UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY
Conflict of Interest (COI)
Dual Use Research of Concern (DURC)
Export Control and Facility Security
Institutional Animal Care and Use Committee (IACUC)
Research Ethics and Integrity (Research Misconduct)
ClinicalTrials.Gov, NIH Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) Compliance
General Research Compliance Activities

Website: RCI.UCSD.EDU
Helpline: (858) 822-4939
Email: rci@ucsd.edu
General Research Compliance

Bec Beutler, Senior Research Compliance Analyst
Diana Kim, Associate Director of RCI
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<th>ClinicalTrials.gov</th>
<th>Exception Requests</th>
<th>Responsible Conduct of Research (RCR)</th>
<th>Good Clinical Practices (GCP)</th>
<th>Other Reviews</th>
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<tr>
<td>ClinicalTrials.gov (CT.gov) is a public registry aimed at increased transparency and improved public awareness of research. ClinicalTrials.gov captures significant summary protocol information before and during the clinical trial as well as summary results and adverse event information of a completed trial.</td>
<td>An exception to the requirement to submit proposals and receive awards through the University must be obtained when conducting research outside of the University.</td>
<td>Responsible Conduct of Research (RCR) is defined as &quot;the practice of scientific investigation with integrity.&quot;</td>
<td>The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials.</td>
<td>1. Conflict of Interest (COI) and Conflict of Commitment (COC) Reviews 2. Category 1 Reviews 3. Foreign Influence Reviews 4. Research Misconduct 5. Other miscellaneous reviews</td>
</tr>
</tbody>
</table>
CLINICALTRIALS.GOV REQUIREMENTS

1. Registration

2. Updating the record

3. Results posting

UCSD Investigators are responsible for determining whether or not they are obligated to register a clinical trial and for any subsequent required updates, including results reporting.
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<tr>
<th>Entity</th>
<th>Registration</th>
<th>Results</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Administration (FDA)</td>
<td>Within 21 days of enrollment</td>
<td>Within 365 of Primary Completion Date</td>
<td>$13,000+/day/study, FDA sanctions, Loss of HHS funding and possible criminal proceedings</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>Within 21 days of enrollment</td>
<td>Within 365 of Primary Completion Date</td>
<td>Loss of grant funding (to include the institution)</td>
</tr>
<tr>
<td>International Committee of Medical Journal Editors (ICMJE)</td>
<td>Prior to enrollment of the first participant</td>
<td>Not Specified</td>
<td>Restricted from publishing in journals</td>
</tr>
<tr>
<td>National Cancer Institute (NCI)</td>
<td>Not Specified</td>
<td>Within 365 of Primary Completion Date</td>
<td>Loss of grant funding</td>
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</table>
EXCEPTIONS TO CONDUCT RESEARCH OUTSIDE THE UNIVERSITY

Exceptions to the requirement to submit proposals and awards through the University may be granted by the Vice Chancellor for Research (VCR) on a case by case basis. See the UC Policy, “Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University.” Also see UC San Diego PPM (PPM 150-82) for the implementation procedures and information on how to submit exception requests to conduct research outside the University.

Please be prepared to provide the following information:

1. A list of the specific proposals, grant applications, and awards that the requestor wishes to be on outside of the University. For each proposal, grant application, and award, the requestor should provide the proposal title, agency, grant time period, their anticipated role, and their anticipated time commitment.

2. The rationale/justification for the request, including anticipated benefits to the University.

3. An explanation for why the requested activity will not interfere with the requestor’s duties and responsibilities to the UC San Diego campus.

4. Information on how the requestor will maintain a clear distinction and separation between the requestor’s service to the University and service to the external party.

5. An affirmation from the requestor that all University personnel, research, and intellectual property policies will be followed and that the University name will not be used by the external party without prior University approval.
Submit the online request form with all applicable information.

The form will be routed to the Department Chair/Dean for their endorsement.

The Vice Chancellor for Research reviews the exception request and determines if the request is permissible.

Email notification is provided to the requestor and their Department Chair/Dean.

