

# Newsletter



## Single IRB Requirements for Human Subjects Research as of January 20, 2020

BY KIP KANTELO



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Multisite research studies increasingly involve arrangements for a single Institutional Review Board (sIRB) to review for all or most sites. Such arrangements reduce redundancy and variation but require additional coordination and communication to account for state law or other local context.

### WHEN IS sIRB REQUIRED?

The National Institutes of Health (NIH) [released a policy](#) in June 2016 requiring that domestic sites conducting the same NIH-supported research protocol rely on a single IRB with few exceptions. That policy took effect in January 2018. Since then, and with the revision of the NIH form set, proposals have had to describe compliance with the policy.

Effective January 20, 2020, the NIH policy will be subsumed by a broader regulatory change. This will apply a similar requirement for domestic sites across all federally-supported cooperative research except for research supported by the Department of Justice (DOJ). The Steps to Take section below will discuss how this change might affect different types of studies.

This regulatory change allows fewer exceptions than the NIH policy. Under the new requirement, the only exceptions are either by decision of the funding agency or if other laws (such as tribal law) require additional IRB reviews. The new requirement also applies to a broader range of sites. Under the NIH policy, only those domestic sites performing the same protocol had to follow the policy. The new requirement is not based on the protocol but on the award.

Aside from the Department of Health & Human Services (HHS), federal agencies have not released guidance about how they will apply or enforce this requirement.

The UC San Diego (UCSD) IRB office will share new information when possible. If your funding agencies make you aware of new expectations, please do not hesitate to pass that information along to the UCSD IRB office as well (see below for reliance contact information).

### WHAT IS sIRB REVIEW?

An sIRB review is when one IRB performs the ethical/scientific review for multiple sites. That IRB might be:

- The IRB of one of the institutions involved
- A commercial IRB not tied to any one institution
- A central IRB created by the funding agency or a consortium of institutions.

There is no consistent national standard for how this works. In general, the sIRB will perform one review of the protocol and master documents (such as the consent form). As sites sign on to a study, the sIRB will not re-review the protocol but will perform specific reviews of each site. The purpose of those reviews is to take local context into account and approve minimally-tailored local versions of the master documents.

The institutions need to document the sIRB arrangement and the division of responsibilities between the reviewing IRB and the relying institution. It is important to remember that even when relying on sIRB services from another institution, each investigator and their institution remain responsible for proper conduct of the research according to the approved protocol, federal and state laws and institutional policies. This includes:

- Obtaining other necessary institutional approvals, such as for radiation safety or conflicts of interest

- sIRB review and approval of modifications to the research
- Continuing sIRB review and approval when required (for example, annually)
- Managing problems, events and new information and, as required, reporting those to the sIRB.

### LOCAL CONTEXT

As noted above, the sIRB has to take local context into account. This refers to differences among sites such as:

- State Laws (e.g., age of majority, privacy, surrogate consent)
- Demographics (e.g., prevalence of certain language groups)
- Qualifications & Training of the study team
- Variations in standard of care across institutions
- Sub-studies done at certain sites
- Certain consent boilerplate (e.g., injury information, local contact)
- Institutional policy (e.g., structure under HIPAA, injury policy)

Local context does not refer to the preferences or internal procedures of the UCSD IRB or its staff.

However, UCSD IRB staff play an important role when relying on an sIRB. This includes tracking the University's portfolio of research, negotiating reliance agreements, contributing local context information, and helping coordinate with other institutional reviews. When a UCSD IRB is the sIRB, our IRB staff are also a resource to the UCSD study teams and to the IRB staff of relying institutions.

### SINGLE IRB OPTIONS

Aside from the federal requirements, industry or other sponsors may ask if you are able to rely on an sIRB.

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UCSD encourages sIRB arrangements in those cases as well.

UCSD has several existing multi-protocol arrangements with local institutions, across the UC system, for several disease-specific networks, and with the NCI Central IRB. UCSD also has master agreements with the two major commercial IRBs, Advarra and WCG.

UCSD is a signatory to the [SMART IRB](#) agreement. Under SMART IRB, any combination of the 600+ signatory institutions can enter into an sIRB arrangement for any study regardless of funding source without negotiating a separate agreement. Use of the SMART IRB agreement is UCSD's preferred arrangement when a project does not fall under another existing arrangement.

