

UCI School of Medicine

Research Development & Administration

New Faculty Orientation

Beverly Alger, MD | Director, Clinical Research Operations, CCR

Caron Miller | Director, Contracts & Grants, SOM Deans Office

Mary Frances Ypma-Wong, PhD | Research Manager, Research Development

Research Highlights

~\$208M in sponsored research funding (\$84M federal) for SOM faculty (FY21)

48th Best US Medical School: Research by US News & World Report (2021)

2 Members of the National Academy of Sciences

3 Members of the National Academy of Medicine

1 Nobel Prize in Chemistry by Irwin Rose (2004)

UCI-SOM faculty administered centers and institutes:

A NCATS-designated
Clinical and Translational
Science Institute

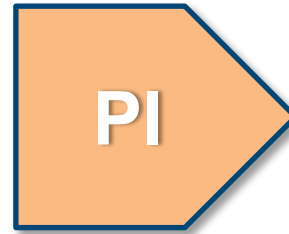
The Sue & Bill Gross Stem
Cell Research Center,
a CIRM Institute

An NCI-designated
comprehensive cancer center

Responsibility of Principal Investigators (PI)

PI Responsibilities

1. Project scientific integrity and management
2. Project financial management
3. Adherence to all internal University policies
4. Adherence to externally imposed Sponsor terms and conditions including reporting and record keeping requirements contained in the award document.



UCI provides assistance, but ultimately, the PI is responsible.

PIs should be familiar with UC Policies relating to C&G activities. These can be located in the [UCOP Contract and Grant Manual \(here\)](#)

Applying for Contract & Grant Funding

Who submits applications?

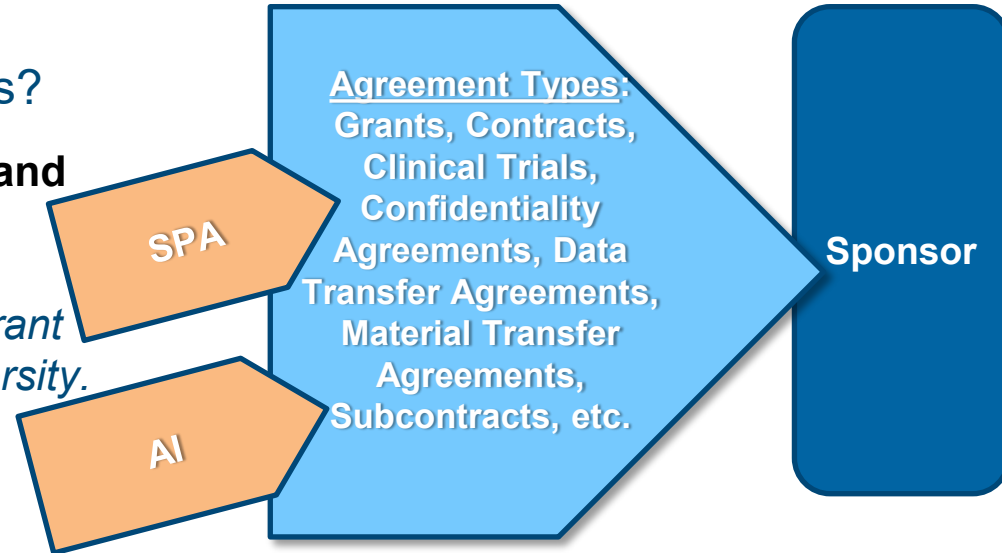
Who signs & accepts awards/agreements?

SPA (Sponsored Projects Administration) and AI (Applied Innovations) do.

Faculty are not authorized to sign or submit grant or contract applications on behalf of the University.

Why?

