ABOUT HEALTHEAST

HealthEast is a full-service health care provider serving the Twin Cities East Metro

- 14 primary care clinics
- 16 specialty care clinics
- Four award-winning hospitals
- 7,500 employees
- 1,100 volunteers
- 850 physicians and providers
- Specialty centers, home care, hospice care
- System wide well-being program
HealthEast supports a centralized and comprehensive Clinical Trials Office

- Focused on industry sponsored research and registry projects
- Principal Investigators in many medical specialties
- 12 dedicated clinical trials team members
- Ability to conduct research studies throughout the HealthEast system

- FDA Audited; No 483 Issued
CLINICAL TRIALS OFFICE
Our Sponsors and CRO Partners

- GSK
- Merck
- BMS
- Bayer
- Roche
- J&J
- Pfizer
- Amgen
- 3M
- Sanofi
- Novartis
- Regen
- BI
- Genen
- Janssen
- Takeda
- St. Jude
- Medtronic
- Boston Sci
- Abbott
- Biotronik
- Genen
- DCRI
- Quintiles
- ICON
- UBC
- C5
- TIMI
- Parexel
- PPD
- Covance
- PRA
<table>
<thead>
<tr>
<th>Study</th>
<th>Patient Population</th>
<th>HealthEast Enrolled</th>
<th>Sponsor Enrollment Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cantos</td>
<td>Inflammation</td>
<td>94</td>
<td>30</td>
</tr>
<tr>
<td>Grand</td>
<td>Diabetes</td>
<td>41</td>
<td>20</td>
</tr>
<tr>
<td>Spire</td>
<td>Cholesterol</td>
<td>85</td>
<td>20</td>
</tr>
<tr>
<td>Carmelina</td>
<td>CAD</td>
<td>87</td>
<td>30</td>
</tr>
<tr>
<td>ICY</td>
<td>EP</td>
<td>41</td>
<td>10</td>
</tr>
<tr>
<td>Fourier</td>
<td>Cholesterol</td>
<td>66</td>
<td>20</td>
</tr>
<tr>
<td>FLU-POC</td>
<td>Influenza</td>
<td>52</td>
<td>25</td>
</tr>
<tr>
<td>Prolia</td>
<td>Osteoporosis</td>
<td>88</td>
<td>40</td>
</tr>
</tbody>
</table>
CLINICAL TRIALS OFFICE
Principal Investigators

- Stuart Adler, MD
  Electrophysiology

- Mudassar Ahmed, MD
  Interventional Cardiology

- Steven Benton, MD
  Pulmonary Hypertension

- Brian Erickson, MD
  Mental Health

- Les Forgosh, MD
  Cardiology

- Alvin Holm, MD
  Alzheimer’s, Dementia

- Yoaav Krauthammer, MD
  Electrophysiology

- Dayuan Li, MD
  Cardiac Imaging

- Laura Li, MD
  Neurology

- Carmelo Panetta, MD
  Interventional Cardiology

- Sandra Rosenberg, MD
  Wound Care

- Rodolfo Soca, MD
  Sleep Medicine
CLINICAL TRIALS OFFICE

Team Members

- Centralized team providing dedicated support to clinical trials throughout the HealthEast Care System
- Director
- Manager
- Nurse Practitioners
- Budget and contract analyst
- Medicare billing and compliance analyst
- Research recruitment specialist
- 5 Research nurses
- 2 Research associates
- 2 Research assistants
- Research schedulers
CLINICAL TRIALS OFFICE
Enhanced Study Start-Up: Parallel Processing for Faster Start-Up

1 Week

2 Weeks

1 Week

Budget Review
Enrollment Simulation
PI Approval
Contract Approvals
ICF Completion
Regulatory Documents
Recruitment Planning
IRB Review and Approval

1 Week

2 Weeks

1 Week
Real-Time Access to patients
- Epic driven
- 4 hospitals
- 14 clinics
- Customized Recruitment Plan for every Study
CLINICAL TRIALS OFFICE

Ability to use Central or Local Hospital IRB

HealthEast IRB

- FDA Audited IRB
- Established 1991
- Review includes all hospitals and clinics
- Meets 3\textsuperscript{rd} Monday of every month
- Results letter available within 4 days of review meeting

- Contact the IRB: 651.232.5363
CLINICAL TRIALS OFFICE

Luxury Monitor Office

- New office suite for monitors
  - Includes en-suite restroom
- Secured access
- High speed wireless internet access
- Dedicated and controlled EHR permissions
- Ample desk space
  - Including new stand-up desk

Remote Monitoring Now Available!

