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Newsletter

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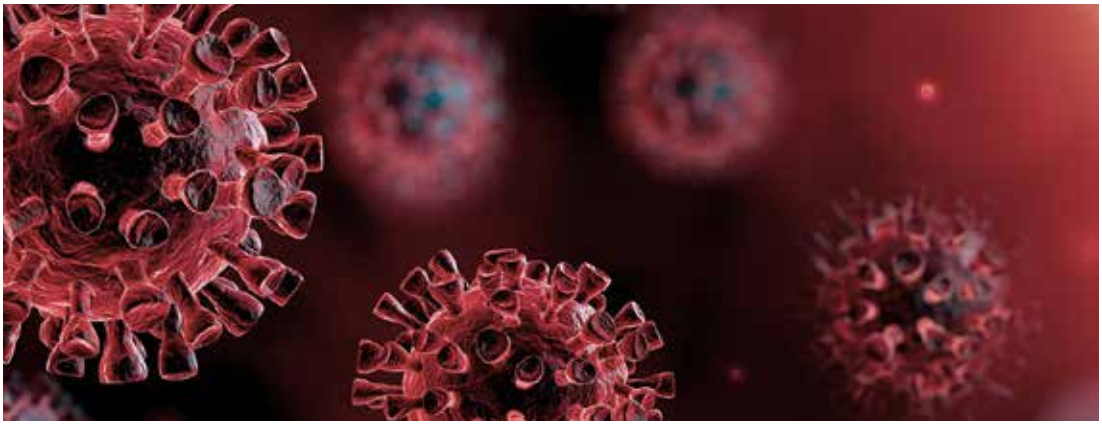
Research Ethics in the Time of Covid-19

BY MARY DEVEREAUX, PHD



"During an infectious disease outbreak, there is a moral obligation to learn as much as possible as quickly as possible in order to inform the ongoing public health response . . . "

—World Health Organization 2016

The Covid-19 global pandemic of 2020 has altered nearly every aspect of life as we once knew it, including how we conduct biomedical research. Last March, UC San Diego, like other universities and research institutions, suddenly faced a host of unusual ethical challenges. Public health measures and a commitment to the safety of the university community required dramatically limiting on-site research by shifting to remote platforms whenever possible. These and related measures posed significant challenges to keeping labs running, caring for research animals, and maintaining on-going clinical trials. What's more, the virulence of SAR-CoV-2 meant prioritizing research directed at understanding and managing the virus itself. The attention of many research groups shifted to a host of urgent questions, including not only understanding the specific pathogen driving the global pandemic, but also its route of transmission, patterns of community spread, impact on human organ systems, and treatment. Among the most pressing research projects was, of course, how to develop a safe, effective vaccine. Addressing these questions in turn led to a flood of Covid-19-related IRB submissions.

The current circumstances present campus researchers, IRB members, and research ethicists with notable challenges. As bioethicists, Bryan Sisk and James DuBois, caution, "pandemics create unique pressures on researchers," pressures that may in turn "encourage subversion of onerous research regulations." Sisk and DuBois distinguish two types of IRB review modifications: 1) administrative fast tracking and 2) reconsidering fundamental elements of human subject protections. Fast tracking, which may involve such things as increasing the number of IRB meetings, simplifying paperwork and advance review of generic protocols, they find unobjectionable. Indeed, from an ethics point of view, urgent health emergencies may arguably require reducing administrative burdens. The second kind of modification, reassessing core elements of human subjects protections, is, they rightly argue, a more serious matter. Does the urgency of our public health emergency justify loosening traditional informed consent or other research subject protections? Should we permit higher risk to trial participants if the benefit is saving thousands – even tens of thousands of lives? Should we alter privacy protections to better track infection rates? (Sisk and Dubois, 2020). And who should bear the risks to provide treatment benefits (or vaccines) for all of us?

