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

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

Thursday, March 14th, 2024
9:00 am - 3:00 pm
IN PERSON presentation
MSB Room 6051
The last day of registration is
Friday, March 8th, 2024

Register [Here](#)

Please reach out to Nate Harris,
harrisnl@ucmail.uc.edu 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
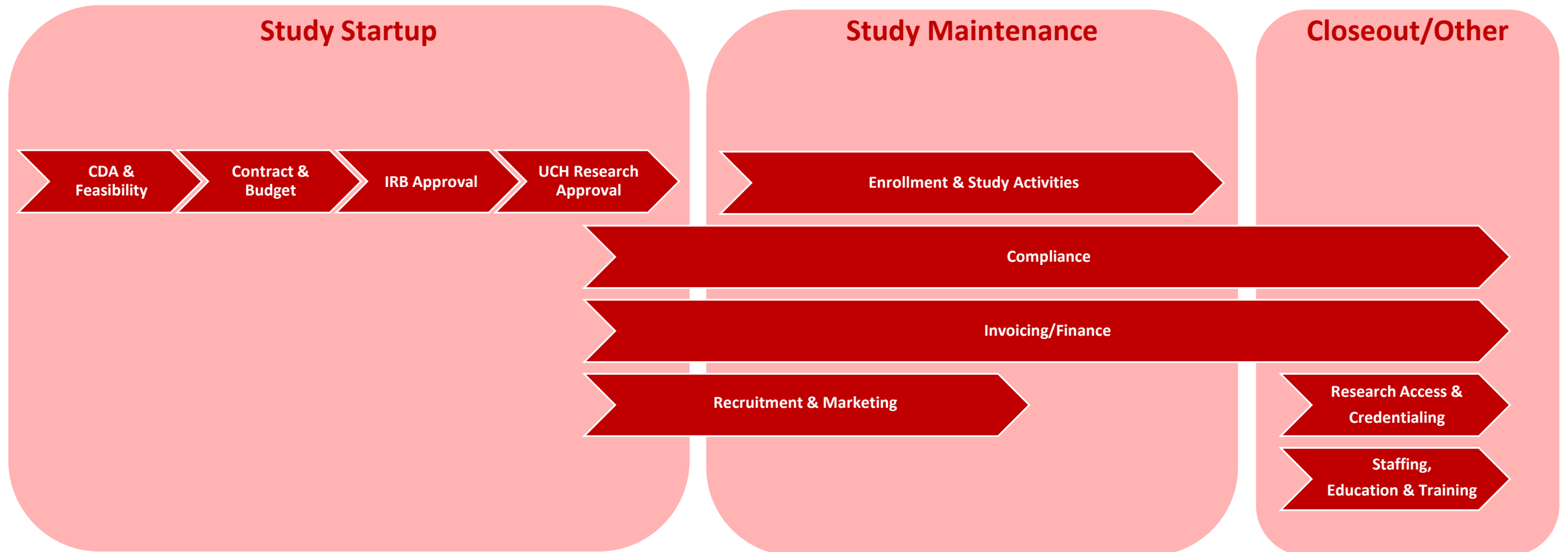# (UC OCR)
Introduction

University of Cincinnati Office of Clinical Research (UC OCR)

