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

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Health Sciences Sponsored Project Pre-Award Office

July 15, 2020
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
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
Examples of Talent Programs:

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

https://www.nature.com/articles/d41586-018-07167-6
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)
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
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
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)
<table>
<thead>
<tr>
<th>COI Research and Other Related Activity Disclosures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
</tbody>
</table>
| Sponsored Research | Federal | National Health Institute (NIH)  
Non-Profit*  
National Science Foundation (NSF)  
Non-Federal |
| Other Related Activity | Non-Federal | For-Profit  
Non-Profit*  
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
<table>
<thead>
<tr>
<th>Type of Interests*</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income / Compensation</td>
<td>Salaries, Consulting, Honoraria</td>
</tr>
<tr>
<td>Ownership / Position</td>
<td>Founder, Partner, Board of Directors, Scientific Advisory Board, Employee</td>
</tr>
<tr>
<td>Equity / Ownership Interest</td>
<td>Stocks, Bonds, Stock Options</td>
</tr>
<tr>
<td>Gifts</td>
<td>From outside entity</td>
</tr>
<tr>
<td>Loans</td>
<td>Money loaned to outside entity</td>
</tr>
<tr>
<td>Travel Expenses / Reimbursement</td>
<td>Paid from outside entity</td>
</tr>
<tr>
<td>Intellectual Property / Patent</td>
<td>Non-UC royalties</td>
</tr>
</tbody>
</table>

*Applies to the Employee, Spouse, Registered Domestic Partner, and Dependent Children*
WHICH COI DISCLOSURE FORMS AND WHEN TO SUBMIT?

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

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

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.
### Thresholds for Disclosure?

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

*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)

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

**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
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?
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
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
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.
<table>
<thead>
<tr>
<th>CONTACTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Compliance and Integrity (RCI)</td>
<td>Angie McMahill</td>
</tr>
<tr>
<td>Export Control</td>
<td>Brittany Whiting</td>
</tr>
<tr>
<td>Conflict of Interest (COI)</td>
<td>Jennifer J. Ford</td>
</tr>
<tr>
<td>Office of Postdoctoral and Research Scholar Affairs (OPRSA)</td>
<td>Jennifer (Oh) Bourque</td>
</tr>
<tr>
<td>Office of Contract and Grant Administration (OCGA)</td>
<td>Linda Collins</td>
</tr>
<tr>
<td>Office of Innovation and Commercialization (OIC)</td>
<td>Paul Roben</td>
</tr>
<tr>
<td>Graduate Division</td>
<td>Paul Yu</td>
</tr>
<tr>
<td>Academic Senate and Council on Research</td>
<td>Andrew Kehler, Robert Horwitz</td>
</tr>
<tr>
<td>Office of International Affairs (OIA)</td>
<td>Chip Schooley</td>
</tr>
</tbody>
</table>
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.”

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:

<table>
<thead>
<tr>
<th>Diversion of intellectual property to foreign entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharing of confidential information by NIH peer reviewers with foreign entities</td>
</tr>
<tr>
<td>Failure by some researchers to disclose substantial resources from other organizations, including foreign entities</td>
</tr>
</tbody>
</table>

• 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.

https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research
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

<table>
<thead>
<tr>
<th>Significant Grant-Related Activities</th>
<th>Examples of Grant-Related Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Involvement of human subjects or research with live vertebrate animals;</td>
<td>• Collaborations with investigators at a foreign site anticipated to result in co-authorship;</td>
</tr>
<tr>
<td>• Extensive foreign travel by grantee project staff to collect data, or conduct surveys or sampling activities; or</td>
<td>• Use of facilities or instrumentation at a foreign site; or</td>
</tr>
<tr>
<td>• Any grantee activity that may have an impact on U.S. foreign policy.</td>
<td>• Receipt of financial support or resources from a foreign entity.</td>
</tr>
</tbody>
</table>
# WHEN & WHERE TO DISCLOSE A FOREIGN COMPONENT

<table>
<thead>
<tr>
<th>Application</th>
<th>Just-in-Time (Prior to Award)</th>
<th>Post-Award / Scientific Progress Report &amp; Final Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biographical Sketch(es)</td>
<td>Other Support</td>
<td>Updates to Biographical Sketch(es)</td>
</tr>
<tr>
<td>• List ALL positions and honors must be listed, both domestic and foreign (including Talent Programs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Support</td>
<td>Changes to or Additions of Key Personnel</td>
<td>Changes to or Additions of Key Personnel</td>
</tr>
<tr>
<td>Performance Site Location(s)</td>
<td>Changes to or Additions of a Foreign Component</td>
<td>Updates to Other Support</td>
</tr>
<tr>
<td>Other Project Information (6 &amp; 12)</td>
<td>Updates to Budget &amp; Budget Justification</td>
<td>Changes to or Additions of a Foreign Component</td>
</tr>
<tr>
<td>• Foreign Subawards/Subcontracts</td>
<td></td>
<td>Publications with Foreign Collaborators</td>
</tr>
<tr>
<td>• Foreign Collaboration that Could Lead to Future Publications</td>
<td></td>
<td>Intellectual Property</td>
</tr>
</tbody>
</table>

