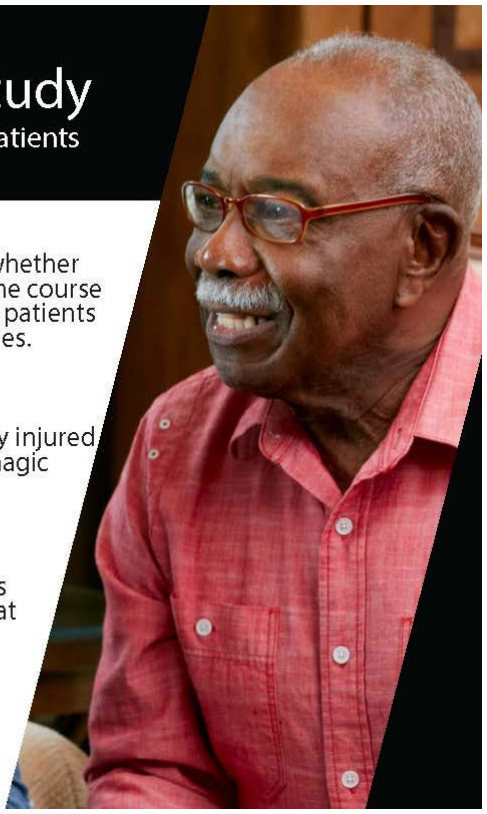
From: "Office of Clinical Research" <Research-Admin@uchealth.com>
To: "Gulasy, Miranda" <miranda.gulasy@uchealth.com>
Date: 1/6/2022 6:59:37 AM
Subject: January OCR Newsletter

Content List:

Study of the Month:

Trauma Research Study

Whole Blood Transfusion in Trauma Patients



What
The purpose of this study is to evaluate whether giving whole blood transfusion early in the course of treatment would help severely injured patients that lose a lot of blood survive their injuries.

Who
Adults 18 to 90 years old who are severely injured patients that lose a lot of blood (hemorrhagic shock).

Details
For more information or to opt-out of this study, contact the TOWAR Study Hotline at (513) 558-6332 or TOWAR@uc.edu.

UC Health

15-21 IRB # 2021-0772

Upcoming Events:

First Friday: 1/7/2022
9:00 - 10:00 am
Virtual Meeting
UC Health Colleges: 200 Years of Innovation

Lunch & Learn: 1/20/2022
12:00 - 1:00 pm
Virtual Meeting
Clinical Research Finance, Accounting, Post-Award, and Invoicing Town Hall

Clinical Research Managers Meeting: 1/28/2022
9:30 - 10:30 am
Virtual Meeting

Click here to submit questions regarding the OCR move

Corrected RedCap Link:
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 (linked below) 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.

Click here to access the Clinical Trial Contract Intake RedCap form

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

Upcoming Special Town Hall
Lunch & Learn Event:

Please join us for our January 20th Town Hall, which 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 this town hall 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!

Increase Awareness of Your Clinical Trials with HighEnroll:

The High Enroll App is available to assist your recruitment efforts. Would you like to have more clinicians looking for potential subjects? Would you like to share information about your studies with colleagues inside and outside of UC? The High Enroll mobile app is available to solve recruitment problems such as these. This tool allows your entire recruiting portfolio of studies to always be updated and available on the phone of everyone who is involved in patient care. A trial summary, inclusion and exclusion criteria, other pertinent study information, and a “one-touch” contact button for the primary research coordinator is available for each study loaded onto the platform.

The app is available for any healthcare provider to download by scanning the QR code above or by searching High Enroll, LLC on the App Store or Google Play

Download the app today and earn Starbucks credits when you create your account!!!!

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 Ginger Conway at 859-992-5339 or gaconway@highenroll.org.

Clinical Trial Agreement (CTA/Contract) and Informed Consent Form (ICF) Agreement / Comparisons:

Compensation in case of injury language must be included in the ICF for research involving greater than minimal risk. The language must explain if compensation or medical treatments are available if research related injury occurs, as well as what any available compensation and/or treatment will consist of and where further information may be obtained.

CTAs will include information regarding compensation for injury. This information in the contents of the CTA and ICF for a clinical trial must be materially consistent.

