Issue 1 - 1Q2021

CVI Research Newsletter

PROGRESS
PROCESS
PEOPLE

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 Spirk
- Stephanie Vehec
- 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

NEW INVESTIGATORS

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

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 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 STUDY ACTIVITY

Activation Pending	Startup in Process		Startup has Begun	
ACT-HF	ALPINE	REAL AF	CRAVE	ROAR
APOLLO B	CHASM	RESONANCE	DEFINE	ROMA RAS
ChEVAS	CORCINCH-HF	RESTORE	Early Bird	SOLANO
Gossamer GB-002	EMERALD II	ROMA QOL	EMBLOK	TARGET IV
HERITAGE	ENCIRCLE	SMART	LOFT-HF	TROPHY
PARAGLIDE	HORIZON	SWIFT	PROTECT IV	VALOR
PV in LVAD	LIB003-07 (OLE)	UNISUS	R1500-HTG	
SELECT	PERFORMANCE II	VITAL KardiaMobile	RECOVER IV	

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

Allegheny Health Network

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

Research How-To Tips: Startup

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

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.

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.

ICF Training Sessions – Next Available Dates:
4/15/2021, 5/20/2021 Training starts at 7am. The Zoom login/registration information is listed below. Registration may be completed ahead of time at the link below, but is not required. Zoom link: https://zoom.us/j/93847716599?pwd=L1Q3TW1QZDVwWFVQT2h4dGhtZGhSdz09 ID: 938 4771 6599 Passcode: 159914

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)

Allegheny Health Network