### STEPS TO TAKE FOR YOUR PROJECTS

- You do not need to do anything differently if your project is federally-supported but had an IRB approval prior to January 21, 2019, or is already using an sIRB, or is not federally-supported.
- If your federally-supported cooperative project first had (or will have) an IRB approval on or between January 21, 2019 and January 19, 2020, you should ask your lead site or funding agency about the requirement UNLESS the project is already

in compliance with the NIH sIRB policy, or is supported by an HHS agency other than NIH, or is supported by DOJ (these three cases are known exceptions to the new requirement).

- If you will be part of a new proposal for federally-supported cooperative research, the new regulation will usually apply. Discuss with your collaborating sites, funding agency and coordinating center to:
  - Develop a communications plan
  - Identify possible sIRB options
  - Find out if an existing reliance agreement (e.g., SMART IRB) can be used
  - Plan resources for coordination and communication among sites and with the sIRB during the study
- Before planning or agreeing to an sIRB arrangement, reach out to UCSD IRB staff early using our dedicated reliance email address: [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).
  - Don't wait until you're funded or about to start the project. Reach out while developing the proposal!

It is important to communicate early and often with your collaborators and with the UC San Diego IRB office. For questions, please contact the UCSD IRB at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).

## Mile Marker 1 on the Innovation Superhighway

BY DAVID GIBBONS



UC San Diego is in a state of transformation with innovation woven throughout new and upcoming programs and facilities across campus. From undergraduate programs and incubator space at [The Basement](#), lean launch programs and mentoring at [The Institute for the Global Entrepreneur](#), to the new public-private partnership at the [Center for Novel Therapeutics](#), innovation is a core theme. With all of this excitement, it can be easy to get caught up in the wave, but do you know where to begin to ensure your innovation experience does not end up on the rocks?

A solid intellectual property foundation is the key to any long term innovative endeavor. Protecting the underlying ideas in your research preserves a potential monopoly in its future use which investors and commercial

partners will rely upon to justify their continued support of your work. To ensure you have a basic understanding of intellectual property (IP) and how it is protected and commercialized, the University of California has prepared a short on-line course, "[Intellectual Property Essentials for Academic Researchers](#)", that is free of charge and accessible to all faculty, staff and students. You are encouraged to check out the course and peruse its contents. You do not need to take the course from start-to finish, rather, navigate the list of topics for quick answers to questions you may have.

As always, reach out to the Office of Innovation & Commercialization any time you have a question about protecting and/or commercializing your research. Please contact [invent@ucsd.edu](mailto:invent@ucsd.edu) or (858) 534-5815.

## NEW REVISED COMMON RULE INFORMED CONSENT FORM REGULATIONS

BY MONIQUE TEIXEIRA

The "Revised Common Rule" requires clinical trials conducted or supported by a Common Rule department or agency to post a copy of the approved informed consent form to a publicly available federal website within a specific timeframe. This new regulation applies to all clinical trials initiated on or after January 21, 2019.

Per the Revised Common Rule, a clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

The informed consent form must be posted on a publicly available federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit. This requirement applies to any clinical trials conducted or supported by a Common Rule department or agency as listed below:

- Department of Homeland Security
- Department of Agriculture
- Department of Energy
- National Aeronautics and Space Administration
- Department of Commerce
- Social Security Administration
- Agency for International Development
- Office of the Director of National Intelligence

- Department of Housing and Urban Development
- Department of Transportation
- Department of Defense
- Department of Education
- Department of Veterans Affairs
- Environmental Protection Agency
- Department of Health and Human Services
- Department of Justice
- Department of Labor
- Central Intelligence Agency
- Consumer Product Safety Commission
- National Science Foundation

The informed consent form must be made publicly available on a federal website that will be established as a repository for such informed consent forms.

Currently there are two options:

- ClinicalTrials.gov: This may be the easiest choice if the clinical trial is already registered on ClinicalTrials.gov.
- Regulations.gov: This is a federal government website that acts as an internet portal and document repository. The [UC San Diego Research Compliance and Integrity Office ClinicalTrials.gov webpage](#) has recently been updated with this regulation and has instructions on how to upload the informed consent form to each publicly available federal website.

