UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
Office of Research Affairs

September 2018 | Volume 1, Issue 2

Newsletter

Research Development: Supporting Faculty Funding Pursuits

BY SHARON FRANKS, WENDY GROVES, SHANNON MUIR, AND LYNSEY FITZPATRICK

In today's intensely competitive research funding environment, generating a winning proposal requires more than technical expertise, clever ideas and writing skill. UC San Diego's recently expanded Research Proposal Development Service (RPDS) can give Principal Investigators (PIs) a leg up in the competition.

INSIDE THIS ISSUE

Research Development encompasses a set of strategic, proactive, catalytic, and capacity-building activities designed to aid individual faculty members, teams of researchers, and central research administrations in attracting extramural research funding, creating relationships, and developing and implementing strategies that increase institutional competitiveness. When working with research development professionals for the first time, some PIs wonder: Can someone without expertise in my field of research really help me craft a stronger proposal? The answer is unequivocally: Yes! From competitive intelligence to detailed, constructive feedback on drafts, RPDS offers faculty many types of support that surprise and consistently impress them.

RD@UC SAN DIEGO

For ten years, RPDS has been helping UC San Diego faculty craft more persuasive, more competitive proposals. As a centralized research-development unit, our focus is on the development of complex, multi-million-dollar, interdisciplinary proposals. The newly expanded RPDS team works directly with PIs and their collaborators to support proposal development. In addition to large-proposal development, we also help early-career faculty members develop their granstmanship skills. We often work with colleagues who are based in campus departments or divisions and whose responsibilities also include aspects of proposal development. Housed within the Office of Research Affairs, RPDS also manages the campus-wide process for limited-submission funding opportunities.

CUSTOMIZED SUPPORT

The support RPDS provides to faculty varies greatly from project to project and depends in large part on the specific needs of the investigators involved. Some PIs need help evaluating the fit of research they intend to propose with particular funding opportunities. Some want help assessing their chances of success and ideas about how to improve their competitiveness. Others request help identifying and recruiting collaborators on and off campus, often to address specific needs, such as broader impacts, program evaluation, data management, dissemination of results, diversity and inclusion, and development of professional looking graphics, to give just a few examples.

RPDS can also help with logistics, for example, preparing a proposal-development timeline for a large, complex project, selecting a file-sharing system appropriate for a team's needs, and setting agendas for team meetings. Investigators at all levels benefit from our critical constructive feedback on drafts, including on graphics (i.e., figures, tables, illustrations, images) as well as text. For investigators who feel they might gain insight from reviewing a previously successful proposal to a particular sponsor or program, we can assist in finding and obtaining such material.

ASK US ANYTHING

Often, we in RPDS serve as general-purpose, go-to allies. Wondering how to go about requesting matching funds from campus? How to approach a program officer… or nudge one who seems to be ignoring your e-mails to respond? Want help planning for and running a productive red-team review meeting? Ensuring that your team is well prepared for an important site visit? Ask us! Want to learn about strategies and tools to discover potentially relevant funding opportunities in a timely manner? Want help analyzing reviews of a declined proposal and prioritizing ways to craft a potentially more successful resubmission? We can help. Drawn from some of the daily inquiries we receive, these examples may give a sense of what's "fair game" to ask of us. When we don't know the answers, we'll do our best to find out who does.

Limited Submissions

What happens when NIH, NSF, and other public or private sponsors limit UC San Diego to a single proposal submission from our campus? RPDS manages a process to alert the campus community to such limited-submission funding opportunities. Interested investigators submit pre-applications, and faculty committees appointed by the Academic Senate recommend the most competitive pre-applications, based on sponsor criteria. The committees also generate brief comments that are sent to prospective applicants. To view current opportunities, visit ucsd.inforeadv4.com. There you'll also find links to subscribe to mail lists to ensure you receive all future opportunity announcements.

Have a proposal development question? Visit the RPDS website, contact us at rapids@ucsd.edu, or give us a call.

Proposal Development:
Sharon Franks: (858) 822-3452
Wendy Groves: (858) 534-9022
Shannon Muir: (858) 822-3144
Limited Submissions:
Lynsey Fitzpatrick: (858) 822-3277

CAN YOU BE BLAMED IF YOUR COLLABORATOR FAKES THEIR DATA?

BY MICHAEL KALICHMAN

A frequent topic in responsible conduct of research courses is the importance of transparent sharing of information and data. However, invariably someone notes that asking a collaborator to see her or his data implies a lack of trust and is destructive to a collegial relationship. Until recently, the most viable counterargument was to emphasize that such sharing should not first be because of lack of trust. Instead, doing so is justified by the potential insights gained by collaborators each

looking at data generated by others, even if in very different fields of research. While all of these arguments remain true, a new dimension is raised by a recent research misconduct court finding, summarized on the Retraction Watch Website.

