NEW STUDY ACTIVITY

<table>
<thead>
<tr>
<th>Activation Pending</th>
<th>Startup in Process</th>
<th>Startup has Begun</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT-HF</td>
<td>ALPINE</td>
<td>CRAVE</td>
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<tr>
<td>APOLLO B</td>
<td>CHASM</td>
<td>DEFINE</td>
</tr>
<tr>
<td>ChEVAS</td>
<td>CORCINCH-HF</td>
<td>ROMA RAS</td>
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<tr>
<td>Gossamer GB-002</td>
<td>EMERALD II</td>
<td>ROMA QOL</td>
</tr>
<tr>
<td>HERITAGE</td>
<td>ENCIRCLE</td>
<td>RESTORE</td>
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<tr>
<td>PARAGLIDE</td>
<td>HORIZON</td>
<td>SMART</td>
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<tr>
<td>PV in LVAD</td>
<td>LIB003-07 (OLE)</td>
<td>SWIFT</td>
</tr>
<tr>
<td>SELECT</td>
<td>PERFORMANCE II</td>
<td>UNISUS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VITAL KardiaMobile</td>
</tr>
</tbody>
</table>

Retro/QI in Process: Residency Project,
Grants in Progress: Raina R01 Sub-Award; Halbreiner

If your trial does not appear in this table, contact Heather McDonald

NEW INITIATIVES

RESEARCH DASHBOARD
Using REDCap, we are creating a dashboard feature for investigators and research staff. This tool will allow you to check the number of studies in your service line, status of new study startup, research staff assigned to your trials, sponsor contacts, enrollment status, and basic study financial tracking. Details will be discussed in the near future.

FEASIBILITY
In order to effectively prioritize and expedite new studies, we are sending out a feasibility survey for new trials. You’ll receive an email with instructions from Heather McDonald or Matt Yeager, and the subject line will contain the trial name.

CATEGORY B DEVICES
Highmark is now covering certain procedures related to the implantation and use of Category B devices in research trials. Your research coordinator will work with OSR to plan the enrollment of these patients.

M365 AND MICROSOFT TEAMS
Highmark is implementing Microsoft Teams, an enterprise-level collaborative project management platform that can enhance productivity. CVI Research is in the process of onboarding this platform and transferring stored files to the M365 Sharepoint Site. For more information, contact Matt Yeager.

NEW RESEARCH STAFF
Ronnie Galuska, RN – CRC – 04/19/21
Caitlin Phalunas, MS – CRC – 05/24/21
2 Additional CRC offers made
DBA and Research Data Scientist in process

NEW INVESTIGATORS
Andrew Oehler, MD
Candice Lee, MD
Farhan Katchi, MD

CVI RESEARCH ADMINISTRATION DIRECTOR
Heather McDonald

OUR TEAM COORDINATION

CLINICAL MANAGEMENT
- Matt Yeager
- HF/PH/Cardiology
  - Joan Rossi
  - Amy Halle
  - Kelly Kuniak
  - New Hire
- MCS/Specimen Banking
  - Laurie Machen
  - Tina Horn
- CTS
  - Tracy Sork
  - Stephanie Vehoc
  - Ronnie Galuska
  - New Hire
- VASC
  - Sheila Bernardini
- EP
  - Adrija Sircar
  - Caitlin Phalunas
- CMRI
  - Geetha Rayarao
- AVH
  - Jessica Burkardt
- SVH
  - Michelle Drexel
  - Brandi Vanerstrom

REGULATORY

START UP
- Vandna Rami

FOLLOW UP
- Marie Rippole
- Laura Chabala

REGULATORY ASSISTANT
- Christine Baehr

OFFICE OF SPONSORED RESEARCH (OSR)

