
INTERNATIONAL ENGAGEMENT – KEY CONSIDERATIONS

NOVEMBER 2020



USC University of
Southern California





EXECUTIVE SUMMARY

US Government sponsors have expressed growing concerns regarding inappropriate influence by external entities over federally funded research and are requiring greater transparency from both institutions and faculty when it comes to international engagements and affiliations.

This training session is designed to inform faculty about their disclosure requirements to research sponsors and to USC.

PRESENTATION AGENDA

1

From the Headlines

2

Sponsor Guidance

3

USC Approach

4

Required Practices

5

FAQs

6

Questions/Resources

FROM THE HEADLINES

Institutions and researchers have faced stiff penalties for failure to appropriately disclose relationships outside the U.S.

CLEVELAND CLINIC – MAY 2020

Former employee was arrested and charged with false claims and wire fraud. The employee failed to disclose an appointment at a Chinese university to NIH as well as an appointment in a Thousand Talents Program and receipt of National Natural Science Foundation of China funding for some of the same research funded by NIH.

UNIVERSITY OF TENNESSEE – FEB 2020

Faculty member arrested for wire fraud and making false statements about affiliations in China.

EMORY UNIVERSITY – FEB 2020

Faculty member pled guilty to tax fraud. The faculty member certified full-time effort at Emory while working part-time in China for 6 month. The part-time work was disclosed to Emory, but Emory did not ensure the faculty member's appointment was adjusted to reflect outside effort.

HARVARD UNIVERSITY – JAN 2020

Charles Lieber, Chemistry Department Chair, arrested for failing to disclose extensive participation in Chinese "1000 Talents" program.

FROM THE HEADLINES (CONT.)

Institutions and researchers have faced stiff penalties in the last year for failure to appropriately disclose relationships outside the U.S.

MD ANDERSON – APRIL 2019

MD Anderson ousts three senior researchers after NIH discovers “serious” violations of peer review confidentiality rules and failure to disclose foreign activities in China.

UNIVERSITY OF KANSAS – AUGUST 2019

Professor indicted for allegedly failing to disclose full-time employment contract with Chinese university. If convicted, he faces up to 20 years imprisonment and several hundred thousand dollars in fines.

NIH INVESTIGATIONS

As of October, 2019, NIH has investigated at least 180 scientists at more than 65 institutions. In part, NIH is using publicly available information from publications to determine who to investigate. Largest number of cases are focusing on transfers of data to China, Russia, and Iran.

VAN ANDEL RESEARCH INST – DEC 2019

\$5.5 million False Claims Act settlement for failure to disclose and investigate a faculty relationship in China.

SPONSORS AND FEDERAL GOVERNMENT SPEAK UP

- August 2018: NIH Director, Dr. Francis Collins, sends a letter to the NIH research community raising concerns about state-sponsored programs seeking to influence NIH research.
- March 2019: The Department of Defense (DoD) issued a memo outlining disclosure requirements, to include listing all current projects the individual is working on, level of commitment associated with those projects, and total support received.
- June 2019: Department of Energy (DoE) issued a directive mandating contractors to fully disclose, and as necessary, terminate affiliations with government-supported talent recruitment programs.
- July 2019: NIH issued guidance reminding research institutions that NIH-funded researchers must “report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap”.
- July 2019: NSF issues a Dear Colleague letter outlining its plans to “address emerging risks to the nation’s science and engineering enterprise”.

SPONSORS AND FEDERAL GOVERNMENT SPEAK UP (CONT.)

- December 2019: NSF releases a report by independent science advisory group (JASON) titled “Fundamental Research Security” analyzing the nature of the threat to research security.
- June 2020: A bipartisan group of Senators introduced the Safeguarding American Innovation Act, a bill that if enacted would impose significant new oversight of sponsored research.
- June 2020: OSTP presentation explaining that the integrity of the U.S. research enterprise rests on certain core principles and values, including transparency; while international collaboration is foundational to the success of U.S.-based research, certain state actors are acting in ways that pose risks to U.S. research security and diversions of intellectual property paid for by U.S. taxpayers.
- August 2020: NIH issued additional information “Protecting U.S. Biomedical Intellectual Innovation” highlighting, among other issues, ways in which affiliations outside the U.S. can raise financial conflict of interest issues

