SPOTLIGHT ON CLINICAL RESEARCH

Starting Your Clinical Research Journey

Heather Madara
Supervisor Research Regulatory and Outreach
Roy S. Small, MD
Medical Director of Clinical Research
Penn Medicine Lancaster General Health Research Institute


Small


Madara

In previous Spotlights, we have highlighted resources available for researchers at Penn Medicine Lancaster General Health, how to submit to the Institutional Review Board (IRB) at the University of Pennsylvania, the One Penn Medicine One Research model, and the process for conducting investigator-initiated studies.

Anyone who wants to participate in clinical research must complete certain requirements, but to be a Principal Investigator for a research study, the standard is higher. This Spotlight outlines the requirements and expectations of Principal Investigators conducting research at LG Health, along with the support available to them.

PRINCIPAL INVESTIGATORS

At Penn Medicine, a Principal Investigator (PI) is:

> ... responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of clinical research.[1]

Much of the research conducted at LG Health falls into the category of sponsored or industry research. You can find information about investigator-initiated research at LG Health in the *JLGH* Winter 2024 Spotlight on Research.[2]

In sponsored research, an external sponsor, such as Medtronic, Eli Lilly, or Novo Nordisk, develops a research study and reaches out to research sites to invite them to participate in the study. Sponsors provide approved sites with all study materials needed to conduct the study, including the protocol, informed consent form(s), pharmacy and laboratory manuals, and recruitment materials.

Before a sponsor will approve a site for participation in their research study, the site must identify a PI. To be eligible to serve as PI of a research study, you must:

- Complete Human Subjects Protection and Good Clinical Practice training.
- Have a valid medical license.
- Practice in the study's field of focus (e.g., interventional cardiology, neurology, oncology).
- Agree to be responsible for the overall conduct of all research activities at the study site.

During the start-up process and throughout the duration of the study, additional requirements and documentation may be needed, including:

- Complete a study-specific financial disclosure.
- Attend a site initiation visit (SIV), typically held virtually.
- Complete study-specific documents (e.g., protocol signature page, investigator agreement).
- Support the informed consent process. The process varies between studies and may require the PI to be the one to consent eligible patients or may allow for other study team members to conduct the informed consent process.
- Review adverse events in participants to determine relatedness to study and severity of the event.
- Complete study update trainings, as needed.

LG HEALTH RESEARCH SUPPORT

The team at the Research Institute is composed of clinical research coordinators, research assistants, project managers, regulatory personnel, and more who are available to support researchers in their research journey. This support includes:

- Communicating with the study sponsor and any other study-related companies.
- Negotiating the study budget and contract.
- Coordinating site initiation visit, monitoring visits, and other study visits/meetings.
- Coordinating and maintaining required training and documentation.
- Submitting the study to the Penn IRB and to the central IRB, if appropriate. This includes initial

submission, study modifications, annual reviews, and all other types of submissions throughout the duration of the study.
- Providing study updates and associated trainings, as needed.

ADDITIONAL INFORMATION

If you are interested in participating in a sponsored research study or have been contacted by an industry sponsor, the Research Institute is available to guide you through the process. Scan the QR code below for more information about the Research Institute and other research teams at LG Health.

REFERENCES

1. Principal Investigator (PI) Training. Penn Medicine. n.d. Accessed October 8, 2025. https://www.med.upenn.edu/clinicalresearch/principal-investigator-pi-training.html
2. Becker H, Madara H. Investigator-initiated research at LG Health. *JLGH*. 2024;19(4):124-125.

Heather Madara
Penn Medicine LG Health Research Institute
133 E. Frederick St.
Lancaster, PA 17602
Heather.Madara@pennmedicine.upenn.edu

Roy S. Small, MD
The Heart Group of LG Health
217 Harrisburg Ave.
Lancaster, PA 17603
Roy.Small@pennmedicine.upenn.edu

Correction: The Spotlight on Research in the Fall 2025 issue of JLGH *contained an error in the print version: Joette Hughes, CRNP, is the sub-investigator for the Lp(a) EZEF – ACCLAIM study. The authors and editors extend an apology to Joette for the error. This was corrected in the online version of the article on September 11, 2025.*

PRINCIPAL INVESTIGATOR TESTIMONIALS

"I could never have embarked on my PI journey without the comprehensive assistance provided to me by the team of research professionals at the Penn Medicine Lancaster General Health Research Institute. I was part of a sponsored study, which required a lot of coordination, but communication from the research team was always timely and appropriate. After guiding me through the required trainings, they paved the way through the whole process, negotiating budgets and contracts, IRB submissions, coordinating the site initiation visit, helping me sort through protocols, protocol amendments, and consent forms, and so much more.

The clinical research coordinators, [many of whom are] experienced RNs, were there with me for consent visits, making sure both I and the participants were supported, and coordinating the next steps. They worked with my busy schedule to make research possible for me, coming to my office whenever needed and making it easy for me to sign off on necessary documents. I felt completely supported throughout the entire process and was never overwhelmed because I always knew what the next step was.

If you are a clinician interested in research, you are very fortunate to have such a knowledgeable and experienced research team right here at LG Health to make your research goals a reality."

— Virginia M. Wray, DO, Bariatric Physician Specialist

* * * * *

"The research team at LG Health paved the way for the Foundation Wellness Programs to Combat Clinician Stress (FACCTS) study and laid a strong foundation from its very inception. This excellent team consisted of the research project manager, research regulatory and outreach supervisor, research director, and research coordinators. This team has been very helpful and supportive with formulating the IRB protocol submission, working on the grant-writing application process, developing the workflow and outreach, and managing the contract processes for this study.

I would also like to thank the Research Institute leadership and executive leadership team at LG Health for being supportive of this study. As a busy clinician balancing clinical responsibilities with research, I am fortunate to be part of this well-articulated team, dedicated to advancing clinical research."

— Mrinalini Meesala, MD, FACC, RPVI, Chief of Cardiology