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
brett.kissela@uc.edu
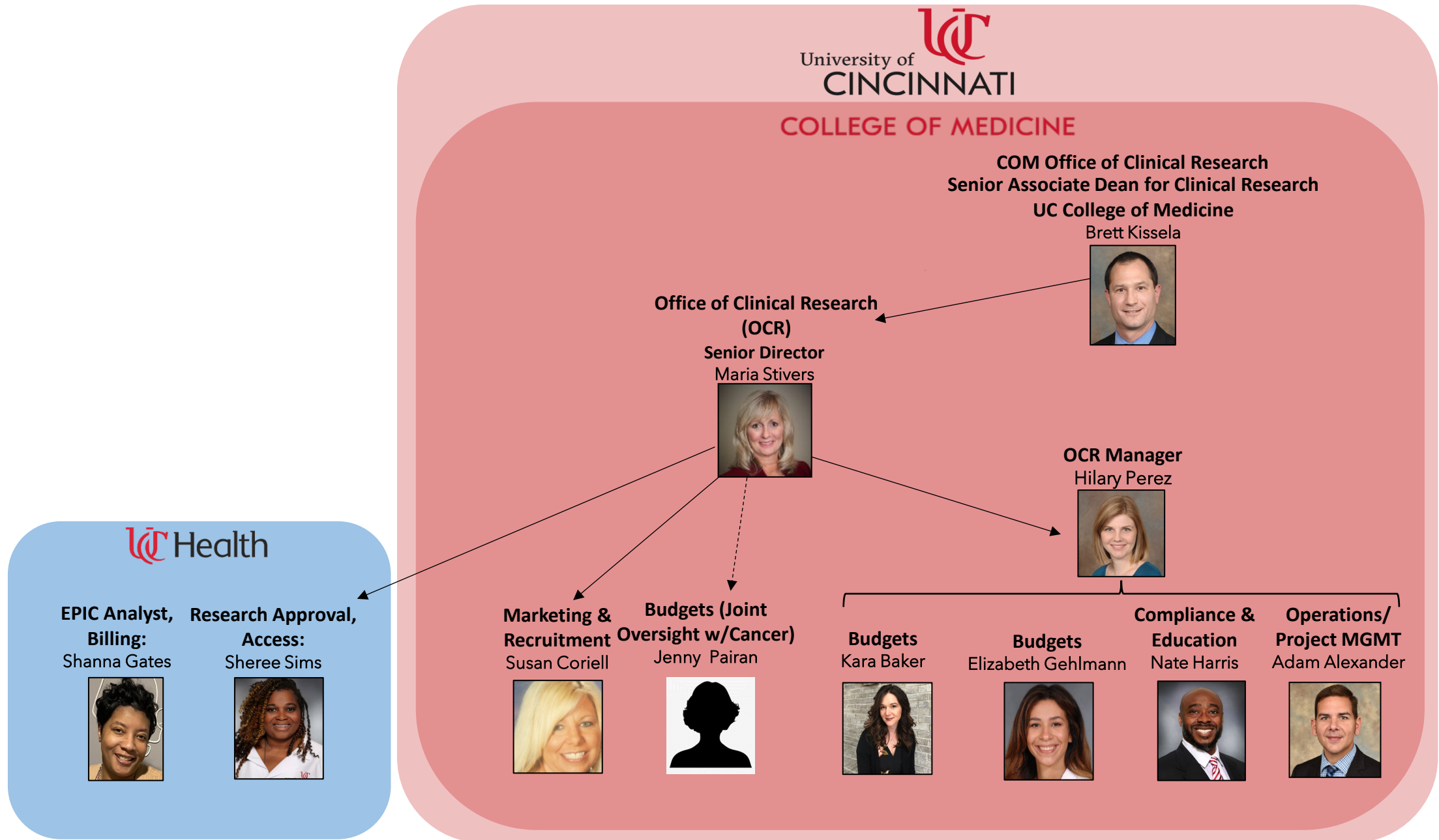513-254-9273