Aside from these ethical questions, researchers also face practical obstacles in enrolling and completing Covid-related clinical trials. The disease is unevenly distributed. It surges in one location, only to have the curve flatten. Some areas of the

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world have seen few cases; others have experienced recurrent waves of infection (Wieten, Burgart, Cho. 2020). Among those infected, Covid-19 also varies widely in its effects, disproportionately impacting individuals according to factors such as gender, race, occupation, and age. This disparate impact raises important questions of fairness. So, for example, what populations have the most to gain from an effective vaccine and are these the groups most likely to enroll in clinical trials? What obstacles do clinical researchers face in winning the trust of groups historically exploited in medical research? Lastly, once effective vaccines emerge, how can they be distributed fairly? The ethical issues here are daunting, including whether those who bore the risks of participating in early vaccine trials should have some priority in receiving the benefits of vaccine.

This short discussion only scratches the surface of the ethical challenges raised in the setting of Covid-19 research. Worth emphasizing, as we continue to make progress in meeting these challenges, is the importance for us, as a research-focused public university, of addressing these issues with a commitment to transparency and fairness. Ultimately the goal of research ethics and compliance requirements is public trust in the research process.

For additional information related to Research Ethics, please visit the Research Ethics Program website.

Works Cited

1. Guidance for Managing Ethical Issues In Infectious Disease Outbreaks, WHO, 2016.
2. Sisk, BA, J. DuBois. 2020. "Research Ethics During A Pandemic: A Call for Normative and Empirical Analysis." The American J of Bioethics 20, No.7, 84-86.
3. Wieten, S, A. Burgart, M. Cho. 2020. "Resource Allocation in COVID-19 Research: Which Trials? Which Patients?" The American J of Bioethics 20, No.7, 86-88.

Scripps Research Institute Pays $10 Million Related to Alleged Mischarging National Institutes of Health (NIH) Grants: Are Your Federal Grants Compliant?

BY JEFFREY WARNER

The Scripps Research Institute recently agreed to a $10 million settlement with the United States government stemming from a whistleblower lawsuit. Scripps Research was accused of establishing requirements that forced certain employees to secure 100% of their salary via grants. As such, the suit alleged that Scripps Research improperly charged grants from the National Institutes of Health for time spent by researchers on activities unrelated to the grants, including supporting effort for writing new grant applications, teaching, and other administrative activities (see the full article from the Times of San Diego and the Department of Justice Press Release).

The direct charging of such unrelated activities to a Federal award conflicts with Federal Cost Principles and Uniform Guidance as direct costs must be allowable under the sponsor's policies and allocable to a project. A cost is allocable to a particular Federal award if the goods or activities involved are chargeable or assignable to that Federal award in accordance with relative benefits received. This allocability standard requires costs to be incurred specifically for and directly benefit the Federal award to which they are being charged (see §200.405 Allocable Costs, Uniform Guidance).

To ensure compliance with Federal Cost Principles and Uniform Guidance, the University of California San Diego (UC San Diego) instituted a policy on the Percent Salary for Principal Investigators Paid Exclusively from Federal Awards. Principal Investigators at UC San Diego must not receive more than 97% of their salary from Federal awards, including Federal flow through-funding. Academic Research appointees (e.g., Research Scientist, Adjunct Professor, etc.) and Project Scientists who are Principal Investigators by exception, must also not charge the entirety of their institutional base salary to Federal awards.

The policy applies to all Principal Investigators whose salary is derived entirely from Federal awards. This Policy does not apply to Principal Investigators who receive partial funding from other sources (e.g., State of California, industry, non-profits). Departments should establish procedures and controls that verify compliance with this policy.

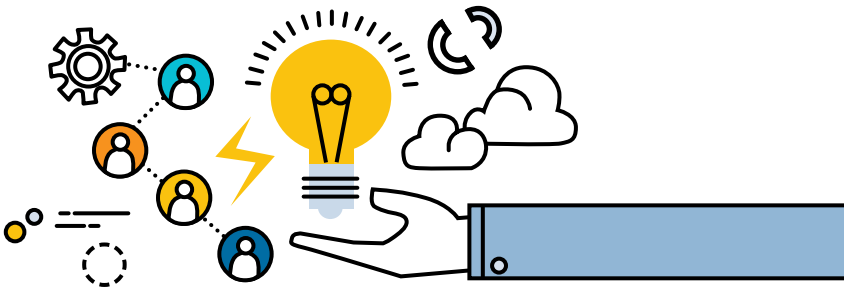
Discretionary fund sources such as core university funds may be used to supplement non-award related activities such as public service, grant-writing, peer-review of papers and proposals, teaching, other administrative activities, etc. A non-federal award may be charged only when there is a corresponding direct benefit to the project for the salary charged.

