The Consent Process for Central IRBs

Thursday, October 21st, 2021

UC Health

UC Health Reminder: Annual Flu Campaign

This year UC Health's annual flu campaign began the week of October 4th. The flu vaccine is a mandatory requirement and of utmost importance this year with the continued challenge of COVID-19.

UC Health Employee Health will be providing the flu vaccine, free of charge, to our employees and affiliates but also willingly accept documentation of the vaccine received elsewhere.

UCH Employee Health will be loading your survey (consent form) into Readyset. This survey must be filled out prior to receiving your vaccine, and also if you receive the vaccine elsewhere, for you to be considered compliant.

October 2021 Study of the Month

Memory Problems?

Memory and Metabolism Study

What
The purpose of this nutritional research study is to evaluate the effectiveness of berry fruits in preventing cognitive decline and improving insulin resistance.

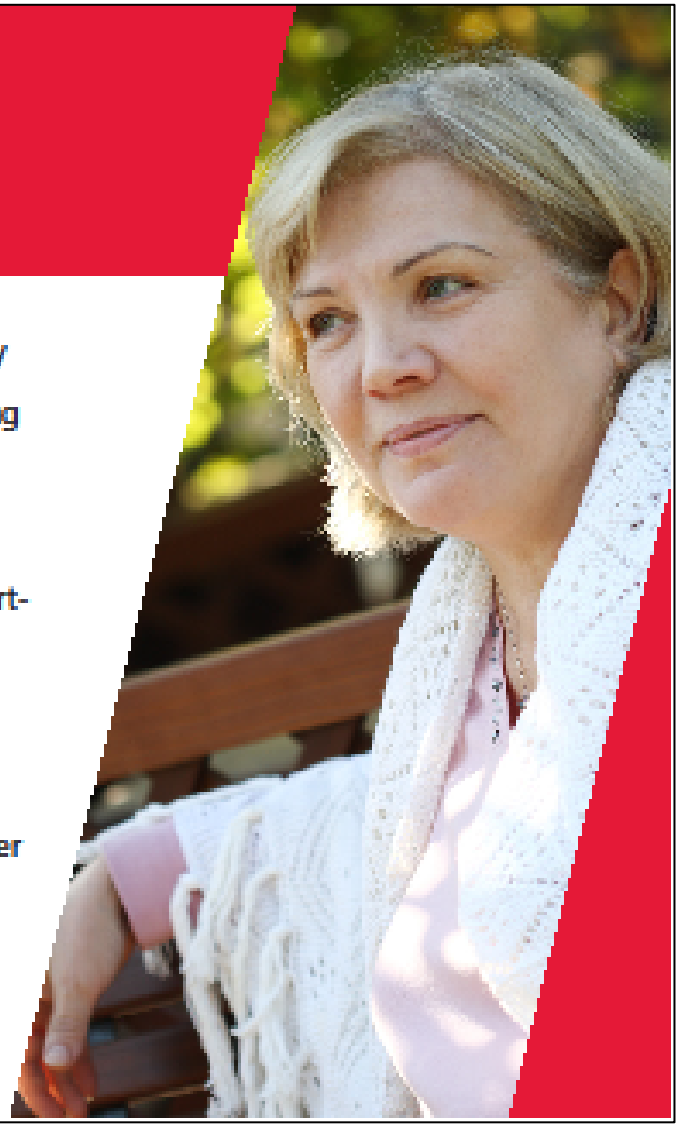
Who
Overweight men and women 50 to 65 years old without diabetes who are aware of mild memory decline such as forgetfulness or short-term memory difficulty.

Pay
Compensation may be available for time and travel for each completed study visit.

Details
For more information, contact Marcelle Shidler at shidlemd@ucmail.uc.edu or call (513) 558-2455.

UC Health.

41-15 IRB # 2015-1256



UC Health

CRP Collaborations:
CCHMC SOCRA EXAMINATION
Friday, December 3rd, 2021

Study Review sessions for the December 3rd SOCRA exam will take place:

- **Study Review Session 1: Thursday, November 11th at 1pm – Microsoft Teams**
- **Study Review Session 2: Friday, November 12th at 10am – Microsoft Teams**

Please join your fellow CRPs for a brief overview of SOCRA Exam studying tools, tips, and tricks! Both sessions are presenting the same content.

Contact Nate Harris or Email CRP@cchmc.org with any questions.

Friday, November 5th, 2021

Ignaz Semmelweis and Childbed Fever

Elizabeth Kopras

Sr. Research Associate, Pulmonary, Critical Care & Sleep Medicine

University of Cincinnati

UC Health

Today's Presentation:

The Consent Process for Central IRBs

A review of reliance on commercial IRBs, including currently executed agreements, number of studies, requirements for reliance determinations, completing the cover page for external IRBs, processes for changes to informed consent language, and approval release for studies housed at Advarra IRB and the WCG Group IRB.

