From: "Office of Clinical Research" < Research-Admin@uchealth.com>

To: "Gulasy, Miranda" < miranda.gulasy@uchealth.com >

Date: 6/4/2021 6:59:30 AM Subject: June OCR Newsletter

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Study of the Month:



and a parent or sibling with Bipolar Disorde

What

The purpose of this research study is to investigate brain changes in adolescents who are currently experiencing depressive and/ or anxiety symptoms and have a family history of bipolar disorder. Participants will be randomized to escitalopram and psychotherapy or placebo and psychotherapy for 16-week treatment.

Who

Adolescents 12 to 17 years of age who are experiencing depressive and/or anxiety symptoms or have been diagnosed with depression and/or anxiety may be eligible to participate.

Pay

Participants will receive compensation for their transportation and/or time for the study visits. All visits, tests, procedures and medication will be provided at no cost to participants.

Details

Participants will have MRI scans. For more information, contact Kaitlyn Bruns at kaitlyn.bruns@uc.edu or call 513-558-5303.







Upcoming Events:

First Friday: 6/4/2021

9:00 - 10:00 am Virtual Meeting

Recruitment and Retention During a Pandemic:

The Experiences of the CTN0080 MOMs Study

June Clinical Research
Orientation and
Training (CRO&T): 6/10/2021

9:00 am - 3:00 pm Virtual Meetina

Lunch & Learn: 6/17/2021

12:00 - 1:00 pm Virtual Meeting

Investigational Drug Services (IDS)

Clinical Research

Managers Meeting: 6/25/2021

9:30 - 10:30 am Virtual Meeting

OCR SharePoint Site:

The Office of Clinical Research now has an active SharePoint site. The goal of this site is to serve as a centralized resource for research professionals to access helpful information that can support your research studies.

Please keep in mind that this SharePoint site is hosted on the UC Health network. If you are using a web browser that is logged into a University of Cincinnati or Children's Hospital Office 365 account, when you click this link, you will get an error message. To prevent this, you will either need to log out of Office 365 and click the link again to log in with your UC Health credentials, or you will need to use a different web browser, copy and paste the link, and log in with your UC Health credentials in order to access this SharePoint site.

Your UC Health log in credentials is comprised of your user ID number followed by @uchealth.com (ex: uid####@uchealth.com).

It is suggested that you bookmark this link in the browser of your choice so that you can remain signed in with your UC Health credentials and you can come back and reference this site at any time.

Click here to visit the OCR SharePoint site.

OCR Team Announcements:

The OCR is conducting a search for an <u>Operations and Project Administrator</u> and a <u>Clinical Research Access/Approvals Administrator</u> to work with our team. Please share these job postings if you know of any interested parties or reach out to Zak Johnson at <u>Zachary.Johnson@uchealth.com</u> for more information.

University of Cincinnati Guidance Updates:

Researchers must comply with university-wide guidance, guidance for any research sites, and <u>current IRB/HRPP guidance</u>. Previously approved COVID 19 response plans may be modified per the current requirements without additional IRB approval. Further details for <u>returning to campus</u> and <u>travel information</u> can found on <u>UC's Public Health website</u>. For IRB specific queries please contact <u>HRPP</u>.

Bioethics, Citizen Science, & Human Subject Protection Conference:

The 2021 Bioethics, Citizen Science, & Human Subject Protection Conference will be held virtually from September 8-12. This conference is co-sponsored by Advarra, Cincinnati Children's, Northern Kentucky University, the University of Cincinnati, and the University of Kentucky. This year's conference will address issues of significant importance to human subject protections and bioethics, including:

- Ethics of engaging patients in research
- Considerations of a research participant and caregiver
- Citizen science and how it fits with traditional research
- Regulatory updates including practical guidance on the Common Rule
- · Conducting reviews on emergent health issues/outbreaks

Click here for more information. Please call 513-761-4100 or email hspconference@advarra.com with any questions.

Access and Authorizations: Updated Appendix A:

Click here for an updated <u>Appendix A</u> for the Access and Authorizations process. <u>Appendix B</u> and <u>Appendix D</u> remain the same. The process continues to be the same, but all researchers, volunteer or paid, should use the newly updated Appendix A.

Please reach out to Research-Credential@uchealth.com with any questions.

Greenphire ClinCard Training Video:

Greenphire has developed a <u>ClinCard Training Video</u> for new users. The video link will be added to the REDCap request form as well as the OCR SharePoint site. We hope this video will be helpful when onboarding new users and serve as a valuable resource for current users. If you have any questions, please contact <u>UCH-Greenphire@uchealth.com</u>.

Greenphire ClinCard System: New Online Submission Platform

The method of requesting Greenphire ClinCards has been updated to an <u>online submission platform</u>.

The older method for requesting ClinCards involved completing a study action form, a study information sheet, and forwarding the request by email. The new ClinCard request process has now been updated to an <u>online electronic request and submission method</u>, eliminating the need to submit the request by email, further streamlining the process.

For detailed information on this update to the Greenphire Clincard request method and the online request form link, please see the recently updated

SOP: UCH-OCR-OPS-SOP-005-02: Greenphire ClinCard Participant Compensation and Reimbursement System

All OCR Policies and SOPs are accessible from the UC Health intranet home page utilizing the policy portal search function, or at the following link.

