

UC San Diego Health

SAN DIEGO DIGESTIVE DISEASES RESEARCH CENTER (SDDRC) WORKSHOP:

DISCLOSURE OF FOREIGN COLLABORATION TO NIH AND UCSD

Presenters:

Erika Wilson, Senior Director (eswilson@health.ucsd.edu)

Health Sciences Sponsored Project Pre-Award Office & Research Service Core

Rachel Cook, Senior Grant Analyst, Supervisor (racook@health.ucsd.edu)

Health Sciences Sponsored Project Pre-Award Office

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AGENDA



- Overview & UC San Diego
 - Foreign Influence
 - Agency Existing & Evolving Policies and Requirements
 - Post Doctoral and Visiting Scholars
 - Export Control
 - Conflict of Interest (COI) and Conflict of Commitment (COC)
- NIH & Foreign Collaboration
- Questions

FOREIGN COLLABORATION & UC SAN DIEGO

GOVERNMENT CONCERN OVER UNIVERSITIES & FOREIGN INFLUENCE

- Public cases of Export Violations involving Universities
- Increased scrutiny by Congress, White House, and Federal Agencies
- Increased visits by federal agencies to Universities, FBI, BIS, ICE
- Economic espionage concerns



WHY DOES IT MATTER?

- Heightened concern at federal level that certain foreign entities may seek to influence U.S. research at all levels including:
 - Peer review
 - Diversion of intellectual property
 - Sharing of confidential information and the use of resources originating outside the U.S. inconsistency in reporting drives federal concern

FEBRUARY 25, 2019

PROFESSOR FOUND GUILTY OF GRANT FRAUD

The screenshot shows the top of a news article on the website 'THE ROANOKE TIMES'. The page number is 36. The article title is 'Ex-Virginia Tech biotech professor found guilty of grant fraud'. The author is Jeff Sturgeon, dated Feb 25, 2019. Below the title is a photograph of a man in a suit and tie walking. To the right of the photo is a sidebar advertisement for AAA towing services, showing prices like \$508, \$52, \$54, and \$57. Below the photo is a 'Buy Now' button and social media icons. At the bottom of the article snippet, it says 'A judge has found a former Virginia Tech professor guilty of federal grant fraud, the U.S. attorney's office announced Monday.' and 'Interactive map'.

- Percival Zhang, founded & Chief Scientific Officer of Cell-Free Bioinnovations, Inc. (“CFB”), was awarded SBIR/STTR by NSF
 - Grad Student was listed at PI and CTO at CFB
 - Postdoc was listed as Chief Scientist at CFB
- Undisclosed external activity:
 - Worked as a paid researcher for the Tianjin Institute of Industrial Biotechnology, Chinese Academy of Sciences
 - Talents Program Funding
- NSF grant funds fraudulently obtained for research, Zhang knew had already been done in China
- Zhang intended to use the grant funds for other CFB projects rather than for the projects for which the funds were requested

https://www.roanoke.com/news/crime/ex-virginia-tech-biotech-professor-found-guilty-of-grant-fraud/article_9d08f719-6a76-528e-8ae5-f57ee7a66851.html <http://apps.washingtonpost.com/g/documents/national/criminal-complaint-for-yiheng-percival-zhang/2558/>

<https://www.justice.gov/usao-wdva/pr/former-virginia-tech-professor-found-guilty-grant-fraud-false-statements-obstruction> <https://www.washingtontimes.com/news/2019/feb/25/yiheng-percival-zhang-ex-va-tech-prof-guilty-fraud/> https://www.theepochtimes.com/a-chinese-american-engineers-scheme-to-profit-from-us-research-grant-money_2818245.html

OCTOBER 24, 2018

CONCERNS OVER TALENTS PROGRAMS


MENU nature Subscribe

China hides identities of top scientific recruits amidst growing US scrutiny

Chinese researchers fear that affiliation with the high-status Thousand Talents scheme could make them targets of FBI investigations.

Smriti Mallapaty

Twitter Facebook Email



US congressman Lamar Smith accused China of planting sleeper agents in US universities to steal scientific breakthroughs at an April 2018 hearing. Credit: Scott J. Ferrell/Congressional Quarterly/Getty

China's flagship science talent recruitment programme, the Thousand Talents Plan, has gone underground amidst intensifying scrutiny by United States government agencies for China's suspected role in the theft of US technologies and intellectual property.

A climate of fear has engulfed Chinese scientists in both countries worried that association with the previously prestigious programme will make them targets of US investigations, including by the Federal Bureau of Investigation (FBI).

