From: "Office of Clinical Research" <Research-Admin@uchealth.com>
To: "Gulasy, Miranda" <miranda.gulasy@uchealth.com>
Date: 12/2/2021 6:59:48 AM
Subject: December OCR Newsletter

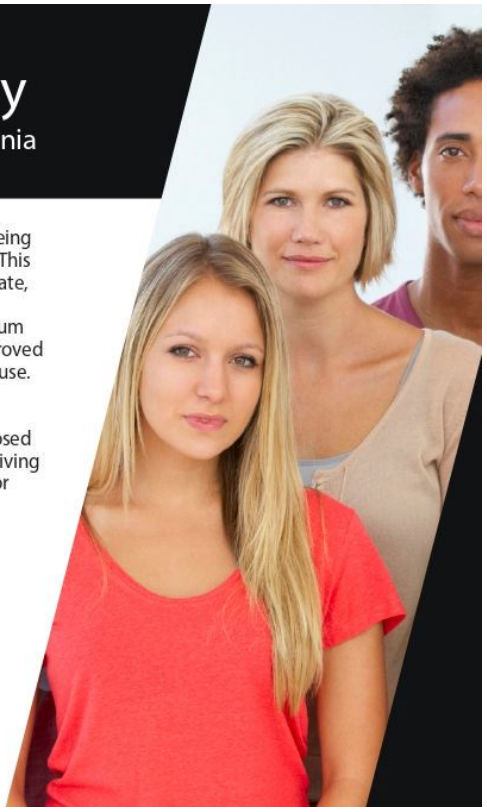
Content List:

- Studies of the Month
- Upcoming Events
- Button to Submit Questions Regarding the OCR Move
- UC OCR Bearcats Landing Site
- Upcoming Special Town Hall Lunch & Learn Events
- West Chester Hospital Research Approval Process
- ICF Language Reviews
- OCR Move to UC Update: Contract Submissions
- Resources For Our Research Community
- Updated Contact List

Studies of the Month:

Schizophrenia Study

Study for Individuals with Schizophrenia



What

Sodium benzoate is a common food additive which is being investigated as a potential treatment for schizophrenia. This outpatient study will look at the safety of sodium benzoate, and at how well it works in improving symptoms of schizophrenia when added to existing medication. Sodium benzoate is investigational because it has not been approved by the U.S. Food and Drug Administration (FDA) for this use.

Who

Men and women 18-45 years old who have been diagnosed with schizophrenia for at least 2 years, are currently receiving outpatient treatment, and have not been hospitalized for schizophrenia symptoms over the last 3 months.

Pay

Participants will receive payment for time and travel up to $600.

Details

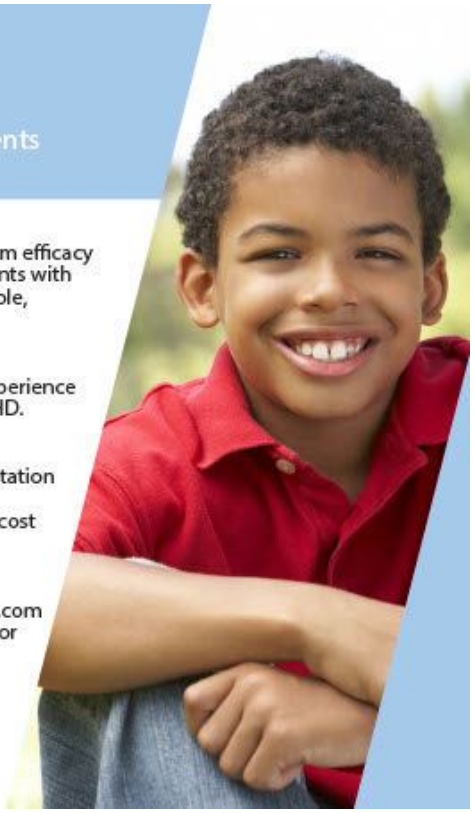
For more information, contact Karen Tugrul, RN at 513-558-6831 or tugrulkc@ucmail.uc.edu.

UC Health

UC 13-18 IRB# 2017-02471

ADHD Study

ADHD Study for Children and Adolescents



What

The purpose of this study is to evaluate the long-term efficacy of an investigational drug for children and adolescents with ADHD for whom stimulant medications are unsuitable, intolerable, or ineffective.

Who

Children and adolescence 6-17 years of age who experience ADHD symptoms or have been diagnosed with ADHD.

Pay

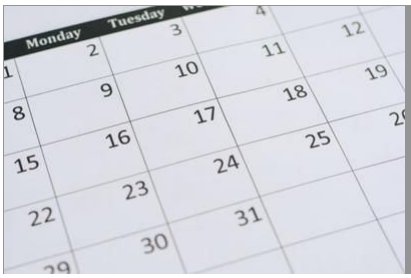
Participants may receive compensation for transportation and/or time for study visits. All study visits, tests, procedures and medications will be provided at no cost to participants.

Details

For more information, visit www.ADHDleaguestudy.com or contact Emily Baltes-Thompson at 513-558-3952 or baltesec@ucmail.uc.edu.