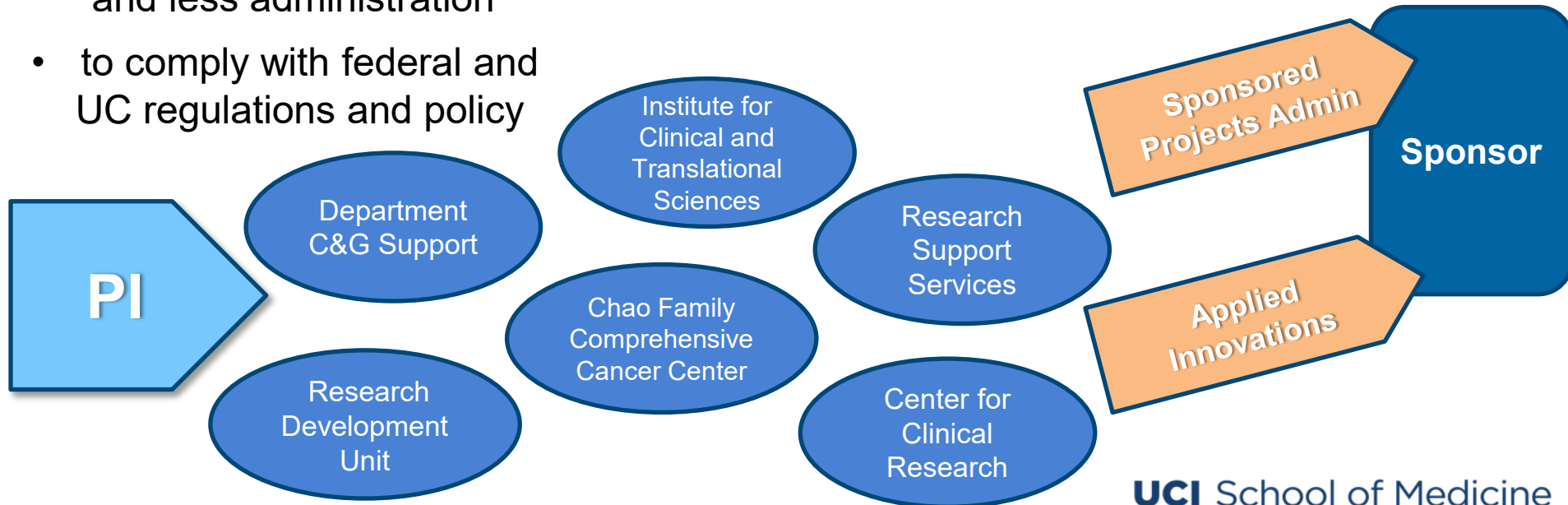
1. Applications for funding must be approved by the delegates of the UC President PRIOR to submission per UC Policy (**UCOP Contract and Grant Manual 13-700**).
2. SPA & AI maintain legal and compliance knowledge on submission for the University.
3. SPA & AI help make sure that required protocols (IRB, IBC, etc.) and other administrative arrangements are in place.



Applying for Contract & Grant Funding

UCI/SOM provides many support services:

- to help PIs do more science and less administration
- to comply with federal and UC regulations and policy



Service Units & Research Resources

- School of Medicine Research Support Services (RSS) – Deans Office
- Center for Clinical Research (CCR)
- School of Medicine Research Development Unit (RDU) – Deans Office
- Institute for Clinical and Translational Sciences (ICTS)
- Chao Family Comprehensive Cancer Center - School of Medicine

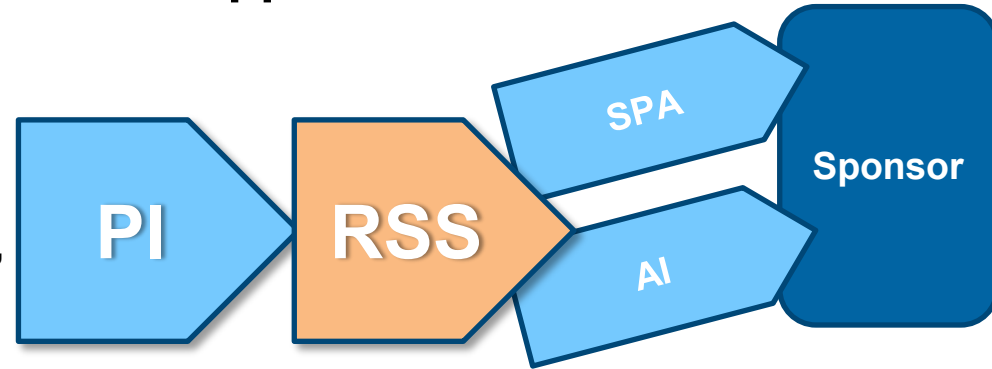
Research Support Services (RSS) – Current Service Depts/Units