RELATED ARTICLES

- US-Chinese trade war p in the cross hairs
- China's plan to recruit t researchers

Read more on Nature Index

SUBJECTS

- Politics
- Research man

Examples of Talent Programs:

- Global Experts
- Thousand Talents
- Project 111
- Yangtze River Scholars

<https://www.nature.com/articles/d41586-018-07167-6>

CHANGING FEDERAL LANDSCAPE

National Institutes of Health

The NIH issued a notice reminding the research community of their obligation to disclose Financial Conflict of Interest (FCOI). They specifically called out foreign financial interests as a concern (March 30, 2018)

- **Over 55 academic and research institutions**
- Publications listing foreign collaborations with support Contracts/Grants & COI
- Affiliations with or without support
- Comprehensive listing of other support (salary or non-salary)
- Research conducted outside U.S.
- Foreign talents programs

Department of Defense

- The National Defense Authorization Act requires the DOD to develop procedures limiting foreign access to technologies through grants, contracts, cooperative agreements or other transactions based on national security interest and to work with academic institutions to limit undue influence, including through foreign talent programs, by countries to exploit United States technology within the DOD research, science and technology, and innovation enterprise (August 13, 2018)

CHANGING FEDERAL LANDSCAPE

National Science Foundation

The National Science Board (NSB), which governs the NSF, issued a statement on national security and science. In it NSB Chair Diane Souvaine affirmed the board's commitment to the free exchange of ideas and information, while also acknowledging the need to create new policies to protect national interests. (October 23, 2018)

Department of Energy

- The DOE issued memos stating:
- Researchers in unspecified “emerging research areas and technologies” would no longer be allowed to collaborate with colleagues from unnamed “sensitive” countries (December 14, 2018)
- Restrictions on funded researchers from participating in any foreign talent-recruitment programs, whether that researcher is a U.S. citizen or not (January 31, 2019)

CHALLENGES WE HAVE IDENTIFIED



- Conflict of Commitment not filed annually
- Conflict of Interest not filed when needed
- “Other Support” reporting is incomplete
- Funding agencies are not updated on new foreign engagements
- Inconsistencies across campus
- Visitor support
- Lack of awareness

AGENCY EXISTING & EVOLVING POLICIES & REQUIREMENTS

FEDERAL FUNDING SUBMISSIONS & REPORTING

- **Disclose foreign affiliations and support on federal applications**
 - List all foreign engagements and affiliations present in your proposal
 - Biosketch, Other Support / Current & Pending
 - Identify foreign engagements and affiliations in each annual progress report and closeout summaries
- **Disclosure foreign engagements in what types of agreements**
 - All types, including research contracts and grants, cooperative agreements and organizational awards, including any from foreign governments or entities
- For DOD proposals, disclose key personnel information as outlined in their memo dated March 20, 2019
- At the time of proposal, NSF requires disclosure of a foreign organization's involvement in a project via a check box and justification as to why that organization's participation is essential

REMINDERS

- Carefully read all proposal guidelines to ensure understanding of any changes to federal policies
- Export Control review must be flagged in the internal proposal record (ePD) to ensure review by UCSD's Export Control Office
- Any materials or information shared with a foreign entity must be covered under a formal agreement (sponsored research, material transfer, data use, confidentiality, collaboration, etc.)
- Disclose any foreign visitors to your departmental leadership *prior* to the visit, as additional on-boarding steps must be taken to ensure compliance

POST DOCTORAL AND VISITING SCHOLARS

Appointment Process

- All Postdoctoral and Visiting Scholars must have an official appointment
- One benefit of the official appointment process is Export Control office checks all foreign Postdoctoral and Visiting Scholars through the Restricted Party Screening system (Visual Compliance)





Do's and Don'ts

- Do communicate/educate your research team on foreign entity issues, export control policies and regulations, and data ownership policy to protect intellectual property and to mitigate risk
- Do safeguard research data by requiring original material remain in the lab and/or on secure, shared servers, and back up frequently
- Do consider location of work assignment as some federal contracts and grants may restrict use of funds for work performed in foreign countries
- Don't pass along IFSO visa processing fee to foreign postdocs as CBA requires department/PI to cover this cost
- Don't charge visa processing fees to grants when expenses are not associated with initial recruitment as it is an unallowable charge

QUESTIONS!!!

What about Visiting Scholars?

Can you subsidize a foreign
paid-direct Post Doc?



Export Control

EXPORT CONTROL OFFICE

- Identifies and manages export risks for U.S. national security & foreign policy to facilitate university research
 - Export Controls
 - Dual Use Research of Concern (DURC)
 - Facility Security
- Advises on and obtains export licenses for:
 - International payments, shipments, travel and collaborations
 - Sanctioned country activities with Cuba, Iran, North Korea, Syria & Sudan
 - Restricted parties
- Develops technology control plans with researchers for export restricted items



SYSTEMS FOR EXPORT REVIEWS

People

- Foreign Visiting Scholars & Grads
- Foreigner access to export restricted technology

Places

- Foreign shipments
- Foreign payments
- Sanctioned countries transactions
- Travel pre-authorization alerts

Things

- Procurement- Purchasing
- Contracts and Grants systems
- Biohazard Use Authorizations
- Chemical Hazard Use Authorizations

PEOPLE: RESTRICTED OR PROHIBITED PERSON OR ENTITY?