In brief, a May 2018 judicial decision emphasized that someone can be found guilty of research misconduct if fraudulent data were reported recklessly, even if neither intentionally or knowingly. Specifically, this was the finding upheld on appeal for a long-running case involving Christian Kreipke, Ph.D., now a former Professor of Anatomy and Cell Biology at Wayne State University in Detroit. While it appears to be generally understood that Dr. Kreipke did not himself falsify or fabricate research data, he was found guilty on the basis that he had been reckless in not sufficiently tracking and monitoring the data produced by others working in his research group. As noted in the Retraction Watch article, "Perhaps the most significant fact in the case is that Kreipke did not falsify or fabricate any data. Nor did he know any data was false." Instead, he was found guilty because "… he didn't detect the falsification done by another scientist." It is likely many scientists would argue that this is an unfair or even untenable standard, but that doesn't change the fact that legally the risk has increased that you could be held liable for insufficient attention to data contributed by collaborators that later turn out to be fraudulent. In addition to being identified as someone guilty of research misconduct, and requirements for retraction of publications containing fraudulent data, Dr. Kreipke has been barred from receiving federal funding and from serving in any advisory capacity for the Public Health Service for five years. Dr. Kreipke has appealed this decision and contends his government-wide sanction is excessive and that he was not afforded the right to contest the debarment.

For additional information, please see the Administrative Law Judge's decision.

What is F&A and Why is it Important?

BY JEFFREY WARNER

Facilities and Administrative (F&A) costs, also referred to as Indirect Costs or overhead, are costs that are not specifically identifiable for a particular project or program. However, F&A costs are real expenses for research, instruction, and other sponsored activities at UC San Diego, and include building use, operation and maintenance, compliance training, and departmental administration. One can think of F&A as supporting expenses that would not need to exist or be used as extensively if UC San Diego did not conduct research.

The present research cost systems at universities, including payment of F&A costs, is based on the enduring and fruitful partnership between universities and extramural sponsors that grew out of World War II. Sponsors rely on universities to conduct research aimed at meeting national goals in areas such as health care and national defense, and develop intellectual property that will benefit the public (e.g., new medicines). However, universities assume the liability for developing and maintaining the infrastructure necessary to have a successful research program, not extramural sponsors. As such, universities must seek reimbursement from extramural sponsors of F&A costs that go to support that infrastructure.

UC San Diego recently executed a new F&A rate agreement with the U.S. Department of Health and Human Services (DHHS), UC San Diego's Cognizant Federal Agency. UC San Diego saw an escalation in our F&A rate, which is great for the University, but did you know that these higher rates still do not cover the full cost of research. The federal government has restricted the administrative portion of F&A rates to 26% since 1991, even with the ever increasing federal regulations and reporting requirements. Moreover, the growth of UC San Diego with regard to the acquisition of new specialized equipment, construction of new buildings, and renovation of older ones is significantly greater than the escalation of our F&A rate. UC San Diego is not alone as in fiscal year 2015, universities across the country contributed more than $4.9 billion in F&A expenditures not reimbursed by the extramural sponsors.

UC San Diego is a nonprofit institute of higher education and research that has limited financial resources. If F&A is not appropriately budgeted in research projects, UC San Diego would run the risk of not being able to build new facilities or maintain existing ones, substandard compliance with governmental regulations due to a lack of administrative support, and/or a reduction in the pipeline of trained researchers in the workforce as a result of reduced training opportunities at universities. Any reduction in F&A is a real cut of costs that reduces the amount of research that universities and their personnel can conduct to improve the lives of people across the world. It is up to research administrators to ensure that F&A is appropriately budgeted in proposals per institutional and sponsor guidelines.

