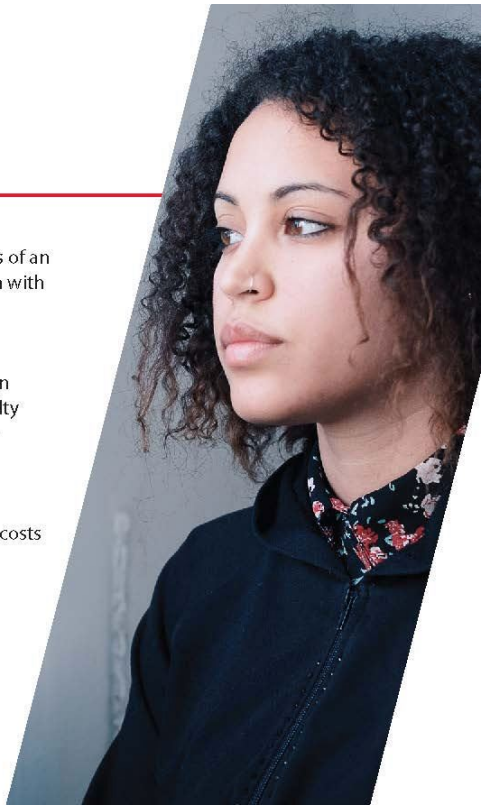
From: "Office of Clinical Research" <Research-Admin@uchealth.com>
To: "UCH-Gulasy, Miranda (Miranda.Gulasy)" <Miranda.Gulasy@UCHealth.com>
Date: 6/3/2022 7:00:09 AM
Subject: June OCR Newsletter

Content List:

Studies of the Month:

Do you have Depression with Sleep Problems?

Are you currently taking an antidepressant?



What
A research study to evaluate the safety and effectiveness of an investigational medicine in people who have depression with sleep problems.

Who
Adults 18-74 with depression who are currently taking an antidepressant medication, and are experiencing difficulty falling asleep or staying asleep, or do not feel rested the next day.

Pay
Participants will be paid $52 per visit for time and travel costs related to the study.

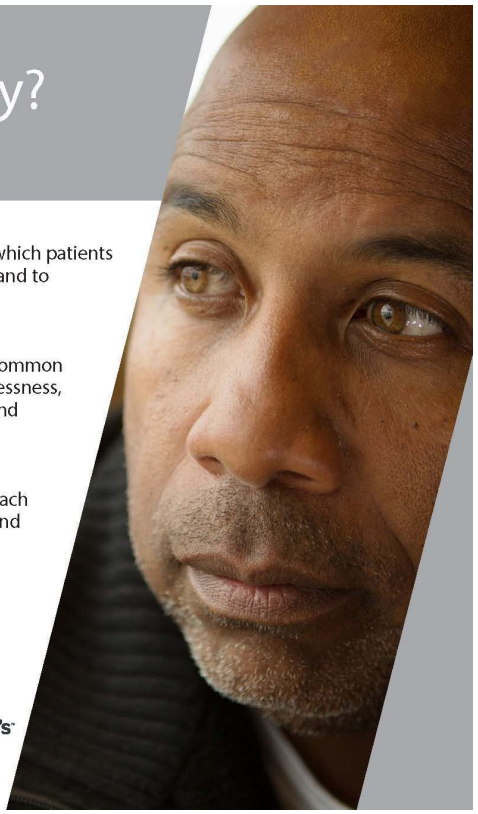
Details
For more information, contact Emily Rummelhoff at (513) 558-4295 or Emily.rummelhoff@uc.edu.

UC Health.

23-21 IRB # 2020-0595

Do You Have Anxiety?

Anxiety Study for Adults



What
The purpose of this clinical research study is to evaluate which patients respond best to which medication treatment for anxiety and to understand long-term recovery from anxiety disorders.

Who
Adults 18 to 50 years old may be eligible to participate. Common anxiety symptoms include uncontrollable worrying, restlessness, discomfort in social situations, irritability, panic attacks, and sleep difficulties.

Pay
Participants will receive payment for time and travel for each completed study visit. All study visits, tests, procedures, and medication will be provided at no cost to participants.

