Small

Madara

Spotlight on Clinical Research

COVID-19 Research Update

Roy S. Small, M.D.
Medical Director of Clinical Research
Heather Madara
Clinical Research Coordinator
Penn Medicine Lancaster General Health Research Institute

The management committee of the Research Institute met in March to determine how the team would approach research studies during the COVID-19 pandemic. In order to maximize patient and staff safety and continue as many operations as possible, the Research Institute implemented the following recommendations:

1. Research studies which require hospital resources will temporarily cease enrollment unless the procedure is part of standard medical care. For example, MORE-CRT MPP requires implanting an ICD.

2. Studies requiring inpatient visits for enrollment (for example, the MINT trial, which involves transfusions in ACS patients) will be temporarily placed on hold.

3. Follow-up visits for research patients will be done remotely (by telephone) if possible, instead of in the office.

4. Research patients requiring face-to-face visits will have follow-up visits scheduled per protocol. Similarly, patients receiving research drugs will continue to receive these drugs per present protocols. Some studies, such as ARTESiA, were granted approval to ship study drugs directly to the patients during this time.

5. Procedures that can be delayed yet remain in the prescribed protocol "window" (for example, HEART-FID in which patients receive iron infusions) will be rescheduled.

6. The Research Institute notified the IRB, all study sponsors, and Principal Investigators (study PI's) of these changes in writing. The study PI's signed off on the interim plans.

The following table identifies the status of all current studies and their departments.

Roy S. Small, M.D.
The Heart Group of Lancaster General Health
217 Harrisburg Ave.
Lancaster, PA 17603
717-544-8300
Roy.Small@pennmedicine.upenn.edu

Heather Madara
Penn Medicine LG Health Research Institute
131 E. Frederick St.
Lancaster, PA 17602
717-544-1777
Heather.Madara@pennmedicine.upenn.edu

Table 1. **Status of Current Studies at Penn Medicine Lancaster General Health**

STUDY NAME	DEPARTMENT	STATUS
AdaptResponse	Electrophysiology (EP)	Standard of care device checks unchanged
AEGIS II	HYPERLIPIDEMIA	Pause enrollment; In-person study visits changed to phone follow-ups
AIM-POWER	Congestive Heart Failure (CHF)	Study start-up
ARTESiA	EP	Pause enrollment
ASCEND-ND	NEPHROLOGY	Pause enrollment
CASCADE HF	HYPERLIPIDEMIA	Pause enrollment
CT-FFR & CT Perfusion	Acute Coronary Syndrome (ACS) & Myocardial Infarction (MI)	Pause enrollment
cvMOBIUS	HYPERLIPIDEMIA	IRB Approval – Pause enrollment start
EMPULSE	CHF	Study Start-Up Phase
GUIDE-HF	CHF	Pause enrollment
HEART-FID	CHF	Pause enrollment; Defer in-person study visit infusions
Indicor Monitor	ACS & MI	Pause enrollment
LINQ COPD	PULMONARY	Study start-up – will not seek IRB approval until Pulmonary has cleared COVID-19 impact.
Lipoprotein (a) & CVD	HYPERLIPIDEMIA	IRB Approval – Remote (telephone) enrollment
MARVEN	EP	Pause enrollment; Standard of care device checks unchanged
METEORIC-HF HFrEF	CHF	Pause enrollment
MINT	ACS & MI	Pause enrollment; In-person study visits changed to phone follow-ups
MORE-CRT MPP	EP	Pause enrollment; Standard of care device checks unchanged
MRI-Abandoned Leads	EP	Study start-up
OPTIMZER PAS	EP	Study start-up
OPTISURE	EP	Standard of care annual device checks unchanged
PEDIATRIC CONCUSSION	SPORTS MEDICINE	Pause enrollment
Product Surveillance Registry	EP	Pause enrollment; Standard of care device checks unchanged
PROTECT ICD	EP	IRB Approval – pause enrollment start
REDUCE Lap - HF II	CHF	Pause enrollment; Standard of care HF visits unchanged
REVERSE VA-ECMO	Cardiothoracic Surgeons of Lancaster (CTSL)	Pause enrollment
SOLVE CRT	EP	Pause study training, no enrollment
STROKE-AF	NEUROLOGY	Standard of care device checks unchanged
TAHFT	ORTHOPEDICS	Conduct
TAVR Prehab	CTSL	Standard of care visits unchanged