The RCI Office will maintain a list of the exception requests (regardless if approved or not).
Responsible conduct of research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

Certain projects funded by the National Institutes of Health (NIH), National Science Foundation (NSF) and National Institute of Food and Agriculture (NIFA) have specific requirements regarding training in RCR.
<table>
<thead>
<tr>
<th>Federal Agency</th>
<th>Minimal Requirement for RCR</th>
<th>Who Must Complete the Training</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH*</td>
<td>At least 8 hours of face-to-face training/interaction (on-line training can be a component of the overall training)</td>
<td>Trainees, Fellows, Postdoctoral Scholars, Graduate Students, Undergraduate Students</td>
<td>At least once during each career stage and no less than once every four years</td>
</tr>
<tr>
<td>NSF</td>
<td>On-line or face-to-face training</td>
<td>Undergraduate Students, Graduate Students, and Postdoctoral Scholars</td>
<td>Each institution is responsible for the frequency with which RCR training must occur</td>
</tr>
<tr>
<td>NIFA</td>
<td>On-line or face-to-face training</td>
<td>Program Directors, Faculty, Undergraduate Students, Postdoctoral Scholars, any staff participating in the project</td>
<td>NIFA requires RCR training be completed before participation or payment from the project</td>
</tr>
<tr>
<td>Options</td>
<td>Availability</td>
<td>Federal Agency Requirements</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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<td>---------------------------------------------------</td>
<td></td>
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<tr>
<td><strong>Research Ethics Program</strong></td>
<td>Everyone</td>
<td>All</td>
<td></td>
</tr>
<tr>
<td>Core Courses</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Ethical Challenges of Research Workshops</strong></td>
<td>Postdoctoral Scholars only</td>
<td>All</td>
<td></td>
</tr>
<tr>
<td>(Office of Postdoctoral Scholar Affairs)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Integrity Tutorial</strong></td>
<td>Undergraduate Students only</td>
<td>Only meets NSF and NIFA requirements, does not meet standard of face-face training for NIH</td>
<td></td>
</tr>
<tr>
<td><strong>CITI RCR Education Courses</strong></td>
<td>Everyone with a UCSD affiliation</td>
<td>Only meets NSF and NIFA requirements, does not meet standard of face-face training for NIH</td>
<td></td>
</tr>
<tr>
<td><strong>Customized Department Courses</strong></td>
<td>Members of the specific departments</td>
<td>Can be customized to meet all requirements</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
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</table>
WHO IS RESPONSIBLE

- Departments are responsible for tracking the completion of training requirements associated with extramural awards, including RCR.

- Documentation of the training is subject to review by the funding agency and/or UC San Diego Research Compliance and Integrity Office upon request.

- RCI will conduct monitoring based on the information included in the grant application/proposal.
  - The results of the monitoring will be provided to the applicable Principal Investigators and Department Chairs/Deans.

- RCI will also provide training and education on the RCR training requirements.
National Institute of Health (NIH) requires that all investigators and staff involved in the conduct, oversight, or management of NIH funded clinical trials must be trained in Good Clinical Practice (GCP).

Effective January 1, 2017
Valid for 3 years
GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. There is no particular GCP course or program that must be taken and some are offered free-of-charge.

Options include:

1. CITI training
2. The National Institute on Drug Abuse
3. The National Institute of Allergy and Infectious Disease
4. National Center for Advancing Translational Sciences (geared toward behavioral clinical trial investigators)
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- Documentation of the training is subject to review by the funding agency and/or UC San Diego Research Compliance and Integrity Office upon request.
- RCI will conduct monitoring based on the information included in the grant application/proposal.
  - The results of the monitoring will be provided to the applicable Principal Investigators and Department Chairs/Deans.
- RCI will also provide training and education on the GCP training requirements.
The General RCI Office performs a host of other reviews, including but not limited to:

- Conflict of Interest (COI) and Conflict of Commitment (COC) Monitoring
- IACUC Interinstitutional Agreements
- Foreign Talents Program Monitoring
- Human Fetal Tissue Monitoring
- Foreign influence Monitoring
- Cannabis Monitoring
- Category I Requests
- FDA Warning Letters
RESEARCH MISCONDUCT

Research misconduct per federal regulations:

- **Fabrication**: Making up data or results and recording or reporting them
- **Falsification**: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
- **Plagiarism**: The appropriation of another person's words, ideas, processes or research results without acknowledgement, and passing them off as one's own

Questionable research practices should be resolved by the appropriate department/research group. Examples include good clinical practices violations, authorship disputes, attribution of credit, data access and use, differences of opinion or honest error. The VCR will provide assistance if necessary.

