



Industry Sponsored Research Contract Submissions in the REDCap System

Thursday, July 21st, 2022

July 2022 Study of the Month #1

Healthy Adults Needed for Cognition Study

Study of brain signals when making decisions and resolving conflicts

What

A study to understand how people can pay attention, remember, and make decisions. We are trying to understand what brain areas that are involved in attention, memory, and decision making and how we can improve them using brain and spinal cord stimulation.

Who

Healthy adults 18 to 80 years old, who have no prior diagnosis of psychiatric illness or stroke.

Pay

Participants will be compensated up to \$60 for their time and travel.

Details

For more information, email Ishita Basu at basuia@ucmail.uc.edu or call 513-558-3991 Mon-Fri 10am-5 pm.


University of
CINCINNATI
04-22 IRB # 2022-0164

 UC Health.



July 2022 Study of the Month #2

Adult Depression Study

Are you troubled by depression?

What

A research study to examine the effectiveness of an investigational medication when taken with antidepressant therapy compared to a placebo taken with antidepressant therapy.

Who

Adults ages 18-65 taking an antidepressant and still experiencing symptoms of depression.

Pay

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

Details

For more information, visit <https://reliancestudies.com/> or contact Dr. Alique Topalian at 513-558-6185 or topaliag@ucmail.uc.edu.


University of
CINCINNATI
06-22 IRB # 2021-0876

 Health.





Friday, August 5th, 2022

Health Literacy for Clinical Research

Angela Braggs-Brown, MA, CIP, RAC

Sr. Director

UC Human Research Protection Program

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions. Low health literacy is more prevalent among: Older adults, minority populations, and those who have low socioeconomic status. This presentation will address the importance of relationship centered communications in health literacy for clinical research.

New Resource: UC Regulatory Channel:

This chat channel was created with the goal of unifying the regulatory communities and specialists at UC/UCH. There are many ways of handling regulatory duties, and this chat is designed to create an open community where any question, suggestion, or inquiry is welcomed. This channel will can provide the following to all who join:

- Aid or advice to new regulatory staff members at UC/UCH
- Potential demo/training opportunities of new systems, regulatory procedures, or submissions
- Discussion or feedback relating to regulatory submissions/approval processes for studies using UC IRB, CIRBs, or external IRBs
- Sharing of regulatory guidance documents and knowledge as it relates to FDA/ICH guidelines or OCR/IRB SOPs and Policies
- A way for regulatory staff to unify and share ideas or create innovative workflows aiding the regulatory processes

For anyone interested in joining this chat channel, please send an email to Kalen Butcher (butchekn@ucmail.uc.edu) to be added or have your team members added.

UC / UC Health Clinical Research Orientation and Training (CRO&T)

Thursday, September 8th, 2022
9:00 am - 3:00 pm
Virtual presentation

The last day of registration is
Friday, September 2nd, 2022

Register [Here](#)

**Please reach out to Nate Harris,
harrisnl@ucmail.uc.edu for any questions**



Today's Presentation: **INDUSTRY SPONSORED RESEARCH CONTRACT SUBMISSIONS IN THE REDCAP SYSTEM**

THE OCR MOVE FROM UCH TO UC HAS IMPACTED CLINICAL RESEARCH WORKFLOWS. A MAJOR CHANGE IS HOW NEW CONTRACTS FOR INDUSTRY SPONSORED RESEARCH ARE SUBMITTED AND MANAGED. PLEASE JOIN US FOR AN OVERVIEW AND REVIEW OF THE OCR INDUSTRY SPONSORED CONTRACTS REDCAP SUBMISSION SYSTEM.

