Promoting Discussions about Research Integrity

BY MICHAEL KALICHMAN

Worries about research integrity seem to be on the rise both in science and among observers of science. The implication is that there is a threat both to the quality of the science and to perceptions of the public, policymakers, and funders of research.

Responding to this threat should be a high priority for the research community. However, it is important to add that lapses in research integrity likely occur more frequently because of ignorance or insufficient attention to good practices of research rather than willful lying, cheating, or stealing. To the extent this is true, one way to better foster a culture of integrity is by stimulating open discussion of the challenges we face and how best to meet them. In recent years, the UC San Diego Research Ethics Program (REP) has sought to meet this goal through a variety of approaches. For example, the REP maintains a twitter feed in which stories relevant to research integrity are regularly posted. These tweets can be found on the REP website home page along with a "Case of the Month" inviting readers to consider and discuss how best to respond to dilemmas in the conduct of research. In addition, the REP periodically hosts a Research Integrity Series on topics such as reproducibility of science, evolving ethical dilemmas in the practice of social science research, and dual use technology.

These efforts have most recently been supplemented by a more unusual approach to promoting discussion in science. In collaboration with the Earl Warren College Office of the Provost and support of the new Institute for Practical Ethics, the REP helped stage readings of two academic dramas. Over 250 members of our community have attended at least one of three recent staged readings of plays about misbehavior in science. On April 12 and 13, 2018, the play Purely Academic, written by an Australian computer scientist (David Abramson), was performed by an acting group consisting of some professional actors as well as students and faculty of the UC San Diego Theatre and Dance program. On May 21, 2018, the play Margin of Error, written by Will Cooper, was performed by the professional actors of the Roustabouts Theatre Co., who had last year staged a full production of the play at the Lyceum Theatre in Horton Plaza. These efforts and others have clearly sparked reflection and conversation that might not otherwise have occurred, but these are only a starting point. Members of the research community are invited to subscribe to our Twitter feed, share and discuss the monthly cases with their colleagues, attend upcoming events, and suggest other ways in which the REP can help stimulate further productive discussion.

For additional information or suggestions, please contact the Research Ethics Program.
SPONSORED RESEARCH WITH INDUSTRY

BY LISA MEREDITH

One of the areas of UC San Diego's sponsored research portfolio that has been growing in recent years is with industry sponsors such as those in the fields of pharmaceuticals, biotechnology and telecommunications. These business sectors seek to collaborate with the researchers and scientists of a world-class institution such as ours, with opportunities to share information about proprietary technologies and cutting-edge developments, and have the opportunity to be the first to access innovations that emerge out of that sponsorship. However, working with industry can be complicated, and is different from academic partnerships or sponsorships by federal grants and other funding sources. Here are some insights into the types of issues to be aware of when our researchers and their support teams are preparing to work with a for-profit sponsor.

NEGOTIATING AGREEMENT TERMS WITH INDUSTRY SPONSORS

Due to the differing missions, cultures, priorities and expectations of Universities and corporations, there is not always a perfect alignment between the objectives of University contract officers and corporate attorneys. Contracts often include complex terms such as rights to intellectual property and future licensing, and usually take longer than other types of agreements to negotiate. In order to short-cut the extended negotiating process, we encourage our researchers to involve their UC San Diego contract officers in the early stages of discussion as extra time may be required to negotiate terms that protect the interests of our researchers and the institution. Patience is still a virtue, and the results can be very rewarding! For questions about sponsored research with industry sponsors, please contact an OCGA Contract Officer or OCGA's Information Desk at OCGAinfo@ucsd.edu.

USING EPD (ELECTRONIC PROPOSAL DEVELOPMENT SYSTEM)

Like all sponsored research projects, those funded by industry must be created and routed using ePD, whether or not there is an external/formal proposal submission required by the company. This includes all extramurally funded clinical trials. While ePD helps us keep track of all proposals submitted through a formal portal or website, and those that are in response to a solicitation, ePD also functions as our institutional system of record for all potential sponsored projects, whether or not there is a required solicitation or funding announcement. For additional information regarding ePD, please visit the ePD website.

BUDGETING PRACTICES FOR INDUSTRY SPONSORS

From the onset of the business relationship, budgets for industry sponsors should be prepared to include direct and indirect costs. Industry sponsors do not know to apply indirect costs to budgets that are presented to them with the direct costs only. They assume the budget presented represents total costs proposed by UC San Diego. They will not necessarily assume that indirect costs need to be added later and they may not realize that UC San Diego is not in a position to negotiate a reduced or waived indirect cost rate for a for-profit entity. To avoid time delays and/or difficult conversations, it's best to start off on the right foot by providing a budget that includes direct and indirect costs, and has been reviewed by OCGA prior to presenting to the sponsor. For additional information regarding indirect costs with industry, please visit the UC Policies on Industry Agreements website.