- The US Government issues various lists of individuals & entities both in the U.S. & abroad that have committed export violations or other serious offenses.
 - Terms & conditions require no debarred, disqualified or ineligible persons
 - Part of funding awards, procurement and service agreements
- Financial dealings or export transactions with Restricted or Prohibited parties is prohibited.
 - Terrorists
 - Weapons Proliferators
 - Export Violators
 - Drug Traffickers
- Visual Compliance Screening Tool



RESTRICTED ENTITY EXAMPLES (NOT COMPREHENSIVE)

- BEIJING UNIVERSITY OF AERONAUTICS AND ASTRONAUTICS (BUAA) AKA BEIHANG UNIVERSITY
- NORTHWEST POLYTECHNICAL UNIVERSITY
- SICHUAN UNIVERSITY
- UNIVERSITY OF ELECTRONIC SCIENCE AND TECHNOLOGY OF CHINA
- NATIONAL UNIVERSITY OF DEFENSE TECHNOLOGY
- MALEK ASHTAR UNIVERSITY OF TECHNOLOGY
- BAQIYATTALLAH UNIVERSITY OF MEDICAL SCIENCES
- IMAM HOSSEIN UNIVERSITY
- BEN GURION UNIVERSITY (BGU)



Conflict of Interest (COI) and Conflict of Commitment (COC)

WHEN ARE CONFLICT OF INTEREST (COI) DISCLOSURES REQUIRED?

COI Research and Other Related Activity Disclosures

Category	Agency	Examples
Sponsored Research	Federal	National Health Institute (NIH) National Science Foundation (NSF)
	Non-Federal	For-Profit Non-Profit*
Other Related Activity	Non-Federal	For-Profit or Non-Profit* <ul style="list-style-type: none">• Gifts• Material Transfer Agreements (MTA)• Service• Unfunded**

* There are non-profit sponsors exempt from the disclosure requirement

** Disclosure may be required for internal University clinical research projects when Human Subjects are involved

WHAT CONSTITUTES A POTENTIAL RESEARCH COI?

Type of Interests*	Examples
Income / Compensation	Salaries, Consulting, Honoraria
Ownership / Position	Founder, Partner, Board of Directors, Scientific Advisory Board, Employee
Equity / Ownership Interest	Stocks, Bonds, Stock Options
Gifts	From outside entity
Loans	Money loaned to outside entity
Travel Expenses / Reimbursement	Paid from outside entity
Intellectual Property / Patent	Non-UC royalties

*Applies to the Employee, Spouse, Registered Domestic Partner, and Dependent Children

WHICH COI DISCLOSURE FORMS AND WHEN TO SUBMIT?

PHS Form submitted at time of proposal and PHS supplement at NOA
9510 and 700U must be completed, signed and dated at time of proposal

Funding Entity / Sponsor	Disclosure Form Required with Initial Submission	Additional Form Required if Positive	When does COI Office review?
Public Health Services (PHS) (NIH and those who have adopted PHS)	PHS Form	Supplement	Notice of Award
Federal Non-PHS (NSF, CIRM, UC Programs)	9510	Addendum	Proposal submission
Non-Federal (For-Profit or Non-Profit)*	700U	Addendum	Proposal or equivalent

* There are non-profit sponsors exempt from the disclosure requirement

THRESHOLDS FOR DISCLOSURE?

Funding Entity / Sponsor	Income / Compensation	Ownership / Position	Investment / Equity	Travel Expenses/ Reimbursement	Loans	Gifts	Intellectual Property / Patent
Public Health Services (PHS)	publicly traded > \$5,000	Any	publicly traded > \$5,000	> \$5,000	> \$5,000	> \$5,000	> \$5,000 (excludes UC)
	non-publicly traded > \$5,000		non-publicly traded ≥ \$0				
Federal Non-PHS 9510	> \$10,000	Any	> \$10,000 or > 5% owner	≥ \$10,000	> \$10,000	> \$10,000	Any royalties (excludes UC)
Non-Federal 700U	>\$500	Any	>\$2,000	≥ \$0	≥ \$500	≥ \$50	Any royalties (excludes UC)

Important: Update of Financial Interests for Sponsored Activities within 30 days

EXAMPLES THAT MAY CREATE A CONFLICT OF INTEREST

- Starting a company
 - Founder and managerial position
- Employee position at a company
- Visiting appointment at a foreign University or foreign Government
- Being on a proposal or award for another entity
- Operating a lab at another entity
- Consulting for a company or foreign University
 - Being on the Scientific Advisory Board (SAB)
- Travel expenses or reimbursement paid by an outside entity



THE INTERSECTION BETWEEN CONFLICT OF INTEREST (COI) AND CONFLICT OF COMMITMENT (COC)?

CONFLICT OF COMMITMENT (COC) AND CONFLICT OF INTEREST (COI)

	<u>Conflict of Commitment</u>	<u>Conflict of Interest</u>
Policies	APM 025 / APM 671	UCSD PPM 200-13, APM 028, OP PHS and NSF*
Disclosure Forms	Category I (prior approval) and II	Dependent on outside funding entity**
Timing	Category I: Prior to Engagement Category II: Annually	Proposal and/or award stages and then dependent on funding
Responsible Offices	Academic Affairs	Conflict of Interest Office

Similarity: Engagement with outside activities

* There are many COI policies, see <http://blink.ucsd.edu/sponsor/coi/policies.html>

** Disclosure may be required for internal funding when Human Subjects are involved

COC AND COI SCENARIO

FOREIGN ENGAGEMENT

Dr. Green, an active NIH grant recipient, has a visiting professor appointment at the Imperial College of London (Imperial). Dr. Green teaches and mentors students in a research lab at Imperial. Dr. Green receives compensation (\$6,000) and travel reimbursement (\$8,500).

