University of CINCINNATI

Research Remote Monitoring through EpicCare Link

Thursday, September 15th, 2022

September 2022 Study of the Month #1

Healthy Participant Study
for Adults 18 to 49 Years Old

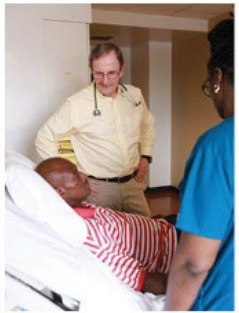
Inpatient Shigella Study

What
A study to learn if an oral Shigella study vaccine can prevent illness caused by one of the most common causes of diarrhea worldwide

Who
Healthy adults 18 to 49 years old who can attend screening visits, receive 2 vaccine drinks, stay in an overnight unit up to 11 days, and be available for 9 follow-up visits and a phone call.

Pay
Up to $4,500 to complete the study over 8 months

Contact
To see if you qualify, go to www.is.gd/gambleprogram or contact the Gamble Program for Clinical Studies at Cincinnati Children's at gambleprogram@cchmc.org or 513-636-7699.



Cincinnati Children's Research Foundation

cincinnatichildrens.org/clinical-studies
facebook.com/cincinnatichildrensstudies
pinterest.com/cincykidstrials

CCHMC IRB # 2019-0600: V2 BRV152411

University of CINCINNATI

September 2022 Study of the Month #2

Binge Eating Disorder Study

For Participants with Obesity

What

The purpose of this research study is to learn more about binge eating disorder (BED). Participants will be asked to come in for 8 visits over 8 weeks. Participants will be asked to wear an activity monitoring watch and provide saliva samples. They will also be randomly assigned to an individualized intervention (morning light and/or nightly melatonin or placebo) in the final four weeks of the study.

Who

Adults age 18-50, currently with obesity and experiencing binge eating disorder symptoms.

Pay

Eligible participants will be paid up to $440.

Details

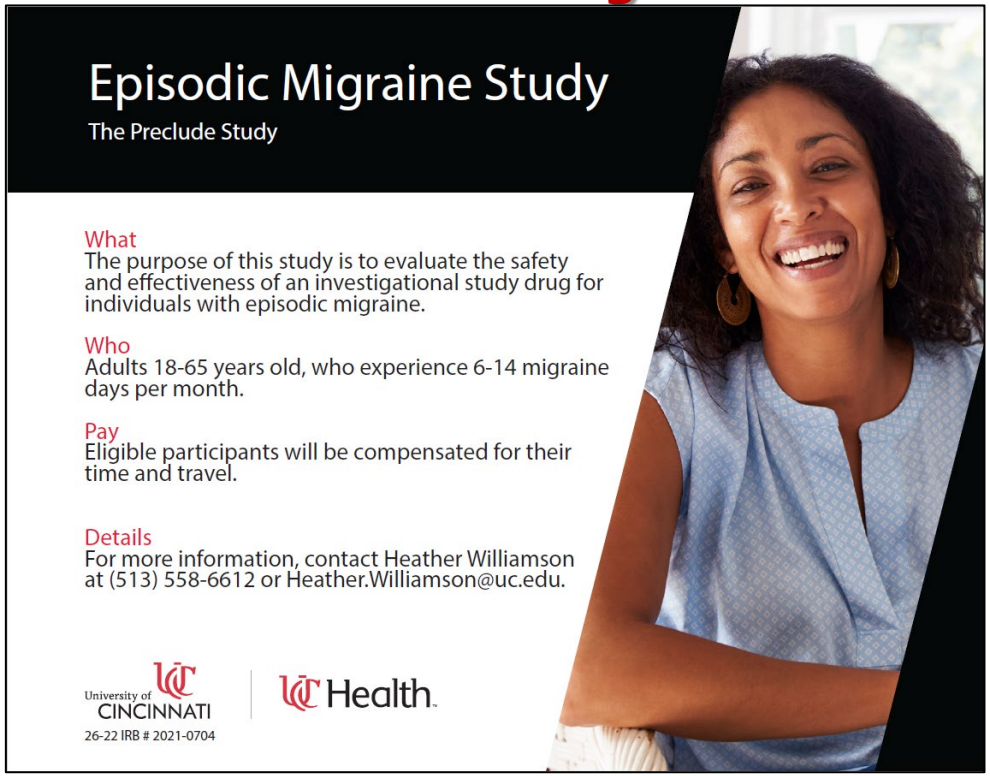
For more information, contact Brian or George at (513) 536-0707 or visit www.LCOH.info and fill out a pre-screen questionnaire. Located at the Lindner Center of HOPE in Mason, Ohio.