Details
For more information, please contact Ashley Specht at 513-558-2868 or huckabam@mail.uc.edu or Heidi Schroeder at 513-558-4422 or heysehk@mail.uc.edu.

University of CINCINNATI | UC Health. | Cincinnati Children's Research Foundation

26-19 IRB # 2019-0691

OCR Team Announcements:

Charlie Fremont, Clinical Research Applications/Systems Administrator, and Heather Roberson, Clinical Research Budget Administrator, will be leaving the OCR on June 3rd 2022. Charlie has accepted an opportunity outside of UC Health and Heather will be joining The University of Cincinnati Cancer Center. The OCR would like to thank Charlie and Heather for their contribution to the advancement of research in Cincinnati and we wish them the best in their new endeavors!

The OCR also thanks you, the research community, in advance for your patience and understanding while we conduct our job search for a Clinical Research Applications/Systems Administrator and a Clinical Research Budget Administrator to work with our team. The Clinical Research Budget Administrator position is currently live and can be accessed by following the appropriate link for either the internal candidate application or the external candidate application.

Please share this job posting if you know of any interested parties or reach out to Maria Stivers at Maria.Stivers@uchealth.com for more information.

One-Employer Model for Clinical Research Employees Effective January 1, 2023:

As UC continues to align and enhance the Clinical Research Structure with UC College of Medicine UC Physicians, Inc. and UC Health it has been decided to move to a one-employer model for the Clinical Research support teams. As a result of this decision, effective January 1, 2023 all dual comp Clinical Research Professionals will become solely employed by the University of Cincinnati. This will be a positive change on our clinical research staff throughout the organization. Please review this letter from Dr. Brett Kissela for more information.

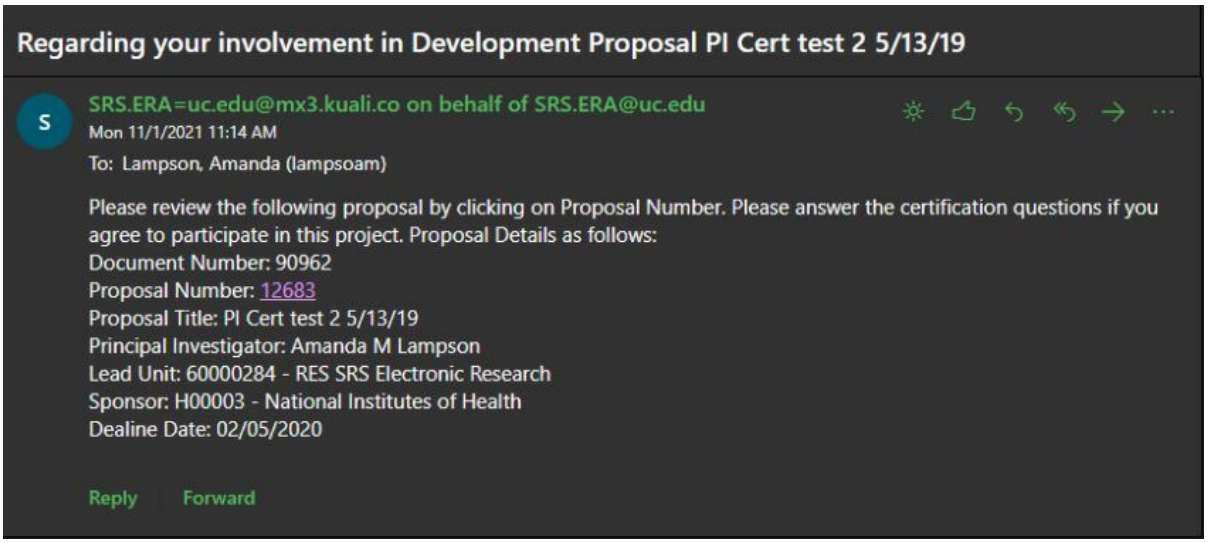
In the upcoming months department leaders and the College of Medicine HR team will guide impacted Clinical Research Employees through the process. Additional information will be forthcoming. Please reach out to your HR Consultant or comhr@uc.edu with any questions.

