SPOTLIGHT ON CLINICAL RESEARCH

Research Infrastructure

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Editor's note: This is the 22nd 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 JLGH editorial offices.

In the previous Spotlight on Research, we highlighted investigator-initiated research and provided guidance on how to turn a research question into a research study. Most research projects require additional infrastructure including data collection, data analysis, and recruitment.

The research team at LG Health is available to guide you through gaining access to these tools and how to use them effectively. We outline some of the most used tools below and provide examples of some current investigator-initiated studies making use of them.

REDCAP

REDCap (Research Electronic Data Capture) is a secure, web-based data-collection and management tool. Users can create databases using a variety of templates or build them from scratch. REDCap is fully customizable and allows users to tailor databases and surveys to meet the specific needs of their studies. REDCap has an intuitive drag-and-drop design and form-building tools that enable users to create and modify data-collection instruments without requiring extensive programming knowledge. Role-based access and control help streamline study operations for research teams and enhance data integrity.

REDCap ensures data accuracy, security, and compliance through features such as automated audit trails and real-time data validation. It is also designed to meet institutional regulatory standards and is HIPAA compliant.

Notable capabilities include electronic consenting, randomization, survey distribution, and data management. REDCap supports remote or electronic consent by allowing the collection of electronic signatures, enabling these processes for research studies. REDCap can randomize participants into various groups or interventions according to customizable parameters.

Surveys can be easily distributed via email, secure web links, or QR codes, with automated email notifications and reminders for participants or team members to help ensure timely data collection, follow-ups, and compliance. Branching logic can be applied in forms and surveys, allowing dynamic questions that adapt based on user responses, resulting in more personalized and efficient data collection.

When a research study ends, REDCap allows data to be exported to common statistical software (e.g., SPSS, SAS, R, or Excel) or integrated with external databases, streamlining data analysis and reporting.

Researchers at LG Health can get access to REDCap by completing a simple User Support Form, available by scanning the QR code below.

Note: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by the Institutional Review Board (IRB) prior to any data collection.

ICONNECT

iConnect is a web-based platform created by TrialX that facilitates patient recruitment. This technology makes it easier for potential research participants to

find studies through web searches and enables study teams to respond to patient referrals and questions more efficiently. The University of Pennsylvania Institutional Review Board (IRB) system automatically creates an iConnect study listing upon study approval. These can be modified by study teams to maximize effectiveness.

iConnect houses a research volunteer registry, to allow searches for potentially eligible volunteers that have already expressed an interest in research participation. This registry can be accessed by LG Health research staff.

Study teams can modify iConnect listings so that patients may refer themselves to a study. They can also create screening surveys to help determine patient eligibility for any given study. Alternatively, teams may create iConnect study listings for merely educational purposes, without referral or contact information listed.

The study status listed in iConnect is what drives patient interaction. Study status options include:

- *Under Review:* Study currently in IRB review process but not yet IRB approved.
- *Recruiting:* Allows patients to submit referrals to the study team. Used for studies in which eligibility criteria and enrollment process make it simple for patients to determine if they might be eligible to participate or that use an iConnect prescreener.
- *Not Recruiting:* Study not open to enrollment — may be closed to enrollment or have enrollment paused.
- *Enrolling by Invitation:* Allows patients to see the study information but does not allow for referrals or contact. Used for studies in which eligibility criteria are complex or the screening process does not allow for patients to identify themselves as eligible.
- *Site Selection:* Study still in a start-up process and not yet ready for enrollment.

The Penn IRB issued a blanket approval to utilize iConnect for recruitment and education; other use of iConnect may require additional IRB approval. Some of the more advanced options available in iConnect include campaign trackers to monitor advertising efforts and study websites.

Readers who would like user-access to iConnect must complete an online training module. To access the training module, email the research team at LGHResearch@pennmedicine.upenn.edu.

INVESTIGATOR-INITIATED STUDIES AT LG HEALTH USING THESE TOOLS

Phlebotomy Education — Gender Diversity Study

Principal Investigator: Christina Pierre, PhD

It is well documented that transgender and gender-nonbinary patients experience significant health disparities. One root cause of disparity in this population is a lack of knowledge regarding gender diversity, which leads to substandard care.

The purpose of this study is to determine if targeted educational training for phlebotomists about gender-cultural competency has an impact on clinical preparedness, attitude awareness, and basic knowledge of how to interact with people who identify as transgender or gender-nonbinary.

The subject population is employed certified phlebotomists working at large academic medical centers or community health systems. Participants will be randomized to either the intervention group — which will receive the web-based educational training — or a control group — which will not receive educational training. Both groups will complete a pretest and a posttest.

This study will utilize REDCap for consenting, randomization, study surveys, and web-based educational training.

DCM-DETECT: Dilated Cardiomyopathy Detection using AI and screening with mobile Technology

Principal Investigator: Roy Small, MD

The DCM-DETECT protocol — previously featured in the Fall 2024 issue of this publication — is a von Hess (LGH internal) funded study that aims to utilize artificial intelligence (AI) to analyze EKGs to screen for dilated cardiomyopathies.

The study enrolls probands, the first family member identified with a non-ischemic DCM, and asks them to:

- Provide family medical history.
- Complete a 6-lead EKG using a mobile EKG device.
- Contact their first-degree relatives (FDRs) to invite them to join the study.
- Complete a survey.

FDRs who choose to participate will also complete the mobile 6-lead EKG and survey.

In addition, they will complete a 12-lead EKG and be encouraged to obtain a transthoracic echocardiogram (TTE) through their health care provider. The primary objective of the study is the uptake of screening TTEs in FDRs of patients with DCM compared to historical controls.

The DCM-DETECT study team utilizes REDCap for study surveys. It also utilizes iConnect for prescreener surveys, recruitment, and education.

FACCTS — Evaluate Foundational Wellness programs to help reduce clinician burnout and improve professional fulfilment in health care professionals

Principal Investigator: Mrinalini Meesala, MD

This research study is being conducted to examine the impact of well-being interventions to help reduce clinician burnout. Eligible participants will be randomized into one of three groups:

1. Sudarshan Kriya Yoga (SKY) Breathing and Sahaj Meditation Program.
2. Mindfulness Based Stress Reduction (MBSR).
3. Control (no intervention).

Participants will complete web-based training and follow-ups throughout their time in the study. The study team will use REDCap for consenting, randomization, and surveys. To be eligible for this study, participants must be:

- 25-70 years of age.
- A University of Pennsylvania Health System or Massachusetts General Hospital clinician (physician, APP, CRNP, PA, or psychologist).
- Able to access a smartphone and the internet.
- Willing to do relaxation exercises every day for 2 months (9 weeks).

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