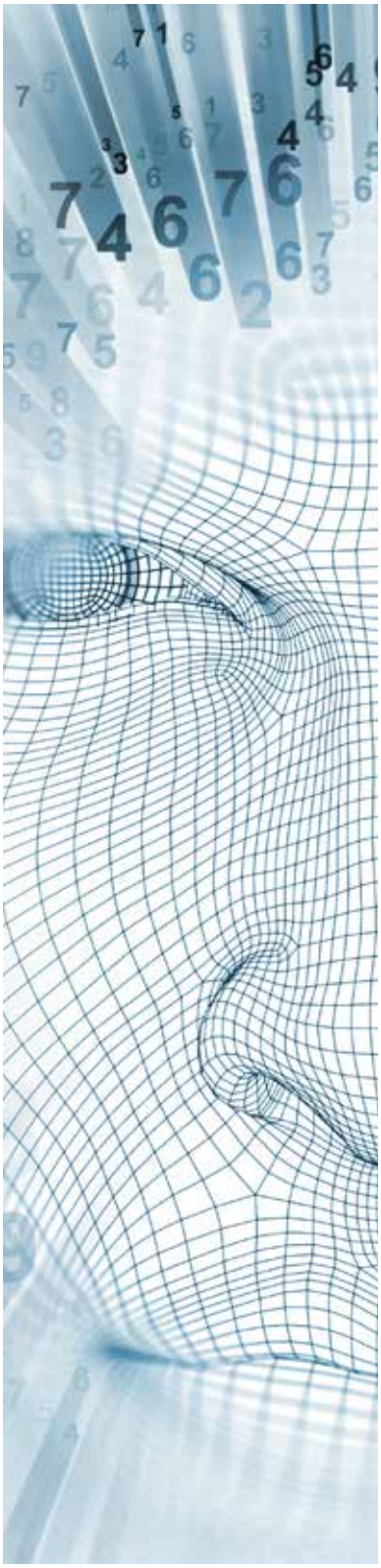
For more information about F&A at UC San Diego, please contact your OCGA Contract and Grant Officer or visit the following blink pages:

- Facilities & Administrative (F&A)/Indirect Costs
- Budgets - Indirect Costs (IDC)

Reference: Association of American Universities and the Association of Public and Land-Grant Universities Primer on F&A.

RECRUITMENT, UNDUE INFLUENCE AND COERCION IN HUMAN SUBJECTS RESEARCH

BY ANTHONY MAGIT, MD, MPH



UCSD human subjects recruitment is the first step in engaging a potential subject in a research study and is governed by regulatory and ethical considerations (UCSD HRPP SOPP 3.17). The recruitment aspect of a research protocol should provide enough information to the prospective subject to decide whether to pursue participation in the study without inappropriate influence. The plan for recruitment must be included in the research plan that is submitted to the IRB, including a description of recruitment materials. The content of flyers, phone scripts, media announcements and other means of communication used for recruitment is evaluated to assure that messaging does not constitute undue influence, i.e. advertise an excessive amount of compensation to offset the level of risk or imply a positive benefit from participation when the phase or design of the study does not support this claim, i.e. therapeutic misconception.

Undue influence may describe a situation where a research subject's social or financial situation places them at risk of agreeing to participate in a study due to the level of compensation. A relatively excessive amount of compensation to participate in a study has the potential of altering a subject's ability to objectively interpret the risks and benefits of participation. Although the distinction between undue influence and coercion may not be clear, coercion is considered to exist when a subject is motivated to participate in a study due to the threat of harm for not participating. Potential harm exists in a variety of situations and relationships (e.g. student-teacher, supervisor-employee, and the eligibility criteria for a study should address the possibility of coercion.

As a large research institution, UC San Diego has to potential to create opportunities for coercion related to subject recruitment that requires active management. Students (undergraduate, graduate, and medical students), and employees of UC San Diego (administrative, clerical, nursing, laboratory technicians, postdoctoral scholars and house staff, etc.) are considered vulnerable to coercion. Such individuals may feel some pressure to participate in a researcher's study, especially if the requesting researcher is their supervisor, instructor, or someone who might be in a position to influence their future. Investigators must exercise great caution to avoid even the appearance of pressuring such individuals into enrollment or continued participation. When a UC San Diego research investigator wishes to include such individuals as human subjects, he or she must indicate so on the initial application or request a modification to an approved protocol.

In general, the IRB does not permit recruitment of employees from the investigator's own laboratory, department, or office, as a matter of local policy. However, for minimal risk studies, the IRB will consider requests for waivers of this policy on a case-by-case basis. Students from an investigator's own laboratory or class may not be actively recruited into their research studies, but such students may freely volunteer to participate, to the same extent as anyone is free to respond to general recruitment advertisements.

When students participate in research studies for class credit, they should be provided alternative methods of getting that credit that do not include participating in an experiment, and it is the investigator's responsibility to determine that those alternative methods exist. Wherever possible, the student should be provided with a choice of research opportunities, including some not under the investigator. The IRB may require the informed consent form to state whether alternatives are available and what are the alternatives. The investigator must provide assurance that a student's experimental results, performance, or any confidential data, will not be given to whomever is grading the student, except for stating whether the student participated or not (unless the approved study design permits this disclosure). Recruitment advertisements need to be approved by the IRB according to previously stated policy. Hospital volunteers are free to participate in research studies, but volunteers working in the investigators own area or laboratory should be afforded similar protections as described above for students.

For questions or additional information, please contact the HRPP at hrpp@ucsd.edu or (858) 246-4777.

CONFLICT OF INTEREST: RESEARCHER'S OBLIGATION TO DISCLOSE

BY JENNIFER J. FORD

In a recent NIH Guide Notice and a letter from Francis S. Collins, NIH Director, the NIH reminded Researchers of their obligations to disclose their financial interests. 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.