*In the interest of full transparency, recipients should err on the side of disclosure.*
• 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
**B. Positions and Honors**

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

**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 Jiejing Group, China |
• 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:

**BIOSKETCH: D. RESEARCH SUPPORT FOREIGN DISCLOSURE OPTION**

**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).

**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

<table>
<thead>
<tr>
<th>Item 6</th>
<th>Item 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>The Foreign Justification should &quot;[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.</td>
</tr>
</tbody>
</table>

• Research Plan
• Subaward Budget & Budget Justification

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.100-how-to-use-the-application-instructions.htm
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.
**OTHER SUPPORT & FOREIGN SUPPORT**

- **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.**

- **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.

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm
### OTHER SUPPORT – JIT & APPLICATION TEMPLATE

<table>
<thead>
<tr>
<th>Other Support</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PI Last Name, First Name</strong></td>
<td><strong>ACTIVE</strong> (DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds)</td>
</tr>
<tr>
<td><strong>Domestic Active Support</strong></td>
<td><strong>Proposal Period</strong> Project Period Effort Calendar Months Agency Title Project Goals/Aims Role: (Not applicable)</td>
</tr>
<tr>
<td><strong>Foreign Active Support</strong></td>
<td><strong>Proposal Period</strong> Project Period Effort Calendar Months Agency Title Project Goals/Aims Role: (Not applicable)</td>
</tr>
<tr>
<td><strong>Pending</strong> (DO NOT INCLUDE gifts, prizes, donors, equipment grants, training grants, or discretionary funds)</td>
<td><strong>Domestic Pending Support</strong> (DO NOT INCLUDE the application being considered)</td>
</tr>
<tr>
<td><strong>Foreign Pending Support</strong></td>
<td><strong>Proposal Period</strong> Project Period Effort Calendar Months Agency Title Project Goals/Aims Role: (Not applicable)</td>
</tr>
</tbody>
</table>
| **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)**  
  - **Award/Grant number** (Funding Agency) if applicable.  
  - **Foreign**  
  - **Agreement Type** (Sponsored Research Agreement, MTA, DTUA)  
  - **Collaborator Name** (s)  
  - **Collaborating Institution**  
  - **Project Title**  
  - **Execution Date**  
  - **Period of performance**  
  - **Effort Calendar Months (if applicable)**  
  - **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 expensed 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, PDP/K, and source for the overall project, and provide all other information for the subproject only.]

---

https://medschool.ucsd.edu/vchs/research-services/hssppo/resources/TOCOTHER%20SUPPORT%20JIT%20OR%20APPLICATION%20TEMPLATE%209-2019.docx
### 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

<table>
<thead>
<tr>
<th>Full Grant Number (PI last name)</th>
<th>Project Period</th>
<th>Effort Calendar Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency</td>
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<td></td>
</tr>
<tr>
<td>Project Goals/Aims</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Role:</strong> Co-Investigator</td>
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</tr>
</tbody>
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#### Foreign Active Grant Support

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<tr>
<td>Project Goals/Aims</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Role:</strong> Role on Project (not for us)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# 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]]

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<td>Role: Role on Project</td>
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</table>

**Foreign Pending Support**

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<td>Role: Role on Project</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
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

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.)”
### G.9 Foreign Component

Provide the organization name, country, and description of each foreign component.

<table>
<thead>
<tr>
<th><strong>Organization Name</strong></th>
<th><strong>Country</strong></th>
<th><strong>Description of Foreign Component</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Kyung Hee University</td>
<td>KOREA REP OF</td>
<td>[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.</td>
</tr>
<tr>
<td>Queen’s University</td>
<td>CANADA</td>
<td>[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.</td>
</tr>
<tr>
<td>Oxford University</td>
<td>UNITED KINGDOM</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

### Fits Foreign Component Definition:
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.

### Fits Other Support Definition:
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

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
</table>
| 2. What does NIH evaluate when reviewing Other Support submissions?      | NIH scientific program and grants management staff review Other Support information to ensure that:  
• 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? | 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). |
| 7. What should I do if I’m not sure if something needs to be included as Other Support? | 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. |

https://grants.nih.gov/grants/faq-other-support-foreign-components.htm
**Question**

2. What are some examples of a “significant element of a project” when making determinations regarding a foreign component?

**Answer**

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:

- 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?

**Answer**

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.
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td>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.</td>
</tr>
<tr>
<td>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?</td>
<td>Since specific circumstances may vary, it would be best to discuss with your Grants Management Officer.</td>
</tr>
</tbody>
</table>
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:

• 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