For questions or additional information, please contact the Research Compliance and Integrity Office at [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu), (858) 822-4939.

## Winter May Not Be Coming, But Cybersecurity Maturity Model Certification Is!

BY MICHAEL CORN

UC San Diego researchers receive more than 1000 grants and contracts from the Department of Defense (DoD) across both campus and the health system. If you are one of those researchers, then you will be affected by forthcoming DoD regulations (by June 2020, you may begin to see the CMMC requirements as part of Requests for Information). The new regulations will require institutions to precertify that they meet the standards set forth in the [Cybersecurity Maturity Model Certification](#) (CMMC) framework. CMMC is a tiered framework and future DoD requests for proposals will specify the tier level that must be precertified in order to even apply for the contract. At this time, only contracts will be covered by the CMMC requirements.

Certification is obtained by engaging a DoD designated auditor (for a fee) to assess the environment in which work will be performed and data stored. It is important to know that CMMC requirements are challenging to meet. They require rigorous and extensive documentation for everything related to how data is collected, stored, accessed and shared as well as how the network and computers used to interact with the data will be monitored.

The university recognizes that meeting CMMC level two and above requires an institutional effort and is beyond the capabilities of even a well-funded research lab. For example, level two requires that all systems involved with a project are secured, managed and enforce a separation of duties between those that manage the systems and the users of the systems. It is anticipated that all DoD related work at UC San Diego will require a minimum of level two certification and many will require level three (data requiring level three is generally referred to as Controlled Unclassified Information (CUI)). Level three projects may require the use of virtual desktops that do not permit local storage of data, aggressive logging of all system activity and interactions, multi-factor authentication, and a host of network and endpoint protections.

The new CMMC requirements may impact your scientific workflow and will require significant advanced planning. Supporting these projects will require a partnership between your laboratory and your local and campus IT support. At this time, the only existing environment at UC San Diego that could receive a level three certification is the [San Diego Supercomputer Center's Sherlock](#) environment. The campus is exploring partnerships with other institutions and vendors for additional options. For additional information, see the [CMMC Frequently Asked Questions](#).

If you have questions about CMMC, please contact Mike Corn, Chief Information Security Office, [mcorn@ucsd.edu](mailto:mcorn@ucsd.edu), (858) 246-4223.



## REPORTING ANIMAL WELFARE CONCERNS

BY THE IACUC OFFICE

The privilege to use live animals for the advancement of science and medicine carries with it the responsibility to follow all applicable laws, policies and procedures concerning animal welfare. UC San Diego is committed to the humane treatment of all animals used in research and teaching. All Principal Investigators (PIs) who use live animals for research or teaching must assure that their lab will adhere to the animal use protocol approved by the Institutional Animal Care and Use Committee (IACUC). The UC San Diego 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, overseeing training and educational programs, and investigating animal welfare concerns.

Federal law and Public Health Service (PHS) Policy require the IACUC to investigate all reports of animal welfare concerns, that reports can be made anonymously and that there will be protection from reprisal or discrimination. Anyone who is aware of potential violations to animal care and use regulations or who observes misuse or mistreatment of animals is strongly encouraged to report their concerns. Reports can be made by phone, email, campus or postal mail. Reports can also be made through the [UC San Diego Whistleblower](#) hotline at (877) 319-0265.

The IACUC encourages anyone with an animal welfare concern to first address their concern with their

supervisor. If discussing the concern with their supervisor is not possible or not successful, the IACUC should be contacted through one of the methods listed at the end of this article. Reports should contain as much information as possible so the IACUC can adequately investigate the concern. Details such as the time, date, and place of the event of concern, names of people involved, the species and number of animals affected, and any other details that may help the IACUC investigate, should be included in the report. Reports can be made anonymously by withholding the name of the reporting party or by requesting anonymity in the report.

Posters that outline the UC San Diego policy on Reporting Animal Concerns are posted at the entrance to each animal facility and in animal use areas.