Researchers must disclose their significant financial interests related to their institutional responsibilities under PHS funded research. The Conflict of Interest Office website includes the criteria on what is considered a significant financial interest. Some common requirements that may be overlooked are:

- Researchers must disclose the financial interest (i.e. equity or income) of a spouse, registered domestic partner, or dependent children of the Researcher.
- Researchers must include the combined financial interest of the Researcher and their spouse, registered domestic partner, or dependent children.
- Researchers must disclose the equity of a formed private company, even if it has no value.
- Researchers, including subrecipient researchers, must disclose financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).
- Researchers must disclose reimbursed or sponsored travel (exceeding $5,000 per entity) that reasonably appears to be related to the Researchers institutional responsibilities. Researchers must update their financial interest disclosures within 30 days of any undisclosed sponsored travel.
- Researchers must disclose any significant financial interest related to their institutional responsibilities annually and within 30 days if there is any new or change in significant financial interests occurring prior to or during the period of an award.

Keep in mind that having an outside financial interest is not automatically a conflict of interest. It is also important to remember that some financial interests do not meet the definition or threshold of disclosable financial interest. Almost all disclosed financial interests and resulting conflicts of interest can either be reduced, eliminated, or managed, so that the research project can be accepted and funded by the proposed sponsor. The conflict of interest disclosure forms can be found on the Conflict of Interest Office website and should be emailed to coiforms@ucsd.edu.

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

THE ENTERPRISE SYSTEMS RENEWAL: Why Business Process Improvements Before System Configurations Matter

BY NICOLE JOYCE

The Enterprise Systems Renewal (ESR) Program is a multi-year initiative that will reshape the way UC San Diego does business. With input from subject matter experts from central offices and academic departments across campus, the program's focus is optimization of core business and administrative practices as well as delivery of new systems that will effectively meet the needs of our growing university. Under this initiative the Kuali Research Project will augment the way we conduct Research Administration at UC San Diego and is aligned with the ESR program's goals and objectives.

As we work toward the Kuali Research system implementation, something we often forget is that technology and software is meant to support business processes and not the other way around. It is easy to find ourselves asking "how will a system do (fill in the blank)?" before we have even examined what our business needs are first. That is because most of the time our processes are invisible to us. However, by utilizing proven business process improvement methodology like Lean Six Sigma, we are able to capture and document them, which further allows us to work through improvements.

Lean Six Sigma allows us to define the opportunity for improvement, measure our past performance, analyze the root causes of performance issues, improve the process by addressing these issues and control the process to ensure process performance. This is known as the DMAIC model (Define, Measure, Analyze, Improve, and Control). In following the DMAIC model and applying a variety of tools from the Lean Six Sigma tool belt, we are able to make our processes more efficient and reduce the variation in what we do and how we do it. This not only helps create a unified best practice that can be adopted institutionally, but it also makes configuration of enterprise systems, like Kuali, much more manageable and assists in making sure we build a system that supports the best possible business processes.

For more information on the ESR Program, Kuali Research Project and/or Business Process Improvement, email esr-researchadmin@ucsd.edu or contact Nicole Joyce, Kuali Research Change Lead and Change Practitioner at njoyce@ucsd.edu.

INTERNATIONAL RESEARCH

PRIVACY UPDATE: TWO NEW LAWS!

BY PEGAH PARSI

The European Union's General Data Protection Regulation (GDPR) took effect on May 25, 2018. In June, the California legislature hurriedly passed the comprehensive California Consumer Privacy Act of 2018 (CaCPA), which goes into effect in January 2020. This article examines the impact these privacy laws have on UC San Diego researchers.

GENERAL DATA PROTECTION REGULATION

The GDPR is a sweeping privacy law that will impact how organizations, including universities, inside and outside the European Union (EU), handle personal data of people within the European Economic Area (EEA). Among other things, the law impacts research participant information, databanks, and coded data.

In all cases where UC San Diego researchers handle any personal data from the EEA[1], they must comply with the GDPR. Researchers who do any of the following can expect to be impacted:

- Conduct studies in the EEA,
- Analyze data from the EEA or from European cohorts,
- Collaborate with entities in the EEA or receive data from EEA sites,
- Conduct telemedicine studies,
- Use EEA research databases,
- Pay collaborators in the EEA, or
- Any other use or processing of data from individuals within the EEA

The concept of "personal data" is broad and encompasses any information relating to a person who can be identified, directly or indirectly. Personal data include the obvious data elements like names, device identifiers, and health and genetic information, but they also encompass less obvious information, such as race and ethnicity, political opinion, and union membership. The GDPR also applies to coded data ("pseudonymized data") where the key can identify individual subjects.