As a responsible steward of Federal funding, UC San Diego must ensure that activities that are considered part of a Principal Investigator's institutional responsibilities and that do not directly benefit a Federal award are ineligible for direct support from extramural sponsors.

Please find the full UC San Diego policy statement on salary limits from Federal awards here. For questions about this UC San Diego policy, please contact your UC San Diego Contract and Grant Officer.

UC San Diego Researchers: Do You Have an Invention?

BY VICTORIA CAJIPE

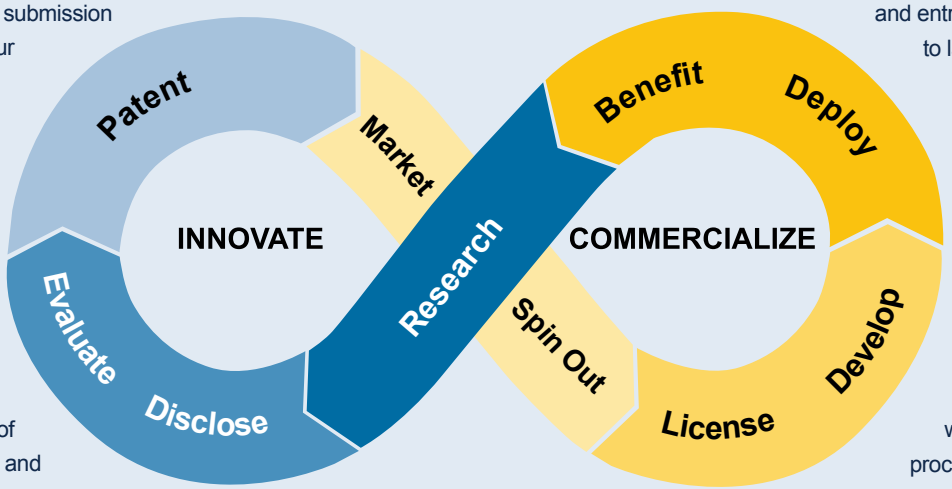


Invention Disclosure is the First Step

Disclosing your invention to the Office of Innovation and Commercialization (OIC) starts the process of converting your research breakthroughs into products that benefit society. The eDisclosure system provides a secure web-based method to submit, update, manage and track your invention disclosure.

When to Submit Your Invention Disclosure?

You should submit an invention disclosure as soon as you think that you have a potentially valuable innovation and can provide a reasonably clear description of it. Early submission will allow OIC to assess your invention towards a timely filing of a patent application with the US Patent and Trademark Office. When in doubt, contact OIC at innovation@ucsd.edu, to discuss your idea. As a rule of thumb, let OIC know about your invention before discussing it with anyone outside your circle of UC San Diego researchers and co-workers. Novelty is a key criterion of patentability, so prior to filing, taking precautions to limit public availability of information about your invention would help ensure the preservation of its patent rights.



What to Expect Upon Disclosing an Invention?

An Innovation and Commercialization Manager (ICM) will be designated to partner with you to formulate and pursue a patenting, marketing and commercialization strategy that aligns with your development efforts and carves a path to success. Your ICM will meet with you to discuss your invention, its applications, possible patent claims (for composition, method, device, article of manufacture), any sponsors and non-UC inventors, potential partners and your plans to publish or present the invention.

