ClinicalTrials.gov is a public registry aimed at increased transparency and improved public awareness of research. ClinicalTrials.gov captures summary protocol information before and during the clinical trial as well as summary results and adverse event information of completed clinical trials.

How do I know if my research study needs to be registered on ClinicalTrials.gov?

There are a number of regulatory bodies and other entities that require registration and results publication on ClinicalTrials.gov. One or more of these policies may apply. Clinical trials that do not meet the Food and Drug Administration Amendments Act (FDAAA) or National Institute of Health (NIH) requirements may still meet the International Committee of Medical Journal Editors (ICMJE) requirements. To determine if your clinical trial qualifies as a clinical trials that is mandated to be registered on ClinicalTrials.gov, view this decision tree.

How do I register my clinical trial on ClinicalTrials.gov?

Studies that must be registered on ClinicalTrials.gov must be registered through the University of California, San Diego (UCSDMED) organizational Protocol Registration and Results System (PRS) account. In order to register a clinical trial on ClinicalTrials.gov through the UCSD institutional PRS account, a new user account must be set up by emailing ctgov@ucsd.edu. Once a user account has been set up, studies can be registered and results can be posted on ClinicalTrials.gov.

Who is responsible for uploading all the information onto ClinicalTrials.gov?

Each clinical trial registered on ClinicalTrials.gov must have a designated Responsible Party (RP). The Responsible Party is legally responsible for registering their clinical trial on ClinicalTrials.gov, and ensuring it is accurate and up-to-date. There can be only one RP for each clinical trial registered.

If a clinical trial is Industry Initiated/Sponsored, the Industry Sponsor must serve as the Responsible Party and will be responsible to initiate and maintain the ClinicalTrials.gov account. Some institutions allow for the Industry Sponsor to transfer the Responsible Party duties to the Principal Investigator, however, this is not permitted at UCSD. UCSD, as an entity, cannot be the Responsible Party.

What are the next steps after I register my clinical trial on ClinicalTrials.gov?

To assist in the monitoring of ClinicalTrials.gov, UC San Diego will be utilizing a tool created by UCLA, PROCoM, to help manage UC San Diego’s ClinicalTrials.gov registered studies and those that are required to report results. As part of this process, you will receive reminder and follow-up emails from “RCI ClinicalTrialsGov,” however, the email address these messages will be coming from is titled “procom@mednet.ucla.edu.” Please note, these are legitimate emails used by the Research Compliance and Integrity (RCI) Office to relay important messages regarding ClinicalTrials.gov. You can reply to these messages and they will be delivered to a RCI monitored email account.

Keep an eye out for upcoming training sessions regarding ClinicalTrials.gov. For questions or additional information, please contact RCI at ctgov@ucsd.edu, (858) 822-4939 or visit the RCI ClinicalTrials.gov information webpage.
Are You Maximizing the Value of your Research Software?
BY DAVID GIBBONS

Long gone is the notion that software development is the domain of computer scientists. Today, every discipline within UC San Diego is creating novel programming applications to further their research. From cutting edge artificial intelligence applications that speed the assessment of medical images to more routine applications to aid in medical billing or population research, new software is abound! But do you know what are your options and the means to leverage software development for additional funding and income opportunities?

There are a number of intellectual property protections that can be afforded to software, including patent rights and copyrights. Patents may be sought on software (despite the recent Supreme Court rulings), but software is always subject to copyright. Copyright ownership of employee generated works is somewhat nuanced, but in general, software created in the course of your employment will belong to the UC Regents. For additional information, see the UC Copyright Ownership Policy.

You have created some software, what now are your options?

First, UC San Diego recommends you apply a copyright notice to your software, usually under a “read me” or “license” link. The recommended UC Copyright Notice is a modified form of the BSD open source license, which enables other academic and non-profit researchers to adopt and modify your software without further license. It is “modified” in that it directs commercial users to UC San Diego’s Office of Innovation and Commercialization (OIC), where a commercial end-use or distribution license may be obtained. Depending upon the utility of your software, these commercial licenses can be lucrative and provide a running stream of income to you or your laboratory for many years to come.

To get started, it is often enough just to host your software with the UC Copyright Notice and see how the market develops.