Clinical Research Pathway at UC/UC Health

Study Startup

Study Maintenance

Closeout/Other

CDA & Feasibility → Contract & Budget → IRB Approval → UCH Research Approval

Enrollment & Study Activities

Compliance

Invoicing/Finance

Recruitment & Marketing

Research Access & Credentialing

Staffing, Education & Training

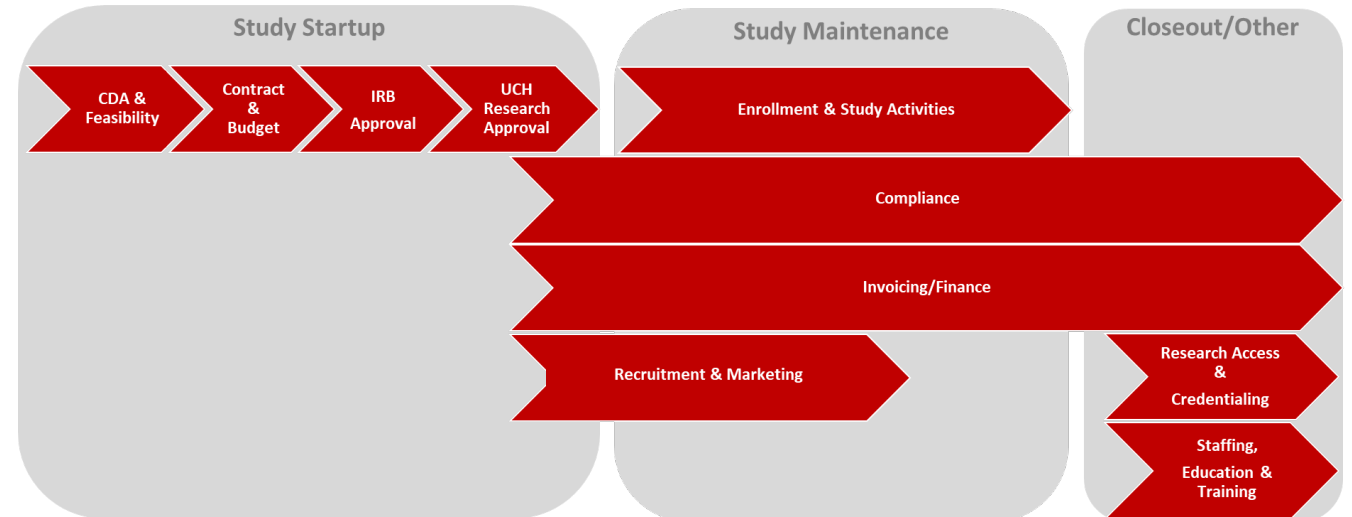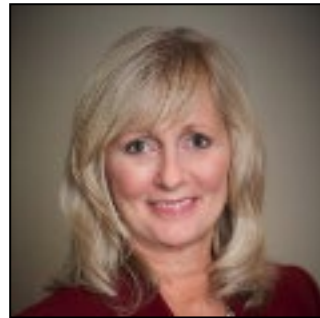# What is OCR's Role in that Pathway?

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

Clinical Research Organization Chart

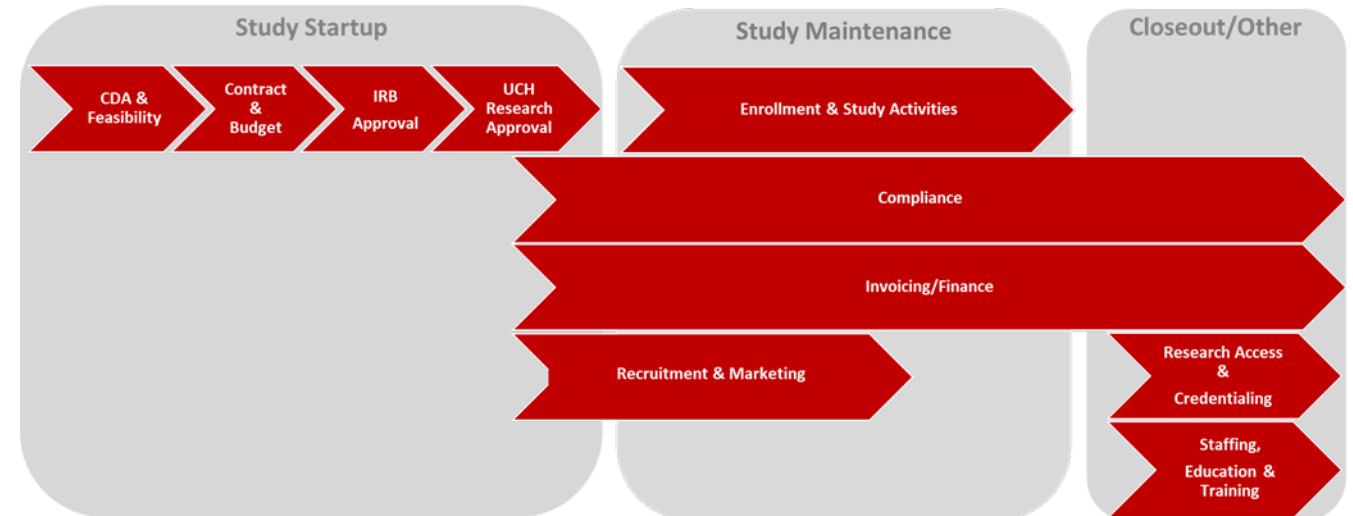# University of Cincinnati Office of Clinical Research