Zak Johnson

Manager

Office of Clinical Research

University of Cincinnati College of Medicine

Nate Harris

**Clinical Research Compliance Administration,
Education and Training**

LUNCH & LEARN: INDUSTRY SPONSORED RESEARCH CONTRACT SUBMISSIONS IN THE REDCAP SYSTEM


Zak Johnson

Manager – Office of Clinical Research

CONTRACT INTAKE SYSTEM

TODAY'S GOALS

- To describe the purpose of the contract intake system and how to access
- Describe the content of the form and important aspects to pay attention to
- Detail the notifications to expect
- Demo the contract status dashboard and show how to monitor the status of contracts & budgets
- Discuss future development and answer questions

Resize font:
+ | -

Clinical Trial Contract Intake

As of July 1, 2021, all new clinical trial contracts will begin being processed by UC rather than UC Health. Existing contracts will continue with UC Health until their conclusion unless assigned to UC.

Please complete the form below to submit a clinical trial agreement or amendment. All fields are required except for optional document uploads and submission comments. This form is not intended to be used for amendments to agreements executed at UC Health. To submit amendments for UC Health agreements, please reach out to UCP-ClinicalTrials@UCHealth.com. Visit the [OCR Bearcats Landing Site](#) for more information on amendments

If you would like to check the status of a previous request, please visit the [Industry Contract Status Dashboard](#)

Please define your request

New Agreement
 Amendment

reset



PURPOSE

PURPOSE

The REDCap clinical trial intake system was designed to integrate information related to clinical trial contracts in one place. It serves as a central place for the following teams to track clinical trial contract progress:

- Research Department
 - Contracting
 - Budgeting
 - Finance
 - Legal
 - OCR
-
- Each team has data collection tools to track progress, complete milestones and share information

ACCESS

- The link to access the contract intake form is on the OCR's Bearcats Landing site on the contracting page
- Researchers can find other useful information about the process on this page as well
- <https://mailuc.sharepoint.com/sites/Clinical-Research/SitePages/Contracts.aspx>

The screenshot shows the Office of Clinical Research website. The navigation bar includes links for Office of Clinical Research, College of Medicine Home, OCR Home, Services & Resources, Ancillary Services, OCR Transition FAQs/Updates, Industry Contract Status Dashboard, and Edit. Below the navigation bar are utility links: New, Send to, Promote, Page details, Immersive Reader, and Analytics.

Contract Submission (REDCap Intake Form)

Both new agreements and amendments must be submitted to the [Sponsored Research Services](#) Contract Management team for processing. The UC SRS contracting team will work closely with the Office of General Counsel to negotiate and execute research agreements. All agreement submissions are to be made in the contract intake REDCap form.

The submission form is designed to collect the required information necessary to begin processing a contract. The form has six major components: contacts, trial information, finance, facilities, documents and attestation. Please ensure the person submitting the contract has the information related to these areas. The essential documents that are expected to be uploaded with new agreements are:

- Clinical Trial Agreement (CTA) or other contract
- Study Protocol
- Budget Template
- Informed Consent Form (ICF)
- Study Manuals (pharmacy, imaging, lab, etc.) (if applicable)
- Investigator's Brochure (IB) (if applicable)

All contract submissions will require a digital attestation that the Principal Investigator agrees to allow SRS contracting to negotiate with the sponsor.

At the end of the form there is an option to save and return later or to submit. If the agreement submitter would like to save their progress and return later, they will be provided with a return code. The return code is required to return to incomplete form. If the code is lost or forgotten, the submitter can reach out to SRS contracting to retrieve their submission. No action will be taken

Clinical Trial Contract Intake Form

For questions, contact SRS contracting:

- O'Shaughnessy, Eileen (oshaugen)**
Sponsored Res Adm Sr-Grants Contracts
- Kellner, Bridget (kellneba)**
Sponsored Res Admin 2-Grants Contracts
- Valdes, Alex (valdesar)**
Sponsored Res Admin 2-Grants Contracts



CONTENT & TIPS

CONTENT

The intake form has seven major components:

- Request
 - Contacts
 - General Information
 - Budget
 - Facilities
 - Documents
 - Attestation
-
- Please make sure to fill out each of these sections to the best of your ability. If you do not know the answers to all the questions, you can save the form and collect them to submit later

TIP: SAVE & RETURN LATER

- The save and return later option allows the submitter to save their responses and return to submit later
- The submitter can have the return link sent to themselves
- If the submitter does not know the answer to all of the questions, the return email can be forwarded to other department team members
- The return page can also be bookmarked

