UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY

- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Ethics and Integrity (Research Misconduct)
- ClinicalTrials.Gov, NIH GCP and RCR Compliance

Website: RCI.UCSD.EDU
Helpline: (858) 822-4939
Email: rci@ucsd.edu
Other Support, Biosketches, and Disclosing a Foreign Component when working with DOD, DOE, and NSF

Presenters:
Jeff Warner, Director, Ancillary Research Agreements
Office of Contract and Grant Administration
Rachel Cook, Senior Grant Analyst, Supervisor
Health Sciences Sponsored Project Pre-Award Office
International Research Collaborations

- As NSF states in guidance that will be discussed in more detail below, international collaboration is essential to pursuing the frontiers of science.

- International engagement refers to scientific research collaborations with transparent and reciprocal exchanges for mutual benefit of parties from different countries.

- International research collaboration can take many different forms:
  - a research project with a subaward to an institution in a foreign country
  - a multi-site clinical trial with sites and participants in a foreign country
  - hosting a visiting researcher from a university in a foreign country
  - establishing an unfunded collaboration agreement with a partner in a foreign country
Recent reports and guidance from the federal government have highlighted the importance of disclosing financial interests, affiliations, activities, and relationships with foreign entities.

Increasing the requirements for Principal Investigators to disclose their foreign sources of support and to disclose how those sources are being used to support proposed and related research.

UC San Diego researchers who receive federal funding for research activities need to be aware of these requirements and how each federal agency interprets what is meant by foreign sources of support.

Some of these federal agency requirements have been in place for some time and others are either new or are being interpreted differently and/or more rigorously than in the past.
Awards by Major Agency
The National Defense Authorization Act (NDAA) for FY 2019, Section 1286, pages 443-445, directs the Secretary of Defense to establish an initiative to work with academic institutions who perform defense research and engineering activities:

1. To support protection of intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security; and

2. To limit undue influence, including through foreign talent programs, by countries to exploit United States technology within the Department of Defense research, science and technology, and innovation enterprise.
Proposers shall submit the below information for all key personnel, whether or not the individuals' efforts under the project are to be funded by the DoD:

- A list of all current projects the individual is working on.
- Any future (pending) support the individual has applied to receive, regardless of the source.
- Title and objectives of each of these research projects.
- The percentage per year each of the key personnel will devote to the other projects.
- The total amount of support the individual is receiving in connection to each of the other research projects or will receive if other proposals are awarded.
- Name and address of the agencies and/or other parties supporting the other research projects.
- Period of performance for the other research projects.
This information should be included in the Senior Key Person Profile form in the proposal.

DoD indicates that failure to submit this information may cause the proposal to be returned without further review.

DoD also reserves the right to request further details from a proposer before making a final determination on funding the effort.

DOD requires disclosure of all projects even if they are unrelated to the DOD-funded proposal.
Department of Energy (DOE)

- **DOE Order No. O 486-1**: Department of Energy Foreign Government Talent Recruitment Programs
  - Prohibits DOE employees and contractors participating in foreign talent recruitment programs from certain countries from receiving DOE funding.
  - The extent and reach of this requirement to recipients and subrecipients of DOE funding is not yet known as the requirement is being first implemented within DOE national labs.

- DOE modified **Order 142.3a** reporting requirements (December 13, 2019)
  - Extent and reach of this requirement is still not certain as discussions between UCOP and DOE are still ongoing.
Department of Energy (DOE)

- Please refer to the Biographical Sketch and Current and Pending Support instructions in the applicable DOE Funding Opportunity Announcement as they contain information about the required forms, the application instructions, and details about how to submit the application.

- Example Guidelines: Provide a biographical sketch for the project director/principal investigator (PD/PI) and each senior/key person listed in Section A on the R&R Budget form. Please include the following:
  - Education and Training
  - Research and Professional Experience
  - Publications
  - Synergistic Activities
  - Identification of Potential Conflicts of Interest or Bias in Selection of Reviewers
Example Guidelines: Provide a list of all current and pending support (both Federal and non-Federal) for the Principal Investigator(s) and senior/key persons, including subawardees, for ongoing projects and pending applications. List all sponsored activities or awards requiring a measurable commitment of effort, whether paid or unpaid. For every activity, list the following items:

- The sponsor of the activity or the source of funding
- The award or other identifying number
- The title of the award or activity
- The total cost or value of the award or activity, including direct and indirect costs. For pending proposals, provide the total amount of requested funding.
- The person-months of effort per year being dedicated to the award or activity
Dear Colleague Letter: Research Protection (NSF 19-200)

- International collaboration is essential to pursuing the frontiers of science.

- NSF has required senior project personnel on proposals to disclose all sources of support, both foreign and domestic since 1978.

- Our science and engineering enterprise is put at risk when another government endeavors to benefit from the global research ecosystem without upholding the values of openness, transparency, and reciprocal collaboration.

- NSF has commissioned a study to assess risks and recommend possible practices for NSF and its awardee organizations to achieve the best balance between openness and security of science.

- NSF personnel and IPAs detailed to NSF cannot participate in foreign government talent recruitment programs.
The policy, outlined in the NSF *Proposal and Award Policies and Procedures Guide* (PAPPG) (NSF 20-1), goes into effect for proposals submitted or due, on or after June 1, 2020.