For additional information regarding contracting with industry sponsors, please visit the Industry Sponsored Research website or contact Lisa Meredith at lmeredith@ucsd.edu.
UC SAN DIEGO’S ENTERPRISE SYSTEMS RENEWAL PROGRAM: INTRODUCING KUALI RESEARCH

BY NICOLE JOYCE

The Enterprise Systems Renewal (ESR) Program aims to reshape the way UC San Diego does business and is the largest technology improvement program ever undertaken at UC San Diego. The ESR is comprised of projects across multiple areas, which will optimize business practices and deliver smarter systems. The project areas include:

- Data and Analytics
- Facilities Information Management
- Human Resources and Payroll
- Research Administration
- Student and Faculty Information
- Supporting Technology Infrastructure

The Research Administration Kuali Research project is focused on the renewal of Pre-Award and Post-Award modules (now currently managed in Coeus). The Pre-Award modules include Proposal Development, Institutional Proposal, and Negotiations, while the Post-Award activities include Awards and Subawards. Kuali Research will offer increased efficiency in developing and submitting proposals as well as tracking sponsored research activity.

Kuali Research is expected to launch in Fall 2019 and is currently in the business process improvements phase of the project. Throughout this phase, the project team is working with the subject matter experts and the Lean Bench (a select set of campus expert practitioners of Lead Six Sigma methodology) to review and improve Research Administration processes that will inform configuration of the Kuali Research System.

For questions or to learn more about Kuali Research, please contact Nicole Joyce, Kuali Research Project Change Management Lead, at (858) 534-9112 or njoyce@ucsd.edu, or visit the ESR website.
Governments and agencies around the world maintain lists of individuals and organizations that have been “black listed” for one reason or another. In U.S. Export Control regulations, where the aim is to protect the national security and foreign policy goals of the U.S., these individuals and entities are known as Restricted Parties.

The U.S. Government alone has multiple lists where certain interactions with these Restricted Parties is illegal without proper prior authorization. The types of interactions that are regulated include, but are not limited to, providing goods, financial support or services. The types of entities that may be designated as Restricted Parties include terrorist supporting groups, weapons proliferators, export violators and drug traffickers. In addition, some Universities and research institutions are listed for their activities that are counter to national security. Additionally, individuals with an affiliation, such as employment or appointment, with a university or organization listed as a Restricted Party are bound by the same restrictions as that entity.

The fines for transacting with Restricted Parties without the proper authorization are between $250,000 and $1,000,000 per violation. In 2015, PayPal was fined $7.7 million by the U.S. Government for hundreds of transactions it facilitated with Restricted Parties and sanctioned countries. Apart from the financial cost, violations could result in significant damage to the University’s reputation and future research sponsorship as well.

Given the number of international researchers who study abroad, along with the global collaborations and interactions that allow UC San Diego to be a top tier research University, the potential risk of engaging with a Restricted Party, as well as the incentive to mitigate that risk while maintaining an open academic environment, comes into clear focus.

The first step to mitigating these risks is identifying Restricted Parties prior to the point of engaging with them. The University of California system uses the Restricted Party Screening (RPS) tool at www.VisualCompliance.com to quickly and effectively screen multiple public lists and identify any Restricted Parties of concern. Faculty, staff and students with active UCSD.EDU email addresses can sign up for and use this tool free of cost. Additional information regarding RPS can be found on the Export Control website. For information on how to complete RPS, please log into the UC Learning Center and search for “Restricted Party Screening Training.”

There are multiple activities where you, as a UC San Diego representative, may engage with foreign parties and should use RPS to ensure compliance, including:

- Collaborations such as MTAs, NDAs or Technology Transfer
- Payments for goods or services (cash, check, wire transfer, or other means)
- Contributions and donations of funds, materials or support (e.g., gifts)
- International shipments, either physical or electronic
- Access to export restricted data or equipment

Any matching hits or alerts returned from the RPS should be escalated to the Export Control Office at export@ucsd.edu, for further review. The Export Control Office can advise on how to proceed while maintaining compliance with the regulations.