Please define your request

New Agreement
 Amendment reset

Type of Agreement

CTA/Work Oder
 Master Agreement
 Other

Contacts

Primary Submission Contact Information

Name

Email Phone

Submitter Name

Submission Timestamp M-D-Y

Test Intake

redcap.research.cchmc.org/surveys/index.php?s=4UgHqKxGZgtHzuus&_return=1

Office Home OCR OneDrive REDCap Epic UserWeb ClinCard Powered b... SignalPath - Commi... SignalPath Bearcats Landing EpicCare Link UC H... Zak Test Page signature-requ

Your survey responses were saved!

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need the survey link to this survey.

Survey link for returning
You may bookmark this page to return to the survey, OR you can have the survey link emailed to you by providing your email address below. If you do not receive the email soon afterward, please check your Junk Email folder.

* Your email address will not be stored

Or if you wish, you may continue with this survey again now.

IMPORTANT CONTENT NOTES

- **Department Business Finance Contact**
 - the person who should be issued the SAP account number
 - Person to ask about funding source
- **Department Invoicing Contact**
 - Who within the department can be contacted for questions about study invoicing (start-up, visits, etc.)
- **Documents**
 - Make sure to upload the correct document to the correct file upload field – incorrect documents can slow the process
 - Manuals and IB are not required uploads
 - Up to 5 additional documents can be uploaded and described



NOTIFICATIONS

NOTIFICATIONS

Research departments will receive notifications based on contract activity. The list below explains what the notification is and who it is sent to.

- Kuali ID – sent by central mailbox when the agreement is assigned a Kuali ID
 - Submitter
 - Business Finance
 - Invoicing
- Coverage Analysis – sent by OCR budget member when the vendor completes the Coverage Analysis
 - Submitter
 - Business Finance
 - Invoicing
- ICF Language – sent by OCR when the ICF review determines that the ICF language does not match the CTA
 - Submitter
- Incomplete Submission – sent by no reply central mailbox when a form is only partially completed, but not submitted – will continue to send until notified to delete or the form is submitted
 - Submitter

DASHBOARD

DASHBOARD

- Intended to give regular updates to the research community on where contracts and budgets are in the process
- Includes contracting and budgeting comments
- Also collects IRB, REDCap ID, Quali ID, SAP Account and study information all in one place
- Updated twice a week
- <https://mailuc.sharepoint.com/sites/Clinical-Research/SitePages/Industry-Contract-Status-Dashboard.aspx>

Industry Contract Status Dashboard

The table below shows all pending and completed industry agreements submitted for review. Agreements that have been designated as canceled are not included. It is recommended to utilize the column filters for department and contract/budget status. The table viewer toolbar located at bottom right of the viewing window can be used to adjust view settings and download the dataset for local analysis.

NOTE: Starting the week of 5/30/22, this dashboard will be updated twice a week on Mondays and Thursdays.

Last Update: 7/18

REDCap ID	Date	Type of Agreement	Investigator	Study Short Name	Department	Sponsor	Contract Status	Contract Admin	Budget Status	Budget Admin	Budget Complete Date	Quali ID	SAP Grant Number	Comments
1	7/9/2021	CTA/Work Order	Gulati	R4336-ONC-20104	Cancer Center	Regeneron	1 - Hold	Eileen	Final	Heather	11/19/2021	17441		
2	7/9/2021	CTA/Work Order	Latif	BB2121-EAP-001	Cancer Center	BMS			Final	Macy	4/19/2022	19140	N/A 6/17/2022 - Labeled CWMS	



HELPFUL TIPS

TIPS

Review documents prior to uploading them to REDCap to ensure the CTA is uploaded in the REDCap record and that it is uploaded in the correct field.