UC Health / UC Health Lindner Center of HOPE

13-21 IRB # 2020-0345

University of CINCINNATI

September 2022 Study of the Month #3



University of CINCINNATI

Human Subject Protection Conference 2022:

I'm Still Standing

Virtual Presentation: The conference will be spread over two days, with three talks each day, from 12:00 - 4:00 pm ET.

Wednesday, October 12th:

- Beyond the IRB: Downstream Social Impacts of Research
- Applying Health Literacy Principles to Clinical Research Studies: Health Literacy in Action
- Adverse Events: Understanding U.S. Clinical Trial Participation in the Context of Social Inequalities

Thursday, October 13th:

- Ethical Challenges in Research Consent: Nudges, Opt-Out Systems, and Direct-to-Patient Invitations
- Recognizing and Preventing Fraud in Online Survey Research: Considerations for Researchers and Institutional Review Boards
- Policy, Regulatory, and Enforcement Updates from the NIH

Click here for more information.

Please call 513-761-4100 or email hspconference@advarra.com with any questions.

Friday, October 7th, 2022

The Value of Engagement:

Seeing Patients/Caregivers as critical research experts

Melinda Butsch Kovacic, MPH, PhD

Professor, Department of Rehabilitation, Exercise, and Nutrition Sciences | Associate Dean of Research | College of Allied Health Sciences | Associate Professor, Department of Pediatrics | College of Medicine |University of Cincinnati

Research has great potential to impact people's lives IF participating patients and their caregivers understand their roles in its success. If CRPs engage their participants and help them see themselves as expert stakeholders, their study's recruitment and retention will benefit. Please join us for this discussion.

Today's Presentation:

Research Remote Monitoring through EpicCare Link

IS&T EpicCare Link team members and OCR leadership with a review and discussion of EpicCare Link workflow and management.

Maria Stivers
Senior Director
Office of Clinical Research
College of Medicine
University of Cincinnati

Stacey Willett
IS&T EpicCare Link Team
UC Health

Malika Daugherty
IS&T EpicCare Link Team
UC Health

Research Remote Monitoring through EpicCare Link

UC Health

Office of Clinical Research

Overview

Remote monitoring by study monitors can be completed using a web-based application called EpicCare Link.

As the name suggests, EpicCare Link establishes a "link" to the EMR to allow for remote access. No additional software is needed and the monitor is able to access released patient records.

Study teams can determine who to release and for how long.

History

This platform was initially used by external general practitioners or specialists. The original intent was to be able to communicate between community doctors and skilled facility teams with the patients' hospital doctors.

UC Health was testing this platform for research purposes when COVID hit. We admittedly had to scramble to fit this process into the monitoring requirements of CROs and Sponsors. Since COVID, this has become a routine process. This is still not a smooth process but getting better all the time.

Quarterly authorizations are required to ensure the right people have the right access to patient records.

We moved between an agreement that could not be edited to our current situation of redline agreements.