- EPIC Care Link

Therapy Dog Available for Monitors
# CLINICAL TRIALS OFFICE

## Site Qualification Information

<table>
<thead>
<tr>
<th>Contact Type</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| Clinical Trials Office     | HealthEast Medical Research Institute  
45 W 10th St  
St. Paul, MN 55102  
Phone: 651.326.4448  
Fax: 651.326.3959 |
| Principal Investigator     | Same as above       |
| Research Coordinator       | Beth Jorgenson, MBA, RN  
Research Manager; Address as listed above  
Phone: 651.232.3274 |
| Regulatory Coordinator     | Beth Jorgenson, MBA, RN  
Research Manager; Address as listed above  
Phone: 651.232.3274 |
| Budgets and Contracts      | Andrew Snyder, MBA  
Research Director; Address as listed above  
Phone: 651.471.2651 |
| Pharmacy                   | Christina Glasgow  
Research Pharmacist; Address as listed above  
Phone: 651.326.3648 |
## Pharmacy

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>Research Pharmacist</td>
<td>HealthEast supports a dedicated research pharmacist and pharmacy technician. These pharmacy professionals have experience in all forms of investigational record keeping, IVRS, etc.</td>
</tr>
<tr>
<td>Drug Storage</td>
<td>All investigational medications are stored in a locked, secured and monitored location.</td>
</tr>
<tr>
<td>Temperature</td>
<td>The pharmacy has a real-time temperature monitoring, recording and alarm systems for all medications stored in the lab quality refrigerator, freezer or ambient storage units.</td>
</tr>
<tr>
<td>Calibration</td>
<td>All calibration and maintenance records available.</td>
</tr>
</tbody>
</table>

## Data Collection

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDC</td>
<td>Research coordinators have experience and training with all of the current EDC systems; including, but not limited to, RAVE, Oracle. Visit data is entered within 48 hours.</td>
</tr>
<tr>
<td>EHR</td>
<td>HealthEast uses the EPIC electronic health record. All source documentation is recorded in EPIC. EPIC supports electronic signatures, Investigator signs labs, etc, in EHR. Secure audit trail.</td>
</tr>
<tr>
<td>Equipment</td>
<td>Research staff members have access to their own computer, phone, fax, high-speed data, wireless.</td>
</tr>
</tbody>
</table>
## Equipment Available

<table>
<thead>
<tr>
<th>Location</th>
<th>Equipment Available</th>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Care Hospitals</td>
<td>-20°C Freezer</td>
<td>EKG</td>
</tr>
<tr>
<td>Outpatient Clinics</td>
<td>-70°C Freezer</td>
<td>EMG</td>
</tr>
<tr>
<td>Secured facility</td>
<td>ABI Ultrasound</td>
<td>MRI; 1.5T and 3.0T</td>
</tr>
<tr>
<td>Secured storage</td>
<td>Blood Pressure</td>
<td>Nuclear Stress</td>
</tr>
<tr>
<td>Secured archive</td>
<td>Centrifuge – Refrigerated</td>
<td>PET Scan</td>
</tr>
<tr>
<td>Cath Lab</td>
<td>Centrifuge – Dedicated Ambient</td>
<td>Scale</td>
</tr>
<tr>
<td>EP Lab</td>
<td>CT</td>
<td>Stadiometer</td>
</tr>
<tr>
<td>Hybrid Suite</td>
<td>Echocardiogram - TTE</td>
<td>Sleep Lab</td>
</tr>
<tr>
<td>Heart Failure Clinic</td>
<td>Echocardiogram – 3D TEE</td>
<td>Surgery</td>
</tr>
<tr>
<td>Infusion Center</td>
<td>6 Min Walk Testing</td>
<td>Xray</td>
</tr>
</tbody>
</table>
CLINICAL TRIALS OFFICE
Please call us to discuss your study!

651.326.4448  research@healtheast.org  www.healtheast.org/clinicaltrials