Departments (A - N)	Departments (O - Z)	Centers/Institutes (All)
Aesthetic & Plastic Surgery	Obstetrics & Gynecology	John Tu and Thomas Yuen Center for Functional Onco-Imaging
Anatomy and Neurobiology	Ophthalmology	Susan Samueli Integrative Health Institute (COHS)
Biological Chemistry	Otolaryngology	
Cancer Center	Pediatrics	<u>Temporary Units:</u>
Dermatology	Physical Medicine & Rehabilitation	Anesthesiology
Emergency Medicine	Physiology & Biophysics	Orthopaedic Surgery
Family Medicine	Psychiatry & Human Behavior	Public Health (COHS)
Medical Education	Surgery	
Neurological Surgery	Urology	
Neurology		

Research Support Services (RSS)

RSS Services - PreAward Administrative Support

- Connect PI to SPA or AI
- Develop budgets, justifications
- Advise on guidelines, timelines
- Acquire materials from subaward sites, senior personnel
- Assist with recharge quotes
- Assist with formatting & compiling proposal materials for submission
- Route the Quali Research (KR) proposal for internal approvals



Additional Post-Submission Support: budget revisions; Just-In-Time (JIT) actions; coordinate between PI, sponsor, SPA/AI as needed during pre-award period.

Research Support Services (RSS)

- Are you preparing to submit a research proposal?
- Did your colleague just ask you to be a subrecipient for his/her project?
- Is a for-profit company offering you research funding?

Whether it's federal, state, local county, international, foundation, or industry*, email us at:

SOMProposalReqs@hs.uci.edu

Please provide 4-6 weeks notice for most submissions.

*Except sponsor-initiated (non-oncology) clinical trials which are administered by the Center for Clinical Research (CCR) service unit.

Center for Clinical Research (CCR)

- Comprehensive administrative support to the conduct of (non-oncology) industry-sponsored clinical trials (CT) from study start up through completion and close out. Services include:

Regulatory and IND/IDE submission support for IRB approval	Clinical coordination resources	SOPs and tight controls for study team guidance
CT pre-award financial management (coverage analysis and budget negotiation)	Data management security and processes	Support for making connections with new studies/sponsors
Timely study activation and management of trial patients	Feasibility assessment to minimize costs on trials that are ultimately not activated	Brand, marketing and communications maintenance to recruit study participants

For more information, visit the [CCR website](#)

To contact the clinical trial start-up team, please email UCIclinicaltrials@hs.uci.edu

CCR (cont'd): Functional capabilities by category

UCI -CCR has expertise in key clinical trials functional capabilities in finance, operations and administration.

Financial management capabilities*		Operations capabilities				Administrative capabilities			
Budget / Calendar	Account Management	Study/ data Management	Clinical Coordination	Biostatistics/ Bioinformatics	Core technology and services	Regulatory	Training and education	Opportunity Management	Contracting
Coverage analysis	Research patient billing/ reconciliation (hospital, professional)	Study activation and close	Research Nursing Services	Design study	Research pharmacy	IRB submission	Process and SOPs	Business development^	CDA/Master Agreement development
Budget development		Site visit coordination	Eligibility determination	CRF design	Drug/ Device management	Committee review	Research Mentorship	Recruitment strategy	CDA/Master Agreement management
Budget negotiation (sponsor and institution)	Study invoicing	Multi site coordination	Patient screening / enrollment	Data integrity/ quality	Biospecimen management	Amendment management	Research navigators	Opportunity capture	Protocol/ grant preparation
	A/P management	CRF development	Patient visit coordination	Quality data registries	Pathology / laboratory services	Site management		Pipeline management	Contracting request creation
Budget approval	A/R management	CRF completion/ eDC	SAE and deviation reporting	Statistical planning/ development	Radiology services	Audit preparation	Feasibility assessment	CTA negotiation (sponsor and institution)	
Calendar development	Cash management	Source document development	Specimen collection coordination	Statistical analysis	Clinical research IT infrastructure	Deviation reporting			
	Financial monitoring	Monitor visit coordination	Lab kit inventory management	Statistical monitoring		FDA processing (IND and IDE submissions)	CTA execution		
	Study reconciliation	SAEs monitoring and reporting	Data management and regulatory liaison						
	Account close-out	Data queries	Patient financial counseling						
		Data safety monitoring	Patient recruitment						
		Protocol reallocation							