Process

- Execute agreement
- Register Site Administrator via Footprints
- Build Patient Group
- Change Site Admin via epic email
- Register Study Monitor via EpicCare Link site
- Release patients by admin or coordinator
- Validation/ Study Maintenance admin

Process Information

Remote Monitoring Bearcats Landing Page

Agreement

To utilize Epic's EHR for remote monitoring the *EpicCare Link UC Health Confidentiality Agreement for Researchers* must be in place with the outside monitoring entity. This is the first step of the remote monitoring setup process.

The EpicCare Link agreement is intended to be executed on an **institutional level**, between UCH and the Outside entity (the company that will need remote access) as this agreement will cover multiple studies/monitors and is not study-specific. With the intent to only execute one agreement per institution, we need an authorized signer of the Outside entity, who has the authority to bind the company to the terms of the agreement to sign the agreement.

If the agreement is signed by a Sponsor and the Sponsor contracts with a CRO, the CRO does not need to sign an additional agreement for EpicCare Link access. The CRO will be acting as an authorized user and agent/contractor under the Sponsor agreement.

The OCR/SRS will maintain a list of executed agreements on the initial request form to help prevent duplicative efforts.

Patient Group Build

- Functionality that creates a “group” that patients can be placed into, and external users can access
- Build request placed through Footprints
- Agreement must be in place with the outside entity (company that will be monitoring) beforehand
- Site Administrator form is attached to request and approved by OCR

Roles

- OCR/UCH Legal
- Site Administrator
- Study Monitor
- Research Coordinator

Role: Office of Clinical Research

- Responsible for approving Site Administrator access
- Approving a change in Site Admin
- Aid in contracting – UCH Legal
- Training

Roles: Site Administrator

- Registered and approved by OCR during the patient group build.
- Responsible for Quarterly Verification of Study Monitors in EpicCare Link (February, May, August, and November)
- Responsible for Terminating access for departed Study Monitors via EpicCare Link
- Responsible for Requesting access for new Study Monitors via the online EpicCare Link form (epiccare link site)
- Responsible for communicating any changes in EpicCare Link functionality to the Study Monitor
- Site Administrator will receive the study monitor log in information via Epic inbasket message once the account is complete. The Site Admin will need to send this information to the monitor.

Roles: Study Monitor

- Register via EpicCare Link
- Logs into EpicCare Link online portal to monitor for the specified study and specified period of time
- Responsible for informing the Research Coordinator/Site Administrator when they roll off a Study

Roles: Study Coordinator

- Requires regular Epic access
- Logs into Epic Hyperspace to release patients to the Study Monitor (can be site admin as well)
- Responsible for informing the Site Administrator of staffing changes with Study Monitors

Release Patients

- Completed using “find patients on my research studies report”
- Can be done by Study Coordinators or Site Administrators – you do not have to be a Site Administrator to do this