BUDGET/CONTRACT
- Cassie Andreas

MEDICARE COVERAGE ANALYSIS
- Lori Hassett

CVI RESEARCH ADMINISTRATION DIRECTOR
- Heather McDonald

CVI Research Newsletter Issue 1 - 1Q2021
IRB REQUIREMENTS

Modules
https://www.citiprogram.org

"Register Here"
Organization Affiliation = AHN
Then AHN Research Institute
Complete Steps 2 through 6, then
Basic Human Subjects – Biomedical
Continue to Step 7
Select Curriculum = Researcher
Complete the form, Q5 = yes
Complete Registration
Finalize Registration
Select Modules:
"Add a Course or Update Learner Groups"
Answer questions as follows:
1. Researcher
2. No, thanks.
3. Not at this time.
4. GCP for Clinical Trials with
Investigational Drugs and Medical
Devices (U.S. FDA Focus)
5. No
6. Not at this time
7. SKIP
8. SKIP
9. Not at this time.
10. Not at this time.
11. No
12. Not at this time.
13. Not at this time.
14. Not at this time.
15. Not at this time.
Click Submit, courses will be added.
Click on the course and complete
Click on the course and complete
Click Submit, courses will be added
Click Submit, courses will be added
Click on the course and complete
Click Submit, courses will be added
Click Submit, courses will be added

Highmark COI Disclosure
https://coi.highmarkhealth.org

Click REGISTRATION
Complete the self-registration, when
done, email to Maria.Motta@ahn.org:
1. Supervisor
2. Name of Department and Facility
   (i.e., Allegheny Clinic, AGH, etc.)
3. User ID (if employed this would be
   your Employee ID; if not, it would be
   your email address)
Maria Motta will complete registration,
and autoemail the link to complete the
COI disclosure. Any questions, call
Maria at 412-578-1028.

If we knew what it was we were doing, it would not be called research, would it?
- Albert Einstein

Research How-To Tips: Startup

GETTING STARTED

IRB Requirements

- CITI Modules
- Highmark Conflict-of-Interest Statement
- Informed Consent Training (if consenting)
These requirements must be completed prior
to any research activity.

Sponsor Invitations

- Confidentiality/Non-Disclosure Agreement (CDA/NDA): If a sponsor reaches out to you with a CDA/NDA
and/or a feasibility survey, do not sign anything. Forward to Heather for processing by the Office of
Sponsored Research (OSR). Signing your name to the CDA puts you at personal risk.
- Cold Calls: Sponsors will nominate you and this site for a study without checking with you first. We need to
carefully evaluate these studies for feasibility, since we may already have an overload of new trials.

Retrospective Chart Reviews/QI Projects

- Protocols: To get started, a protocol will need to be written using the AHN IRB’s protocol template, which
Heather can provide. The PI must be an attending/ faculty mentor. You should expect the IRB submission
and approval of these projects to take one month, so starting early is key, since chart review cannot begin
until the IRB approval letter is released.
- Key Study Personnel: If you choose to add additional residents, they must also have completed the IRB
requirements prior to their addition. If they haven’t it will delay the approval.

CLINICAL TRIALS: SPONSORED AND INVESTIGATOR-INITIATED

StartUp, Stepwise:

Contract and Budget
1) Contract review begins; redlines returned to sponsor for negotiation. Even in cases where no funding is
   provided, if data is transferred this is necessary.
2) Budget preparation, even if all Standard Care (SOC) procedures, CRC time and regulatory fees must be
   budgeted.
3) Budget meeting with PI to determine SOC vs. research procedures
4) Budget negotiation with Sponsor and finalization
5) Contract terms agreement, including cost to subject and compensation for injury language
6) Contract execution

IRB and Regulatory Documents*
7) Informed consent preparation, including insertion of the agreed-upon cost and compensation language
8) Consent negotiation with sponsor
9) IRB document preparation and submission
10) Regulatory document preparation
11) IRB approval

Study Activation
12) Site Initiation Visit
13) Study Launch

*Because step 7 requires that step 5 has been completed, we cannot submit to the IRB prior to the final contract signoff.

For more information, or to post an update,
contact Heather McDonald 412-513-5321 (mobile)