Next Steps, Moving Your Innovation Forward

- Your ICM will perform a preliminary assessment of the pertinent intellectual property landscape and provide guidance on filing a provisional patent application, which will establish a priority date for your invention. Key questions include:
  - ✓ Does your invention meet the criteria of subject matter eligibility, novelty, non-obviousness or inventive step and usefulness?
  - ✓ Is there sufficient enablement of your invention (details of making and using it)?
  - ✓ Will there be further development within the coming year?
  - ✓ Would your invention be of commercial value and interest?
- Assuming your invention is viable and/or a provisional application is filed, OIC will conduct research into the relevant markets.
- With your input and participation, OIC will market the technology and engage with potential licensees, including existing corporate entities and entrepreneurs seeking to launch a new startup (possibly with you as founder).
- You should keep your ICM updated on subsequent progress in the development of the invention. This will be a factor in deciding whether or not to proceed with a full application by the one-year anniversary of the provisional filing.
- In the absence of further technology advancement and evidence of commercial value and interest, a full patent application will typically not be pursued. Under certain conditions, it is possible for UC to release the invention to you.
- Pursuit of a full patent application involves stages of patent prosecution which are directed towards the issue of potentially valuable patent claims.
- Ideally, OIC will be able to license your invention, providing tangible validation of your innovation as well as economic and social benefit.

Learn More about Patents

Intellectual Property Essentials for Academic Researchers

OIC assists UC San Diego researchers throughout the entire innovation and commercialization cycle. For additional information regarding inventions and patent rights, please contact OIC at innovation@ucsd.edu.

RESOURCES FOR UNANNOUNCED AGENCY AND LAW ENFORCEMENT VISITS

The Research Compliance and Integrity Office (RCI Office) is here to support faculty, staff members and students in the event of an unannounced agency and/or law enforcement visit. The university's research activities take place in a heavily regulated environment and are subject to oversight by a wide range of federal and state agencies. As a result, UC San Diego can expect occasional site visits by outside agencies as part of routine oversight activities and when there are specific ongoing investigations. Examples of outside agencies that may conduct unannounced visits include the USDA, NIH, NSF, CDC, DEA, FDA, FBI, OEE (Office of Export Enforcement), Customs, ICE (Immigration and Customs Enforcement), etc. It is the university's policy to cooperate with outside investigating agencies to the fullest extent required by law, while seeking to protect the rights and privacy of our faculty, staff members, students, and research subjects.

In many cases, the most important action taken by the person who is the first point of contact (whether a Principal Investigator, a student working in a laboratory or a research staff member) is to promptly contact the RCI Office so that someone who is familiar with state and federal laws and the university's obligations can participate in the event of a site visit. If an outside investigating agency presents a subpoena, search warrant, court order, national security letter, or other document compelling the university or an individual to produce documents or otherwise provide information, immediately notify the RCI Office and campus counsel.

For additional information on how to manage an unannounced visit and FAQs, please visit the RCI Office website or call (858) 822-4939.

For after-hours and weekends, please call (858) 246-4600.

National Institutes of Health Data Management and Sharing

BY DIANA D. KIM

The National Institutes of Health (NIH) issued its Final NIH Policy for Data Management and Sharing, on October 30, 2020, requiring NIH funded researchers to prospectively submit a plan outlining how scientific data will be managed and shared. The policy establishes the baseline expectation that data sharing is an essential component of the research process and stresses the importance of good data management practices. In doing so, the policy aims to lay the foundation for effective data sharing and enhance the reproducibility and reliability of research findings.

The NIH will assess the data management and sharing plans for all research funded or conducted by the NIH that results in the generation of scientific data. Considering any potential restrictions or limitations, researchers must describe how scientific data and accompanying metadata will be managed and shared in a plan with a summary of the elements below:

- Type of data to be managed, preserved, and shared
- Related tools, software and/or code
- Standards to be applied
- Data preservation, access, and associated timelines
- Access, distribution, or reuse considerations
- Oversight of data management and sharing

The policy will take effect on January 25, 2023, to allow the scientific community time to accommodate to the new requirements. More information, support, and tools will be made available by the NIH. With the release of the policy, the NIH provided supplementary information on:

- Elements of data management and sharing plan,
- Allowable costs for data management and sharing, and
- Selecting a repository for data resulting from research.

The policy notes that any approved plan may be made publicly available. This policy reinforces NIH's commitment to data sharing and establishes a requirement for submitting a plan and being compliant with the implementation of the described plan. Any plan approved by the NIH will become an enforceable term and condition of the funding award. Non-compliance may place additional terms and conditions on the award and/or affect future funding decisions.