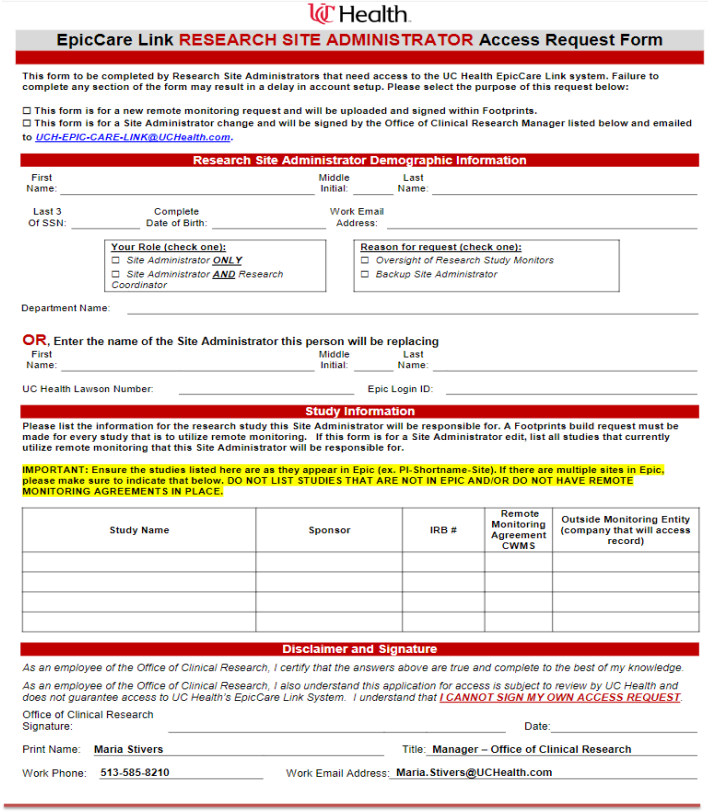
Study Maintenance

- Study teams may need to add coordinators to a study to allow for releasing records. Historically only one person was added to a study in Epic.
- In preparation for this tool, we have allowed for study teams to manage their own study teams in Epic using the “Research Study Maintenance” activity on the research dashboard.

UC Health

Visualization

Site Administrator Form



UC Health

EpicCare Link RESEARCH SITE ADMINISTRATOR Access Request Form

This form to be completed by Research Site Administrators that need access to the UC Health EpicCare Link system. Failure to complete any section of the form may result in a delay in account setup. Please select the purpose of this request below:

☐ This form is for a new remote monitoring request and will be uploaded and signed within Footprints.
☐ This form is for a Site Administrator change and will be signed by the Office of Clinical Research Manager listed below and emailed to UCH-EPIC-CARE-LINK@UCHealth.com.

Research Site Administrator Demographic Information

First Name: _____ Middle Initial: _____ Last Name: _____

Last 3 Of SSN: _____ Complete Date of Birth: _____ Work Email Address: _____

Your Role (check one):
☐ Site Administrator ***ONLY***
☐ Site Administrator ***AND*** Research Coordinator

Reason for request (check one):
☐ Oversight of Research Study Monitors
☐ Backup Site Administrator

Department Name: _____

OR, Enter the name of the Site Administrator this person will be replacing

First Name: _____ Middle Initial: _____ Last Name: _____

UC Health Lawson Number: _____ Epic Login ID: _____

Study Information

Please list the information for the research study this Site Administrator will be responsible for. A Footprints build request must be made for every study that is to utilize remote monitoring. If this form is for a Site Administrator edit, list all studies that currently utilize remote monitoring that this Site Administrator will be responsible for.

IMPORTANT: Ensure the studies listed here are as they appear in Epic (ex. PI-Shortname-Site). If there are multiple sites in Epic, please make sure to indicate that below. DO NOT LIST STUDIES THAT ARE NOT IN EPIC AND/OR DO NOT HAVE REMOTE MONITORING AGREEMENTS IN PLACE.

Study Name	Sponsor	IRB #	Remote Monitoring Agreement CWMS	Outside Monitoring Entity (company that will access record)

Disclaimer and Signature

As an employee of the Office of Clinical Research, I certify that the answers above are true and complete to the best of my knowledge.

As an employee of the Office of Clinical Research, I also understand this application for access is subject to review by UC Health and does not guarantee access to UC Health's EpicCare Link System. I understand that ***I CANNOT SIGN MY OWN ACCESS REQUEST****.*