UC Health

16-20 IRB # 2019-1098



Upcoming Events:

First Friday: 12/3/2021
9:00 - 10:00 am
Virtual Meeting
Umbrella Protocols

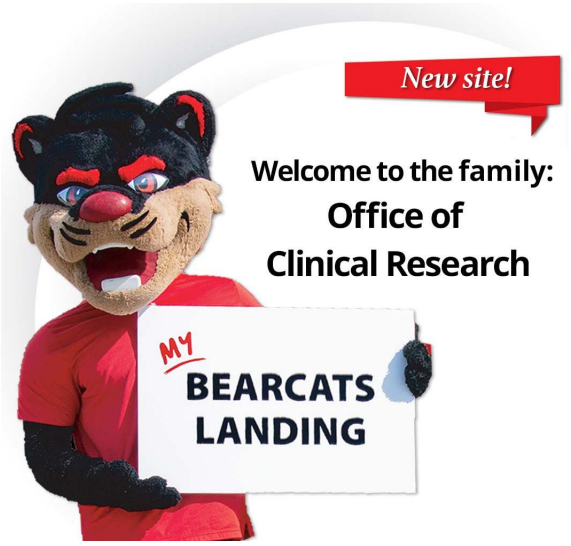
UC/UC Health Clinical Research Orientation and Training (CRO&T): 12/9/2021
9:00am - 2:30 pm
Virtual Meeting
Register Here

Clinical Research Managers Meeting: 12/10/2021
9:30 - 10:30 am
Virtual Meeting

Lunch & Learn: 12/16/2021
12:00 - 1:00 pm
Virtual Meeting
General Clinical Research Town Hall

Click here to submit questions regarding the OCR move

UC OCR Bearcats Landing Site:



We are excited to announce the launch of 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!

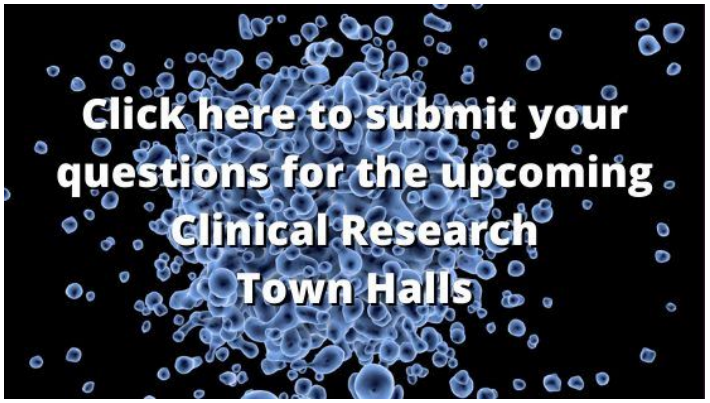
Bearcats Landing, UC's new faculty/staff only intranet, was launched in 2019 providing an online resource that will enable internal communication, empower collaboration, and unify our digital workspace. Visit Bearcats Landing by entering my.uc.edu into your web browser (UC login required).

If you have questions about Bearcats Landing, please visit the Bearcats Landing FAQ page.

Upcoming Special Town Hall Lunch & Learn Events:

Please join us in December and January for two special CRP Lunch & Learn Town Hall sessions. The December Town Hall will focus on general questions and topics related to the OCR move to UC. The January Town Hall will have a clinical research Finance, Accounting, Post-Award, and Invoicing focus.

The UC OCR is requesting that you submit your questions as soon as possible for both town halls to ensure that the appropriate people join the call to answer your questions. Questions that are submitted ahead of time will take priority during both events, but there may be time at the end for additional questions. Please submit your questions and tune in to learn more!



West Chester Hospital Research Approval Process:

Clinical research studies at West Chester Hospital (WCH), including hospital-based clinics, must go through WCH senior leadership for approval before research begins. WCH approval is usually the last step in the UCH Research Approval Process, allowing all ancillary services to review feasibility and approve prior to WCH approval. Please note: WCH Executive Leadership meets on Mondays and Fridays. Depending on when the ancillary services approve the research impacts when it is scheduled for WCH review. The research can be approved for other locations without WCH review and approval with WCH approval to come at a later date, or the WCH site can be added to the REDCap submission at a later time.

ICF Language Reviews:

Informed consent language reviews will be conducted by the UC IRB for industry sponsored CTAs initiated under UC and processed by the contracts specialists through the UC SRS Office.

The OCR will continue to review edits to the HIPAA language. The OCR will continue to review all ICF language for consistency with the CTAs initiated under UC Health until they have all been processed.

Please reach out to the OCR with any questions or concerns.

OCR Move to UC Update: Contract Submissions:

As we work through the processes for clinical research at UC, a few contract submission requests have come up:

- When submitting a Master CTA, please check the “Master Agreement” for Type of Agreement and indicate in the Submission Comments text box in RedCap if there is a Work Order, Appendix, or SOW for the first study also attached as an additional document.
- Facility Use Agreements (FAUs) should be submitted with the CTA as "Other Documents" via RedCap. Please utilize the comment section to explain and provide as much information as possible.
- All other research related documents (those that require a purchase requisition or approval of other non-OGC parties at UC) should be submitted through PACE. Please add “research related” in the title of the document, using this for true documents associated with CTAs or research studies. Again, please add as much information/comments as possible and add the CTA Kuali number (PD#) in the comment section, if appropriate.
- Please enter contact information for both the Sponsor and CRO if available, and attach any W-9s they received with the study packet as additional attachments to the REDCap form. We are getting feedback from many sponsors that they send the W-9 with the study packet. The contracts team needs the W-9 and contact information for accounting set up.

For more information, please contact UC-MTA@ucmail.uc.edu.

Resources For Our Research Community:

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, December 9, 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.

Updated Contact List:

Director: Maria Stivers (Maria.Stivers@uchealth.com)
Manager: Zak Johnson (Zachary.Johnson@uchealth.com)
Budgets: Heather Roberson (Heather.Roberson@uchealth.com) & Macy Michael (Macy.Michael@uchealth.com)
Coverage Analysis: Heather Roberson (Heather.Roberson@uchealth.com) & Macy Michael (Macy.Michael@uchealth.com)
UC Health Contracting: Heidi Rowles & Stuart Engel (UCP-ClinicalTrials@uchealth.com)
Billing: Charlie Fremont (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: Nate Harris (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

OCR Website

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