DATA MINIMIZATION AND SECURITY

Researchers should conduct a data minimization assessment (similar to the "minimum necessary" concept under HIPAA) for every study, and use the least amount of and least intrusive data when possible. If the research can be accomplished using pseudonymized data, then pseudonymized data must be used. Data should be maintained only as long as required for the specific research purpose.

Appropriate security measures must also be in place to protect personal data at all stages of processing, from collection, to storage, use and disclosure, and destruction or archiving.

CONSENT AND TRANSPARENCY

Researchers must articulate specific research purposes to individuals, and any use of data must be in line with that stated purpose. Consent for use of personal data must be freely given, specific, informed, unambiguous, and a clear indication of wishes. GDPR requires additional consent elements not captured by current standard IRB consent templates, such as a statement that GDPR applies to the subjects' data, purpose of the data processing, data subject rights, and consent for secondary use, among other requirements.

The UC San Diego IRB is working with privacy officers and UCOP to provide detailed guidance on consent language.

A NOTE ABOUT GDPR AND HIPAA

Note that compliance with HIPAA is not necessarily sufficient to meet GDPR requirements. Conversely, compliance with the GDPR is also not sufficient for HIPAA. They cover different types of entities and data and specify different assessments, documentation, and security standards.

For example, the GDPR concepts of pseudonymization and anonymization are not the same as the HIPAA Safe Harbor concept of "de-identification." Under HIPAA, if a researcher removes 18 identifiers from a dataset, that dataset is considered "de-identified" for HIPAA Safe Harbor purposes. However, because "personal data" under the GDPR is so broad and the anonymization standard is so high, removal of these identifiers is insufficient to render that dataset anonymized.

THE CALIFORNIA CONSUMER PRIVACY ACT

The California Consumer Privacy Act (CaCPA) is modeled in spirit on the GDPR, giving California residents control over their personal data and rights related to that data. CaCPA will take effect in January 2020 and may impact researchers who collaborate with industry partners, or use external service providers, such as third party apps, devices, cloud storage solutions, and the like.

CaCPA is still being amended for technical corrections and clarifications, but the essence of the law will likely remain unchanged. Key details of CaCPA include:

- Businesses must reveal what personal data they have and what they use the data for,
- Individuals can ask businesses to 1) not sell their data, or 2) delete their data,
- Individuals can sue businesses for violations, and
- The Attorney General may levy fines for violations

Both the GDPR and CaCPA require that organizations know what data they have and where that data are. While awaiting detailed guidance, researchers should conduct an inventory of the personal data they handle, regardless of where they are stored.

RESOURCES

These two laws signal a major shift in paradigm; so, most organizations are working through the intricacies and ambiguities while awaiting detailed guidance. A UC San Diego privacy group is assessing the impact of the laws on operations. In the meantime, researchers should assess their studies' data needs and reduce their data processing where possible.

The Campus Privacy Office's GDPR introductory training sessions are listed here. The UC Office of General Counsel has provided GDPR advisories for researchers. Stay tuned for more information on CaCPA. For specific consultations, please contact the Campus Privacy Officer at privacyofficer@ucsd.edu or the Health Sciences Privacy office at privacy@ucsd.edu.

[1] Note that the GDPR does NOT apply to individuals in the U.S., including European citizens who are in the U.S.

REGULATORY AND POLICY UPDATES RELATED TO INTERACTIONS WITH FOREIGN COUNTRIES AND ENTITIES

BY BRITTANY WHITING

There are a number of federal law and policy changes coming from Congress, the White House, and federal agencies with regards to foreign countries and entities that impact academic institutions. Below is a summary of the changes. In addition, to address questions regarding how these changing laws, regulations and policies will impact research, a Town Hall will be held at UC San Diego on October 17, 2018, with Sandra Brown, Vice Chancellor for Research, Angela Phillip Diaz, Executive Director of Government Research Relations and Brittany Whiting, Export Control Officer. Details on the time and location will be distributed in the near future.

SUMMARY OF CHANGES:

1. **The John S. McCain National Defense Authorization Act FY19 (NDAA):** On August 13, 2018, the NDAA was signed for Fiscal Year 2019 and government agencies are promulgating regulations and policies defining the specific requirements for Department of Defense (DOD), other federal agencies and federal contractors, like UC San Diego, regarding national security, export controls and restrictions regarding a number of Chinese companies. The sections to note are:

Section 871
PROHIBITION ON ACQUISITION OF SENSITIVE MATERIALS FROM NON-ALLIED FOREIGN NATIONS
Addresses sourcing or exporting materials such as samarium-cobalt magnets; neodymium-iron-boron magnets; tungsten metal powder; and tungsten heavy alloy or any finished or semi-finished component containing tungsten heavy alloy with restricted countries: North Korea; China; Russia; and Iran.