Reports can be submitted to:

- The IACUC Office at [iacuc@ucsd.edu](mailto:iacuc@ucsd.edu), (858) 534-6069 or mail code 0071.
  - The UC San Diego Hotline at (877) 319-0265.
- For additional information, please see the following:
- [UC San Diego Institutional Animal Care and Use Committee \(IACUC\) Policy on Reporting Animal Concerns](#)
  - [Reporting Animal Care and Use Concerns](#)
  - [UCSD Hotline Information](#)

For questions, please contact the IACUC Office at [iacuc@ucsd.edu](mailto:iacuc@ucsd.edu) or (858) 534-6069.

# Food and Drug Administration: The Big Five Common Compliance Hurdles in Clinical Research

BY JEFFREY SIMMONS

Out of the many Food and Drug Administration (FDA) regulations governing clinical research, there are five common compliance issues that may trigger FDA sanctions. Enforcement of the FDA regulations can be in the form of warning letters, debarments, and in the extreme, shutting down the research. Many of these problems surface because of inadequate recordkeeping or a lack training. The figure<sup>1</sup> below summarizes the five most common issues that can trigger an FDA enforcement action.

ISSUES	ACTUAL FDA WARNING LETTER CITATIONS	OTHER PROBLEMS
1. Informed Consent	"Failure to obtain informed consent from study subjects"	Improperly executed informed consent, Outdated informed consent form used
2. Protocol Deviations & Violations	"Failure to inform the IRB of change to the protocol" "Failure to conduct your study in accordance with the approved protocol"	Changes made to the protocol without first notifying the sponsor & IRB
3. Drugs & Device Accountability	"Failure to maintain device accountability records"	Inadequate record keeping related to investigational drugs & devices
4. Inadequate Medical Records	"Failure to maintain adequate and accurate records" "Failure to maintain accurate, complete, and current subject records"	Trial related source documentation is not properly recorded which can lead to problems especially if the subject suffers an adverse event
5. IRB approval not obtained	"Failure to adhere to the general and specific responsibilities of a clinical investigator"	IRB approval not obtained or lapse in IRB approval (no continuing review)

The following suggestions will help you and your study team avoid these common hurdles.

- Informed consent:** Verify that the consent form is current and stamped by the Institutional Review Board (IRB) prior to use. If someone other than the Principal Investigator (PI) serves as the person obtaining consent from the study subject, verify that they are trained according to regulatory agency requirements and are designated to obtain consent in the study protocol and/or in a Delegation of Responsibility Log for the study. Make sure the study subject signs and dates the consent form. The person obtaining consent must do the same. If the IRB approved consent form for the study requires the printed name of the participant and/or time of consent, be sure to include them on the consent form. See, Human Research Protection Program (HRPP) [SOPP 3.4 Informed Consent](#).
- Protocol deviations and violations:** The protocol sets forth what takes place during the study. This includes time sequences, tests, enrollment criteria, etc. When there is any deviation to the protocol, it must be reported in writing to the IRB and sponsor for approval. This includes over-enrolling or increasing the enrollment for the study. Include a copy of all correspondence regarding the deviation in the regulatory binder. See, HRPP [SOPP 3.14 Protocol and Regulatory Violations and Exceptions](#).
- Drug and device accountability:** Keep all appropriate records in order to carefully track investigational drugs. Sponsors will generally require that surplus investigational drugs be returned to them at the end of the study. Keep track each time the investigational or study drug is

dispensed, to whom it is being given, and the amount dispensed. This includes returning the unused investigational drug to the sponsor or destroying the investigational drug if directed by the sponsor. The use of a [Device or Drug Accountability Log and a Drug Dispensing Log](#) is recommended for record keeping purposes, even when using the Investigational Drug Service at UC San Diego. See, [UCSDHP 341.1 Investigational Drugs, Devices and Procedures](#).

- Inadequate medical (research) records:** Trial related documentation is imperative. It is the source which verifies the findings of the study. Improper recordkeeping can also jeopardize the safety of a study subject. "This can lead to problems if the subject suffers an adverse event because a baseline for the subject's condition is not clearly established." (Purner, Clinical Trials Compliance, September 2003). See, [ICH Harmonised Guideline Integrated Addendum To ICH E6\(R1\): Guideline For Good Clinical Practice ICH E6\(R2\) ICH Consensus Guideline: Section 4.9](#).
- IRB approval not obtained:** Approval from the IRB is required on an annual basis following the initial study approval by the IRB. Be sure to know the initial approval date and the date for submitting documents for continuing review by the IRB. The Principal Investigator must obtain continuing review and approval by the IRB one year after the date the trial is approved. See, [HRPP SOPP 3.11 Continuing Review](#).