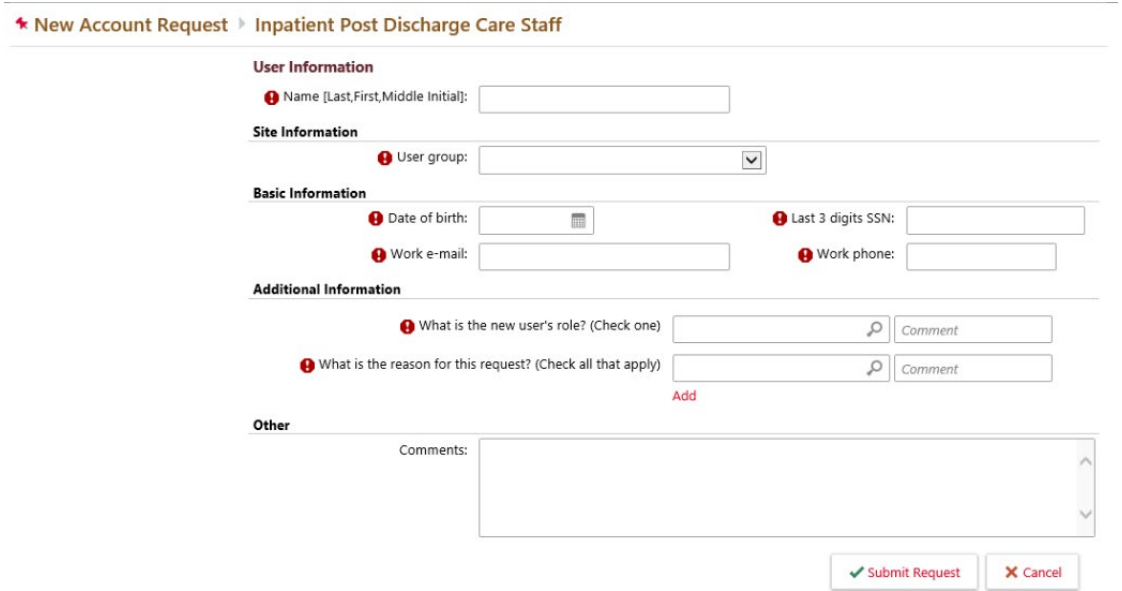
Office of Clinical Research Signature: _____ Date: _____

Print Name: Maria Stivers Title: Manager – Office of Clinical Research

Work Phone: 513-585-8210 Work Email Address: Maria.Stivers@UCHealth.com

Last Revised ***10/15/2020***

Study Monitor Access Form



UC Health

Discussion

Estimated Timeline

- EpicCare Link agreement: variable (depends on outside entity agreeing to terms)
- OCR Footprints approval: 1-2 business days
- Epic build: 3-5 business days
- Study Monitor registration: 1-3 business days (depends on HR due to OneTouch changes. May be 3-5 business days)

Helpful Tips

- Complete steps in sequential order… this is important!
- Make sure that you correctly certify who is the monitoring entity and that this entity matches the agreement cwms number you provide in the Footprints request.
- Reference Bearcats Landing page for exact steps on how to place the Fooprints request.
- Please try and maintain a consistent naming convention for your study across the forms. The study name should match what the study is called in Epic. We don’t know all the different names you can call your study!

Helpful Tips Part 2

- If you are a Site Administrator, make sure you complete your verifications on time. Lapsed verifications can introduce unnecessary complications and frustration. You will lose Epic access! It is automated now.
- Don’t hesitate to send the EpicCare Link handbook to monitors (included in the build notification). This has useful information on the EpicCare Link platform.

Helpful Tips Part 3

- A Site Administrator form must be completed for each person, but multiple studies can be created and assigned on the same form
- Site Admin changes/replacements do not need to be uploaded to footprints - Maria and EpicCare Link can approve via email
- If a monitor should be assigned to more than one study, you can list multiple studies in the comments box in the EpicCare Link online form.

Helpful Tips Part 4

- Once the Site Administrator requests access for a monitor, the request is sent to HR and IS&T EpicCare Link team will build the account in Epic
- A Site Admin cannot be logged in to Epic Hyperspace and EpicCare Link at the same time
- You DO NOT have to be a site admin to release patients

UC Health

Questions?

Contacts

Operations

Maria Stivers - stivermi@ucmail.uc.edu

Agreement/Contracting

UCP-ClinicalTrials@UCHealth.com

EpicCare Link Technical Team

UCH-EPIC-CARE-LINK@UCHealth.com

Monitor/Study Team Access Issues

UCH IS&T: 585-MYPC