Legend:

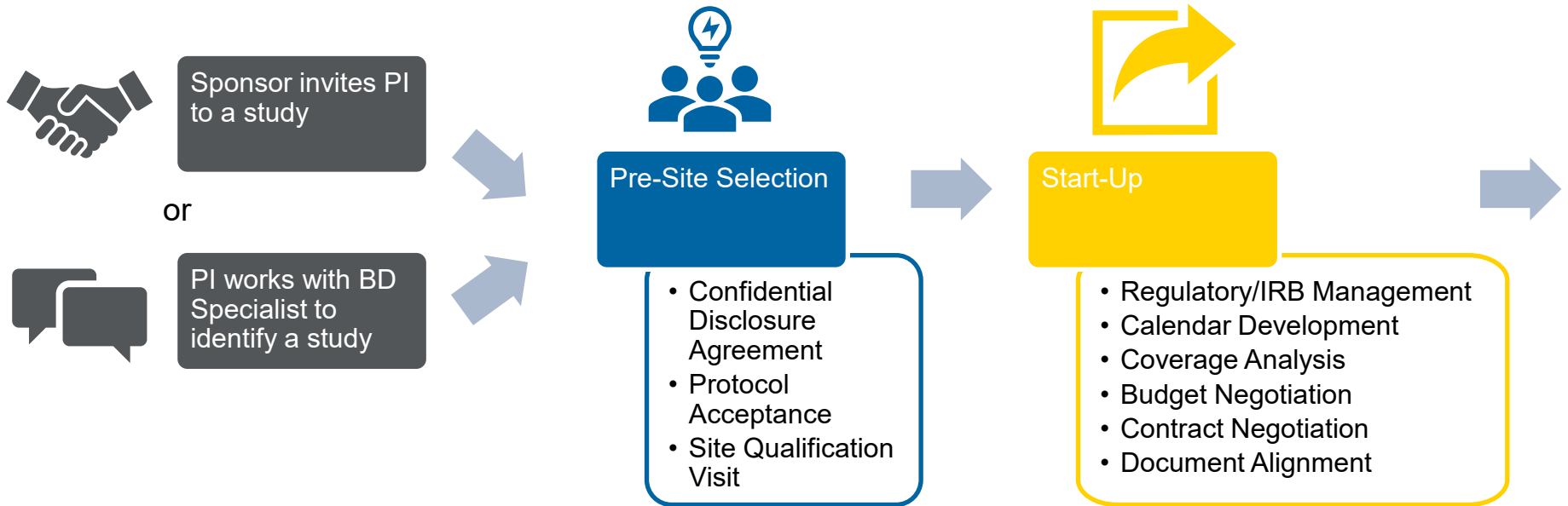
Financial Mgmt.	Operations	Admin.	Ancillary Services
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Notes:

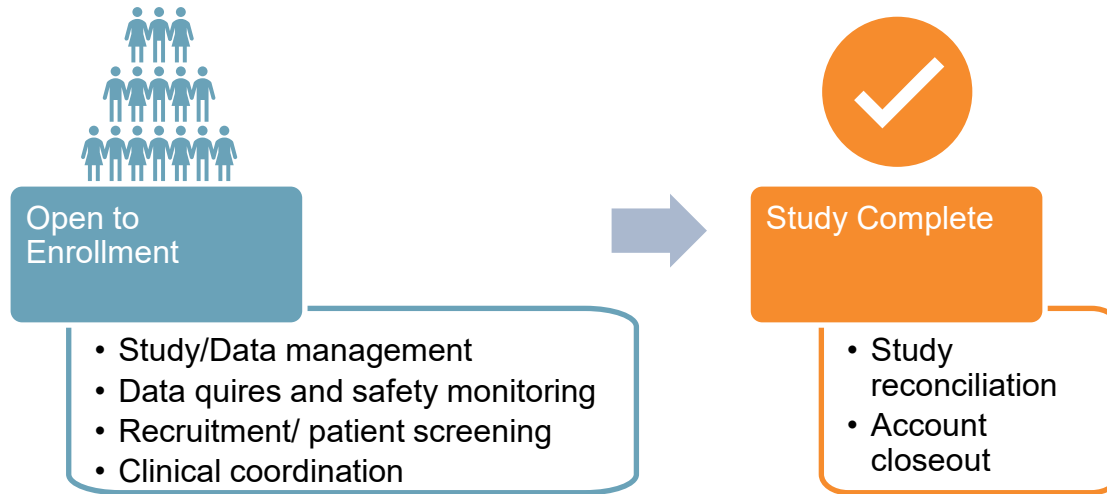
*Financial management capabilities will be developed with strong consideration to segregation of duties and internal controls

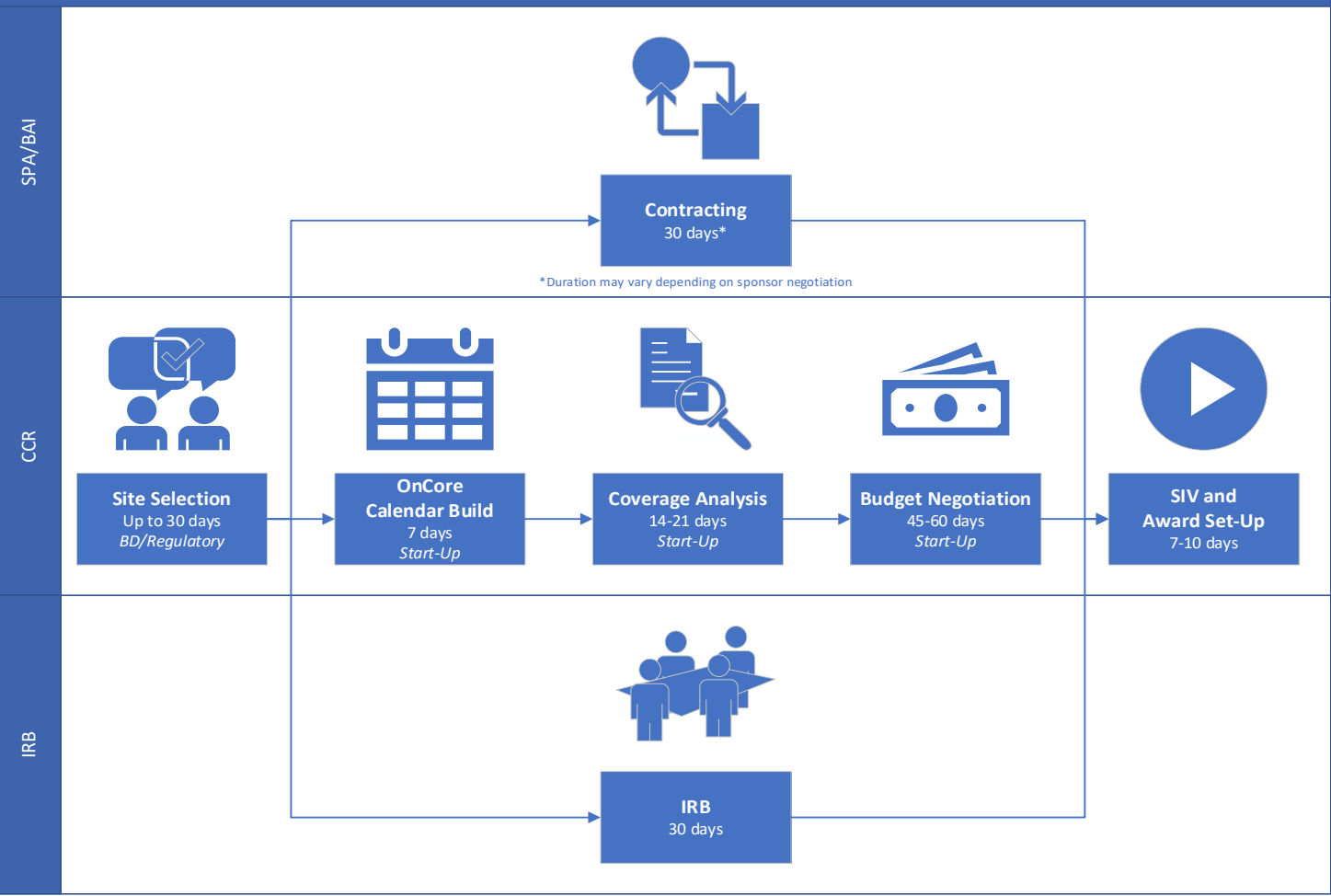
^Business development includes a sponsor-relations person(s), who will be responsible for identifying new sponsors and getting the sponsors acclimated to the UCI culture