With proper awareness of Restricted Parties, diligence in screening and collaboration with the Export Control Office, the University has mitigated millions of dollars in potential risk over the past five years. Every person researching, working or studying at UC San Diego plays a role in Export Control compliance, and preserving and furthering the University’s mission and vision of education, research and public service.

For additional information, please visit the Export Control website.
New Guidance on International Travel and Cybersecurity

BY MICHAEL CORN

Tossing a laptop and a passport in your shoulder bag used to be all it took to embark on an international trip. Unfortunately, U.S. researchers and University staff are finding this to no longer be the case. For several years now, it has become increasingly common for travelers to have their laptops and mobile devices seized for inspection while traveling to China and other countries, not only by the other countries agencies, but also U.S. customs and border control agents. As of March 2017, the Department of Homeland Security requires all passengers traveling on direct flights to the U.S. from selected airports in Egypt, Turkey, Saudi Arabia, Kuwait, Morocco, Qatar and the United Arab Emirate, to store all personal electronic devices larger than cell or smart phones in checked baggage. Items such as laptops, iPads and cameras are not allowed in carry-on luggage.

However, whether you are traveling abroad for University business or pleasure, there are a handful of simple precautions you can take to ensure your data, privacy and accounts are secure, even when traveling to countries where hostile governments control the network. Below are some simple recommendations to follow (please see the updated International Travel Cybersecurity website for a full set of recommendations):

- If you are traveling abroad, take a loaner laptop or tablet, and do not reconnect it to any network upon your return. Both UCSD Health and ITS have laptop loaner programs.
- Make sure you have a secure backup of your system and data before you travel.
- Do not connect to any accounts without a two-step (Multi-Factor) login. Most personal services such as Facebook or Gmail support a two-step login. The two-step process has already been implemented at UC San Diego Health and the campus will be implementing this process in the Fall.
- Always use the Campus or Health System VPN service when connecting from abroad.
- Enable encryption on your device(s) before you travel: Use Filevault on a Mac and Bitlocker on a PC. Both are free and built into the computer (if you’re traveling with a University owned laptop, encryption should already be enabled, check with your IT support or bring the device to ITS or Health System Service Desk to confirm).
- Always change your passwords when you return (even if you use two-step login) but not from the computer you traveled with.

Traveling with electronics can be challenging. Fundamentally, in many parts of the world you should assume that any data you travel with is likely to be stolen or in transit over insecure networks. Laptops, phones, and tablets lost or stolen overseas have no chance of being recovered. Don’t take highly confidential or unrecoverable data with you. If you work on high confidential information and/or export controlled data or technology, please contact the Export Control Office at export@ucsd.edu, before you travel. The Information Security Office (ISO) is also available to assist with securing your data and equipment prior to travel. Please contact the ISO at security@ucsd.edu.

HUMAN RESEARCH PROTECTIONS PROGRAM UPDATES

BY ANTHONY MAGIT

APPROVAL DATES: The UC San Diego Human Research Protections Program (HRPP) is committed to protecting research subjects while providing opportunities to ease the burden on our researchers. To provide the maximal time for approval for new studies requiring full IRB committee review, the approval date for new studies is now the date when all criteria for approval have been satisfied. This will be the date of the convened IRB meeting if all criteria are satisfied at the time of the meeting. If review of the continuing review submission occurs within 30 days of the current expiration date, the anniversary date of last approval will be used rather than the date of the meeting where continuing was approved, as was the previous practice. Please refer to the HRPP FAQs for more information.

The majority of non-federally funded minimal risk studies will have 3-year approval for initial and continuing reviews. For more information regarding study eligibility, please see the Initial Application Review for 3-Year Approval.

RAPID CYCLE REVIEW: Eligibility for “Rapid Cycle Review” (RCV) for a subset of clinical trials has been expanded from Phase 3 and 4 clinical trials involving adults to Phase 2b studies and qualifying pediatric studies. RCV review acknowledges that commercially sponsored, multi-center studies with FDA oversight have undergone rigorous scientific review prior to being submitted to the IRB. For more information regarding “Rapid Cycle Review” please see the Rapid Cycle Review Checklist and IRB Standard Operating Policy and Procedures 3.10.

EXEMPT STUDIES: Additional revisions also include expanded eligibility for Exempt Studies. Expanded eligibility for Exempt Studies will affect research on educational practices.

EXPANDED ACCESS: The use of experimental treatments and devices for treatment of patients outside of a research protocol is available through the FDA process of emergency Investigational New Drug (IND) application or other expanded access programs. To learn more about expanded access for drugs, please see the Investigator Initiated Clinical Trials/IND Applications Fact Sheet. For expanded access for investigational devices, please see the Expanded Access Investigational Device Fact Sheet.

