CONTACT:**
Ezi Ebere
Ezi.Ebere@allina.com | 612-863-4393

**SPONSOR:**
Amgen Inc.

**OPEN AND ENROLLING:**
Please Refer Patients!
MHIF FEATURED STUDY:  
VISITAG SURPOINT

DESCRIPTION:
Primary objective of study is to demonstrate safety and 12-month effectiveness of Tag Index-guided ablation using VISITAG SURPOINT™ Module with External Processing Unit when used with THERMOCOOL SMARTTOUCH® SF (STSF) and THERMOCOOL SMARTTOUCH® (ST) catheters for pulmonary vein isolation (PVI) in the treatment of subjects with drug refractory symptomatic paroxysmal AF.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion
1. Symptomatic paroxysmal AF; had at least 1 AF episode electrocardiographically documented within 1 year prior to enrollment
   Documentation may include ECG, TTM, Holter monitor or telemetry strip
2. Failed at least 1 antiarrhythmic drug (AAD Class I or III) as evidenced by recurrent symptomatic AF, or intolerable to the AAD

Exclusion
1. Previous surgical or catheter ablation for AF
2. Previous cardiac surgery (including CABG) within past 6 months (180 days)
3. Valvular cardiac surgical/percutaneous procedure (i.e., ventriculotomy, atriotomy, and valve repair or replacement and presence of a prosthetic valve)

AF is the most common sustained arrhythmia.
It affects 0.4% to 1% of the general population, and increases in prevalence with age.

CONDITION:  
Atrial Fibrillation (AF)

PI:  
Daniel Melby, MD

RESEARCH CONTACT:  
Jacob Cohen  
Jacob.Cohen@allina.com | 612-863-4022

SPONSOR:  
Biosense Webster

OPEN AND ENROLLING:  
EPIC message to “Research MHIF Patient Referral”
MHIF FEATURED STUDY:  
**WARRIOR - Women’s Ischemia Trial**

**DESCRIPTION:**
The purpose of WARRIOR (Women’s Ischemia Trial to Reduce Events in Non-Obstructive CAD) is to evaluate if intensive medical therapy (IMT) (potent statin plus ACE-I or ARB) is better than usual care in women who have s/s of suspected ischemia but no obstructive CAD (defined as <50 stenosis). The hypothesis is that IMT will reduce MACE 20% vs. usual care.

**CRITERIA LIST/ QUALIFICATIONS:**

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signs and symptoms of suspected ischemia prompting referral for further evaluation by coronary angiography or coronary CT angiogram within previous 3 years</td>
<td>Hx NIHCM</td>
</tr>
<tr>
<td>Non-obstructive CAD defined as 0-50% diameter reduction of a major epicardial vessel</td>
<td>ACS within 30 days</td>
</tr>
<tr>
<td></td>
<td>LVEF&lt; 40% NYHA HF class III-IV</td>
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<tr>
<td></td>
<td>Prior intolerance to ACE/ARB</td>
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<tr>
<td></td>
<td>ESRD on dialysis</td>
</tr>
<tr>
<td></td>
<td>Severe valvular disease requiring TVAR within 3 years</td>
</tr>
<tr>
<td></td>
<td>Stroke within 180 days</td>
</tr>
</tbody>
</table>

**CONDITION:**
Non-Obstructive CAD in Women

**PI:**
Retu Saxena, MD

**RESEARCH CONTACT:**
Steph Ebnet  
Stephanie.ebnet@allina.com  
612-863-6286

**SPONSOR:**
University of FL Funded by the Department of Defense
CALLING FOR RESEARCH REFERRALS!

Talk with your patients about their options, including clinical research.

Bookmark this link as a resource to access current, featured studies and MHIF research contact information:

mplsheart.org/studies
# MHIF Research Team Contacts

## Valve / Structural Heart

<table>
<thead>
<tr>
<th>Name</th>
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</tr>
</thead>
<tbody>
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</table>
### MHIF Research Team Contacts

**Interventional / Endovascular / Imaging / CCAD Science Center**

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</tbody>
</table>
# MHIF Research Team Contacts

**EP / Prevention**

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</tr>
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