For additional information and resources, please visit the NIH Office of Science Policy page.

The Kuali Institutional Review Board (IRB) Module is Coming Soon

BY KIP KANTELO AND CHRISTOPHER GERRITY

As UC San Diego continues with its enterprise systems renewal (ESR) program, consistent with the implementation of Kuali Research for contracts and grants, and Kuali Conflict of Interest (COI) for conflict of interest disclosures, the Kuali Institutional Review Board (IRB) module is scheduled to be released in the summer of 2021. The Kuali IRB module will replace the existing UC San Diego IRB application and review processes. Like the previously implemented Kuali modules, the Kuali IRB module will include dynamic web forms and integrated comments and responses, creating greater efficiency in the overall IRB submission process. In addition, the Kuali IRB module will eventually interface with the other implemented Kuali modules which will reduce re-entry of the same data into multiple systems. Information and training on the Kuali IRB module will be provided well in advance of its implementation and updated on the ESR Kuali IRB Project website.

For additional information, please participate in the January 20, 2021, Research Compliance and Integrity's Hot Topics and Training Program session, "IRB Town Hall." Kip Kantelo, IRB Director, will share more about the Kuali IRB implementation, including how it reflects recent regulatory updates and changes and improvements to the IRB processes.

Session registration information is available here.

PROTOCOL-GRANT CONGRUENCE VERIFICATION FOR ANIMAL RESEARCH

BY THE IACUC OFFICE

Federal funding agencies like the National Institutes of Health (NIH), the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA), and some private extramural funding agencies require a "congruence verification" before funding is released. **The NIH Grants Policy Statement states, "It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the Institutional Animal Care and Use Committee (IACUC)."** The Office of Laboratory Animal Welfare, which oversees the care and use of research animals in Public Health Service funded research, defines congruence as "agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC." It is left to the grant recipient institutions how to implement this congruence verification.

At UC San Diego (UCSD), for animal research, the congruence review is performed by the IACUC Office. The Sponsored Project Offices (OCGA, HSSPPO and SIO OCGA) generally contact the IACUC Office when a Just-in-Time (JIT) notice is received or when funding for a grant is imminent. The IACUC Office compares grant and animal use protocols and provides a confirmation to the Sponsored Project Office, which will then provide the assurance to the funding agency. If congruence cannot be verified, the IACUC Office and Sponsored Project Office will work with the Principal Investigator (PI) to determine how to modify the grants or protocols and ensure a timely release of funds.

If UCSD is the primary recipient of the grant, but funds are used to pay for animal work conducted at other institutions, congruence review also covers animal use protocols from those institutions. The other institutions must provide the relevant documents to the UCSD IACUC Office. All subcontract locations must be AAALAC accredited, as required by IACUC policy 21 on Inter-Institutional Research. No expenditures for activities with live vertebrate animals may be charged to an NIH grant if there is not a valid IACUC approval.

To prevent delays during the congruence verification, PIs should routinely amend their animal use protocols to match any new or supplemental grant proposals. When a new grant is submitted, a review of the protocols for all performance sites listed on the grant should be conducted to ensure the fundamental components of the proposal, such as animal species, major experiments and procedures and experimental compounds, are listed and approved.

For additional information regarding grant congruency or IACUC processes, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

CAN AN INVESTIGATOR HAVE FINANCIAL INTERESTS AND STILL PARTICIPATE IN RESEARCH?

BY JENNIFER J. FORD

Investigators owe their primary professional allegiance to the University, and their primary commitment of time and intellectual energies should be toward education and research programs of the University.

A conflict of interest may occur when an opportunity arises for an investigator to influence University business decisions, for instance in a research project, which may result in personal financial gain and potentially compromising the integrity of research by the investigator with the financial interest. A conflict of interest refers to a situation in which outside financial interests or other personal considerations may compromise or have the appearance of compromising an investigator's actions or judgments in the administration, management, or performance of their professional activities.