Maria Stivers, MS
Sr. Director
Office of Clinical Research
College of Medicine
University of Cincinnati
stivermi@ucmail.uc.edu
(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

University of Cincinnati Office of Clinical Research

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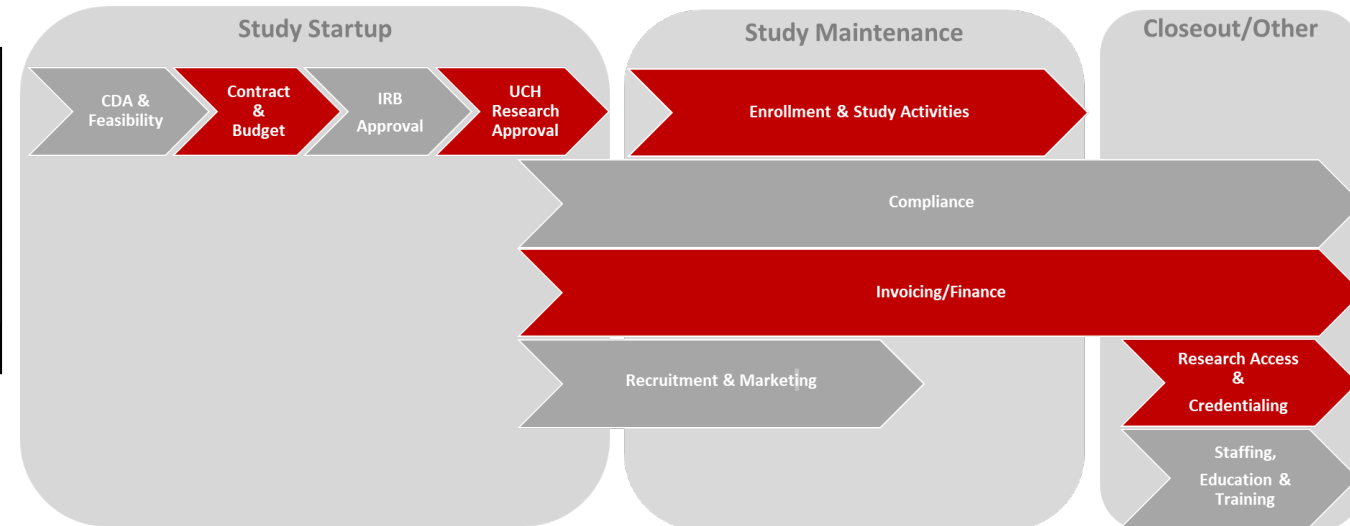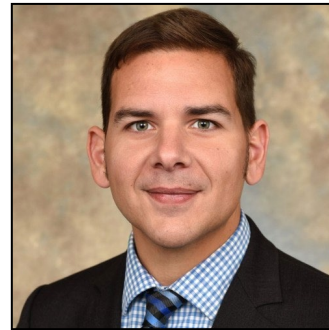perezhe@ucmail.uc.edu
(513)558-9038

- **Operations and Workflow**
  - Study Startup - Improve efficiency in Research Approval process
  - 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**