For assistance, contact Angela McMahill, amcmahill@ucsd.edu, (858) 534-7321
RESEARCH MISCONDUCT FLOW

Research Misconduct Review Process

- Allegations of research misconduct
  - Sent to UCD, who provides notification to respondent for assessment (24 days)
  - Final Investigation report incorporates comments and revised by appropriate
  - Final copy provided to RIO

- Investigation Committee drafts Investigation Report
  - Conducted by Investigation Committee
  - Starts within 30 days of inquiry determination; complete in 330 days
  - If Research Misconduct occurred and is proven
  - Result: Research misconduct
    - Respondent committed the misconduct intentionally, knowingly, or recklessly
    - Relevant information and evidence
    - Additional interviews of respondent, complainant, or other person identified as having relevant information
    - Requested and provided to interview for corrections
    - Based on all evidence, including evidence of additional instances of misconduct

- Potential Research Misconduct (FRP)
  - False Information
  - Fabrication
  - Plagiarism

- Other Complaints
  - Authorship dispute
  - Data ownership
  - Copyright infringement
  - Collaboration or supervisory issues

- End

- RIO reviews and determines type of concern

- Assessment of allegations conducted by RIO to be completed in timely, reasonable time period
  - Allegation sufficiently credible and specific
  - Fails under definitions of misconduct (FRP)
  - Jurisdiction under policy and specific institutional or federal funding source requirements
  - No interview or data gathering necessary beyond the initial allegation, except as necessary to determine the above criteria

- Refer to Department Chair Dean, Compliance Office or appropriate agency

- Inquiry Conducted by Inquiry Committee
  - Starts at RIO notification of committee chair; complete in 180 calendar days
  - Determine:
    - Whether an Investigation is warranted
    - Reasonable basis for concluding that allegation falls within definition of research misconduct
    - Research misconduct may have occurred
    - Probable cause
  - By:
    - Initial review of evidence
    - Initial testimony of respondent, complainant, and key witnesses
    - Evaluation of evidence and testimony

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DEFINITIONS:
- Allegations: Oral or written statement or other evidence of apparent instance of Research Misconduct.
- Department Head: Head of the Academic or Research Unit in which Research Misconduct is alleged to have occurred.
- Research Integrity Officer (RIO): The Vice Chancellor for Research is the RIO for UCD and is responsible for implementation of the University Research Misconduct Policy.
UNANNOUNCED VISITS BY FEDERAL AND STATE AGENCIES

UC San Diego can expect site visits by outside agencies as part of routine oversight activities and for specific ongoing investigations.

The University’s practice is to cooperate with outside investigating agencies, while protecting the rights and privacy of the students, faculty, staff and research subjects.

Promptly contact Research Compliance and Integrity who will provide assistance or alert appropriate institutional offices.

For additional information and FAQs, please see https://blink.ucsd.edu/research/policies-compliance-ethics/index.html
COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
- RCI Office Hours, Tuesdays from 11-12: https://calendly.com/ucsdrcioffice
- Conflict of Interest Helpline: (858) 534-6465, info-coi@ucsd.edu
- Export Control Helpline: (858) 246-3300, export@ucsd.edu
- IACUC Helpline: (858) 534-6069, iacuc@ucsd.edu
- Unannounced Governmental and Law Enforcement Hotline: (858) 246-4600
- Hot Topics Eblasts and Newsletters: http://blink.ucsd.edu/sponsor/rci/news.html

- RCI Hot Topics Training Program: https://blink.ucsd.edu/sponsor/rci/research-compliance-hot-topics.html
- To be added to the RCI list serv, please email rci@ucsd.edu
Research Compliance and Integrity
Phone: (858) 822-4939
Email: rci@ucsd.edu
Website: rci.ucsd.edu
PLEASE COMPLETE THE SURF EVALUATION

We want to hear from you!