Optionally, OIC can work with you to proactively market your software to potential customers. Whether identified through marketing or directed in by the UC Copyright Notice, once a license is signed, you have a few more choices. The standard policy for copyright income at UC San Diego is 1/3 to the authors (paid each November), 1/3 to your department (paid the following Winter) and 1/3 to the campus. Another option is if the author(s) waive his/her income share, OIC can direct 85% of all licensing income back to the author’s lab as discretionary income. OIC has a number of past and current cases where this exceeds $100K per year, making for a nice reserve as you pursue new grants, upgrade lab equipment or invest in further development of your research. The income waiver is also a good option if you have a large or revolving team of software contributors for which the 1/3 income share might not be meaningful. OIC can help lay the ground work for this arrangement early, to avoid future complications.

Open Science needs Cybersecurity
BY MICHAEL CORN

As UC San Diego’s Chief Information Security Officer, researchers that work in many of the physical sciences often tell me that “my data is about objects or I’m going to publish it all, so go away you pesky cybersecurity bureaucrat!” It is true that a lot of what we security professionals worry about is keeping personally identifiable data private, after all “Confidentiality” has been one of the three pillars of information security since the late 1970’s. But the other two pillars, “Integrity” and “Accessibility” are equally as important, and in many cases more relevant. Cutting edge instrumentation can be easily knocked out of service for days or weeks resulting in unrecoverable losses. In 2018, astronomers at the University of Western Australia were trying to point their remote telescope to the location of the LIGO gravitational wave source, when they found they were under a sustained cyber-attack and unable to move the telescope (to read the story, see https://www.abc.net.au/news/2017-10-17/cyber-attack-almost-costs-team-look-at-colliding-neutron-stars/9055816). Not only can events like this ruin scientific opportunity, they can have real costs associated with them as well as placing the entire research program under stress.

There are two questions all researchers should consider:
1. What would it cost me if my laboratory instrumentation or my computing resources were unavailable?
2. Is the data I collect or produce truly backed up?

Neither of these seem like particularly security focused questions, however for the open science community, they are at the heart of protecting our research mission and lowering the level of risk from cyber-attacks. For data storage options, consider the UC San Diego Research Storage Finder, which is a tool to help researchers discover storage resources available on campus. Researchers should also consider what data must be retained and what/when research data may be destroyed (as an informational item, please see the link to an article by our UK colleagues on data retention).

For assistance, contact the UC San Diego Security Office at security@ucsd.edu or the ITS Research IT Office at research-it@ucsd.edu. For additional questions or assistance, please contact Michael Corn, Chief Information Security Officer at mcorn@ucsd.edu.
International Research Collaborations and Participation

If you have foreign activities or funding, foreign participants in the U.S. or research sponsored by Department of Defense, Homeland Security or Intelligence Agencies, you need to consider export controls at the proposal stage. There is significant federal scrutiny on universities’ foreign activities. Proposal preparation is one way to address that scrutiny and address export control risks. International collaborations and participation in research are a vital component of UC San Diego’s (UCSD) research enterprise.

There are a few steps that UCSD Principal Investigators (PI) and research administrators take at the proposal stage for research being proposed to the federal government, industry collaborators and non-profit institutions to demonstrate not only innovative science, but also a thoughtful approach that ensures the participation of our international researchers on campus or abroad as well as addresses security concerns by not collaborating with restricted entities, protecting sensitive or restricted data and having plans to address export controls should a license or technology control plan be required to support the research. These steps can include reviewing the solicitation, preparing a budget that includes costs to manage controlled unclassified information (CUI), properly completing ePD (UCSD’s internal proposal system) proposal records, including required ITAR language in the Scope of Work (demonstrating the civilian application for projects funded by the Department of Defense), and a contract officer cover letter.

When reviewing the solicitation, consider the following:

- Are there any publication or citizenship restrictions?
- Will UCSD receive or generate CUI or export controlled information, technology or materials or CUI?
- Are there specific IT cybersecurity requirements should be described in the solicitation such as NIST 800-171?