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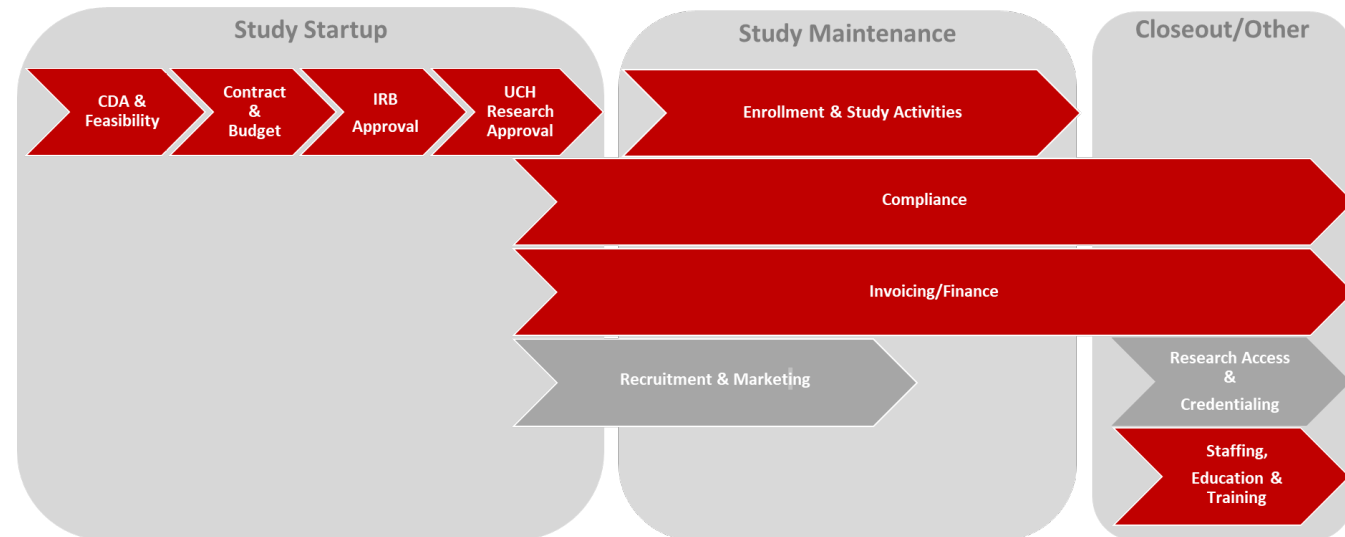
Adam C. Alexander
Clinical Research Administrator
Office of Clinical Research
College of Medicine | University of Cincinnati
alexana5@ucmail.uc.edu
(513) 558-9044

- 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

University of Cincinnati Office of Clinical Research

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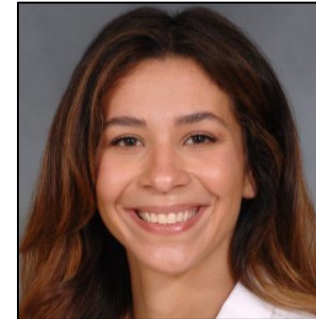harrisnl@ucmail.uc.edu
(513) 558-9068

Study Startup
- CDA & Feasibility
- Contract & Budget
- IRB Approval
- UCH Research Approval

Study Maintenance
- Enrollment & Study Activities
- Compliance
- Invoicing/Finance
- Recruitment & Marketing

Closeout/Other
- Research Access & Credentialing
- Staffing, Education & Training

- 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
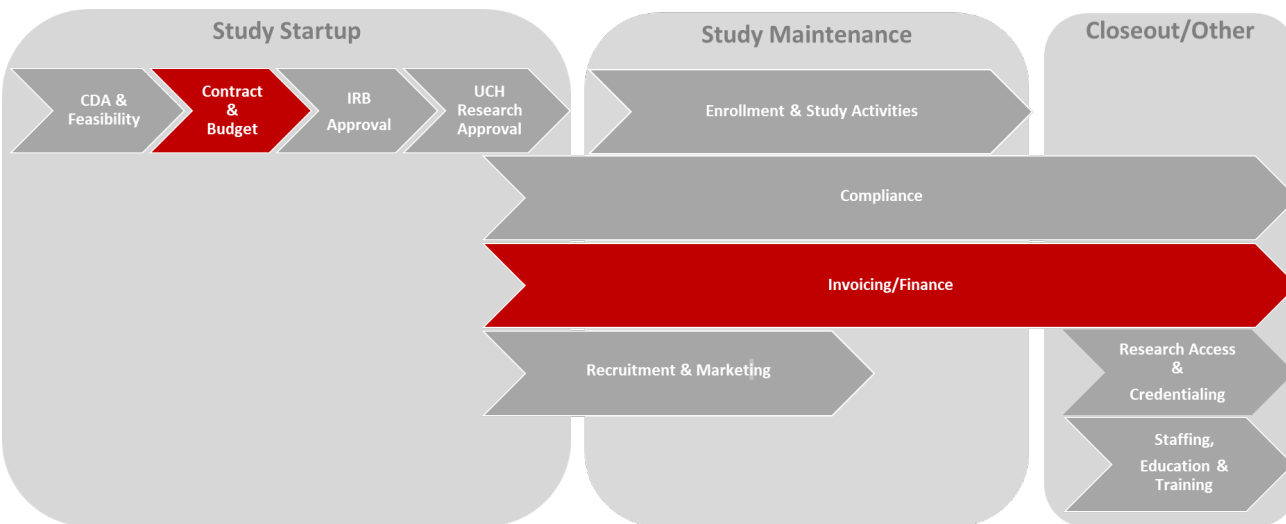- Nate's Birthday is NEXT THURSDAY, FEBRUARY 22nd, 2024