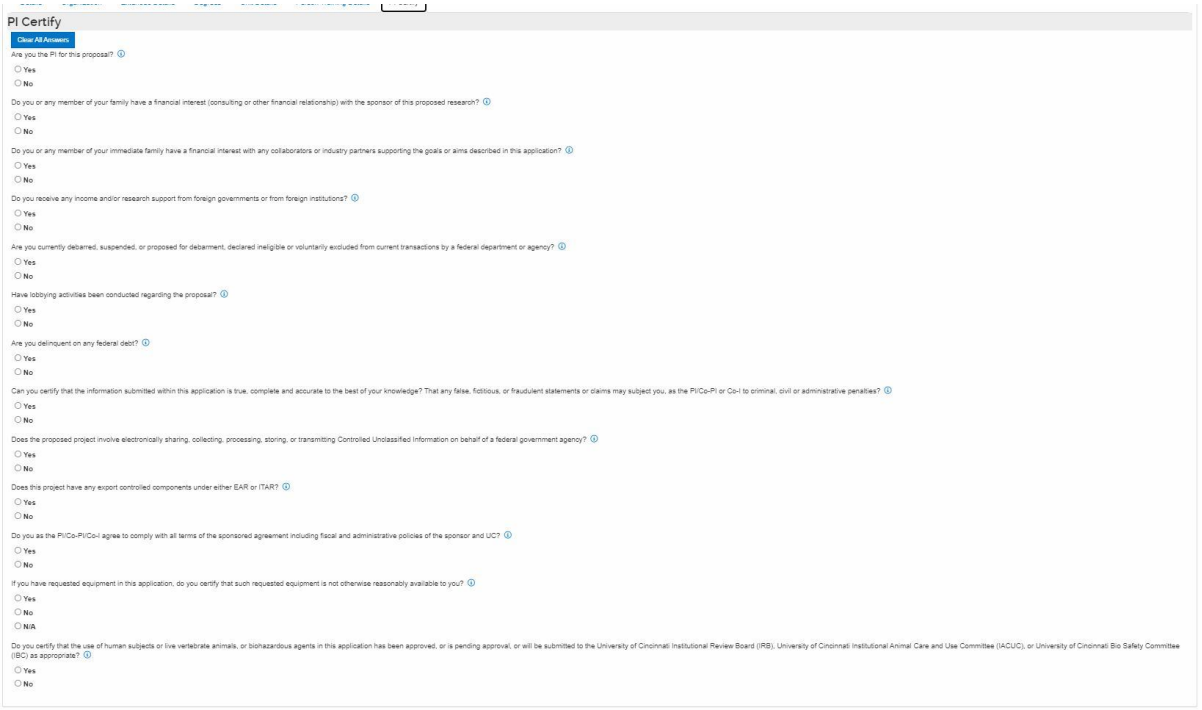
Please refer to the following recently updated SOP:
UCH-OCR-OPS-SOP-015-02**:** Process for Review of Informed Consent Form and Clinical Trial Agreement Subject Injury Compensation, and Payment and/or Reimbursement for Participation Language

All OCR SOPs are accessible from the UC Health intranet home page utilizing the Compliance 360 policy search function, or reach out to the Office of Clinical Research with any questions or concerns.

PI Certifications in KUALI:

Sponsored Research Services (SRS) requires completion of the PI Certification questions in Kuali. This action is required for each study for which you are listed as the PI. Please refer to these instructions for using Kuali for approvals in case you are not familiar with the process. Please visit this site for more general Q&A about Kuali. The Certification Notification was sent from the email SRS.ERA@uc.edu. This certification questionnaire will be sent for every study and can be completed either now, or when the CTA is finalized and routed for approval. When the CTA is final and routed for approval, you will receive another email from SRS.ERA@uc.edu.

See below for a screenshot of the PI Certification survey for reference.


PI Certify

Clear All Answers

Are you the PI for this proposal?
Yes
No

Do you or any member of your family have a financial interest (consulting or other financial relationship) with the sponsor of this proposed research?
Yes
No

Do you or any member of your immediate family have a financial interest with any collaborators or industry partners supporting the goals or aims described in this application?
Yes
No

Do you receive any income and/or research support from foreign governments or from foreign institutions?
Yes
No

Are you currently debarred, suspended, or proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?
Yes
No

Have lobbying activities been conducted regarding the proposal?
Yes
No

Are you delinquent on any federal debt?
Yes
No

Can you certify that the information submitted within this application is true, complete and accurate to the best of your knowledge? That any false, fictitious, or fraudulent statements or claims may subject you, as the PI/Co-PI or Co-I to criminal, civil or administrative penalties?
Yes
No

Does the proposed project involve electronically sharing, collecting, processing, storing, or transmitting Controlled Unclassified Information on behalf of a federal government agency?
Yes
No

Does this project have any export controlled components under either EAR or ITAR?
Yes
No

Do you as the PI/Co-PI/Co-I agree to comply with all terms of the sponsored agreement including fiscal and administrative policies of the sponsor and UC?
Yes
No

If you have requested equipment in this application, do you certify that such requested equipment is not otherwise reasonably available to you?
Yes
No
N/A

Do you certify that the use of human subjects or live vertebrate animals, or biohazardous agents in this application has been approved, or is pending approval, or will be submitted to the University of Cincinnati Institutional Review Board (IRB), University of Cincinnati Institutional Animal Care and Use Committee (IACUC), or University of Cincinnati Bio Safety Committee (IBC) as appropriate?
Yes
No

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.

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, January 13, 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: 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