- The proposal budget should include as direct costs any IT resources required to manage project information. For CUI NIST 800-171 requirements, San Diego Super Computer Center’s Sherlock can provide a quote for the costs to implement the cybersecurity needs for the proposal.
- Will classified research be required?
- Will items need to be transferred either electronically or physically abroad?
- Is the sponsor a foreign entity or is there a foreign collaborator?
- Ensure that restricted party screening is completed on foreign collaborators listed on the proposal. All federal and most industry and non-profit funders require no debarred or restricted entities participate in sponsored research.

These are important considerations and should be brought to the attention of the UCSD Export Control Office and your UCSD contract officer at the proposal stage for advice on strategies to address those items in the proposal and to answer the export control questions in ePD.

It is imperative that when creating a new ePD record, departments take the time to correctly complete the export control questions. An affirmative response to any of the ePD export control questions, requires a special review be added for Export Control. This notifies the Export Control Office that a review is required before an award can be accepted to ensure that the award terms and conditions are acceptable, no export license is required for the research activities on that award or if a license is required that the application is started as soon as possible to obtain permission from the relevant agency to minimize impact to the research timeline. The UCSD Export Control Office works closely with researchers and the contract officers to ensure that UCSD can conduct its important research while remaining in compliance with regulations.

If a DoD agency is a sponsor of the project, the PI’s Statement of Work must include the following, “It is understood that any developmental items and specially designed parts, components, accessories and attachments fabricated under any Department of Defense award resulting from this proposal are being developed for civil and potential military applications. An example of a civil application is ______.”

DOD expects researchers to indicate in proposals why the research is fundamental research and demonstrating a civilian application illustrates that.

At the proposal stage, the contract officer can issue a cover letter to be included with the proposal that addresses any export control concerns raised in the solicitation or ePD record, including publication or citizenship restrictions.
The UC San Diego Institutional Animal Care and Use Committee (IACUC) oversees the university’s animal care and use program and is responsible for reviewing all animal use protocols, ensuring compliance with federal regulations, inspecting animal facilities and laboratories, and overseeing training and educational programs. Reviewing animal use protocols is one of the most important responsibilities of the IACUC as the review is meant to assure the implementation of the criteria established in the Public Health Service (PHS) Policy, the Animal Welfare Regulations (AWRs), and the Guide for the Care and Use of Laboratory Animals. In its review of protocols, the IACUC’s primary goal is to ensure animal welfare as well as compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

Once protocols are submitted to the IACUC, they are extensively pre-reviewed by Animal Care Program (ACP) veterinarians, IACUC Office analysts and Environment Health & Safety (EH&S) specialists. Questions from pre-reviewers are sent to the Principal Investigator (PI) and alternate contacts in a “Missing Information” email, along with instructions about how to respond and resubmit the protocol for review by the IACUC. This extensive pre-review is meant to help facilitate a more efficient review by the IACUC.

Mechanisms by which protocols may be reviewed are defined by federal regulations and depend on the nature of the protocol or amendment. The IACUC always attempts to review protocols by the most efficient mechanism possible. Please see the protocol review mechanisms below:

**Full Committee Review (FCR):**
Mechanism by which protocols are reviewed at a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that for proposals reviewed by the full committee, a simple majority vote of the members present is required for approval.

**Designated Member Administrative Review (DMA):**
Mechanism by which changes to a protocol may be approved administratively if they meet the criteria for an administrative approval.

**Veterinary Verification and Consultation (VVC):**
Mechanism by which an amendment to a protocol can be administratively approved in consultation with a veterinarian designated by the Attending Veterinarian, who is authorized by the IACUC to review and verify that the proposed amendment conforms to specific approved IACUC policies or documents.

For details about which types of protocols are eligible for which type of review, please review the IACUC Policy 39 - IACUC Protocol Review Process.

**Designated Member Review (DMR):**
Mechanism by which one or more qualified IACUC members are assigned to review a protocol outside of FCR. This may only occur after the entire IACUC has been notified of the protocols eligible for DMR and has been given at least two business days to call for any of the protocols to be reviewed by FCR.

**Designated Member Administrative Review (DMA):**
Mechanism by which changes to a protocol may be approved administratively if they meet the criteria for an administrative approval.