Section 885
PROCESS TO LIMIT FOREIGN ACCESS TO TECHNOLOGY
Requires DOD to develop procedures to limit foreign access to technologies through grants, contracts, cooperative agreements or other transactions based on national security interests. The DOD must draft a report by September 1, 2019, to specify how it will address this requirement.

Section 889
PROHIBITION ON CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT
Federal agencies may not enter into a contract (or extend or renew a contract) with an entity that uses any equipment, system, or service that uses covered telecommunications, surveillance or other infrastructure equipment relating to the following companies:

- ► Telecommunications: Huawei Technologies Company, ZTE Corporation, or any subsidiary or affiliate of these entities
- ► Video surveillance and telecommunications equipment produced by: Hytera Communications Corporation, Dahua Technology Company, Hangzhou Technology Company or any subsidiary or affiliate of these entities

Federal contractors, including UC San Diego, must comply with this prohibition by August 13, 2020. Failure to comply may jeopardize future federal funding. After broad campus consultation and preliminary guidance from federal agencies regarding the regulations for restricted Chinese entities, for a six-month period (August 13, 2018 to February 12, 2019), UC

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INTERNATIONAL RESEARCH (continued)

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San Diego will not accept or enter into any engagement, agreement, gift, or funds from entities listed in section 889 or their subsidiaries.

Section 1049
CRITICAL TECHNOLOGIES LIST Requires DOD to develop a list of critical technologies to maintain U.S. national security advantage.

Section 1286
INITIATIVE TO SUPPORT PROTECTION OF NATIONAL SECURITY ACADEMIC RESEARCHERS FROM UNDUE INFLUENCE AND OTHER SECURITY THREATS
The Secretary of Defense shall … establish an initiative to work with academic institutions who perform defense research and engineering activities (1) to support protection of intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security; (2) to limit undue influence, including through foreign talent programs, by countries to exploit United States technology within the Department of Defense research, science and technology, and innovation enterprise; and (3) to support efforts toward development of domestic talent in relevant scientific and engineering fields. This section goes on to state, ...(5) Regulations and procedures will be implemented for government and academic organizations and personnel to support the goals of the initiative; and that are consistent with policies that protect open and scientific exchange in fundamental research. The requirements of the initiative include policies to limit or prohibit funding provided by the Department of Defense for institutions or individual researchers who knowingly violate regulations developed under the initiative, including regulations relating to foreign talent programs.

UC San Diego is following this initiative closely and will continue to work closely with researchers on campus that receive Department of Defense funding to convey information on these evolving policies and regulations. If there are questions regarding talents programs or if you have been contacted by a federal government agency regarding foreign activities, please contact the Export Control Office.

Section 1741
EXPORT CONTROL REFORM ACT OF 2018 (Included in NDAA)
The new Act codifies previous export control law and regulations. However, it specifically addresses emerging critical technologies, calling for a modified process to identify and regulate them. Section 1753(b)(7) identifies academic institutions for specific enforcement attention.

2. **June 19, 2018 Congressional letter to Department of Education Secretary re: Huawei and Universities:** The letter indicates that Huawei Technologies has formed a series of research partnerships with 50 Universities in the United States that threaten national security. Congress calls on Department of Education to immediately request (and require) information from U.S. universities involved in any partnership with Huawei. If researchers or staff are contacted by any federal agency officials conducting inquiries, please contact Brittany Whiting, Export Control Officer, to coordinate a response with campus officials.

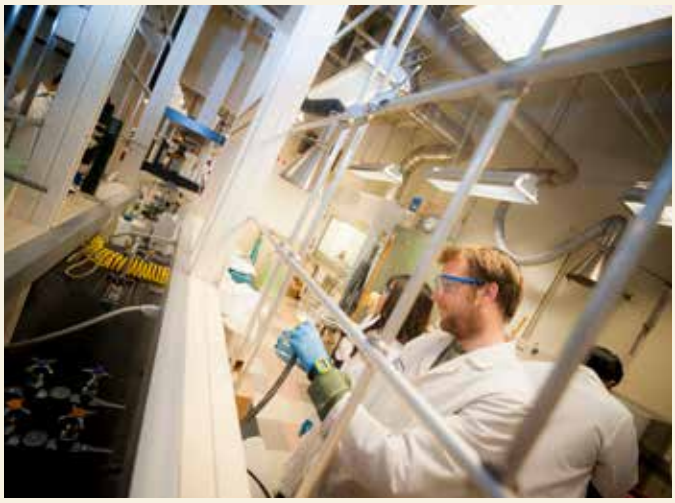
3. **June 2018 White House Report, "How China's Economic Aggression Threatens the Technologies and Intellectual Property of the United States and the World":** Highlights to note from the report are listed below. See the full report for additional details.