- Is COC reporting and PHS disclosure required?
Yes
- What must be disclosed?
Visiting Professor appointment, income and travel
- Which category type?
Category I
- Prior approval required?
Yes, for the visiting professor appointment
- Will COI disclosure be reviewed by the IRC committee?
Yes, if the relatedness assessment by the COI Office determines that the interest and the scope of work are related
- What might be the COI IRC management strategies?
Disclose in Publications, Presentations, and to research team, disclose inventions, consult with OCGA to determine if foreign component prior approval is required

QUESTIONS!!!

How and where do we disclose an honorarium or an invitation to attend and/or to present at an international conference?

What about documenting the transfers of materials (MTAs) and disclosures?



Question!!!

What if you have a multi-site clinical trial with participants in foreign countries?



WHAT CAN WE DO TO PROTECT UC SAN DIEGO?

- Follow established UC and UC San Diego Procedures
- UC Policies on COI, COC and External Research outline responsibilities for reporting
 - For PHS, disclose Foreign Institutions and Governments:
 - Disclose financial interests including foreign Universities and foreign governments
 - Income OR travel expenses/reimbursement over \$5,000 (disclose within 30 days)
- Our existing procedures for proposals, agreements, purchasing and visiting scholars are in place to comply with regulations and alert us to address risks
- Use visual compliance for screening foreign collaborators, including visitors, funding entities, purchases or shipments
 - Restricted parties lists are being updated every few days by the USG
- **Be transparent with UCSD and Federal Agencies**
- Escalate any requests for information from federal authorities on national security or export controls

UC SAN DIEGO

- A Good Rule of Thumb
 - Any external support (whether financial or not) or engagement that you would acknowledge in public presentations or publications is something that you should also disclose in grant applications, annual reports and closeout summaries and in university-related COI and COC disclosure forms (as required).
- “Transparency and compliance with UC and federal requirements are mechanisms to support all investigators and faculty.”
- Resources Online: <https://blink.ucsd.edu/research/foreign-engagements.html>

UNANNOUNCED VISITS BY FEDERAL AND STATE AGENCIES

- UC San Diego can expect site visits by outside agencies as part of routine oversight activities and for specific ongoing investigations
- The University's practice is to cooperate with outside investigating agencies, while protecting the rights and privacy of the students, faculty, staff and research subjects
- **Promptly contact Research Compliance and Integrity** who will provide assistance or alert appropriate institutional offices

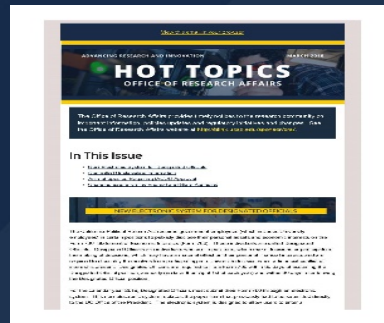
For additional information and FAQs, please see
<https://blink.ucsd.edu/research/policies-compliance-ethics/index.html>

CONTACTS

Research Compliance and Integrity (RCI)	Angie McMahill
Export Control	Brittany Whiting
Conflict of Interest (COI)	Jennifer J. Ford
Office of Postdoctoral and Research Scholar Affairs (OPRSA)	Jennifer (Oh) Bourque
Office of Contract and Grant Administration (OCGA)	Linda Collins
Office of Innovation and Commercialization (OIC)	Paul Roben
Graduate Division	Paul Yu
Academic Senate and Council on Research	Andrew Kehler Robert Horwitz
Office of International Affairs (OIA)	Chip Schooley

COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
- Conflict of Interest Helpline: (858) 534-6465. info-coi@ucsd.edu
- Export Control Helpline: (858) 246-3300, export@ucsd.edu
- IACUC Helpline: (858) 534-6069, iacuc@ucsd.edu
- Hot Topics and Newsletters:



- Website: <http://blink.ucsd.edu/sponsor/rci/news.html>
- Research Compliance and Hot Topics Training Program
- To be added to the RCI list serv, please email rci@ucsd.edu



FOREIGN COLLABORATION & NIH

“The recent cases of foreign influence have exposed activities and resources that should have been reported to institutions and NIH, and were not.”

– Wendy D. Streitz, President, Council on Governmental Relations (COGR)



NOT-OD-19-114: NIH’s intent for this notice was “to **remind** the extramural community about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap.”

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html>

PROTECTING THE INTEGRITY OF U.S. BIOMEDICAL RESEARCH

- On 8/20/2018, Dr. Francis Collins, NIH Director issued a statement identifying three areas of concern:

Diversion of intellectual property to foreign entities

Sharing of confidential information by NIH peer reviewers with foreign entities

Failure by some researchers to disclose substantial resources from other organizations, including foreign entities

- As a result, NIH has increased their efforts in ensuring compliance with reporting requirements. It is **important faculty and researchers maintain their diligence in disclosing all forms of research support, affiliations, and foreign components** as required by Federal regulations.

NIH DEFINITION OF A FOREIGN COMPONENT

- A foreign component is defined as significant scientific activity that was or will be performed outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds were expended.