Certifying and Approving Industry Proposals in Kuali :

The Investigator is responsible for both certifying proposal content and approving finalized agreements in the Kuali platform. These are two distinct steps the study Investigator must complete for every clinical trial. Failure to complete these steps in a timely manner could result in delays.

PI Certification

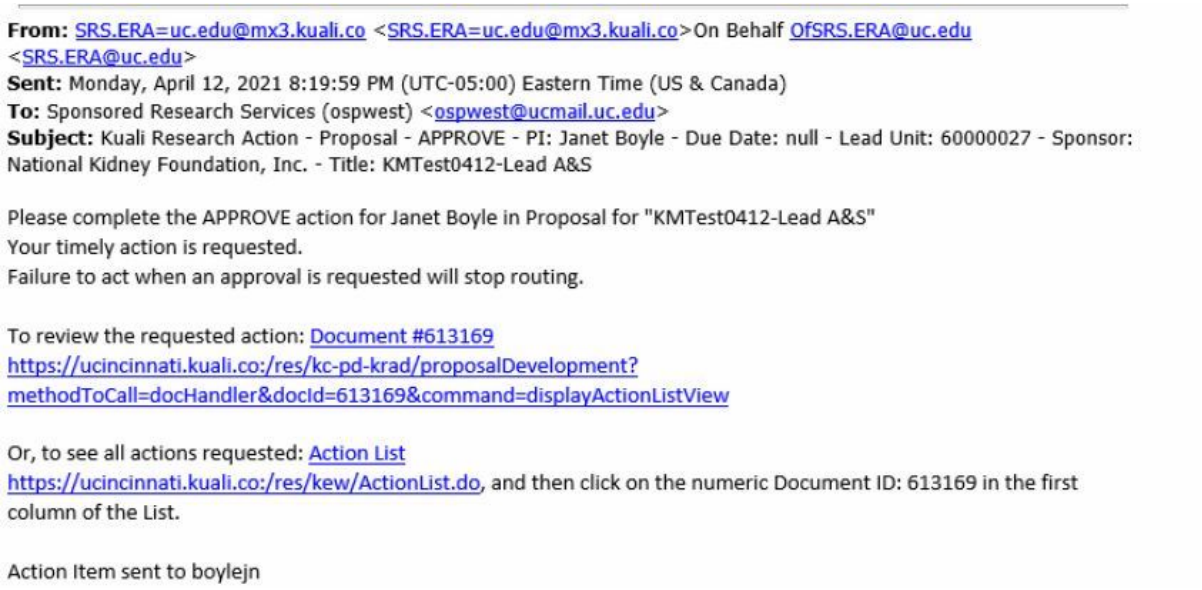
For every industry trial, Sponsored Research Services (SRS) requires the Investigator to complete Kuali proposal certification questions. As soon as a Kuali proposal is created for a study and an Investigator name is added to that record, the SRS contracting team will select the option to "Notify PI" within Kuali. This selection will alert the PI to the existence of the Kuali proposal and request that he/she complete the certification. The certification notification will be sent from SRS.ERA@uc.edu. See the example below:



If the PI does not complete the PI Certification prior to the proposal being routed for final approval, he/she will have to complete the certification before approving the proposal. Kuali will not allow the PI to approve the proposal until the certification is complete.

PI Approval of Finalized Agreement

Once the agreement and budget have been negotiated and finalized, every proposal must be routed through a series of approval steps within Kuali to complete execution. The Investigator's approval is the first stop on this routing path. When it is time for the Investigator to approve a proposal, he/she will receive an email from SRS.ERA@uc.edu like the one shown below.



From: SRS.ERA=uc.edu@mx3.kuali.co <SRS.ERA=uc.edu@mx3.kuali.co>On Behalf OfSRS.ERA@uc.edu <SRS.ERA@uc.edu>
Sent: Monday, April 12, 2021 8:19:59 PM (UTC-05:00) Eastern Time (US & Canada)
To: Sponsored Research Services (ospwest) <ospwest@ucmail.uc.edu>
Subject: Kuali Research Action - Proposal - APPROVE - PI: Janet Boyle - Due Date: null - Lead Unit: 60000027 - Sponsor: National Kidney Foundation, Inc. - Title: KMTest0412-Lead A&S

Please complete the APPROVE action for Janet Boyle in Proposal for "KMTest0412-Lead A&S"
Your timely action is requested.
Failure to act when an approval is requested will stop routing.