**Veterinary Verification and Consultation (VVC):**
Mechanism by which an amendment to a protocol can be administratively approved in consultation with a veterinarian designated by the Attending Veterinarian, who is authorized by the IACUC to review and verify that the proposed amendment conforms to specific approved IACUC policies or documents.

For details about which types of protocols are eligible for which type of review, please review the IACUC Policy 39 - IACUC Protocol Review Process.

If you have questions or concerns regarding protocol reviews, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069. The IACUC Office staff is here to assist you.
Tips for **PRESENTING SCIENTIFIC IMAGES WITH INTEGRITY**

Images should clearly and correctly represent research results. Minor image processing may be acceptable but, as depicted below there’s a fine line between enhancing an image and distorting it. **BE AWARE:** Undocumented image manipulations can lead to accusations of research misconduct. 67% of ORI’s closed research misconduct cases involved image manipulation.*

*between 2011 and 2015

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**WHAT ELSE MUST YOU DO?**

- Clearly document all changes made to an image.
- Retain the unprocessed image for your records.
- Follow journal guidelines for premissible processing.

**LEARN MORE ABOUT IMAGE PROCESSING:**

http://ori.hhs.gov/ImageProcessing

Office of Research Integrity,

https://ori.hhs.gov/infographics, March 12, 2019

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Reference: The Office of Research Integrity, Image Manipulation (PDF), https://ori.hhs.gov/sites/default/files/2017-12/6_Image_Manipulation.pdf

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RESEARCH COMPLIANCE AND INTEGRITY: FACILITATING RESEARCH, INNOVATION AND EDUCATION, RESPONSIBLY FOR GLOBAL EXCELLENCE
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. 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.
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 sessions have been scheduled:

- **International Shipping Considerations Within an Academic Research Environment Workshop**
  April 24, 2019, 11:00 – 12:30 p.m.
  Leichtag, Room 107

- **Research Data Integrity, Sensitivity and Security: Protecting Your Work in the Changing Landscape of Sponsored Research**
  May 22, 2019, 11:00 – 12:30 p.m.
  Leichtag, Room 107

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

ONLINE TRAINING AND CERTIFICATION FOR SHIPPING OF BIOLOGICAL SUBSTANCES AND DRY ICE

**BY SCOTTIE PROFITT**

Great news for researchers, the required training certification course for shipping biological materials and dry ice is now offered online through UC Learning. This self-paced course replaces the in-person training that previously was offered once per quarter. To register for the online training and certification course log in to UC Learning and search for “Shipping Biological Substance and Dry Ice.” Failure to comply with international and federal transportation regulations when shipping hazardous materials can result in civil penalties of $78,376 per occurrence and criminal penalties may include up to 10 years of imprisonment in addition (49 CFR 107.329-107.333).

Avoid costly fines and take steps to get certified today. After you complete the course and pass the online test, you will be certified to ship Biological Substances and Dry Ice for two years.

If you need assistance or have any questions, email the Outbound Team at outboundshipping@ucsd.edu.

The Outbound Team is here to help!
Recombinant DNA in Clinical Trials and the Human Gene Therapy Institutional Biosafety Committee

BY SETH MULLEN

Biological agents such as viruses, bacteria, and plasmids have been used to transfer recombinant nucleic acids into human research participants since 1989. Recently, we have seen the pace of human gene transfer (HGT) trials increase world-wide (see the table below), and we have seen five HGT products achieve Food and Drug Administration (FDA) drug approval. One of our UC San Diego (UCSD) investigators participated in clinical trials that supported the FDA approval of Talimogene laherparepvec (an oncolytic virus). UCSD remains at the forefront of HGT research. At the end of 2018, UCSD had twenty four active HGT trials.

The National Institutes of Health (NIH) is evolving with the increase of clinical human gene therapy trials with the goal of reducing the wait time and administrative tasks in approving trials. The NIH Recombinant DNA Advisory Committee (RAC) no longer reviews or registers HGT clinical trials. The responsibility for review of human gene therapy trials is now assigned to the Food and Drug Administration (FDA), the local Institutional Biosafety Committee (IBC), and the local Institutional Review Board.

