

Office of Clinical Research Full Staff Open House Thursday, February 15th, 2024



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

<u>Thursday, March 14th, 2024</u> 9:00 am - 3:00 pm

Virtual presentation

The last day of registration is Friday, March 8th, 2024

Register <u>Here</u>

Please reach out to Nate Harris, <u>harrisnl@ucmail.uc.edu</u> for any questions





Friday, March 1st, 2024

Women's Herstory Month Presentation

Women in Medicine and Science (WIMS)





Today's Presentation:

Office of Clinical Research Full Staff Open House

OCR Leadership and Staff

Office of Clinical Research College of Medicine | University of Cincinnati



The University of Cincinnati Office of Clinical Research (UC OCR) Introduction

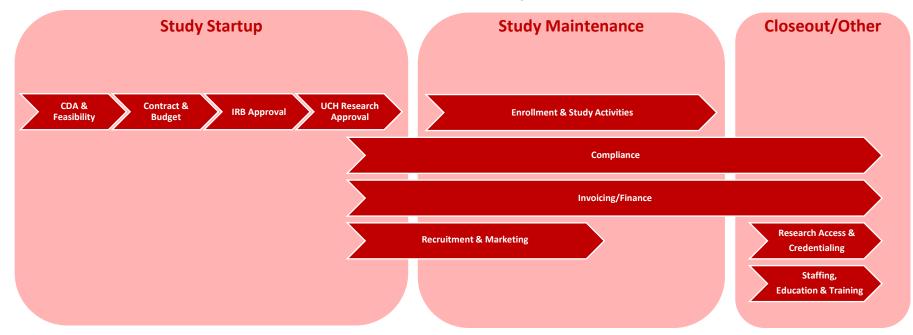




Brett Kissela, MD, MS Albert Barnes Voorheis Professor and Chair Department of Neurology and Rehabilitation Medicine Executive Vice-Dean, UC College of Medicine Senior Associate Dean for Clinical Research UC College of Medicine Chief of Research Services, UC Health <u>brett.kissela@uc.edu</u> 513-254-9273



Clinical Research Pathway at UC/UC Health



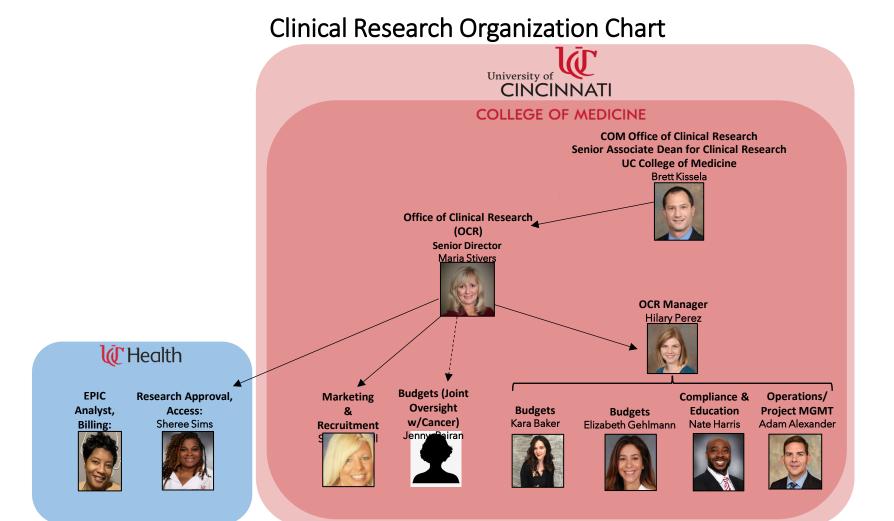


What is OCR's Role in that Pathway?