University of Cincinnati Office of Clinical Research

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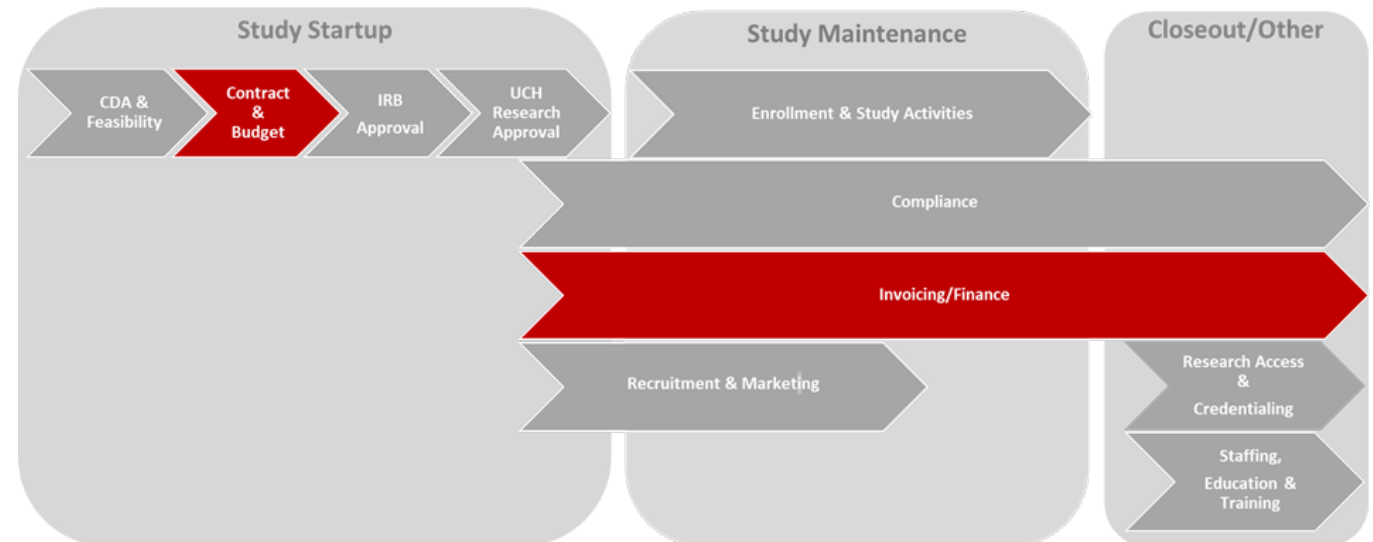baker2k9@ucmail.uc.edu

Elizabeth Gehlmann, MBA
Clinical Research Study Budget Administrator
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Study Startup