- How China Seeks to Acquire Technologies and Intellectual Property and Capture Industries of the Future: Chinese industrial policy seeks to "introduce, digest, absorb, and re-innovate" technologies and intellectual property (IP) from around the world.
- Chinese Nationals in the U.S. as Non-Traditional Information Collectors: How Chinese nationals collect information of all types to return to China.
- Recruitment of Science, Technology, Business, and Finance Talent: China's talent recruitment strategically complements China's efforts to target emerging high technology industries and involves well-established Chinese government programs and large, stable funding streams to recruit both Chinese and non-Chinese talent, particularly in Science, Technology, Engineering and Math (STEM) areas.

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

Principal Investigator Responsibilities in Animal Research

BY THE IACUC OFFICE



When using animal models in research at UC San Diego, there is a great deal of information that the Principal Investigator (PI) and research staff are responsible for knowing. UC San Diego's Policy on the Use of Animals in Research and Teaching PPM 100-6 and the UCSD Institutional Animal Care and Use Committee (IACUC), along with federal laws and regulations, assign a number of responsibilities to the Principal Investigator who is granted the privilege of using animals in research.

An early part of this process is submitting an online Animal Use Protocol to the UC San Diego IACUC. The IACUC website provides a number of resources, including Principal Investigator requirements, responsibilities and information needed to submit an animal use protocol. When a PI submits a protocol for review, he/she acknowledges that by clicking the "Submit for Review" button within the protocol, it is equivalent to an electronic signature and that he/she is providing their assurance for the humane care and use of animals used in teaching and research.

Below is a list of the PI's Assurances for the humane care and use of animals used in teaching and research:

1. I agree to abide by PHS Policy, USDA Regulations, UC San Diego policies for the care and use of animals, the provisions of the ILAR Guide to the Care and Use of Laboratory Animals, and all other federal, state, and local laws and regulations governing the use of animals in research.
2. I understand that emergency veterinary care will be administered to animals showing evidence of pain or illness, in addition to routine veterinary care as prescribed for individual species. I understand that it is my responsibility to provide current and updated emergency contact information for personnel who must be contacted in an animal emergency. I understand that any unanticipated pain or distress must be reported to the veterinarian or his/her designee.
3. I assure that I have consulted a veterinarian in the preparation of this proposal, if it includes procedures that could cause pain and distress to a vertebrate animal.
4. I declare that all experiments involving live animals will be performed under my supervision or that of another qualified biomedical scientist listed on this protocol.
5. I certify that all personnel having direct animal contact, including myself, have been trained in humane and scientifically acceptable procedures in animal handling, administration of anesthetics, analgesics, and euthanasia to be used in this project.
6. I certify that all personnel in this project will attend the mandatory Orientation to Research at UCSD class and all other mandatory classes as determined by the Personnel Qualifications Form of each individual.
7. I understand that the use of hazardous agents in animals may only be initiated after approval from EH&S.
8. I certify that all personnel working on this protocol will be given the opportunity to participate in the Medical Monitoring Program at the Center for Occupational and Environmental Medicine. All personnel on this protocol will be made aware of the hazards involving the use of live animals and tissues.
9. I understand that I must submit an amendment for any proposed changes to this protocol and wait for IACUC approval before beginning the work.
10. I understand that should I use the project described in this application as a basis for a proposal for funding (either extramural or intramural), it is my responsibility to ensure that the description of animal use in such funding proposals are identical in principle to that contained in this application.

When using animal models in research at UC San Diego, there is a great deal of information that the Principal Investigator (PI) and research staff are responsible for knowing.

11. I understand it is the responsibility of the PI to ensure the safe and ethical conduct of all research conducted under this protocol, and to assure that all research is carried out following federal, state, local, and UC San Diego policies governing animal research.
12. I certify that I will maintain complete, up-to-date and accessible records of procedures on animals as required by policy and regulation.
13. I declare that the information provided in the accompanying protocol is accurate to the best of my knowledge.
14. I certify that all state, federal and international permits for the use of the animals described in this protocol are in place (or will be in place before studies begin) including those permits mandated by the Department of Commerce, Marine Mammal Protection Act, Bureau of Land Management, National Forest Service, and foreign countries.

Please keep in mind that the IACUC Office staff is here to assist you. If you have questions or concerns regarding the above PI responsibilities, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

USING A THUMB DRIVE?

BY MICHAEL CORN

Savvy travelers often use thumb drives (also known as USB drives or USB memory sticks) as a convenient way to back up or transfer data when traveling. As thumb drives have gained in capacity and have relatively low costs, i.e., a 64 GB drive can be purchased for under $15, their ability to hold large data sets or entire research projects makes them all the more tempting to use. The allure of these devices hides several concerns that should not be ignored, both when using thumb drives at home or traveling.