CCR Services



CCR Services (cont.)





CCR Clinical Team Structure

Team A (Veronica Martin)	Team B (Rosie Magallon)	Team C (Lizette Spiers)	Team D (Nour Alsharif)
Neurology	Ophthalmology	OB-Gynecology	Inf. Disease (non-COVID)
Rad. Science	COVID	Surgery	Gastroenterology
Pathology	Emergency Medicine	Orthopedics	Nephrology
Family Medicine	Immunology	Cardiology	Dermatology
Neurosurgery	Pulmonology	Anesthesia	Pediatrics
PM&R		Urology	Psychiatry
			Rheumatology

Research Development Unit (RDU)

- Provide high quality services that help faculty find funding, develop funding strategies, clarify the grants process and write better grants, with a particular emphasis on junior faculty. Services include:
 - Education
 - Individual PI Support and Peer Review
 - Program Development & Administration
 - Other Grant Support



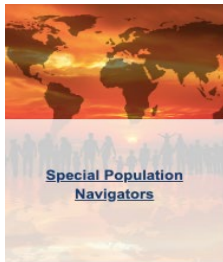
Research Development Unit (RDU) Services

Education	Individual PI Support & Peer Review	Program Development & Administration	Other Grant Support
New Faculty Orientation and Outreach	FoA identification	NIH Boot Camp-R01	NIH T32 data tables
Info Sessions with faculty panels grantsmanship & funding mechanisms (DP2, S10)	1:1 consults	NIH Resubmission Program	Large multidisciplinary funding mechanisms (e.g. P01, U54,)
Provide funding & policy updates in SOM Research Insider	Proposal review & editing by RDU	Physician Scientist Training Program- K08/K23	Provide boilerplate materials Draft ancillary proposal documents (e.g. LOS)
Provide grant writing resources for basic and clinical faculty	Arrange pre-submission grant review by subject matter experts	Intramural Seed & Bridge Funding	Grant Incentive Programs

For assistance, email us at somrd@uci.edu and visit us [here](#).

Institute for Clinical & Translational Science (ICTS)

- UCI is one of more than 50 medical research institutions across the nation to receive a CTSA from the NIH, which enables UCI-ICTS to provide research resources that accelerate the translation of research discoveries from the lab and translate them into clinical care.



For more information, visit <https://icts.uci.edu/services/>



Chao Family Comprehensive Cancer Center

- UCI-CFCCC is the only National Cancer Institute (NCI)-designated comprehensive cancer center in Orange County. <http://www.cancer.uci.edu/>
- Relevant service units and research resources include:
 - **Stern Center for Cancer Clinical Trials & Research**
 - Clinical Trials Unit (CTU)
 - Protocol Review & Monitoring Unit (PRM)
 - Regulatory Affairs Unit (RA)
 - **Seven Shared Resources** that foster innovative research into the causes, diagnosis and treatment of cancer.
 - Transgenic Mouse Facility (TMF)
 - Optical Biology Core (OBC)
 - Genomics High-Throughput Facility (GHTF)
 - In Vivo Functional Onco-Imaging (IVFOI)
 - Experimental Tissue Resource (ETR)
 - Biostatistic Shared Resource (BSR)
 - Biobehavioral Shared Resource (BBSR)