Significant Grant-Related Activities	Examples of Grant-Related Activities
<ul style="list-style-type: none">• Involvement of human subjects or research with live vertebrate animals;	<ul style="list-style-type: none">• Collaborations with investigators at a foreign site anticipated to result in co-authorship;
<ul style="list-style-type: none">• Extensive foreign travel by grantee project staff to collect data, or conduct surveys or sampling activities; or	<ul style="list-style-type: none">• Use of facilities or instrumentation at a foreign site; or
<ul style="list-style-type: none">• Any grantee activity that may have an impact on U.S. foreign policy.	<ul style="list-style-type: none">• Receipt of financial support or resources from a foreign entity.

WHEN & WHERE TO DISCLOSE A FOREIGN COMPONENT

Application	Just-in-Time (Prior to Award)	Post-Award / Scientific Progress Report & Final Report
Biographical Sketch(es) <ul style="list-style-type: none"> List <u>ALL</u> positions and honors must be listed, both domestic and foreign (including Talent Programs) 	Other Support	Updates to Biographical Sketch(es)
Other Support	Changes to or Additions of Key Personnel	Changes to or Additions of Key Personnel
Performance Site Location(s)	Changes to or Additions of a Foreign Component	Updates to Other Support
Other Project Information (6 & 12)	Updates to Budget & Budget Justification	Changes to or Additions of a Foreign Component
<ul style="list-style-type: none"> Foreign Subawards/Subcontracts 	<p style="text-align: center;">In the interest of full transparency, recipients should err on the side of disclosure.</p>	Publications with Foreign Collaborators
<ul style="list-style-type: none"> Foreign Collaboration that Could Lead to Future Publications 		Intellectual Property

BIOGRAPHICAL SKETCHES & FOREIGN COLLABORATION

- NIH requires applicants to list all positions and scientific appointments both **domestic and foreign** held by senior/key personnel **that are relevant to an application including affiliations with foreign entities and/or governments**. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).
- Where would this go on the Biosketch?
 - B. Positions and Honors
 - D. Research Support

BIOSKETCH: B. POSITIONS AND HONORS

B. Positions and Honors

Positions and Employment

2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-	Research Associate, Smithsonian Tropical Research Institute, Panama
2002-2011	Assistant/Associate Professor, Washington University, St. Louis, MO
2009-	Adjunct Professor, Department of Chemistry, Aberdeen University
2012-	Professor, University of California San Diego
2017	Ningbo Yue-Kong Pao Lecturing Professorship, Ningbo University, China

Other Experience and Professional Memberships

2000-	Associate Editor, Psychology and Aging
2003-05	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11	NIH Risk, Adult Addictions Study Section, members

Honors

2004	Excellence in Teaching, Washington University, St. Louis, MO
2013-	Invited Member of the Faculty of 1000
2015-18	1000 Foreign Talent Program, Shandong Jieijing Group, China

BIOSKETCH: D. RESEARCH SUPPORT FOREIGN DISCLOSURE OPTION

- After the Active Support and Completed Support we have had a small number of investigators added a foreign disclosure section for transparency. *Note, this is not currently in the SF424 R&R Guidelines.* Here is an example:

Foreign Disclosures

Co-authored publications: As a computational scientist, Dr. [REDACTED] collaborates with researchers worldwide. She has co-authored papers with investigators from Netherlands, France, Germany, and Australia (see MyBibliography for details [REDACTED]).

Postdoctoral fellowship support: Between 01/01/2018 and 12/31/2019, Dr. [REDACTED], a postdoctoral fellow in the [REDACTED] lab, was supported by the [REDACTED] Fellowship [REDACTED], via a postdoc paid direct format.

Foreign grants: Dr. [REDACTED] currently has a grant proposal under consideration at NHMRC in collaboration with Dr. [REDACTED] from [REDACTED] Institute, Melbourne, Australia. The grant has been submitted in June 2020 to NHMRC in response to the "2020 Ideas Grants" RFA and assigned Sapphire ID [REDACTED]. The grant title is "[REDACTED]". The proposal contains small budget (\$14,540 total costs over the entire project period) to support cloud computing expenses in the [REDACTED] lab.

DISCLOSING FOREIGN COLLABORATION IN AN APPLICATION THAT WILL RESULT IN A SUBAWARD/SUBCONTRACT

- **R&R Other Project Information Form**

Item 6	Item 12
Does this project involve activities outside of the United States or partnerships with international collaborators? If Yes, list the country(ies) as well as you are required to upload a Foreign Justification under Item 12: Other Attachments.	The Foreign Justification should "[d]escribe special resources or characteristics of the research project, including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.