CDA & Feasibility → Contract & Budget → IRB Approval → UCH Research Approval

Study Maintenance

Enrollment & Study Activities

Compliance

Invoicing/Finance

Recruitment & Marketing

Closeout/Other

Research Access & Credentialing

Staffing, Education & Training

- 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

University of Cincinnati Office of Clinical Research

Jennifer Pairan
Clinical Research Administrator
College of Medicine
Office of Clinical Research
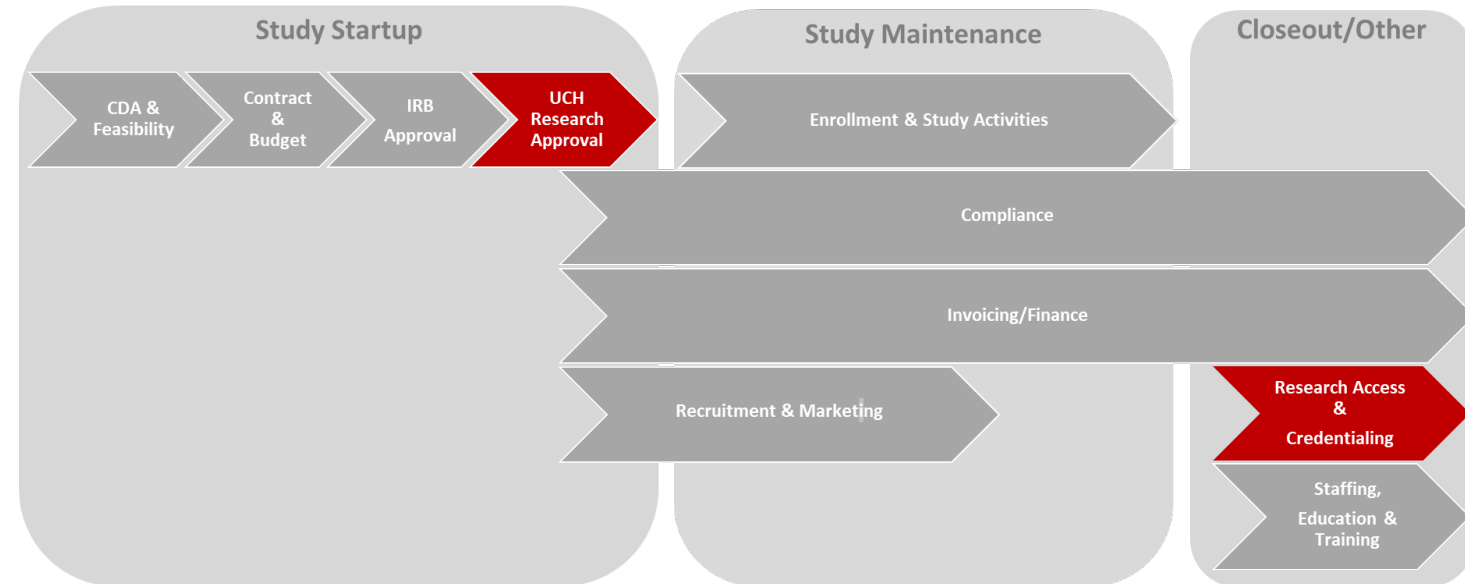pairanjr@ucmail.uc.edu
(513) 558-9043

- 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)

University of Cincinnati Office of Clinical Research

Sheree Sims, BA, MA
Clinical Research Administrator
UC Health Office of Clinical Research
simssr@ucmail.uc.edu

Study Startup
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- Contract & Budget
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Closeout/Other
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Access and Authorizations
- Facilitate UCH credentialing, including the College of Medicine pathway, and UC Health pathway.
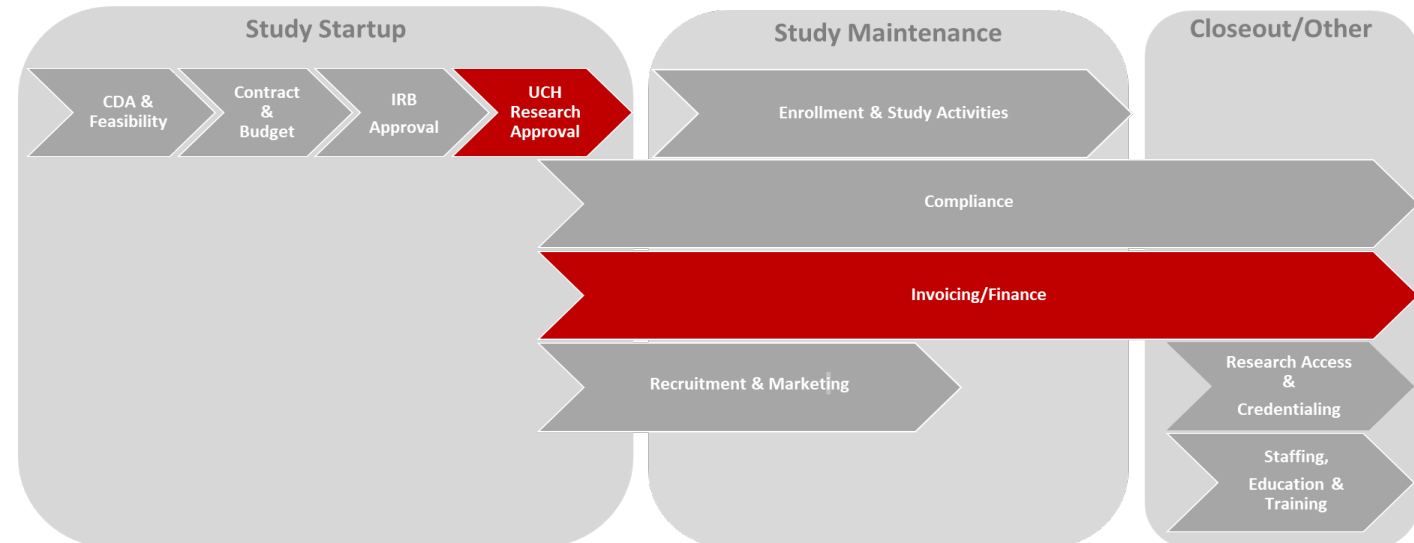- Scheduling EPIC training (Research Basic, and EPIC Print view).