To review the requested action: Document #613169
https://ucincinnati.kuali.co:/res/kc-pd-krad/proposalDevelopment?methodToCall=docHandler&docId=613169&command=displayActionListView

Or, to see all actions requested: Action List
https://ucincinnati.kuali.co:/res/kew/ActionList.do, and then click on the numeric Document ID: 613169 in the first column of the List.

Action Item sent to boylejn

When approving a proposal, if a PI gets the error "Validation errors exist. Please correct these errors prior to submitting to workflow routing." This error occurs when the PI has not completed certifications. Ask the PI to click on the top right "Data Validation" blue link. This will show the one error that exists. Clicking on "Fix it" should take them to the page where they can complete the certifications. After certifications are completed, PI can come back to the "Summary and Submit" section and Approve.

Please refer to these instructions for using Kuali for approvals in case you are not familiar with the process.

Please visit the Kuali Bearcats Landing site for more general Q&A about Kuali.

Informed Consent Forms (ICFs) in Epic:

A scanned copy of the ICF for each research study in which a patient is enrolled must be included in the electronic medical record (EMR), Epic. This is an institutional policy required to facilitate Joint Commission audits. See below for updated instructions for uploading scanned copies of ICFs into EPIC that will assist in streamlining this process.

- The preferred method is to send a PDF of scanned ICFs to the Medical Records common mailbox:
  - UCMC-Scanning@uchealth.com
  - Please use a departmental Printer/Scanner to produce a PDF of the ICF(s).
  - **Study teams do not have to scan ICF documents into EPIC themselves.**
- Any PDF sent to the medical records common mailbox will be evaluated and identified as a consent for Clinical Research based on the following criteria:
  - The first page of the scanned document contains the following words:
    - "Consent"
    - "Research"
    - "IRB" (The acronym, NOT Institutional Review Board)
  - And a "CONSTY" Bar Code
    - (CONSTY Barcoded Labels are available from the OCR. Plans for a PDF of the barcode attached to the SOP for this process are in development)
  - Once the medical records office identifies any PDF as an ICF for clinical research based on this criteria, it will be saved in the media tab for the appropriate patient as document type "Consent for Research Study". The ICF will also be available in the patient's Consents Tab.
  - Multiple ICFs for patients in the same study can be included in one PDF. All pages of each individual ICF in one PDF must be kept together.
- ICFs can also be faxed to (513)584-4295.

The OCR Standard Operating Procedure **UCH-OCR-DOC-SOP-002-Scanning of Patient Specific Research Information into EPIC** will be updated with this information.

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

High Enroll:

High Enroll was created to improve research recruitment! The phone-based app allows care providers and community partners to instantly see studies that are available and recruiting. App users can browse for a study within categories (cancer, cardiology, neurology, etc.) or utilize the powerful search engine to really pinpoint what they are looking for (a disease condition, medication, NCT number, study name, etc.)

Poor patient recruitment is said to be the largest operational and cost barrier to clinical research. The goal is for more care providers to be looking at and considering your studies when they have a patient in front of them needing care. High Enroll helps with all this!

Care providers using the app have basic study information (summary, visits, duration, inclusion /exclusion criteria), as well as links to ClinicalTrials.gov or other websites at their fingertips. There is also an integrated means of reaching the study team to ask questions or make referrals. App users can even share studies with colleagues or “favorite” a study for future use!

You’ve heard the phrase “it takes a village.” High Enroll builds that village…that community of people looking to improve care by improving recruitment. The app is available for any healthcare provider (inside or outside UC) to download by scanning the QR code here or by searching “High Enroll, LLC” on the App Store or Google Play. Download the app today and get on top of your recruiting studies! Create a verified account and High Enroll will thank you with a $5 Starbucks card!

Download on the App Store

GET IT ON Google Play

For more information on how to get your studies on the app, please reach out to Mina Busch at 513-993-0225 or education@highenroll.org.

