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ADVANCING RESEARCH AND INNOVATION

DECEMBER 2017

# HOT TOPICS

OFFICE OF RESEARCH AFFAIRS

The Office of Research Affairs provides timely notices to the research community on important information, policies updates and regulatory initiatives and changes. See the Office of Research Affairs website at <http://blink.ucsd.edu/sponsor/ora/>.

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### UNFUNDED AGREEMENTS: THE 5 W'S

#### WHY do we need to establish Unfunded Agreements?

Researchers often collaborate with other scientists, institutions, or industry partners without sending or receiving funding. For many of these unfunded endeavors, a written agreement is beneficial and necessary. Unfunded agreements set out expectations, terms, and requirements to protect the interests of the investigators and the participating organizations involved, while maintaining UCSD's adherence to UC policy and federal and state laws and regulations.

Unfunded agreements can contain restrictive language that may conflict with basic academic and intellectual property rights and other terms that must be negotiated. This is why they should be sent to [OCGA Business Contracts](#) prior to execution so that a Contract Officer can review the terms to make sure they are in agreement with UC Policy and to negotiate the terms if necessary.

**WHAT** are some of the most common Unfunded Agreement Types?

- CDA/NDA: Confidentiality / Non-Disclosure Agreement
- DUA: Data Use Agreement
- SLA: Software License Agreement
- UCA: Unfunded (Research) Collaboration Agreement
- MOU: Memorandum of Understanding
- TA: Teaming Agreement
- VSA: Visiting Scientist Agreement

**WHO** at UC San Diego handles Unfunded Agreements?

Unfunded Agreements at UC San Diego are handled by the Office of Contract and Grant Administration's Business Contracts Group. Requests for review of an Unfunded Agreement can be submitted by completing the [Unfunded Agreement Request eForm](#). After the form is submitted, the requestor will receive an email confirmation and a Case # to track the request.

**WHERE** can I send general questions about Unfunded Agreements?

If you have questions about unfunded agreements, then please send a message to the shared inbox that handles Unfunded Agreements at [OCGAContractSupport@ucsd.edu](mailto:OCGAContractSupport@ucsd.edu).

**WHEN** should I send my Unfunded Agreement to OCGA Business Contracts for review?

As soon as possible! Once you become aware that you have an Unfunded Agreement that requires review, you should complete the [Unfunded Agreement Request eForm](#). Requests are handled in the order received, but do let us know if you need something urgently.

**Did you know?**

Unfunded Agreements are institutional, meaning they are signed by a UC San Diego Contract Officer who has delegation of authority to sign on behalf of The Regents of the University of California. Principal Investigators departmental administrators are not Designated Officials and do not have signature authority to sign Unfunded Agreements. OCGA Business Contracts processes over 2,000 unfunded agreements per year!

For more information, email [OCGAContractSupport@ucsd.edu](mailto:OCGAContractSupport@ucsd.edu).



The National Institutes of Health (NIH), National Science Foundation (NSF) and most federal extramural funding agencies require verification that the Institutional Animal Care and Use (IACUC) has approved all proposed animal studies before they will fund grant proposals. The NIH Grants Policy Statement states, "It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC." The Office of Laboratory Animal Welfare

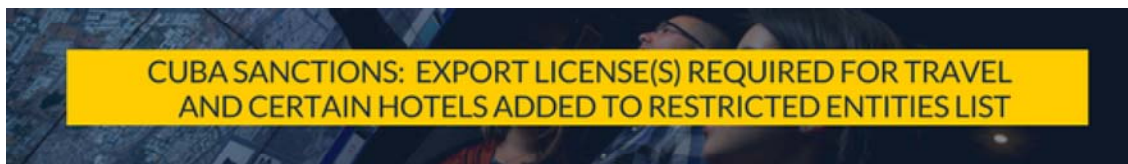
oversees the care and use of research animals in Public Health Service funded research and defines congruence as “agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC.”

At UC San Diego, the IACUC Office performs the congruency review and provides confirmation of the IACUC approved protocols. The Sponsored Project Offices (OCGA, HSSPPO and SIO) work directly with the IACUC Office to attain assurance of congruence. Generally, this occurs if a Just-in-Time notice is received or when funding is imminent. The Sponsored Project Offices will provide the assurance to the funding agency.

No expenditures for activities with live vertebrate animals may be charged to an NIH grant if there is not a valid IACUC approval. Principal Investigators should submit and/or routinely amend their animal use protocols to match any new or supplemental grant proposals to avoid delays at funding time.

Please see the [NIH Grants Policy Statement](#) (NIH GPS, chapter 4.1.1.2) for additional information.

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



The [Office of Foreign Asset Controls](#) (OFAC) updated regulations regarding the sanctions on Cuba on November 8, 2017. Specifically, OFAC issued changes to restrict persons subject to U.S. jurisdiction from engaging in direct financial transactions with entities and subsidiaries identified on the State Department's List of Restricted Entities and Subsidiaries Associated with Cuba ("[Cuba Restricted List](#)"). Any payments or services with these entities on the list are prohibited, unless an exception applies.

The amended regulations add requirements to certain categories of educational travel, remove the authorization for individual people-to-people educational travel, add requirements to the travel authorization "Support for the Cuban People" and amend the definition of "Prohibited Officials of the Government of Cuba." These changes require that all travel to Cuba be licensed either through a general or specific license, and records be maintained. Specific licensing can take months to obtain from OFAC.

If you are planning any travel to Cuba for University business purposes, please contact Brittany Whiting, Export Control Officer, [brwhiting@ucsd.edu](mailto:brwhiting@ucsd.edu), as soon as possible so the proper license and documentation may be obtained in advance.

For more information on the OFAC sanctions, please search "OFAC" in UC Learning. For questions, please contact Brittany Whiting, Export Control Officer, [brwhiting@ucsd.edu](mailto:brwhiting@ucsd.edu).

## DISCLOSURE REQUIREMENTS: CHANGES IN FINANCIAL INTERESTS FOR PHS FUNDED RESEARCH

The Public Health Service (PHS) regulations on [Objectivity in Research](#) 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 an Investigators' Financial Conflicts of Interest (FCOIs). The rules for FCOI in all research sponsored by PHS, including the National Institutes of Health (NIH) and other non-federal sponsors who have adopted the PHS FCOI regulations, require disclosure of significant financial interests by Investigators who participate in PHS funded research either directly or through a subaward.

All PHS funded Investigators planning to participate on a proposed PHS Research Activity will be required to disclose any Significant Financial Interest (SFI) related to their Institutional Responsibilities at the following times:

- At the time of the initial proposal submission, continuation, renewal or supplemental funding, and at least annually
- Whenever new personnel are added
- Within 30 days if there is any new or change in SFIs occurring prior to or during the period of an award
- When a project is awarded through a subaward and the awarding agency is PHS or another agency who has adopted the PHS financial disclosure requirements

A financial interest is anything of monetary value, whether that value can be easily determined or not, that is held by the investigator, 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 your 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 your University appointment/employment is based, AND
- Meets any of the PHS reporting categories and thresholds.

In addition, all Investigators are required to complete PHS training prior to engaging in PHS funded research and at least every four years while engaging in PHS funded research.

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

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