Some of the most common conflict of interest issues identified are:

- Consulting agreements while also having basic research, gifts, services, clinical trials, or other human subject research
- Equity ownership in an investigator's start-up company
- Stock options in investigator's participation as a scientific advisory board member of a company
- Management positions in outside entities
- Visiting professor positions at foreign institutions
- Foreign travel with foreign institutions or companies
- Small business grants (SBIR/STTR) with investigators who are the inventor and/or founder

Having a financial interest is not automatically a conflict of interest. It is also important to remember that some financial interests are of such low value and/or limited duration that they do not meet the definition or threshold of disclosable financial interests.

What Happens After an Investigator Discloses a Financial Interest?

Once a financial disclosure is submitted to the Conflict of Interest Office (COI), the investigator's financial disclosure form is reviewed by the COI Office. The COI office must apply the applicable COI policies and regulations based on the investigator's specific University sponsored activity or other related activity, i.e., gifts, service, MTA, etc. Depending on the scope and nature of the disclosure and/or project, the conflict of interest may need to be reviewed by the Independent Review Committee (IRC) on Conflict of Interest. The IRC is a committee of faculty members from disciplines all across the campus and functions as the principal advisory committee to the Chancellor for conflict of interest related to research and other related activities. The charge of the IRC is to review situations where a potential, perceived, or real conflict of interest exists by virtue of financial interest and determine whether these interests constitute significant conflicts of interest that must be eliminated, reduced, or managed before research support can be accepted.

The IRC reviews focus on three areas:

- The actual or the appearance of a conflict of interest
- The risk for bias by the conflicted investigator
- The risk to the reputation of the conflicted investigators and the University

If the IRC determines that the research support may be accepted, they then also recommend to the Chancellor appropriate strategies for the management of any significant conflict of interest. The IRC applies management strategies that have evolved over time, based on their prior experience, the appearance of new types of conflicts, and input from the local and national research community. The oversight role of the IRC endeavors to safeguard the interests of the University and individual researchers and ensure compliance with state and federal government regulations and policies. With appropriate intervention, often research that may technically have a conflict of interest is permitted to proceed with management strategies.

The IRC's most common management strategies are disclosure in publications, presentations, to the research team, ensuring protection of students and postdoctoral scholar, and, if human subjects are involved, disclosure in the informed consent. The IRC attempts to mitigate the conflict of interest situation by recommending changes in financial arrangements, or implementing some form of faculty accountability for research by monitoring and oversight. Once the IRC has made their decisions, the COI Office informs the applicable institutional office to ensure funds are released to the investigator.

If you have questions or need additional information, please contact the COI Office at (858) 534-6465 or info-coi@ucsd.edu.

EDUCATION

New ClinicalTrials.gov Video Series

BY MONIQUE M. TEIXEIRA

The Research Compliance and Integrity (RCI) team is excited to announce the creation of a new ClinicalTrials.gov Video series. The short videos will walk through each step of registering and posting results on ClinicalTrials.gov. The following videos are available on the RCI website:

STUDY REGISTRATION

- Study Identification
- Study Status
- Sponsor/Collaboration
- Oversight
- Study Description
- Conditions
- Interventional or Observational Study Design
- Arms and Interventions for Interventional Studies
- Groups and Interventions for Observational Studies
- Outcome Measures
- Eligibility
- Contacts and Locations
- IPD Sharing
- References

RESULTS POSTING

- Preparing to Enter Results
- Entering Participant Flow Information
- Entering Baseline Characteristics Information
- Entering Outcome Measures and Statistical Analysis Plan
- Outcome Measures FAQ
- Entering Adverse Events
- Entering Limitations and Caveats
- Entering More Information
- Uploading Study Documents

To view these videos, visit the Research Compliance and Integrity ClinicalTrials.gov Blink webpage and click on the **NEW ClinicalTrials.gov Video Series**. For additional information regarding ClinicalTrials.gov, please visit the Frequently Asked Questions (FAQ) page. If you have any questions or suggestions for videos you think would be helpful, please contact RCI at (858) 822-4939 or ctgov@ucsd.edu.