In response to this change, the UCSD IBC has approved of the creation of a separate, independent IBC to review human gene transfer and human gene editing. The IBC’s goal is to assure safety of health care workers handling Investigational New Drugs and family members that may be exposed to shedding of a potentially infectious agent. The Human Gene Transfer Institutional Biosafety Committee (HGT-IBC) has been reviewing clinical protocols since the last quarter of 2018. This new committee has allowed our campus to easily adapt to the changing NIH regulations and to provide a platform for an increased number of reviews.

Environment, Health, and Safety (EH&S) has also contracted a new vendor Clinical Biosafety Services (CBS) for review of human gene transfer clinical trials and administration of the HGT IBC. CBS provides a comprehensive service by working with Clinical Coordinators to prepare the Biohazardous Use Authorization (BUA), which is submitted to document the Principal Investigator’s project and aid the committee in conducting a comprehensive risk assessment.

In collaboration, CBS and EH&S have developed an online biosafety training class for clinical setting use of recombinant DNA. This training allows health care workers the flexibility to learn biosafety principles at their own pace.

The HGT IBC looks forward to working with the leaders in clinical research as they advance the field of human gene therapy.

For more information, please visit the HGT IBC website or contact Seth Mullen, Human Gene Therapy Biosafety Officer, at ehsbio@ucsd.edu.
I have PHS research and collaborate internationally, what do I need to disclose for conflict of interest?

**Answer:** If you receive income, travel expenses or any type of reimbursement over $5,000 from a foreign entity (includes companies, foreign institutions/universities and foreign governments) in the prior twelve-month time period, you must disclose on your conflict of interest PHS disclosure form. For additional information, please see the Conflict of Interest Office Disclosure Requirements Quick Reference or email info-coi@ucsd.edu.

I am uncertain about referencing my financial interests in a publication or presentation, what should I do?

**Answer:** Transparency is key and it is recommended that you disclose your financial interests related to the funding source and research project in presentations, publications, to the audience, and your research team.

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

What are my options for Responsible Conduct of Research (RCR) training at UCSD?

**Answer:** There are a number of options, both in person and online, to complete your RCR training requirements. Remember, depending on your funding agency, the requirements for RCR training may vary. For a listing of the agency requirements (NIH, NSF and NIFA) as well as the training options, please visit the Research Compliance and Integrity Office Responsible Conduct of Research Institutional Plan for more details. Please note that RCR training is separate from human subjects training required for Institutional Review Board (IRB) submissions.

If you have a question about your particular research or circumstances, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

How do I add someone to my IACUC approved protocol?

**Answer:** Only the Principal Investigator (PI) or alternate contacts on the protocol may add, edit or delete personnel on the respective protocol. It is important that the person you are trying to add has logged into the Animal Use Protocol System at aup.ucsd.edu, as they will not exist in the IACUC personnel database until they have done so. From the Investigator menu, select “Add or Edit Personnel on Protocol” (enter your protocol #), then click “Add/Edit Personnel.” Once the personnel section of your protocol opens, click “Add Personnel.” In the “Search for User” text box, enter the person’s first or last name, then click on “Add Person” next to their name. Select all relevant responsibilities for the person on that protocol, then click on “Save Protocol Personnel.”

For assistance or additional questions, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

How do I remain within the Fundamental Research Exclusion (FRE) for purposes of export control regulations when lecturing abroad?

**Answer:** When presenting research results abroad, attending professional conferences, etc., as long as what is being presented is the result of FRE intended for publication, there is no export license requirement. However, if there is any proprietary or restricted information by the sponsor’s contract or funding mechanism, then the FRE education and conference exclusions no longer apply. Defense services will still require an export license. If you have any presentations in Cuba, Iran, North Korea, Syria or Sudan, please contact the Export Control Office for guidance as soon as you learn of the presentation as these are considered sanctioned countries and special requirements apply. Note: When you are presenting at a professional conference, that conference must be normally associated with the academic or professional subject at hand and not closed in a way that is contrary to the premise of published fundamental research.

For more information, please contact the Export Control Office at export@ucsd.edu or (858) 246-3300.

“After all, the ultimate goal of all research is not objectivity, but truth.”

—Helene Deutsch