As can be seen in a recent FBI flash notification, some Chinese made thumb drives have been shown to contain malware, in this instance, bank credential-stealing malware. This is by no means a unique occurrence; last year even IBM shipped thumb drives to customers that were pre-infected with malware. Though the vast majority of thumb drives are safe, it is strongly recommended to avoid thumb drives manufactured in China or Eastern Europe.

While the risk from malware on thumb drives is real, a more important consideration is how easy they are to lose or steal. You get home and open your bag to grab your thumb drive, and it's gone. Did you lose it at the airport, in the cab, the hotel room or in the street? If the thumb drive is lost, the data is lost and it will not be recovered. If you're traveling to or through countries that are known to search electronic equipment, your thumb drive may simply be taken from you and not returned. Thumb drives are not considered an appropriate medium for the transfer or storage of personally identifiable information or any UC San Diego regulated data. If you lose a thumb drive with confidential UC San Diego data, contact security@ucsd.edu immediately.

Alternatives and Use Recommendations to Thumb Drives

If you are traveling within the United States or to locations where you will have network access, rely on campus provided cloud services such as UC San Diego's Gdrive or OneDrive to store and access your data. Always use the campus VPN when traveling (in some countries using the campus VPN will enable you to access services such as Google that are otherwise unavailable). You can even ensure the security of your VPN account by using the two-step login (also known as multi-factor authentication) by enrolling at twostep.ucsd.edu.

Guidelines for Thumb Drive Use

If you must use a thumb drive, follow these guidelines:

- Use American-made thumb drives from reputable manufacturers
- Ask the IT staff in your Department/unit to scan the drive for malware before inserting into your computer
- If the drive is lost or handled by someone else while traveling, do not insert it into your computer, but assume it has been compromised
- Purchase an encrypted password protected drive

If you have questions or need assistance, please contact the Information Assurance Office at security@ucsd.edu or the ITS Service Desk at servicedesk@ucsd.edu.

Q&A

Ask the Questions . . .

Are Responsible Employees required to report disclosures about Prohibited Conduct received in the course of conducting Institutional Review Board ("IRB") approved or certified exempt human subject research?

Answer: Responsible Employees are not required to report disclosures of Prohibited Conduct made by an individual when participating in human subjects research that has either been approved by an Institutional Review Board (IRB) or certified as exempt from IRB review under one or more of the categories in 45 CFR 46.104. When conducting research that is designed, or likely, to elicit information about sexual violence or sexual harassment, researchers are strongly encouraged to provide information about University and community resources to research participants. Disclosures of incidents of alleged Prohibited Conduct made during an individual's participation as a subject in an IRB–approved or certified exempt human subjects research protocol will not be considered notice to the University for purposes of triggering its obligation to investigate. The reporting exemption that this section describes (for disclosures made by an individual when participating in IRB-approved or certified exempt human subjects research) does NOT apply to disclosures made to research personnel outside of the course of the research protocol (e.g., to faculty during office hours or while providing academic advising). This reporting exemption does not affect mandatory reporting obligations under federal, state, or local laws, such as the Clery Act and the California Child Abuse and Neglect Reporting Act (CANRA), and other policies or laws that require reporting to campus or local law enforcement, or Child Protective Services.

For more information, please see the Policy.

I have a financial interest in a company that wants to apply for an SBIR or STTR grant, can I participate?

Answer: Yes, but not in both the research being conducted by the company and research to be conducted at UC San Diego, as the academic collaborator. The Principal Investigator for the small business and the Principal Investigator for the subcontracted work to UC San Diego must be different individuals. If a UC San Diego Principal Investigator has significant financial interest in a small business entity, that individual may not bring research into his/her own laboratory under a SBIR or STTR subcontract from that same small business unless the Independent Review Committee (IRC) reviews the disclosure to determine if the interest(s) can be managed.

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

Are there any restrictions or problems in communicating with or assisting foreign governments on my research being conducted at UC San Diego?

Answer: There are some considerations which specifically apply to communicating with foreign governments. If the research involves International Traffic in Arms Regulations (ITAR) technical data and you are training or assisting the government representative to be able to use it in a manner which constitutes a "defense service", this would trigger a license requirement. This applies even if the data is already in the public domain. Data not yet in the public domain and provided to a foreign defense organization constitutes a defense service and requires a Technical Assistance Agreement export license authorization. Note that even dual use technical data (items that can be used for both civil and military applications) being provided to a foreign defense organization for a defense purpose may constitute a defense service.

For more information, please contact the Export Control Office at export@ucsd.edu.

Science brings society to the next level; ethics keep us there.

— Dr. Hal Simeroth

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