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

The UC San Diego Research Compliance and Integrity Office is pleased to offer the Research Compliance Hot Topics and Training Program (Program) to all UC San Diego faculty, staff and students. The Program will offer training through a variety of forums, including workshops, videos, newsletters and other activities, and is designed to serve as an educational resource to assist the UC San Diego research community with the complexities of conducting research. The following session has been scheduled:

- **IRB Town Hall**
  January 20, 2021
  11:00 a.m. - 12:30 p.m., via Zoom (to register, click on this link)

Information on registration and additional sessions will be provided soon. For questions, please contact rci@ucsd.edu.

Q&A

Ask the Questions . . .

"Research is creating new knowledge."

— Neil Armstrong

I have a financial interest in an outside company; can they sponsor my research project at UC San Diego?

Yes, but financial interest(s) must be disclosed using the proper form(s), and the Independent Review Committee (IRC) must review the disclosure to determine whether the interest(s) constitute significant conflicts of interest that must be eliminated, reduced, or managed before research support can be accepted.

For additional questions or guidance, please contact the Conflict of Interest Office at (858) 534-6465 or info-coi@ucsd.edu.

Can the Food and Drug Administration (FDA) impose penalties related to ClinicalTrials.gov?

The FDA can impose civil monetary penalties against the Responsible Party for failure to submit the required clinical trial registration and/or results information to ClinicalTrials.gov. The FDA will send a Preliminary Notice of Noncompliance (Pre-Notice) Letter that describes the potential violation, requesting that the recipient makes the necessary corrections within 30 days. After 30 days, the FDA will conduct a review and issue a Notice of Noncompliance if it determines that a violation still exists. If you are in receipt of such letter from the FDA, please contact the Research Compliance and Integrity (RCI) Office at ctgov@ucsd.edu or (858) 822-4939.

For additional information, please see the FDA's guidance Civil Monetary Penalties relating to the clinicaltrials.gov Data Bank and visit the RCI ClinicalTrials.gov webpage.

When do I have to report a new appointment and/or affiliation on my Other Support or Biosketch for my National Institutes of Health (NIH) grant?

When a new appointment and/or affiliation occurs, please reach out to your UC San Diego contract officer as soon as possible to assist you in notifying the NIH. Do not wait until your next Research Performance Progress Report (RPPR) to report the appointment or affiliation. If you are receiving new support not in the form of an appointment, this new support can be reported on your next RPPR.

The Sponsored Projects Office contacts are OCGA and HSSPPO.

For what animal species must I submit an Animal Use Protocol?

You need to submit an animal use protocol if you are conducting research, training or testing using any vertebrate animal. Although the definition of "animal" differs slightly between Public Health Service (PHS) Policy and the United States Department of Agriculture's (USDA) Animal Welfare Act, all vertebrates are covered and UCSD requires an animal use protocol for any of the activities mentioned above. The IACUC ensures the campus is in compliance with all applicable regulations by applying the USDA and PHS regulations to all vertebrate animal use on campus for teaching and research.

If you are unsure, please feel free to contact the IACUC Office for guidance regarding your particular animal model, (858) 534-6069, iacuc@ucsd.edu.

It is permissible to charge Personal Protective Equipment (PPE) to National Institutes of Health (NIH) Grants?

Yes, see the NIH Notice NOT-OD-20-164. This applies to NIH awards issued on or after September 11, 2020. PPE expenses may be charged to NIH grants conducting clinical trials and clinical research as defined in the NIH Grants Policy Statement section 1.2. This does not apply to grants or cooperative agreements that are not conducting clinical trials/clinical research.

For additional information, see the NIH's PPE Frequently Asked Questions.

RESEARCH COMPLIANCE AND INTEGRITY
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RESEARCH COMPLIANCE AND INTEGRITY

Do what is right,

Facilitating Responsible Research, Innovation and Education for Global Excellence

not what is easy.

- ClinicalTrials.Gov
- Conflict of Interest
- Dual Use of Research Concern
- Export Control
- Good Clinical Practices
- Institutional Animal Care and Use Committee
- Research Misconduct
- Responsible Conduct of Research

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Please contact the Research Compliance and Integrity Office for questions or assistance.