- Research Plan
- Subaward Budget & Budget Justification

FOREIGN JUSTIFICATION

This project involves collaborations with six experts from Europe:

1. Dr. X, a computational biophysicist from the Faculty of Medicine in the University of _____. Drs. [PI] and X have collaborated for the past year applying the methods and _____. Dr. Y, a postdoc from Dr. X's group, has worked in Dr. [PI] lab at UC San Diego for six months in 2018 as a visiting scientist funded by the Faculty of Medicine of the University of _____, studying the _____. The results of this work formed the basis of a collaborative manuscript currently in preparation. The _____ methods that were developed through this work for _____ are highly relevant for the present proposal, justifying continuation of this collaboration.
2. Dr. Z, a medicinal chemist at the University of _____. Dr. Z. is the co-developer of the _____ (some of which are unpublished) for _____ efforts in this proposal.
3. Dr. R, a pharmacologist from the _____. Dr. R's research is focused on the discovery, design, and development of new drug leads for _____ and _____. Her group contributes to the pharmacological characterization of the compounds used for _____.
4. Dr. S., Division of Medicinal Chemist at _____. Dr. S has been one of the prominent female leaders in the _____ and focuses on targeting _____ with novel nanobody approaches. She will supply nanobodies for our _____ and functional studies. One of her nanobodies is particularly exciting because it _____, which will help us to understand _____.
5. Dr. T, Division of Medicinal Chemist at _____. Dr. T's research focus is on structure-based drug design of Division of Medicinal Chemist at _____. He is supplying us with novel _____ targeting compounds including a rare example of _____.
6. Dr. V _____, a pharmacologist and molecular virologist from the Department of Infection and Immunity at the _____. Dr. V has been collaborating with us for the past few months to make nanobodies that could facilitate _____.

The collaborations do not involve any paid effort for any of these foreign collaborators. The use of foreign resources is restricted to the nanobodies provided by Drs. S and V., and the chemical compounds provided by Drs. Z, R, and T for our _____ studies. These collaborations are anticipated to result in **co-authored publications in the future.**

DISCLOSING FOREIGN COLLABORATION IN AN APPLICATION THAT COULD RESULT IN A PUBLICATION

<https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Documents/Foreign%20Justification%20Example%20Language.docx>

OTHER SUPPORT & FOREIGN SUPPORT

Include support from foreign talent programs!

All resources, domestic or foreign, directly supporting the individual's research endeavors have been reported.

- **INCLUDE:** Federal, non-Federal, commercial or institutional, such as research grants, cooperative agreements, contracts, and/or institutional awards.
- **DO NOT INCLUDE:** gifts, prizes, donors, equipment grants, training grants, discretionary funds, or UC San Diego start-up packages.

Sufficient levels of effort are committed to the project.

There is no scientific, budgetary, or commitment overlap.

Only funds necessary to the approved project are included in the award.

<https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Pages/Templates--Boilerplates.aspx>

OTHER SUPPORT – JIT & APPLICATION TEMPLATE

PI Last Name, First Name

ACTIVE **[[DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds]]**

Domestic Active Grant Support

Full Grant Number (PI last name) Project Period Effort Calendar Months
Agency *Annual: Total Cost* *Entire Period: Total Cost*
Title
Project Goals/Aims
Role: **Co-Investigator**

Foreign Active Grant Support

Full Grant Number (PI last name) Project Period Effort Calendar Months
Agency *Annual: Total Cost* *Entire Period: Total Cost*
Title
Project Goals/Aims
Role: **Role on Project (not for us)**

PENDING **[[DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds]]**

Domestic Pending Support **[[DO NOT INCLUDE the application being considered]]**

Full Grant Number (PI last name) Project Period Effort Calendar Months
Agency *Annual: Total Cost* *Entire Period: Total Cost*
Title
Project Goals/Aims
Role: **Role on Project**

Foreign Pending Support

Full Grant Number (PI last name) Project Period Effort Calendar Months
Agency *Annual: Total Cost* *Entire Period: Total Cost*
Title
Project Goals/Aims
Role: **Role on Project**

OTHER AGREEMENTS, RESOURCES, AND SIGNIFICANT COLLABORATIONS **[[DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds]]**

Domestic

Agreement Type **[[Sponsored Research Agreement, MTA, DTUA]]**
Collaborator Name (s)
Collaborating Institution
Project Title
Execution Date Period of performance Effort Calendar Months (if applicable)
Funds if applicable (Total costs)
Award/Grant number (Funding Agency) if applicable.

Foreign

<https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Pages/Templates--Boilerplates.aspx>

Agreement Type **[[Sponsored Research Agreement, MTA, DTUA]]**
Collaborator Name (s)
Collaborating Institution
Project Title
Execution Date Period of performance Effort Calendar Months (if applicable)
Funds if applicable (Total costs)
Award/Grant number (Funding Agency) if applicable.

START-UP PACKAGE **[[DO NOT INCLUDE UC San Diego start-up packages]]**

Dr. XXX received a start-up package from The Jackson Laboratory. Funds are currently being expended on this Start-up. (...OR All funds were expended by 2016.) **[[NIH is not looking at the \$ award amount, but at the source of funding, esp. if it is a foreign source.]]**

OVERLAP

None

[[Note for Overlap: Include a brief description of the project; and a statement addressing overlap. If overlap exists, please provide details on adjustments and plans to eliminate any overlapping support if this application is funded. Moreover, the total level of effort for each investigator may not exceed 12 person months with the addition of effort proposed in the application being considered. If effort exceeds 12 person months, please include a detailed description of adjustments to be made in the event this application is funded. If there is no overlap, state: "There is no scientific or budgetary overlap" beneath each source of other support.]]

[[Additional note for Other Support provided under a consortium/contractual arrangement or that is part of a multi-project award: Indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.]]