Make sure to pay attention to the funding source for clinical trial agreements, because some may not be industry/for-profit sponsors. If the sponsor is not industry/for-profit, the agreement should not be submitted to REDCap for the SRS ICT team, it should be submitted for SRS Grants/Contracts team's review. If the department is unsure or have questions, contact David Gearing: gearridd@ucmail.uc.edu

The background of the slide is a solid red color. In the center, there is a faint, semi-transparent image of two hands shaking, symbolizing agreement or partnership. The text 'FUTURE DEVELOPMENT' is overlaid on this image in a large, bold, white font.

FUTURE DEVELOPMENT

METRICS

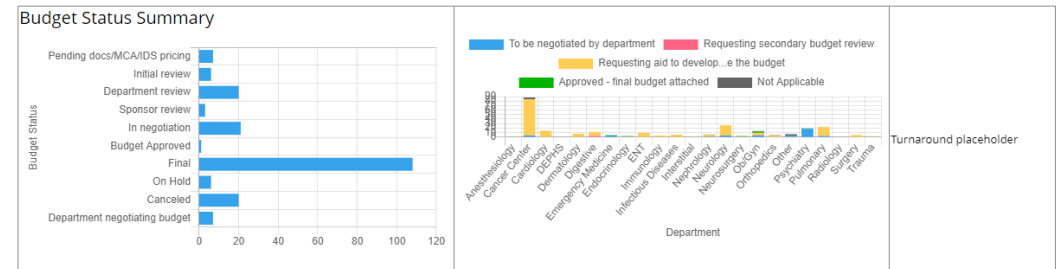
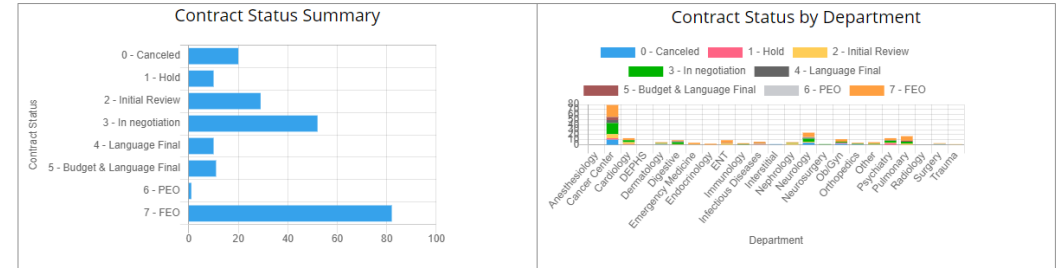
- Future development will allow for more detailed metrics on agreements
- Public dashboard to show where all agreements are with contracting and budgeting
- Numerical values on number of days will be added to the department dashboard
- Real time status dashboard

Contract Dashboard Test

Displaying recently generated information

[Edit](#) [Export as PDF](#)

Mean Execution Days X	Median Execution Days Y	Total Pending Agreements Z	Total Submitted Agreements
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Study ID	1
Total Days	42 View equation
Days to KualI Upload	2 View equation
Initial Business Review Time	24 View equation <small>This is the time that the contract is submitted to when the contract administrator sends the initial business review to legal and they begin their review.</small>
Initial Review to Legal	<input type="text"/> View equation
Attorney Assignment	0 View equation
Initial Legal Review Time	0 View equation
Days to Finalized Legal Review	21 View equation
Number of Rounds	4 View equation
Budget	
Days to Upload Budget to KualI	21 View equation
Days to Finalized Budget	21 View equation

AMENDMENTS

Currently amendments are submitted as separate forms and are not inherently connected to the original contract in REDCap. Future development will allow study teams to submit amendment requests right from the status dashboard.

RESEARCH APPROVAL

We are looking at a way to incorporate the UC Health Research Approval process into this system. This idea is still early in development, but the intent is to submit once for contract review and research approval is built into the process.

REDCAP OFFICE HOURS

For the past several months, the central service teams have been meeting to improve operations of the REDCap system. We would like to suggest that anyone who is interested in joining the group, please reach out to Zak Johnson to be invited.

We are hoping to gain further feedback about how the system is working and how it can best benefit everyone involved.



QUESTIONS

THANK YOU