The HRPP will be updating its procedures in the coming months and providing additional educational opportunities for investigators and research staff. Please consult the HRPP website for new information.
Conflict of Interest PHS Disclosure Requirements

BY JENNIFER J. FORD

Federal regulations and the University of California policy on “Disclosure of Financial Interests and Management of Conflicts of Interests, Public Health Services Research Awards”, require researchers who receive funding from the Public Health Services (PHS), inclusive of subawards or agencies who have adopted the PHS financial conflict of interest regulations, to disclose certain financial interests. The PHS regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS research activities will be free from bias resulting from a researcher’s financial interests.

A financial interest is anything of monetary value, whether that value can be easily determined or not, that is held by the researcher, their spouse or registered domestic partner, and dependent children. Under the PHS definitions, a financial interest becomes significant when it:

- Reasonably appears to be related to or is in the same field of expertise as the researcher’s Institutional Responsibilities.

  Institutional Responsibilities include the teaching/education, research, outreach, clinical services, training and University and public service performed on behalf of the University and directly related to those credentials, expertise and achievements upon which the researcher’s University appointment/employment is based, and

- Meets any of the PHS reporting categories and thresholds.

Researchers must disclose their significant financial interests related to their institutional responsibilities that meet the following thresholds:

- **Publicly-Traded Entity:** Any income received from an entity during the 12 months prior to disclosure which, when combined with the value of any equity interest held in the entity, exceeds $5,000. This may include salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value. These activities include providing consulting services, serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal; reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- **Non-Publicly Traded Entity:** Any compensation received from an entity during the 12 months prior to disclosure that exceeds $5,000 or any equity interest of any amount held in that entity. This may include stock or stock options in a company that is developing, manufacturing or selling products or providing services used in the researcher’s clinical practice, teaching, research, administrative or committee responsibilities.

- **Intellectual Property Rights and Interests:** Intellectual property income (e.g. royalties or licensing fees) received from an entity, other than the UC Regents, during the 12 months prior to disclosure that exceeds $5,000. This may include receipt of income such as royalties or licensing fees from an organization other than the UC Regents for use or sale of patented or copyrighted intellectual property (e.g. software, textbooks, or other scholarly works).

- **Travel:** Sponsored travel or reimbursements made to or on behalf of the researcher, exceeding $5,000 during the twelve months prior to disclosure, from a for-profit or non-profit entity related to the researcher’s institutional responsibilities. This includes travel paid for or reimbursed by a professional society, a company for which the researcher is consulting, or any other for-profit or non-profit organization. Travel disclosures only applies to the researcher’s significant financial interests. Travel significant financial interests do not include:

  - Mutual funds or other investment vehicles such as retirement funds as long as the researcher does not directly control the investment decisions.

  - Payment made to the researcher by UC for salary, stipends, royalties, honoraria, reimbursement of expenses or any other remuneration received from the University.

  - Income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.

  - Travel paid for or reimbursed by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.

  - Travel paid for or reimbursed by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.

  - Intellectual property income (e.g. royalties or licensing fees) received from an entity, other than the UC Regents, during the 12 months prior to disclosure that exceeds $5,000. This may include receipt of income such as royalties or licensing fees from an organization other than the UC Regents for use or sale of patented or copyrighted intellectual property (e.g. software, textbooks, or other scholarly works).

All researchers, including senior-key personnel, are required to take PHS compliant training prior to engaging in PHS-funded research. The training is also required immediately if a researcher is new to the institution, if the UC policies change in a way that affects researcher requirements, if UC finds that a researcher is noncompliant with any policy or management plan and at least every four years. This training requirement also applies for other funding agencies that have adopted the PHS regulations. The training must be completed in the UC Learning Center. To access the UC Learning Center, from Blink select “Personal Tools” and then log in with your single sign-on. In the search field of the UC Learning Center, enter “COI-PHS.” If you have any questions regarding the requirement to complete this course, please email coitraining@ucsd.edu.

For additional information, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.
Cybercriminals use phishing—a type of social engineering—to manipulate people into doing what they want. Social engineering is at the heart of all phishing attacks, especially those conducted via e-mail. Technology makes phishing easy. Setting up and operating a phishing attack is fast, inexpensive, and low risk: any cybercriminal with an e-mail address can launch one.