USC APPROACH

- October 2018: Office of Research memo on “Service Commitments, Faculty Commitments and NIH/FBI Focus on Foreign Relationships”.
- June 2019: Office of Research issues FAQ’s regarding faculty disclosure obligations to the university and to sponsors of outside activity, including activity abroad.
- July 2019: Office of Research reminder memo to faculty with NIH research on disclosure obligations.
- November 2019: USC Global, Office of Research, and Office of Culture, Ethics and Compliance issue memo providing guidance on disclosure obligations and restrictions on activities in certain countries under Department of Treasury regulations (OFAC).
- Continued engagement with Vice Deans of Research and educational materials distributed through Department of Contracts & Grants Newsflashes, Office of Research monthly updates and administrator and faculty trainings conducted by the Office of Culture, Ethics and Compliance

REQUIRED PRACTICES – FOREIGN COMPONENTS

- ***Foreign components of federally-funded research should be disclosed on proposals and progress reports.***
- A “foreign component” is defined as “any significant scientific element or segment of a project outside of the United States...whether or not grant funds are expended;” indicia of a foreign component include collaborations that:
 - May result in co-authorship
 - Involve use of facilities or instrumentation at a foreign site
 - Result in receipt of financial support or resources from a foreign entity.
- Foreign components must be disclosed:
 - In grant applications or RPPRs
 - By listing a “non-US performance site”
 - Checking “yes” to the question on the Cover Page supplement Form asking: “Does this project involve activities outside of the United States or partnerships with international collaborators?”

REQUIRED PRACTICES – OTHER SUPPORT

- ***USC researchers should disclose all applicable “Other Support” as required by federal sponsors.***
- Other support may include resources and/or financial support, from domestic or foreign sources. Such support should be disclosed on an “Other Support” or “Current & Pending” form.
- Examples of other support include:
 - Grants and contracts (without regard for whether they are administered by USC)
 - Faculty or other positions or appointments, regardless of remuneration
 - Post docs, students, or visiting scholars supported by a foreign government or institution
 - Income, salary, consulting fees, and honoraria in support of an individual's research endeavors
 - Participation in “foreign talent programs” such as China’s Thousand Talents Program.
 - In-kind support (e.g. office/laboratory space, equipment, supplies, employees).
- Other support must be disclosed even if it is provided outside of a researcher’s appointment period (e.g. summer for 9-month faculty)
- Consult with the Office of Culture, Ethics and Compliance if you are unclear about whether an outside activity must be disclosed as “other support”.

REQUIRED PRACTICES – BIOSKETCHES, TALENT POSITIONS AND FCOI

- ***Biosketches should disclose all relevant non-U.S.C. affiliations, positions, appointments, and affiliations even if volunteer, honorary or adjunct***
- ***USC requires disclosing all non-U.S. appointments and participation in talent programs***
- ***USC researchers must adhere to existing university policy on Conflicts of Interest***
- Recent NIH guidance has arguably expanded FCOI inquiries
 - Compensated appointments outside the U.S.
 - Participation in a talent program
 - In-kind contributions supporting research

HOW DO I DISCLOSE TO USC?

- USC policy requires that researchers disclose certain outside relationships for review prior to engaging in the activity. **This is in addition to the requirement to disclose to research sponsors.** Please keep the following in mind:
 - Faculty are not permitted to conduct paid research outside of USC without an exceptional approval from the applicable Dean and VP of Research.
 - Academic titles (regardless of title) at a domestic or foreign institution require approval of the Executive Vice Provost for Faculty Affairs, upon recommendation of the appropriate Dean.
 - Disclosure of consulting payments and ownership interests that benefit from research being conducted at USC.
 - Annual reporting of all significant financial interests is required of HHS-supported faculty.
- All outside relationships that might create an appearance of a conflict of interest must be disclosed via “diSClose”, USC’s on-line disclosure system (disclose.usc.edu).
- Consult with the Office of Culture, Ethics and Compliance for guidance on your disclosure obligations under USC’s Conflict of Interest policies.

FAQS

- I am an NIH PI and also have an unpaid appointment at a foreign institution where I have access to lab space, research resources, and staff. Under what conditions would this require a disclosure to a federal sponsor?

This is a form of Other Support that should be disclosed through the Just-in-Time process before an award is made or through a progress report if the affiliation arises post-award. It does not matter that the position is unpaid; the lab, resources, and staff are supporting your research and should be reported to NIH.