Additional research facilities and other resources

UC IRVINE ORGANIZED RESEARCH UNITS

- Cancer Research Institute
- Center for Molecular and Mitochondrial Medicine and Genetics (MAMMAG)
- Center for Virus Research
- Developmental Biology Center
- Genetic Epidemiology Research Institute (GERI)
- Health Policy Research Institute
- Institute for Genomics and Bioinformatics
- Institute for Immunology
- Institute for Memory Impairments and Neurological Disorders (UCI MIND)
- Reeve-Irvine Research Center (RIRC)

CENTERS & INSTITUTES

- Ablative Oncology Center*
- Academic Geriatric Resource Center*
- Beckman Laser Institute and Medical Clinic
- Brain Imaging Center
- Center for Artificial Intelligence in Diagnostic Medicine
- Center for Autism Research and Translation (CART)*
- Center for Cancer Genetics Research and Prevention*
- Center for Diabetes Treatment and Research*
- Center for Epigenetics and Metabolism*
- Center of Excellence on Elder Abuse & Neglect*
- Center for Future Health Professionals*
- Center for Occupational & Environmental Health
- Center on Stress and Health
- Center for the Study of Cannabis

For a complete list: https://som.uci.edu/centers_institutes.asp

A banner for 'Research Insider Seminars & Funding Opportunities'. The background is dark blue with white icons representing various scientific fields: a microscope, a beaker with a flame, a lightbulb, a molecular structure, a satellite, and a DNA helix. The text 'Research Insider' is in large yellow font, and 'Seminars & Funding Opportunities' is in white. Below this, a white box contains the text 'SOM Applications for Bridge Funding Due Jan. 25' and a paragraph of information about the deadline and application process.

Research Insider
Seminars & Funding Opportunities

SOM Applications for Bridge Funding Due Jan. 25

Please note that the next UCI Office of Research Deadline for Bridge Funding is **Tuesday, Feb. 1**. Complete applications must include a signed letter of support by your department chair showing financial commitment. **Applications are due to the SOM Office of Research via SmartSheet on or before Tuesday, Jan. 25, 2021.** [Read more.](#)

JANUARY 4, 2022

NIH Notice of Intent to Publish a Funding Opportunity Announcement for Health Care Models for Persons with Multiple Chronic Conditions from Populations that Experience Health Disparities (R01 Clinical Trials Optional)

The overarching goal of this FOA is to support innovative, multidisciplinary, and multi-level and/or multi-component research through existing or newly proposed health care models designed to optimize the care of persons with MCCs from U.S. populations that experience health disparities through the adaptation, integration, and implementation of evidence-based or recommended guidelines of care for different and coexisting MCCs with a holistic perspective, and focused on attaining optimal health outcomes as the primary goal. [View details.](#)

Department of Defense Ovarian Cancer Research Program Pre-announcement

The FY22 Defense Appropriations Act is anticipated to provide funding for the OCRP to support patient-centered research to prevent, detect, treat, and cure ovarian cancer to enhance the health and well-being of Service Members, Veterans, their family members, and all women impacted by this disease. The OCRP is providing the information in this pre-announcement to allow investigators time to plan and develop ideas for

Things to remember ...

- Secure approval from an authorized institutional official for all business and research activities.
- Start work after regulatory approvals are in place
- The routing and review process takes time – start early!
- Use your support resources – we are here to help!

Contact Information

Beverly Alger, MD
Director, Clinical Research Operations,
Clinical Center for Research
Campus: 250 Irvine Hall
Phone: (949) 824-2488
Email: balger@uci.edu

Mary Frances Ypma-Wong, PhD
Research Manager
Deans Office, Research Development
Campus: 240 Irvine Hall
Email: m.ypmawong@uci.edu

Caron Miller
Director, Contracts & Grants
Deans Office, Research Support Services
Campus: 247C Irvine Hall
Phone: (949) 824-3236
Email: caron@hs.uci.edu

Lauren Nguyen
Senior Research Development Analyst
Deans Office, Research Development
Campus: 240 Irvine Hall
Email: Insoto@uci.edu