Research Development & Administration

New Faculty Orientation

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Research Highlights

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


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

SOMPProposalReqs@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:

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

For more information, visit the [CCR website](#)
To contact the clinical trial start-up team, please email [UCIclinicaltrials@hs.uci.edu](mailto: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.

<table>
<thead>
<tr>
<th>Financial management capabilities*</th>
<th>Operations capabilities</th>
<th>Administrative capabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget / Calendar</td>
<td>Study/ data Management</td>
<td>Regulatory</td>
</tr>
<tr>
<td>Account Management</td>
<td>Clinical Coordination</td>
<td>Training and education</td>
</tr>
<tr>
<td>Coverage analysis</td>
<td>Biostatistics/ Bioinformatics</td>
<td>Opportunity Management</td>
</tr>
<tr>
<td>Budget negotiation (sponsor and institution)</td>
<td>Core technology and services</td>
<td>Contracting</td>
</tr>
<tr>
<td>Study invoicing</td>
<td>Study activation and close</td>
<td>IRB submission</td>
</tr>
<tr>
<td>A/P management</td>
<td>Research Nursing Services</td>
<td>Process and SOPs</td>
</tr>
<tr>
<td>Budget approval</td>
<td>Design study</td>
<td>Committee review</td>
</tr>
<tr>
<td>A/R management</td>
<td>Research pharmacy</td>
<td>Research Mentorship</td>
</tr>
<tr>
<td>Calendar development</td>
<td>CRF design</td>
<td>Recruitment strategy</td>
</tr>
<tr>
<td>Cash management</td>
<td>Drug/ Device management</td>
<td>CDA/Master Agreement</td>
</tr>
<tr>
<td>Financial monitoring</td>
<td>CRF completion/ eDC</td>
<td>Opportunity Management</td>
</tr>
<tr>
<td>Study reconciliation</td>
<td>SAE and deviation reporting</td>
<td>CDA/Master Agreement</td>
</tr>
<tr>
<td>Account close-out</td>
<td>Quality data registries</td>
<td>Business development*</td>
</tr>
<tr>
<td>Study activation and close</td>
<td>Statistical planning/ development</td>
<td>Protocol/ grant preparation</td>
</tr>
<tr>
<td>Site visit coordination</td>
<td>Statistical analysis</td>
<td>Site management</td>
</tr>
<tr>
<td>Eligibility determination</td>
<td>Clinical research IT infrastructure</td>
<td>Pipeline management</td>
</tr>
<tr>
<td>Multi site coordination</td>
<td></td>
<td>Audit preparation</td>
</tr>
<tr>
<td>Patient screening / enrollment</td>
<td></td>
<td>Deviation reporting</td>
</tr>
<tr>
<td>CRF development</td>
<td></td>
<td>FDA processing (IND and IDE submissions)</td>
</tr>
<tr>
<td>Patient visit coordination</td>
<td></td>
<td></td>
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<tr>
<td>Source document development</td>
<td></td>
<td></td>
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<tr>
<td>Monitor visit coordination</td>
<td>Specimen collection coordination</td>
<td></td>
</tr>
<tr>
<td>Lab kit inventory management</td>
<td>Data management and regulatory liaison</td>
<td></td>
</tr>
<tr>
<td>Data queries</td>
<td>Data management and regulatory liaison</td>
<td></td>
</tr>
<tr>
<td>SAEs monitoring and reporting</td>
<td>Data safety monitoring</td>
<td></td>
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<tr>
<td>Protocol reallocation</td>
<td>Patient financial counseling</td>
<td></td>
</tr>
</tbody>
</table>

**Legend:**
- Financial Mgmt.
- Operations
- Admin.
- Ancillary Services

**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

Sponsor invites PI to a study

or

PI works with BD Specialist to identify a study

Pre-Site Selection
- Confidential Disclosure Agreement
- Protocol Acceptance
- Site Qualification Visit

Start-Up
- Regulatory/IRB Management
- Calendar Development
- Coverage Analysis
- Budget Negotiation
- Contract Negotiation
- Document Alignment
CCR Services (cont.)

Open to Enrollment
• Study/Data management
• Data queries and safety monitoring
• Recruitment/ patient screening
• Clinical coordination

Study Complete
• Study reconciliation
• Account closeout
Clinical Trials Activation Timeline

**SPA/BAI**
- **Site Selection**: Up to 30 days
- **BD/Regulatory**: Up to 30 days

**CCR**
- **Site Selection**: Up to 30 days
- **OnCore Calendar Build**: 7 days
- **Coverage Analysis**: 14-21 days
- **Budget Negotiation**: 45-60 days
- **SIV and Award Set-Up**: 7-10 days

**IRB**
- **IRB**: 30 days

Contracting: 30 days*

*Duration may vary depending on sponsor negotiation
## CCR Clinical Team Structure

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

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

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

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