Indirect/Liaison Role

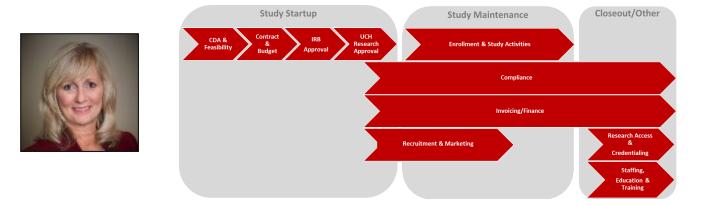
Direct/Process Role

| What | Type of Role | Person |
|-------------------------------------|--|---|
| CDA & Feasibility | Liaison/Education & Training | Nate |
| Contract | Liaison/Education & Training Operational Support (REDCap), Status Updates, Communication, etc. Budget Development & Negotiation (Amendments) | Nate Adam, Maria, Hilary Kara, Liz, Jenny |
| IRB Approval | Liaison/Education & Training | Nate |
| UCH Research Approval | Direct Oversight and Processing, including ancillary services approval Billing review | Sheree & Hilary Shanna |
| Recruitment/Marketing | Shared responsibility with department study teams Liaison with UCH Marketing | Susan Susan |
| Enrollment & Research Activities | Limited - Liaison/Education & Training (purview of department study teams) Study Management Support (SignalPath, Complion, Greenphire, etc) | Nate Adam & Hilary |
| Compliance | Limited - Liaison/Education & Training (purview of department study teams) ICF Injury language, ICF scanning, liaison for MIDAS | Nate Nate |
| Invoicing/Finance | Limited - Liaison/Education & Training (purview of dept study teams & SRS) SignalPath Budget Building | Nate Jenny & Adam |
| Research Access | Direct Oversight and Processing | Sheree & Nate |





Maria Stivers, MS Sr. Director Office of Clinical Research College of Medicine University of Cincinnati <u>stivermi@ucmail.uc.edu</u> (513)558-9036

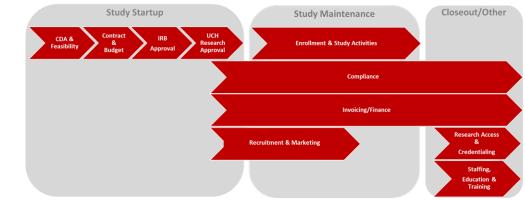


- Direct and oversee the Office of Clinical Research
- Create strategic processes, communication avenues and relationships, to better understand and continually evaluate clinical research workflows
- Manage strategies and objectives for the team and develops budgets/policies/procedures to support the infrastructure
- Serve as an expert resource to internal and external stakeholders, applying general knowledge of business, regulatory and system requirements to enhance clinical research operations, to provide education to the research community and to solve problems
- Invoicing, contracts, compliance, HIPAA for UCH



Hilary Perez, PhD Clinical Research Manager Office of Clinical Research College of Medicine University of Cincinnati perezhe@ucmail.uc.edu (513)558-9038





• Operations and Workflow

- o Study Startup Improve efficiency in Research Approval process
- o Study Startup Implement merged REDCap system for Contracts and Research Approvals
- Digital Integrations Identify/implement ways to reduce redundant data entry; increase cross-talk across various research-related platforms and processes
- REDCap solutions: Research Access and Authorizations, UC Health Contracts, maintenance and updates for other OCR REDCap systems
- General OCR management/point of contact/backup for Maria/liaison to other offices and teams



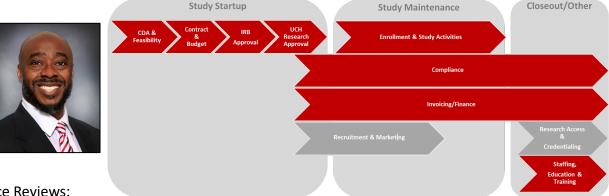
Adam C. Alexander Clinical Research Administrator Office of Clinical Research College of Medicine | University of Cincinnati <u>alexana5@ucmail.uc.edu</u> (513) 558-9044

| | Study Startup | Study M | laintenance | Closeout/Other |
|---|--|-------------------------|--------------------|---------------------------------------|
| 0 | CDA & Contract & IRB UCC Feasibility Budget Approval Approval | rch Enrollment | & Study Activities | |
| | | | Compliance | |
| | | | Invoicing/Finance | |
| | | Recruitment & Marketing | | Research Access & Credentialing |
| | | | | Staffing, Education & Training |

- SignalPath Implementation and workflow optimization
- Epic Research functionality (now "Research-Clinical" certified)
- OCR REDCap design & maintenance (in addition to Hilary)
- Data Analytics and other special projects/workflow redesign
- Secondary contact for Research Billing-related issues



Nathaniel L. Harris, BS Clinical Research Compliance Administration, Education and Training Office of Clinical Research University of Cincinnati | College of Medicine <u>harrisnl@ucmail.uc.edu</u> (513) 558-9068