<https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Documents/OTHER%20SUPPORT%20JIT%20OR%20APPLICATION%20TEMPLATE%209-2019.docx>

OTHER SUPPORT TEMPLATE

OTHER SUPPORT TEMPLATE

OTHER SUPPORT – JIT & APPLICATION TEMPLATE

PI Last Name, First Name

ACTIVE [[DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds]]

Domestic Active Grant Support

Full Grant Number (PI last name)

Agency

Title

Project Goals/Aims

Role: Co-Investigator

Project Period

Annual: Total Cost

Effort Calendar Months

Entire Period: Total Cost

Foreign Active Grant Support

Full Grant Number (PI last name)

Agency

Title

Project Goals/Aims

Role: Role on Project (not for us)

Project Period

Annual: Total Cost

Effort Calendar Months

Entire Period: Total Cost

OTHER SUPPORT TEMPLATE

PENDING **[[DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds]]**

Domestic Pending Support **[[DO NOT INCLUDE the application being considered]]**

Full Grant Number (PI last name)

Agency

Title

Project Goals/Aims

Role: Role on Project

Project Period

Annual: Total Cost

Effort Calendar Months

Entire Period: Total Cost

Foreign Pending Support

Full Grant Number (PI last name)

Agency

Title

Project Goals/Aims

Role: Role on Project

Project Period

Annual: Total Cost

Effort Calendar Months

Entire Period: Total Cost

OTHER SUPPORT TEMPLATE

OTHER AGREEMENTS, RESOURCES, AND SIGNIFICANT COLLABORATIONS [[DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds]]

Domestic

Agreement Type [[Sponsored Research Agreement, MTA, DTUA]]

Collaborator Name (s)

Collaborating Institution

Project Title

Execution Date

Period of performance

Effort Calendar Months (if applicable)

Funds if applicable (Total costs)

Award/Grant number (Funding Agency) if applicable.

Foreign

OTHER SUPPORT TEMPLATE

Agreement Type [[Sponsored Research Agreement, MTA, DTUA]]

Collaborator Name (s)

Collaborating Institution

Project Title

Execution Date

Period of performance

Effort Calendar Months (if applicable)

Funds if applicable (Total costs)

Award/Grant number (Funding Agency) if applicable.

START-UP PACKAGE **[[DO NOT INCLUDE UC San Diego start-up packages]]**

Dr. XXX received a start-up package from The Jackson Laboratory. Funds are currently being expended on this Start-up. (...OR All funds were expended by 2016.) **[[NIH is not looking at the \$ award amount, but at the source of funding, esp. if it is a foreign source.]]**

- Note, the Other Support for an RPPR does include the award the RPPR is being submitted for and it does not include Pending Support.
- Link to Other Support Template for an RPPR: <https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Documents/OTHER%20SUPPORT%20RPPR%20TEMPLATE%209-2019.docx>

OVERLAP IN OTHER SUPPORT NOTES

OVERLAP

None

[[Note for Overlap: Include a brief description of the project; and a statement addressing overlap. If overlap exists, please provide details on adjustments and plans to eliminate any overlapping support if this application is funded. Moreover, the total level of effort for each investigator may not exceed 12 person months with the addition of effort proposed in the application being considered. If effort exceeds 12 person months, please include a detailed description of adjustments to be made in the event this application is funded. If there is no overlap, state: "There is no scientific or budgetary overlap" beneath each source of other support.]]

[[Additional note for Other Support provided under a consortium/contractual arrangement or that is part of a multi-project award: Indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.]]

THREE TYPES OF OVERLAP IN OTHER SUPPORT

- **Scientific**
 - Substantially the **same** research is proposed in **more than one application** or is submitted to two or more different funding sources for review and funding consideration
 - A specific research objective and the research design for accomplishing that objective are the **same** or closely related in two or more applications or awards, regardless of the funding source
- **Budgetary**
 - Duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but *are already provided for by another source*
- **Commitment**
 - Key or senior personnel time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application

HOW TO ADDRESS OVERLAP IN OTHER SUPPORT

- **Explain**
 - Potential scientific, budgetary and/or commitment overlap when submitting other support
- **Resolution of Overlap**
 - Address at the time of award in conjunction with applicant institution officials, the PD/PI, and awarding agency staff
- **The PI should always address any scientific overlap**
 - “Potential commitment overlap for Dr. _____ between (insert grant #) and the application under consideration. If the application under consideration is funded with Dr. _____ committed at (insert calendar months), Dr. _____ will (ex. request approval to reduce months, reduce effort accordingly, etc.)”

DISCLOSING A FOREIGN COMPONENT IN AN RPPR

G.9 Foreign Component: Provide the organization name, country, and description of each foreign component.