FAQS

- I have an appointment at a lab in a foreign country; while there I do not do any work related to my NIH grant, does this create a foreign component?

No, because the work at the foreign lab is not related to your NIH project; but as explained in the prior example the appointment at the foreign lab would be disclosable as a form of Other Support.

FAQS

- I am working on a project in my USC lab and consult with a colleague in another country who offers some advice, does that create a foreign component?

It depends; a key element of a foreign component is the significance of the work done outside the U.S., a phone call or two to provide some advice may well not rise to that level

- What if the colleague's contribution rises to the level of creating a co-authorship situation?

NIH views co-authorship as indicia of the requisite level of significance

- How about if the discussions lead to the colleague carrying out experiments that further the aims of my NIH grant but NIH does not get charged?

Performance of work furthering the NIH grant would likely create a foreign component; the absence of any payment does not change the analysis

Reminder

NIH guidance focuses on the significance of work performed outside the U.S.; expenditure of NIH funds is not required.

When in doubt ask.

FAQS

- I have a student, post-doc, or visiting faculty supported by a foreign government working in my lab. Do I need to disclose this to federal sponsors?

Yes, this would need to be disclosed as Other Support, even if they are not working on a federally sponsored research project.

- What if they are working on a federally sponsored research project and they continue the work when they return to their home institution?

This would likely need to be disclosed as a Foreign Component.

The lesson here is that it's important to consider your relationship with any visitors to your lab once they return home.

FAQS

- I received a gift from a foreign entity to support my research at USC, does this need to be disclosed to federal sponsors?

A gift is something offered with no expectation of anything in return and no expectation of an associated time commitment. If the gift meets these qualifications and the one below, it does not need to be disclosed.

From: <https://research.usc.edu/policies/agreement-terms/>

The distinction between gifts and grants is sometimes unclear. If any one of the following conditions appears in an award, the award is generally considered a grant or contract, rather than a gift.

- The proposed work binds the University to a specific line of scholarly or scientific inquiry which requires either a work statement or the testing of specific hypotheses, methodology, or validation of particular approaches.



QUESTIONS

RESOURCES

USC EDUCATIONAL MATERIAL: WEBSITE

USC Office of Culture, Ethics and Compliance

[Institutional](#)[Research](#)[Healthcare](#)[Data Privacy](#)[Conflict of Interest](#)[International Activity](#)[Ethics at USC](#)[Culture Journey](#)[Search](#)

[Home](#) > [International Activity](#) > International Collaborations and Disclosure Requirements

International Collaborations and Disclosure Requirements

USC is engaged in far-reaching, global research and learning programs and recognizes the importance of these international collaborations. As research and learning programs are becoming ever more global, federal sponsors are placing increased emphasis on the disclosure of foreign affiliations and sources of support. The resources on this page aim to assist faculty in ensuring relationships with foreign entities comply with federal disclosure requirements.

 [Quick Guide on Disclosure of Foreign Relationships](#)

 [Foreign Relationship Reporting Guidance: When and Where to Report](#)

<https://ooc.usc.edu/international-activity/international-collaborations-and-disclosure-requirements/>

INTERNATIONAL ACTIVITY

International Collaborations and Disclosure Requirements

[Research and Export Controls](#)

[Office of Foreign Assets Control \(OFAC\)](#)

[International Business](#)

[International Travel Guidance](#)

[Troublesome Clauses](#)

USC EDUCATIONAL MATERIAL: ONE-PAGER

FEDERAL MANDATE FOR YOU TO DISCLOSE INTERNATIONAL COLLABORATIONS

USC is engaged in far-reaching, global research and learning programs and recognizes the importance of these international collaborations. As research and learning programs are becoming ever more global, federal sponsors are placing increased emphasis on the disclosure of foreign affiliations and source of support. This guide aims to assist faculty in ensuring relationships with foreign entities comply with federal disclosure requirements.



What needs to be disclosed?