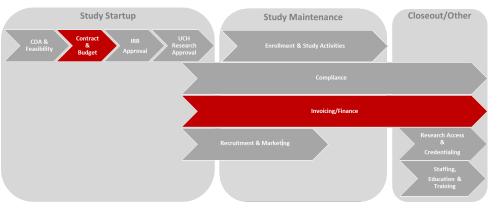


- Compliance Reviews:
 - Contract/ICF Language Reviews, IRB, MIDAS
- Facilitation of Committees and Meetings:
 - Contract/ICF Language Reviews, IRB, MIDAS
- Maintenance of Clinical Research SOPs and Policies
- Educational Initiatives:
 - CRP First Friday, CRP Lunch & Learn Clinical Research Orientation & Training (CRO&T)
- UCH Greenphire Administration
- Backup UCH Study Approval
- General tenured go to guy for all Clinical Research Related inquiries
- Nate's Birthday is NEXT THURSDAY, FEBRUARY 22nd, 2024





Kara Baker Clinical Research Study Budget Administrator Office of Clinical Research University of Cincinnati | College of Medicine <u>baker2k9@ucmail.uc.edu</u>

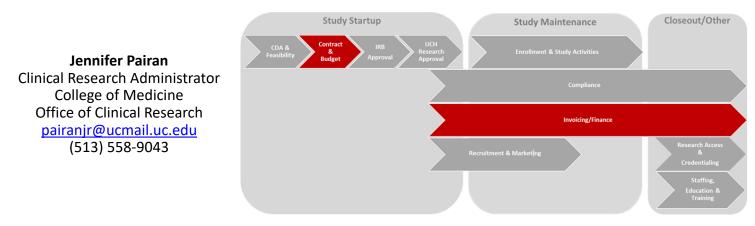




Elizabeth Gehlmann, MBA Clinical Research Study Budget Administrator Office of Clinical Research University of Cincinnati | College of Medicine <u>gehlmaem@ucmail.uc.edu</u> (513)500-4370

- Assist in obtaining IDS quotes if a study needs Pharmacy services for a trial
- Assist in obtaining Coverage Analysis if you are partnering with a sponsor in a qualifying trial
- Liaison for Budget Negotiations for industry sponsored trials





- Budget-building within Verily/Signal Path
- Contract Amendments upload to REDCap for review; follow-up on status daily w/sponsor/CRO
- Medicare Coverage Analysis (MCA) request amendment (if applicable)



 Study Startup
 Study Maintenance
 Closeout/Other

 Con & Confract & IRB Budget
 IRB Approval
 UCH Research Approval
 Enrollment & Study Activities

 Compliance
 Invoicing/Finance
 Credentialing

 Credentialing
 Staffing, Education & Training

Access and Authorizations

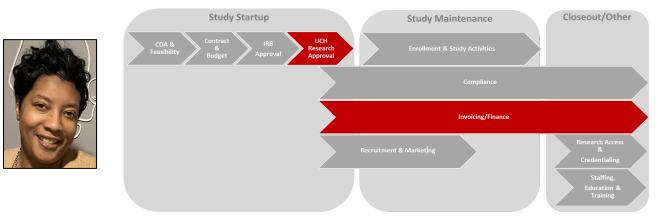
- Facilitate UCH credentialing, including the College of Medicine pathway, and UC Health pathway.
- Scheduling EPIC training (Research Basic, and EPIC Print view).

UC Health Research Approvals

- Supports recruitment initiatives.
- Facilitate communication with the ancillary service reviewers.

Sheree Sims, BA, MA Clinical Research Administrator UC Health Office of Clinical Research <u>simssr@ucmail.uc.edu</u> (513)332-4674





- Create Research billing calendars (PRL) in Epic
- Create Research encounter forms (REF's)
- Facilitate Research billing review for studies/clinical trials
- Assist Research teams in setting up and maintaining billing tracking processes
- Assist in process improvement by developing standard procedures and operations

Shanna Gates, BA, MBA Research Billing Analyst Remote UC Health Office of Clinical Research <u>shanna.gates@uchealth.com</u>



Susan Coriell Clinical Research Recruitment Administrator Office of Clinical Research College of Medicine University of Cincinnati <u>corielsn@ucmail.uc.edu</u> (513) 558-7333

| | Study Startup | Study Maintenance Closeout/Oth | er |
|---------------------------|--|--------------------------------------|----|
| Contraction of the second | CDA & Contract & IRB UCH Research Budget Approval Approval | Enrollment & Study Activities | |
| | | | |
| | | Invoicing/Finance | |
| | | Recruitment & Marketing | |
| | | Staffing, Education & Training | |

- Assist study teams with clinical research participant recruitment.
- Work with UC Health Marketing on clinical research recruitment initiatives.
- Coordinate Study of the Month announcements with CCHMC and UC Health, etc.
- Submit newsletter articles. I will be responsible for the OCR Newsletter later this year.
- Administrative Assistant to the OCR team.