For FDA related questions, please contact the UC San Diego Health Sciences Office of Compliance and Privacy at (858) 657-7487 or [hscomply@ucsd.edu](mailto:hscomply@ucsd.edu).

<sup>1</sup>See, [Portier, Wendy and Claire Dunne. "Current challenges and opportunities in clinical research compliance." The Ochsner journal vol. 6.1 \(2006\): 21-4, \(citing Clinical Trials Compliance \(June 2003\) FDA warning letter signals move to tighten oversight. Strategies for Medicare Billing, FDA, and Research Compliance, 2, 1-12\) \(citing also, Clinical Trials Compliance \(September 2003\) "Sidestepping the five most common FDA compliance pitfalls," 2\(9\):1-3, Strategies for Medicare Billing, FDA, and Research Compliance\).](#)

## INTERNATIONAL RESEARCH

# Export Control Red Flags When Buying Items

BY BRITTANY WHITING



UC San Diego purchases equipment, materials, technology and software to conduct research and aid the campus in operating. Purchasing an item is the one of the first opportunities to identify if the item is restricted and requires export licensing or a technology control plan. If you are purchasing items, you are responsible for identifying red flags and escalating to the UC San Diego Export Control Office.

## WHAT ARE THE REQUIREMENTS?

The United States (U.S.) Government regulates the export of certain items and technologies, not only for physical exports but also for providing technology to foreign persons in the U.S., referred to as deemed exports. Export licenses are required depending on the particular jurisdiction for the law and agency, the specific export classification of the item (which includes the reason for export control), the country of destination, the recipient, end user(s) and end use. If a license is required, the license or a license exception/exemption must be in place prior to export.

## WHAT ARE YOU RESPONSIBLE FOR IN PURCHASING?

- Identify export restricted equipment and material at the time of purchase
- Identify export compliance language
- Ensure the vendor has been screened on [Visual Compliance](#) and verified not to be a restricted entity; and
- HOLD and escalate any issues for the Export Control Office to review

## EXAMPLES OF EXPORT RESTRICTED ITEMS (THIS LIST IS NOT ALL INCLUSIVE)

Nuclear materials, Ceramic based or Composite Materials, Certain Pathogenic Micro-organisms or Toxins, Neural Computers, Optical ICs, Cryptographic enabling equipment or technology, Infrared and High speed Cameras, Lasers and Sensors, Pressure Transducers, Navigation and Avionics, Military (ITAR) and/or space technology (e.g., satellites, propellants, military vehicles, vessels, and equipment), Field-Programmable Gate Array (FPGA), Robots, Radar, Gallium nitride substrates and UAVs.

## RED FLAG WORDS

Watch for particular terminology on the vendor website, product information, quote, or in the correspondence with the vendor that may indicate an item might be export controlled. Phrases include:

- “No foreign nationals” or “Restricted to US persons only”
- “ITAR” or “USML category” or “Military strategic goods”
- “Export restricted”
- “EAR” or “ECCN”
- “US only” or “no foreign national access”

Escalate these red flags and requests from vendors to sign an “end use” statement to the UC San Diego Export Control Office at [export@ucsd.edu](mailto:export@ucsd.edu).

## REQUESTING EXPORT CLASSIFICATION

- **Is the item a defense article or considered strategic goods?** If yes, please provide the International Traffic in Arms Regulation (ITAR) category (roman numeral).
- **Is the item a dual use article controlled under the Export Administration Regulations (EAR)?** If yes, please provide the Export Control Classification Number (ECCN).

Escalate all ITAR and dual use EAR items other than EAR99 to the UC San Diego Export Control Office for review at [export@ucsd.edu](mailto:export@ucsd.edu).

## IMPACT TO RESEARCH

If the export classification is obtained as part of the quote or purchasing process, it is possible to identify other options for equipment or materials to be purchased that are not export restricted, allowing for greater access by the research team in the lab or for international research. There may be delays to research if export licenses have not been obtained for foreign person access or for export of shipments. This could lead to potential delays to research timelines.