UC IRB Number Requirement for Clinical Trial Contract Submissions :

Effective 5/9/2022, a UC IRB number will be required when submitting clinical trial contracts. There are several reasons this identifier is being required when a study is submitted to REDCap. The UC IRB number in REDCap will be used to further strengthen study identification across collaborative teams and will help support the UC IRB in some of their internal processes. The information required to generate a UC IRB number is minimal and the pre-submission information can be edited as more information becomes available.

This change may require minor adjustments to departmental start-up processes. If your team has not historically created UC IRB numbers this early in start-up, please make sure to account for how this will affect other regulatory processes within your department.

UC Health One Touch:

Since the recent launch of Oracle One Touch/Learners, the Office of Clinical Research has been experiencing challenges including login issues for research affiliates and issues with training modules not loading properly in the system. UC Health Human Resources and IS&T Service Desk have been made aware of these issues and are working diligently to resolve these problems. In the meantime, please see below for information that may be useful in avoiding delays:

- Guidance for logging into One Touch
- When logging in to One Touch your username is **UID#@uchealth.com**.
- When logging in to One Touch your password is **Uc** (capital U, lowercase c) + **last three digits of SSN** + **DOB (00/00/0000)**, i.e. Uc84505081992.
- When contacting the IS&T Service Desk, always have your EIN# handy as an identifier for verification purposes.
- Check your UC Health email for UC Health updates, One Touch updates, newsletters, and other important information.

If you have any technical issues with the modules (login, password, and/or software issues), please contact UC Health Service Desk at 513-585-MYPC. Please contact Sheree Sims with any other questions.

Upcoming Events:

First Friday: 5/6/2022
9:00 - 10:00 am
Virtual Meeting
The Training and Roles of Infectious Disease Pharmacists

Lunch & Learn: 5/19/2022
12:00 - 1:00 pm
Virtual Meeting
Investigational Imaging Services (IIS)

Clinical Research Managers Meeting: 5/27/2022
9:30 - 10:30 am
Virtual Meeting

Resources For Our Research Community:

UC OCR Bearcats Landing Site

Please check out the UC Office of Clinical Research site on Bearcats Landing! The goal of this site is to serve as a centralized resource for the entire clinical research community. Use our new site as a way to learn about UC OCR news and events, access tools and services, and much more!

Visit Bearcats Landing by entering my.uc.edu into your web browser (UC login required). If you have questions about Bearcats Landing, please visit the Bearcats Landing FAQ page.

Access and Authorizations: Updated Appendix A

Click here for an updated Appendix A for the Access and Authorizations process. Appendix B

and Appendix D 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 ClinCard Training Video 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 UCH-Greenphire@uchealth.com.

CCTST Online Educational Library, CTROnline

CTRonline 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 9, 2022
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.

Updated Contact List:

Director: Maria Stivers (Maria.Stivers@uchealth.com)
Manager: Zak Johnson (Zachary.Johnson@uchealth.com)
Budgets: Macy Michael (Macy.Michael@uchealth.com)
Coverage Analysis: Macy Michael (Macy.Michael@uchealth.com)
UC SRS Contracting: Eileen O'Shaughnessy, Bridget Kellner, & Alex Valdes (Click here for assistance with Contracts)
UC Health Contracting: ucp-clinicaltrials@uchealth.com
Operations: Adam Alexander (alexana5@ucmail.uc.edu)
Billing: (Research-Finance@uchealth.com | UCP-ClinicalTrialBilling@uchealth.com)
Research Access & Authorizations: Sheree Sims (Research-credential@uchealth.com)
UCH GreenPhire: Nate Harris (UCH-GreenPhire@uchealth.com)
UCH Research Approval: Sheree Sims (Research-Admin@uchealth.com)
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 (Nate.Harris@uchealth.com)
Training and Education: Nate Harris (Nate.Harris@uchealth.com)

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

UC OCR BearCats Landing Site

UCH OCR Website

Our mailing address is:
UC Health Office of Clinical Research
3200 Burnet Ave | BAP B 25 | Cincinnati, OH 45229