UC Health Research Approvals
- Supports recruitment initiatives.
- Facilitate communication with the ancillary service reviewers.

University of Cincinnati Office of Clinical Research

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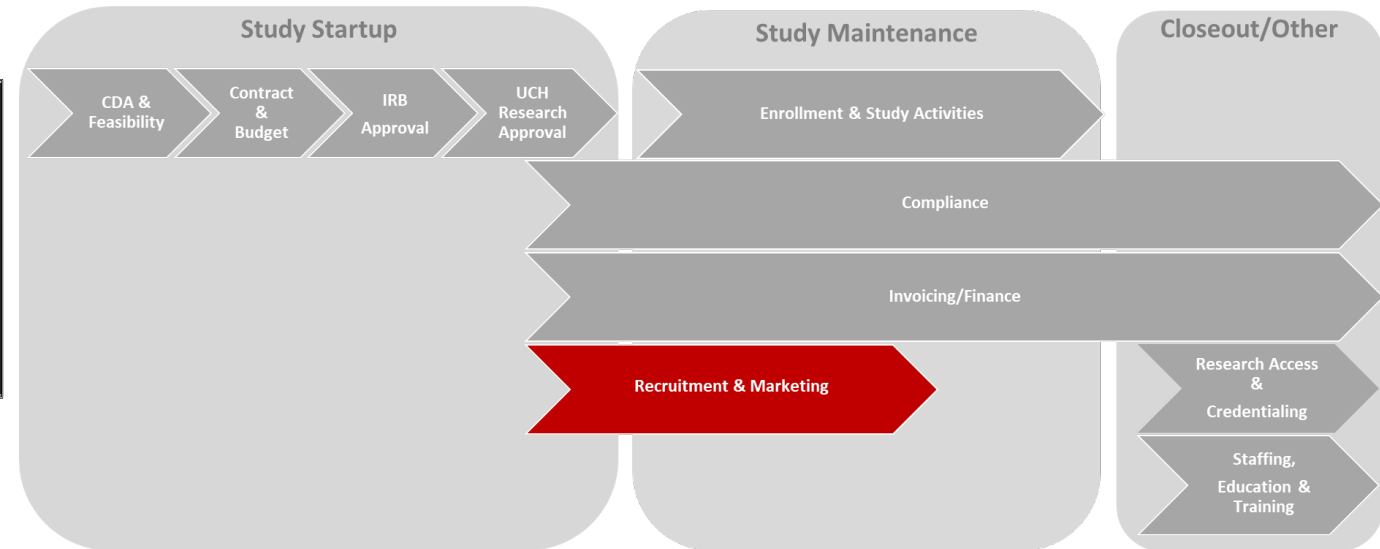Research Billing Analyst
Remote
UC Health Office of Clinical Research
shanna.gates@uchealth.com

- 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

University of Cincinnati Office of Clinical Research

Susan Coriell
Clinical Research Recruitment Administrator
Office of Clinical Research
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University of Cincinnati
corielsn@ucmail.uc.edu
(513) 558-7333

Study Startup

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Study Maintenance

Enrollment & Study Activities

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Recruitment & Marketing

Closeout/Other

Research Access & Credentialing

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.