## TECHNOLOGY CONTROL PLANS

Technology Control Plans (TCPs) are the method that the campus uses to document and inform on the controls with regards to particular export restricted items. TCPs require physical, IT and foreign national access controls depending on the export control status of the item.

## EXPORT LICENSING

Export licensing is required for all ITAR items for international field research, export shipments and hand carry abroad as well as foreign person access to ITAR items. Dual Use export restricted technology will require export licensing for certain foreign persons. Licensing can take months to obtain from the Department of State or Department of Commerce. Licenses must be in place prior to export or access by foreign persons in the U.S.

## PENALTIES

Penalties for non-compliance with export control regulations include criminal and civil penalties for the University AND individual for violations, which could include up to \$1 million or more in fines per violation. In criminal convictions, imprisonment is possible. Ultimately, export violations may include reputational damage and loss of funding from sponsors.

For additional information or assistance, please contact the [UC San Diego Export Control Office](#) at [export@ucsd.edu](mailto:export@ucsd.edu) or (858) 246-3300.

# Disclosing Financial Interests to the Public

BY JENNIFER J. FORD

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For decades, Investigators at UC San Diego have been advised by UC San Diego's Independent Review Committee (IRC) on Conflict of Interest to disclose their interests in publications, presentations, the informed consent of human subject research and to the research team, including students. In September of 2018, [Propublica and the New York Times, coauthored a story](#) about, "[t]he researcher, Dr. José Baselga, a towering figure in the cancer world, is the chief medical officer at Memorial Sloan Kettering Cancer Center in New York. He has held board memberships or advisory roles with Roche and Bristol-Myers Squibb, among other corporations; has had a stake in start-ups testing cancer therapies; and played a key role in the development of breakthrough drugs that have revolutionized treatments for breast cancer ... **failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles** in prestigious publications like The

New England Journal of Medicine and the Lancet." This article generated another article about other prominent researchers who failed to disclose, such as, the dean of Yale's Medical School ([full article](#)).

**The public and the scientific community are served best by authors, physicians, or presenters whom are being open and transparent by disclosing their financial interest(s) for patients, readers, reviewers and colleagues to evaluate.**

UC San Diego's IRC on Conflict of Interest strives to manage conflicts of interest by increasing the visibility and transparency of the conflict of interest review process to help assure the public of the integrity of research results. When individuals engaged in research submit manuscripts for publication or present, they should disclose any financial interests they have which are related to the research or required to be disclosed by the IRC. The appropriate disclosure of an investigator's financial relationship with, or interest in, a company must

be made in all relevant publications in any form, including electronic publications and presentations.

Clinical research, including clinical trials, poses special situations that require close scrutiny. UC San Diego is responsible for ensuring that human subjects are fully informed and not placed at additional risk because of financial interests on the part of the Investigator(s). **If a potential conflict of interest is disclosed, the IRC's strategies for management of conflicts of interest are all directed at ensuring integrity, protecting human subjects, and maintaining public trust.** Since the informed consent document is considered the principal means by which to advise potential human subjects of any risks associated with their participation in a clinical trial, when appropriate, a conflict of interest disclosure is included in informed consent.

If an Investigator's financial interest(s) are related they must include their financial interest(s) disclosure in internal presentations at UC San Diego, starting at the level of the department, such as grand rounds or seminar

presentations. A relationship with, or financial interest is relevant and should be disclosed if the information in the publication or presentation could be perceived as potentially benefiting the company; or the company's technology/product is integral to the research being reported and the publication or presentation could be viewed as an endorsement benefiting the company.

Many scientific journals and funding agencies have implemented requirements for authors to disclose related financial interests to improve the integrity of science and manage conflicts of interest. Full disclosure removes the suspicion that something of relevance to objectivity is being hidden, allows the readers to form their own opinions on whether a conflict of interest exists and what relevance that interest has to the study. For examples of disclosure statements, see the [Conflict of Interest website](#).