- The two NSF-approved formats are [SciENcv: Science Experts Network Curriculum Vitae](https://www.sciencenetقد/curriculumvitae), and an NSF Fillable PDF.

- NSF recently recorded [a webinar about the requirement to use an NSF-approved format](https://www.youtube.com/watch?v=example) for both the biographical sketch and current & pending support documents as part of proposals submitted to NSF.
Chapter II.C.2.f, Biographical Sketches, has been modified to require use of an NSF-approved format in submission of the biographical sketch.

- NSF will only accept PDFs that are generated through use of an NSF-approved format.

- Biographical Sketches must include:
  - Professional Preparation - individual's undergraduate and graduate education and postdoctoral training
  - Appointments - reverse chronological order by start date of all the individual's academic, professional, or institutional appointments
  - Products - (i) up to five products most closely related to the proposed project; and (ii) up to five other significant products, whether or not related to the proposed project
  - Synergistic Activities - up to five distinct examples that demonstrate the broader impact of the individual's professional and scholarly activities
Approved formats for creating biographical sketches are:

- **SciENcv** - NSF has partnered with NIH to use [SciENcv: Science Experts Network Curriculum Vitae](https://sciencv.islab.org) as an NSF-approved format for use in preparation of the biographical sketch section of an NSF proposal.
  - Adoption of a single, common researcher profile system for Federal grants reduces administrative burden for researchers.
  - SciENcv will produce an NSF-compliant PDF version of the biographical sketch. Proposers must save these documents and submit them as part of their proposals via FastLane, Research.gov or Grants.gov.
- **FAQs on using SciENcv**

- **NSF Fillable PDF** - NSF is providing a fillable PDF for use in preparation of the biographical sketch. Proposers will be able to download it from this page, complete the form, and upload it as part of their proposal via FastLane, Research.gov or Grants.gov.
- **FAQs on using NSF Fillable PDF**
National Science Foundation (NSF)

- Chapter II.C.2.h, Current and Pending Support, has been modified to require use of an NSF-approved format in submission of current and pending support information.

- NSF will only accept PDFs that are generated through use of an NSF-approved format.

- It assess an individual's capacity to carry out the research as proposed, as well as to help assess any potential overlap or duplication with the proposed project.
National Science Foundation (NSF)

- Current and Pending Support:
  - Must be separately provided for each individual designated as senior personnel.
  - Includes all resources made available to an individual in support of and/or related to all research efforts, regardless of whether or not they have monetary value.
  - Includes all in-kind contributions, even if it is not intended for use on the project/proposal being proposed.
  - Must be provided for this project, for ongoing projects, and for any proposals currently under consideration from whatever source.
  - The total award amount for the entire award period covered (including indirect costs) must be provided, as well as the number of person-months (or partial person-months) per year to be devoted to the project by the individual.
  - If the project (or any part of the project) now being submitted has been funded previously by a source other than NSF, information must be provided regarding the last period of funding.

Please note concurrent submission of a proposal to other organizations will not prejudice its review by NSF.
Approved formats for creating current & pending support are:

- **SciENcv** - NSF has partnered with NIH to use [SciENcv: Science Experts Network Curriculum Vitae](https://sciencv.org) as an NSF-approved format for use in preparation of the current and pending support section of an NSF proposal.
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Foreign Collaboration & NIH

- with Rachel Cook, M.A., Senior Grant Analyst, Supervisor – HS SPPO
“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:
  - 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.

[Link to NIH statement](https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research)
NIH’s 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.

<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 (NIH)</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 is justification)</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.*
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
**Other Support & Foreign Support**

- **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.

- **✓ 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.**

Other Support Templates

NIH Other Support Template for JIT or Application


NIH Other Support Template for RPPR

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](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.100-how-to-use-the-application-instructions.htm)
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

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 a Foreign Component in an RPPR

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

<table>
<thead>
<tr>
<th>Organization Name</th>
<th>Country</th>
<th>Description of Foreign Component</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>
**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.

<table>
<thead>
<tr>
<th>Fits <em>Foreign Component</em> Definition:</th>
<th>Fits <em>Other Support</em> Definition:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>
Real Life Scenarios

<table>
<thead>
<tr>
<th>Scenario #1</th>
<th>Scenario #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>If a PD/PI of an NIH-funded grant has a collaborator outside of the U.S. who performs experiments in support of the PD/PI’s NIH-funded project, this would constitute a foreign component, regardless of whether the foreign collaborator receives funding from the PD/PI’s grant.</td>
<td>Additional funding from a foreign source for the NIH-supported research of a PD/PI at a U.S. institution would not constitute a foreign component but would necessitate reporting as other support.</td>
</tr>
</tbody>
</table>

**Example Answer:** a Post Doc leaves your lab and returns their home country. They continue to assist with a portion of your research there. Regardless of compensation, this would be considered a foreign component because work is being done outside the US.  

**Example Answer:** Visiting Foreign Paid-Direct Post Doc in lab working on NIH award. All work is being done in the US, thus not a foreign component, but could be considered Other Support.
NIH & HS SPPO RESOURCES

• NIH Other Support & Foreign Component FAQs: https://grants.nih.gov/grants/faq-other-support-foreign-components.htm


• 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
Any questions?
RCI 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