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SPOTLIGHT ON CLINICAL RESEARCH

Investigator-Initiated Research at LG Health

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Editor's note: This is the 21st in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH *at 717-544-8004.*

Health care providers are in a prime position to answer the questions faced in day-to-day practice and improve how health care is offered. One way to do this is through clinical research.

Penn Medicine Lancaster General Health (LG Health) is among the most active community-based health systems in the nation for clinical research. Because research ideas often arise while caring for patients, our investigator-initiated studies, often referred to as IIS, are a unique resource for LG Health clinicians. These research questions, and subsequent research studies, have the potential to offer new treatments that can save lives and improve quality of life for the patients of LG Health. It also provides professional development opportunities for providers and staff.

Acting on an idea or solution for one of these research questions may seem like a daunting task. At LG Health, dedicated research professionals provide investigators with the guidance, resources, and infrastructure needed to conduct clinical research aimed at improving and advancing medical care. The Research Institute also ensures that all research remains safe for patients and other study participants.

The Research Institute offers support throughout the entire lifecycle of an investigator-initiated study. The study lifecycle follows six steps (see Fig. 1):

1. Proposal Development
2. Funding
3. Study Startup (Protocol Development)
4. Study Activation
5. Participant Enrollment
6. Data Analysis and Dissemination (Close-out)

During proposal development, the design and methods for the study are established. The design of a research study is the overall plan or blueprint that guides the process of conducting research and will encompass the methods that will be used to collect and analyze data. The research design will include the research objectives and hypothesis, which define the goals of the research study and answer the question regarding what the research is trying to demonstrate.

Collected data will be qualitative, quantitative, or a mix of both (mixed methods research). The research design (e.g., experimental, observational, survey, case study, longitudinal, etc.) will help determine the methods used for data collection and subject sampling.

The research team offers special attention to feasibility, budget, timeline creation, and staffing needs. They can then help apply for and secure internal (e.g., Louise von Hess Research Grant) or external funding for the research project. If support is needed for billing at any point during the study, the research team can provide guidance regarding that as well.

Once funding has been obtained, the research team will work with investigators to develop a research protocol. They will support the investigator through developing study-related materials (e.g., informed consent form, data-collection tools, promotional materials, etc.) and submitting to the University of Pennsylvania Institutional Review Board (IRB) for approval.

After IRB approval, the study activation process can be initiated. This step focuses on implementing the protocol and training those conducting the project. This may include pharmacy staff, unit staff, research coordinators, or anyone else needed per the protocol.

After all team members are trained, study activities can begin. These activities focus on enrolling participants and may include recruitment, obtaining consent, and collecting data. Each research project is unique, and not all projects have the same activities or procedures. For example, retrospective data-

collection studies do not typically involve patient consenting due to the study design and data confidentiality measures in place. It is important to be aware of the research requirements that apply to your project.

After all study activities are completed and data collection ends, data analysis and results dissemination can begin. This step often includes final analysis, closing the project with the IRB, manuscript writing, and document storage. Statisticians who work in collaboration with the research team can provide the tools and expertise needed to analyze and draw conclusions about the study's findings. Some funding sources, like the Louise von Hess Research Grant, have a publication requirement that must be met, so it is crucial to be aware of all required steps.

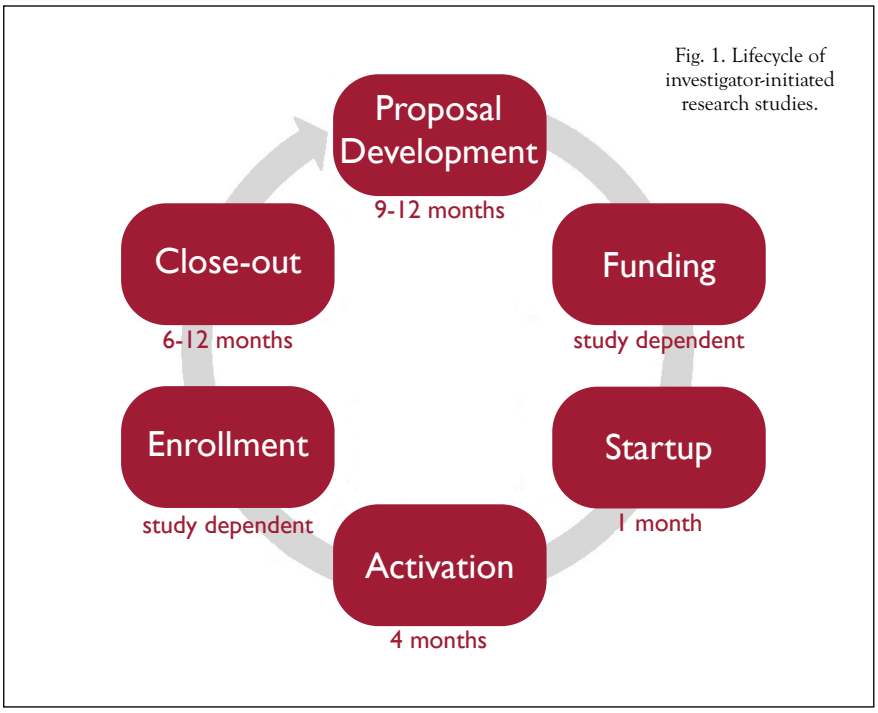

Fig. 1. Lifecycle of investigator-initiated research studies.

The research team is available to provide information, guidance, and logistical support to help researchers be effective and remain compliant at every stage of a project. For general research inquiries, you can explore the Research Institute web page accessible via Star*Net* or email the team at LGHResearch@pennmedicine.upenn.edu. For additional information about investigator-initiated studies, please reach out to Halle Becker, research project manager at the LG Health Research Institute.

To learn more about research at LG Health, health care professionals are invited to join the newly launched monthly Research Grand Rounds, where investigators and other research professionals present on the latest research topics in various therapeutic areas. Our next Research Grand Rounds will be presented by Alexis Ogdie, MD, on Thursday, January 9, 2025.

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