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

## Integrity of Research: Rigor and Reproducibility

BY MICHAEL KALICHMAN

One of the most important expectations of experimental science is that researchers can rely on what their colleagues have published. There are of course some exceptions to this rule when published work has been intentionally fabricated or falsified, but this is likely unusual. On the other hand, an observer of science ([Ioannidis, 1995](#)) suggested that the risks to the "truth" of published work are much more insidious. The title of Ioannidis' paper was "Why most published research findings are false." In his thoughtful analysis, Ioannidis described a variety of ways in which the pursuit of " $p < 0.05$ " as a standard for publication can readily, even if unintentionally, result in false positive research findings. Although his claim may seem strong, subsequent studies by [Bayer](#) and [Amgen](#) found that they could reproduce far less than half of the studies they attempted to repeat. It is noteworthy that these challenges to the integrity of research are not due to intentional misconduct, but far more likely due to ignorance and a failure to take steps that are often easy, low cost, and effective to increase the rigor of published research. While there are certainly many steps that might be taken by funders of research, journals, professional societies, and research institutions, much



of the challenge to reproducible research can be solved by researchers themselves. A few examples include blinding of study data to minimize risk of bias, conducting experiments with sufficient positive and negative controls, repeating surprising findings, understanding and correctly using statistics, and thoroughly reporting exclusion and inclusion criteria as well as statistical methods. In addition to asking themselves if some of these strategies could be easily adopted, we want to encourage all UC San Diego researchers to include conversations with their peers about reproducible research as one important dimension of good practices of science.

For additional information, please visit the Research Ethics Program website or contact the Research Ethics Program at (858) 822-2647, [ethics@ucsd.edu](mailto:ethics@ucsd.edu).

## E D U C A T I O N

## 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:

- ▶ **Using Single IRBs in Multisite Human Subjects Research**  
January 21, 2020, 11:00-12:30 p.m.  
ACTRI Auditorium
- ▶ **Good Clinical Practices**  
February 27, 2020, 12:30-2:00 p.m.  
ACTRI Auditorium



Information on registration and additional sessions will be provided soon. For questions, please contact [rci@ucsd.edu](mailto:rci@ucsd.edu).

## Research Compliance and Integrity Knowledge Briefs!

Some of the core areas within the Research Compliance and Integrity Office have created short informational videos for UC San Diego researchers and staff on a variety of topics, policies and procedures. The videos can be accessed through [UC Learning](#).

### CONFLICT OF INTEREST VIDEOS

1. **[Roles and Services of the Conflict of Interest \(COI\) Office:](#)**  
Provides an overview of the roles and services of the Conflict of Interest (COI) Office.
2. **[What is a Conflict of Interest \(COI\) in Research and Other Related Activities:](#)**  
Provides information on what is a conflict of interest in research and other related activities.
3. **[700U Conflict of Interest \(COI\) Disclosure:](#)**  
Provides the State of California Statement of Economic Interest 700U disclosure for researchers.
4. **[Public Health Services \(PHS\) Financial Conflict of Interest \(FCOI\) Disclosure:](#)**  
Provides information on the Public Health Services Financial Conflict of Interest (PHS-FCOI) form for researchers.  
Note: This video does NOT SATISFY PHS mandatory training.
5. **[Non-PHS 9510 Conflict of Interest \(COI\) Disclosure:](#)**  
Provides information on the Non-PHS (Public Health Services) federal disclosure of financial interests for researchers.
6. **[What Happens When a Conflict of Interest \(COI\) Disclosure is Submitted to the Independent Review Committee \(IRC\):](#)**  
Provides information on what happens when a Conflict of Interest (COI) disclosure is referred to the Independent Review Committee (IRC).

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

### EXPORT CONTROL VIDEOS

1. **[Export Control for Restricted Parties:](#)**  
Provides an overview of Restricted Party and Sanctions Screening and answers the “what, when and how” regarding the responsibility of researchers to screen all potential collaborations, awards, agreements and financial transactions with foreign entities or persons against US government watch lists.

### 2. [Restricted Party Screening:](#)

The U.S. government restricts collaborating with or shipping to certain individuals or organizations. In this video you will learn what

a restricted party is, when to screen for them, and how the screening

is done here at UC San Diego in order to maintain compliance with United States Export Control Regulations.

### 3. [Export Control for Temporary Exports:](#)

Provides information about Temporary Exports (exported goods which will return to the U.S. within (1) year) including the various ways to ship or hand-carry goods internationally and the trade, duty and tax implications and exemptions of the various methods.