As always, please reach out to Nate Harris at Nate.Harris@uchealth.com with any clinical research compliance, Standard Operating Procedure, or policy questions or concerns.

Remote Monitoring with EpicCare Link

EpicCare Link is a feature of UC Health's EMR. Only IRB approved studies can be monitored through the use of EpicCare Link.

Access to EMR for auditing and monitoring purposes is required and remote monitoring is an IRB and FDA approved method. When requesting remote monitoring using EpicCare Link, please be sure to check if an **EpicCare Link UC Health Confidentiality Agreement for Researchers** document has been executed between UC Health and the Sponsor/Company that is requesting remote monitoring, keeping in mind that only one agreement is required between UC Health and the Sponsor/Company in order to monitor multiple studies the Sponsor/Company may have active at UC Health. A new agreement is not needed per study. But remote monitoring must be requested per each individual study.

For detailed information on the remote monitoring process, please see the following SOP: UCH-OCR-ACC-SOP-003-Access to Electronic Medical Records by Study Monitors, Auditors, and External Research Staff for the Purpose of Human Subjects Research

All OCR Policies and SOPs are accessible from the UC Health intranet home page utilizing the policy portal search function, or at the following link.

As always, please reach out to Nate Harris at Nate.Harris@uchealth.com with any clinical research compliance, Standard Operating Procedure, or policy questions or concerns.

EpicCare Link Remote Monitoring Verification Reminder for Site Administrators:

This reminder applies to those of you that serve as a Site Administrator for EpicCare Link use by external monitors. Please note, EpicCare Link requires Site Verification to be performed by Research Site Administrators in the months of **February**, **May**, **August** and **November**. The Site Verification begins on the 1st of the month and ends on the 22nd of the month at which time a report is automatically generated of the sites that have not completed Site Verification and sent to the Epic Security Team for accounts to be blocked. It is required that Research Site Administrators complete this practice by logging into link.uchealth.com to verify. Failure to complete Site Verification could result in the loss of access to EpicCare Link for external users and both EpicCare Link and Epic Hyperspace for Research Site Administrators.

Please reach out to <u>UCH-EPIC-CARE-LINK@uchealth.com</u> with any questions or concerns.

Resources For Our Research Community:

Article: Justice, Diversity, and Research Ethics Review

<u>Justice, Diversity, and Research Ethics Review</u> is a thought-provoking Science Magazine article reviewing the ethics of inclusion, and includes discussion questions.

UC Health: Healthcare Worker's Booklet for the COVID-19 Vaccine

Healthcare Worker's Booklet for the COVID-19 Vaccine.

Delight Health Services: I n-Home Support for Your Clinical Trials

<u>Delight Health Services</u> can provide your study with in-home clinical trial services.

CCTST Online Educational Library, CTROnline

<u>CTRonline</u> offers an array of clinical and translational research training modules and event recordings. All videos are free and open to any learner looking for a brief introduction to (or a refresher on) specific research topics.

ResearchMatch Online Training Thursday, June 10, 2021 2:00-3:00 PM

ResearchMatch offers free, online training for anyone in the research community interested in learning how to use ResearchMatch as a recruitment tool. This training will teach you how to get started and will share tips for ensuring that your experience with ResearchMatch is successful, including defining your demographics and key terms.

Register here: ResearchMatch Researcher Training.

<u>Updated Contact List:</u>

Director: Maria Stivers (Maria.Stivers@uchealth.com)

Supervisor: Trina Mcfarland (<u>Trina.Mcfarland@uchealth.com</u>) Manager: Zak Johnson (<u>Zachary.Johnson@uchealth.com</u>)

Budgets: Heather Roberson (<u>Heather.Roberson@uchealth.com</u>) & Macy

Michael (Macy.Michael@uchealth.com)

Coverage Analysis: Trina Mcfarland (Trina.Mcfarland@uchealth.com)

Contracting: Heidi Rowles & Devon Sanford

(UCP-ClinicalTrials@uchealth.com)

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Research Access & Authorizations: (Research-credential@uchealth.com)

UCH GreenPhire: Trina McFarland (<u>UCH-GreenPhire@uchealth.com</u>) UCH Research Approval: Nate Harris (<u>Research-Admin@uchealth.com</u>)

EPIC Research Tools: Zak Johnson (Research-Admin@uchealth.com)

& Miranda Gulasy (Miranda.Gulasy@uchealth.com)

Marketing: Miranda Gulasy (Miranda.Gulasy@uchealth.com)

Compliance Administration: Nate Harris (<u>Nate.Harris@uchealth.com</u>)
Training and Education: Nate Harris (<u>Nate.Harris@uchealth.com</u>)

Join the Mailing List:

We have moved our mailing list to an electronic system. New staff or faculty that wish to join the mailing list can now click the button here or on the OCR website to join.

If you received this newsletter, you are already on the list. No need to re-join, but we encourage you to share with your colleagues, especially those new to UC Health and UC.

Sign up to receive communications from the UC Health Office of Clinical Research on the topics of new SOPs, education sessions, news, events and information geared towards the UC/UCH Research Professionals community.

Click Here to Join the Mailing List









OCR Website

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