- Any remuneration received from (i) a foreign institution or affiliated research institute; (ii) a foreign academic teaching hospital or medical center; (iii) the government of a foreign country (which includes local, provincial, or equivalent governments); and/or foreign for-profit and non-profit businesses.
- Involvement or selection in a Foreign Talent Recruitment program, whether or not any remuneration is received.
- Foreign components of federally funded research, which includes any significant scientific element of a project that occurs outside the United States, whether or not grant funds are expended. Examples include:
 - Collaborations with investigators at a foreign entity that may result in co-authorship;
 - Use of facilities or instrumentation at a foreign site; and/or
 - Receipt of financial support or resources from a foreign entity.
- Foreign Funding, Appointments and Other Activities, regardless of whether they include any remuneration or are based at USC, including:
 - All positions/appointments outside USC, domestic or foreign, including full-time, part-time, visiting, adjunct, honorary or voluntary appointments;
 - Activities at foreign entities including summer months and/or sabbaticals.
 - Extramural funding, including gifts, from USC or another organization;
 - "In-kind" support received from an entity (e.g., office/laboratory space, equipment, supplies, personnel (including visitors who are supported by their home institution), and scientific materials).



Where/how should disclosures be made?

- In Proposals, Progress Reports, and Final Reports:
 - Identify all Performance Site(s) where work will be performed, domestic and abroad.
 - Biosketch: Identify all appointments at foreign entities, participation in foreign talent program(s) and all foreign relationships and activities.
 - Current & Pending Support: Identify all financial resources, domestic and foreign, supporting your research.
 - Foreign components: Identify all known foreign components to a research project in the initial proposal and update as necessary via subsequent progress reporting.
- During the Award: If a foreign component arises during the life of the award and was not disclosed in the initial proposal, obtain sponsor's approval through a progress report or stand-alone request.
- At the University:
 - All research activity at another institution requires disclosure and approval from the appropriate Dean and the Vice President of Research.
 - Academic titles at other institutions (foreign or domestic), including full-time, part-time, visiting, adjunct, honorary, or voluntary appointments, require disclosure and approval of the Executive Vice Provost after recommendation from the applicable Dean.
 - All HHS-supported faculty must annually disclose all outside activities that relate to USC responsibilities via diSClose (disclose.usc.edu).
 - All researchers regardless of sponsor must make disclosures of outside activities that create a potential conflict of interest via diSClose.

Questions? Consult with the Office of Culture, Ethics, and Compliance (compliance@usc.edu or 213-740-8258) if you need assistance in determining whether or not to disclose commitments or other support to a sponsor.

USC EDUCATIONAL MATERIAL: ONE-PAGER ON DISCLOSURE



Foreign Relationship Reporting Guidance

When and Where to Report



| Type of Activity | Disclosure Required in diSClose | Dean and Faculty Affairs/VP of Research Approval Required | Contact Office of Compliance | List in NIH, DOD, NSF, DOE, etc. Biosketch | List as Other Support for NIH, DOD, NSF, DOE, etc. | List as NIH Foreign Component | List on NSF Cover Sheet |
|--|---------------------------------|---|------------------------------|--|--|--------------------------------------|-------------------------|
| Performance of any significant part of an NIH project outside the United States either by project personnel or a foreign researcher | | | | | | X | |
| Any NSF funded activity carried out in cooperation with international parties abroad or virtually in the U.S. | | | | | | | X |
| Post-doc or student funded by foreign government or institution working in your USC lab | | | | | X | | |
| Use of facilities or instrumentation at a foreign site | | | | | X | X if related to specific NIH project | |
| In-kind contributions from a foreign institution or government (office/lab space, equipment, supplies, employees, students, travel support, living expenses) that support <u>any</u> of your research activities | | | | | X | | |

CONTACT US

Ben Bell

Assistant Director, Research Compliance

benjamab@usc.edu

Daniel Shapiro

Assistant Vice President, Research Compliance and Research Conflict of Interest

daniel.shapiro@usc.edu

BUT WAIT...THERE'S MORE (OFAC)

- Under Department of Treasury regulations administered by the Office of Foreign Assets Control (OFAC), certain individuals, entities, and countries are subject to economic sanctions.
- As a result, depending on the person, entity, or country, collaborations may be either limited (requiring specific authorization from OFAC in the form of a license) or prohibited entirely. *This can include even basic research collaborations intended to be shared in the public domain (so-called “fundamental research”).*
- Countries that are comprehensively sanctioned include Iran, Cuba, North Korea, Sudan, Syria, and others.
- China, while not subject to comprehensive sanctions, has seen increased numbers of entities and individuals placed on OFAC sanction lists in recent years.
- All collaborations, institutional or individual, with OFAC-sanctioned countries, entities, or individuals, must be disclosed to the Office of Culture, Ethics and Compliance and appropriate licenses from OFAC obtained where required prior to undertaking collaboration.