It also covers required Electronic Export Information filing (EEI) for Temporary Exports.

### 4. [Foreign National Export Control Considerations:](#)

Provides information about what qualifies as an export (disclosures

of “controlled” technical data or technology, whether written, oral or visual to a “foreign person” in the U.S. or abroad) and how to know when an export license is required. It also provides an overview of Fundamental Research Exemption (FRE) and the conditions under which they may or may not apply to your export.

For questions or additional information, please contact the Export Control Office at [export@ucsd.edu](mailto:export@ucsd.edu) or (858) 246-3300.

### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE VIDEOS

**Links to various Institutional Animal Care and Use Committee (IACUC) informational videos are available on the Investigator menu in the Animal Use Protocol System (AUPS).** For questions or additional information, please contact the IACUC Office at [iacuc@ucsd.edu](mailto:iacuc@ucsd.edu) or (858) 534-6069.

# Q&A

## Ask the Questions . . .

### **Which informed consent form must be posted under the Revised Common Rule?**

The Revised Common Rule requires clinical trials conducted or supported by a Common Rule department or agency to post an informed consent form. One unsigned IRB-approved form that has been used to enroll participants must be posted on ClinicalTrials.gov or Regulations.gov. Even if there are multiple consent forms for different populations (i.e., assent forms) or phases in the research, only one form is required to be posted. The Principal Investigators for multi-institution studies must agree and designate a single entity to post the consent form ahead of time since only one posting is required.

For more information, please visit the Research Compliance and Integrity (RCI) website or contact the RCI Office at [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu) or (858) 822-4939.

### **Is there any easy way to distinguish between what is classified as Export Administration Regulation (EAR) v. International Traffic in Arms Regulation (ITAR) item for export license purposes, such as laboratory research tools? What if the classification is not clear from the use of the vendor's specifications?**

Typically, UC San Diego's research instruments are not categorized as ITAR items on the United States Munitions List (USML), however, they may be dual-use controlled under the EAR and therefore

require a license. Where an item is specifically designed or modified for defense purposes as defined under the USML, it is likely ITAR controlled. When an item is procured, this designation may be referenced in the vendors' Operation Manual or sales documentation. Unfortunately, research institutions transferring ITAR items during the course of collaborative research do not always identify such items as ITAR controlled and you cannot always determine whether an item is EAR or ITAR controlled merely by looking at the material transfer agreement or procurement documentation. Technical parameters can change the classification

When in doubt or if you have any questions, contact the UC San Diego Export Control Office at [export@ucsd.edu](mailto:export@ucsd.edu) or (858) 246-3300.

### **I have never written an animal protocol before. How can I get help?**

There is a wealth of information on the IACUC Blink page. Look for the "What You Need to Know" section, click on the links and read the brief articles. Before responding to the questions on the protocol form, read all of the questions first so you know what information is requested in each section.

For additional help, please contact the IACUC Office at [iacuc@ucsd.edu](mailto:iacuc@ucsd.edu) or (858) 534-6069. The IACUC Office staff have over 80 combined years of experience in research with animals and working with the IACUC and are happy to help you.

**"After all, the ultimate goal of all research is not objectivity, but truth."**

—Helene Deutsch

### **Are there rules or general guidelines as to what may or may not be acceptable financial interests?**

The Independent Review Committee (IRC) reviews each financial disclosure in accordance with various UC COI Policies. The IRC then determines whether the financial interest represents a real or perceived conflict of interest, and if so, whether any action should be undertaken to eliminate, reduce, or manage the conflict of interest. The IRC applies standards 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.

If the Independent Review Committee (IRC) determines that the disclosed financial interests constitute a real or perceived conflict of interest, they will recommend actions designed to eliminate, reduce or manage the conflict of interest. In some instances, the IRC may simply recommend disclosing the interest in all presentations, abstracts and publications. Depending on the facts, the IRC may also recommend other measures such as divestiture of all equity interest in the sponsor or elimination of any consulting arrangement with the sponsor or other entity. In some cases, the IRC may attempt to mediate the conflict of interest situation by recommending changes in financial arrangements to protect the interests of UC San Diego or implementing some form of faculty accountability for research by monitoring and oversight.

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

### **RESEARCH COMPLIANCE AND INTEGRITY**

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