Sample Language		
<p>Organization Name: Kyung Hee University</p> <p>Country: KOREA REP OF</p> <p>Description of Foreign Component: [Cite publication reference information here]. This is a review and not a research paper. Both Drs. X and B co-wrote this article. Dr. B is a faculty at Kyung Hee University, South Korea.</p>	<p>Organization Name: Queen's University</p> <p>Country: CANADA</p> <p>Description of Foreign Component: [Cite publication reference information here]. This work was mainly done at Queen's University, Canada. No specific experiments were performed in Dr. X's laboratory at UC San Diego. Dr. T provided scientific/technical advice and reagents for this paper.</p>	<p>Organization Name: Oxford University</p> <p>Country: UNITED KINGDOM</p> <p>Description of Foreign Component: X were visiting graduate students. They were financially supported by a scholarship from the foreign government, which covered their living expenses in San Diego, with no fund brought here to support their research work in the lab at UC San Diego. All the research work and experimental data reported in our most recent paper were done in Dr.'s X UC San Diego's lab.</p>

<https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Documents/RPPR%20G.9%20FOREIGN%20COMPONENT%20Example%20Language.docx>

FOREIGN COMPONENT OR FOREIGN OTHER SUPPORT

NIH requires recipients to determine whether activities it supports include a foreign component, defined as: the existence of any “significant scientific element or segment of a project” outside of the United States, in other words

- Performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended and/or
- Performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended.

<i>Fits Foreign Component Definition:</i>	<i>Fits Other Support Definition:</i>
If a recipient determines that a portion of the project will be conducted outside of the U.S., the recipient then will need to determine if the activities are considered significant. If both criteria are met, then there is a foreign component.	If an activity does not meet the definition of foreign component because all research is being conducted within the United States, but there is a non-U.S. resource that supports the research of an investigator and/or researcher, it must be reported as other support.

STANDOUT NIH OTHER SUPPORT FAQs

Question	Answer
2. What does NIH evaluate when reviewing Other Support submissions?	<p>NIH scientific program and grants management staff review Other Support information to ensure that:</p> <ul style="list-style-type: none">• All resources, domestic or foreign, directly supporting the individual's research endeavors have been reported• Sufficient levels of effort are committed to the project• There is no scientific, budgetary, or commitment overlap• Only funds necessary to the approved project are included in the award
3. I am a PI on an NIH award to a domestic university and have an unpaid appointment at a foreign university. At the foreign site I have access to lab space, research materials, and staff. Should I report this as Other Support?	<p>Yes. While the researcher is not receiving monetary compensation, the lab space, materials, and staff are resources made available to them in support of and/or related to their research efforts. Other payments, such as travel or living expenses must also be reported. As outlined in NOT-OD-19-114 this appointment must be reported as Other Support. NIH requires applicants to list all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).</p>
7. What should I do if I'm not sure if something needs to be included as Other Support?	<p>What should I do if I'm not sure if something needs to be included as Other Support? In the interest of full transparency, recipients should err on the side of disclosure. Researchers should consult with their institutional officials for guidance to ensure compliance with institutional and NIH policies. NIH requires complete and accurate reporting of all sources of research support, financial interests and affiliations, both foreign and domestic.</p>

STANDOUT NIH FOREIGN COMPONENTS FAQs

Question	Answer
2. What are some examples of a “significant element of a project” when making determinations regarding a foreign component?	<p>The recipient institution should evaluate the element of the project that is being conducted outside of the United States within the context of the project as a whole when making determinations about significance. Some examples of activities that may be considered a significant element of the project include, but are not limited to:</p> <ul style="list-style-type: none">• collaborations with investigators at a foreign site anticipated to result in co-authorship;• use of facilities or instrumentation at a foreign site; or• receipt of financial support or resources from a foreign entity.
5. What is an example of an activity that is not a foreign component, but would meet the definition of Other Support? What is the difference?	<p>This response is dependent upon specific details that surrounding the activity. For instance, one model could be that a PI on an NIH grant may have an appointment and a lab at a foreign university. The research being done at the foreign lab is unrelated to the PI’s NIH project. This would not qualify as a foreign component of the NIH research, as the foreign work is not part of the NIH-funded project. However, it is a resource made available to the researcher in support of their research. Therefore, it must be reported as Other Support.</p>

STANDOUT NIH FOREIGN COMPONENTS FAQs

Question	Answer
6. I am the PI on a NIH grant to a domestic university. I have a visiting post-doctoral fellow in my lab, who works on my NIH grant and does all of his/her work in the United States. The fellow's salary is paid by a foreign government. Is this a foreign component?	In general, no. The first step in determining whether research constitutes a foreign component is to evaluate whether a portion of the research is being conducted outside of the United States. In this case, all of the work is being conducted in the US, so there is no foreign component.
7. I am a PI on an NIH award to a domestic university. I will have a visiting fellow joining my lab whose salary will be supported by a foreign university. Do I need NIH prior approval before the fellow can work on my NIH funded research?	Since specific circumstances may vary, it would be best to discuss with your Grants Management Officer.

NIH & HS SPPO RESOURCES

- **NIH Other Support & Foreign Component FAQs:**
<https://grants.nih.gov/grants/faq-other-support-foreign-components.htm>
- **NOT-OD-19-114: Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components:**
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html>
- **NIH Biosketches FAQs:** <https://grants.nih.gov/faqs#/biosketches.htm>
- **HS SPPO & Foreign Involvement:**
<https://medschool.ucsd.edu/vchs/research-services/hssppo/review/Pages/Foreign-Involvement.aspx>
- **HS SPPO Templates & Boilerplates:**
<https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/Pages/Templates--Boilerplates.aspx>