Kareemah Mills

Associate Director

Human Research Protection Program

UC Office of Research Integrity

UC Health

University of CINCINNATI

CONSENT PROCESS FOR CENTRAL IRBS

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ASSOCIATE DIRECTOR, UC HRPP

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RELIANCE ON COMMERCIAL IRB OVERVIEW

CURRENTLY EXECUTED CONTRACTS, NUMBER OF STUDIES, AND REQUIREMENTS FOR RELIANCE

CURRENTLY EXECUTED AGREEMENTS

UC currently has contracts with the following commercial IRBs

- WIRB Copernicus Group Institutional Review Board (WCG IRB)
- Advarra IRB

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CURRENT NUMBER OF STUDIES

2021 reliance on commercial IRBs

- 603 active reliance studies
- Advarra – 250 studies
- WCG IRB – 353 studies
- 67% increase from 2019

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REQUIREMENTS FOR RELIANCE DETERMINATIONS

Current criteria for reliance on commercial IRBs

- Completed RAP submission
- Phase 2-4 clinical trials (currently only phase 1 Oncology trials are eligible for commercial IRB review, all other specialties will be reviewed on a case-by-case basis)
- Studies that require IBC or RSC review are now eligible for reliance (IBC and RSC ancillary reviews apply)
- Other study types are now eligible, including UC Sponsor-Investigator initiated trials (additional ancillary reviews apply)

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PROCESS FOR ESTABLISHING RELIANCE ON COMMERCIAL IRB

- Submits directly to commercial IRB
- Approves commercial IRB ICF revisions and answers questions with the involvement of Sponsor or CRO

UC Research Team

- Completes RAP reliance submission
- Obtains instructions for COI ICF disclosure, signed cover page, etc.

- Incorporates UC local context and ICF template language
- Sends external IRB approval and approved documents to the UC research team (will no longer hold for release of indemnification)

Commercial IRB

UC HRPP

- Sign-off on cover page after verification that institutional requirements are satisfied
- Approves ICF template changes (excluding HIPAA language reviewed by OCR)

VERIFICATION OF INSTITUTIONAL REQUIREMENTS

UC HRPP is responsible for verifying the following:

- Human subjects research training completion (CITI and FDA)
- Disclosure of potential financial conflicts
- PI UC affiliation (indicated on CV)
- Record of protocol and any other pertinent study documents
- Reliance information (HRP-508R)
- PRMC approval (Oncology studies only)
- Applicable cover page
- Applicable ancillary review (Biosafety, Radiation Safety, etc.)

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COMMERCIAL RELIANCE FEES

UC HRPP will charge a one-time handling fee for each new reliance submission.

- $625 handling fee
- Contact the commercial IRB for further billing information

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CONTINUED UC HRPP OVERSIGHT

The following must be maintained in the RAP system when relying:

- Research personnel changes (RAP modification)
- Continuing review updates (includes updating RAP with approval letter, expiration date, training, and COIs, if applicable)
- Study closure (includes updating RAP with closure letter)
- Notification of suspension or termination (RAP RNI submission)

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ADVARRA STUDIES

COMPLETING COVER PAGE AND HIPAA WAIVERS

ADVARRA COVER PAGE

Sections1 and 2 are submission instructions for Advarra's CIRBI platform

- Enter UCHealth/University of Cincinnati as the Organization/Company Name
- Add Kareemah Mills to the submission as administrative personnel (UC IRB other primary role, Yes allowed to edit and copied on emails)

ADVARRA COVER PAGE CONTD.

Section 3 specifies applicable informed consent template language:

- HIPAA language incorporated in ICF or standalone form
- Injury language (sponsor will only pay for emergency care or sponsor will pay for any study related injuries)
- Risk of Hepatitis B reactivation from investigational drugs

Section 4 captures the research teams main point of contact, the PI, protocol number, sponsor name, study title, RAP ID, and UC HRPP signature

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HIPAA WAIVERS

Advarra will serve as the Privacy Board and can consider and approve any one of the 3 HIPAA waivers for research:

- Partial waiver for screening purposes
- Complete waiver
- Alteration (for example, an investigator or sponsor with a waiver of a documentation of consent also would like to waive the requirement for a signed HIPAA authorization)

Advarra prefers that ICFs include HIPAA language rather than a stand-alone HIPAA document.

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WCG IRB STUDIES

COMPLETING COVER PAGE AND HIPAA WAIVERS

WIRB COVER PAGE

Indicates the UC HRPP determined reliance on WCG IRB is acceptable.

- Captures the name, address, phone number, and email address of the PI
- Captures study title, RAP ID, grant title/id (if applicable), and UC HRPP signature

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HIPAA WAIVERS

WCG IRB will serve as the Privacy Board and will review requests for waivers and partial waivers of HIPAA authorizations an:

- WCG IRB forms for requesting review of partial and full waivers are available on the WCG IRB website and system smart form.

If the HIPAA language is embedded in the ICF, then WCG IRB will review it. If the language is in a standalone, WCG IRB will only review the standalone upon request.

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PROCESSES FOR CHANGES TO ICF

CURRENT AND FUTURE PROCESSES FOR CHANGES TO ICF LANGUAGE

CURRENT PROCESSES FOR CHANGING UC BOILERPLATE LANGUAGE

IF CONTRACT CURRENTLY NEGOTIATED BY UCHEALTH:

- Changes to HIPAA language must be reviewed by OCR
- Changes to injury language must be reviewed by OCR
- All other changes must be reviewed by UC HRPP
- Release of indemnification will be provided by OCR

IF CONTRACT CURRENTLY NEGOTIATED BY UC SRS:

- Changes to HIPAA language must be reviewed by OCR
- All other changes must be reviewed by UC HRPP
- Release of indemnification can be provided by UC HRPP

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FUTURE CHANGES TO PROCESSES

Once all contracts currently being negotiated by UCHealth are executed the following changes will apply:

- No longer hold approval for release of indemnification (will apply to all studies regardless of the IRB of record)
- Contract and informed consent document language will be audited after contract execution and IRB approval (if language is included in the ICF that is conflicting with the contract, a modification to the ICF will be requested – will apply to all studies regardless of the IRB of record)
- Injury boilerplate language with Advarra and WCG IRB will no longer be verbatim

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THANK YOU

QUESTIONS?