The education sector has seen a rise in social engineering–based attacks.* Students, staff, and faculty all suffered losses when personal data and research were disclosed to unauthorized parties. Phishing played a part in more than 40% of these breaches. Knowing what you’re up against can help you be more secure. Here are a few things you can do to guard against phishing attacks:

- **Limit what you share online.** The less you share about yourself, the smaller the target you are for a phishing attack. Cybercriminals use information you post online to learn how to gain your trust.
- **Protect your credentials.** No legitimate company or organization will ask for your username and password or other personal information via e-mail. The University definitely won’t. Still not sure if the e-mail is a phish? Contact your IT help desk.
- **Beware of attachments.** E-mail attachments are the most common vector for malicious software. When you get a message with an attachment, delete it unless you are expecting it and are absolutely certain it is legitimate. If you’re not sure, call the sender at a number you know is legitimate to check.

- **Confirm identities.** Phishing messages can look official. Cybercriminals steal organization and company identities, including e-mail addresses, logos, and URLs that are close to the links they’re trying to imitate. There’s nothing to stop them from impersonating the university, financial institutions, retailers, a wide range of other service providers, or even someone you know.
- **Trust your instincts.** If you get a suspicious message that claims to be from an agency or service provider, use your browser to manually locate the organization online and contact them via the website, e-mail, or telephone number that you looked up – not what was provided in the message.
- **Check the sender.** Check the sender’s e-mail address. Any correspondence from an organization should come from an organizational e-mail address. A notice from your college or university is unlikely to come from IThelpdesk@yahoo.com.
- **Take your time.** If a message states that you must act immediately or lose access, do not comply. Phishing attempts frequently threaten a loss of service unless you do something. Cybercriminals want you to react without thinking; an urgent call to action makes you more likely to cooperate.

- **Don’t click links in suspicious messages.** If you don’t trust the e-mail (or text message or post), don’t trust the links in it either. Beware of links that are hidden by URL shorteners or text like “Click Here.” They may link to a phishing site or a form designed to steal your username and password.

For other effective cybersecurity habits, check out UC’s “Make It a Habit” webpage.
See the full Phishing Awareness Toolkit.


This article has been adapted from an Educause Review blog, “Don’t Let a Phishing Scam Reel You In.” © EDUCAUSE, licensed under the Creative Commons BY-NC-SA 4.0 International license.
Do I need to worry about Restricted Parties if I’m only engaging in Fundamental Research?

**Answer:** Fundamental Research is defined as “basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community”, and not subject to Export Control regulations. This regulatory carve out is called the Fundamental Research Exclusion and the research must meet specific criteria to qualify. So while interacting with Restricted Parties in the course of Fundamental Research is possible, the circumstances for qualifying for and applying this Exclusion are nuanced and oftentimes not desirable to the investigator. The Export Control Office can work with you to decide the best way to move forward.

What is a financial interest?

**Answer:** A financial interest is anything of monetary value, including a fiduciary relationship with an outside entity. Financial interests are the most important component or components of a conflict of interest for researchers. Some examples include, but are not limited to:

- Salaried or unsalaried positions with the sponsor or entity
- Scientific advisory board memberships
- Vested or non-vested stock or stock options
- Gifts
- Loans
- Travel payments/reimbursements
- Income received through honoraria or consulting

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

What is a conflict of interest?

**Answer:** For all employees at UC San Diego, the basic definition of 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 employee’s actions or judgments in the administration, management, or performance of their professional activities. For researchers at UC San Diego, the definition is more specific as it refers to a situation in which outside financial interests may compromise, or have the appearance of compromising, a researcher’s professional actions or judgments in the design, conduct, or reporting of their research results.

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

---

**Q&A**

Ask the Questions . . .

**What do I do if I receive an Interinstitutional Assurance for animal research from an external institution with which I am collaborating?**

**Answer:** If you will be performing NIH funded animal research at UC San Diego as part of a collaboration with an outside entity that does not have its own animal care and use program, and the outside entity is the prime awardee, UC San Diego can serve as the Assured Institution for the animal research. Once you receive the signed Interinstitutional Assurance from your collaborator, please route the completed form (sections I. and II.A. should be completed) to the UC San Diego Institutional Animal Care and Use Committee (IACUC) Office with the relevant UC San Diego IACUC approved protocol number on which the animal work will be performed. The form should be sent to iacuc@ucsd.edu. The IACUC Office staff will confirm the approval date of the protocol and obtain the signature of the IACUC Chairperson as well as the Institutional Official and return the signed form to you as soon as possible.

For additional information, please see OLAW instructions regarding Interinstitutional Assurances. For assistance, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.