

University of Southern California Statement of Outside Interests Related to Research

Purpose

This form should be used to disclose any actual or apparent conflicts of interest associated with research at USC, as defined in the *USC Conflict of Interest in Research: Policy and Procedure* (“Policy”, which can be found at <http://policies.usc.edu>). Research includes government and non-government funded projects, clinical trials and unfunded research projects. In the case of human subjects research, conflicts should also be identified to the Institutional Review Board, and in the case of funded research, conflicts should also be identified on the Proposal Approval Review (PAR) form.

Other types of conflict of interest, such as conflict of commitment, should be separately disclosed, following the procedures in *USC’s Conflict of Interest and Ethics Policy*, which can be found at <http://policies.usc.edu/>.

Answers are provided for several Frequently Asked Questions (FAQs) at the end of this form. Additional FAQs can be reviewed at <http://ooc.usc.edu>.

If you have any additional questions, please contact the Office of Compliance at (213) 740-8258 or via email: complian@usc.edu.

This form should be submitted if you answer “yes” to the questions indicated in section 2 or 3. You can submit this form electronically to Jeffrey Wiginton at the Office of Compliance via email to jwiginton@ooc.usc.edu. **By submitting this statement, you declare that you have used all reasonable diligence in preparing this statement, and that to the best of your knowledge, it is true and complete.**

You must also provide any and all supporting documentation that will assist the Conflict of Interest Review Committee in evaluating your disclosure. Examples of applicable documentation include:

- Documents that substantiate equity interests in an outside entity.
- Consulting agreements.
- Documents related to intellectual property rights.
- Proposals, including statements of work, on research related to a disclosure.
- Written confirmation from investigators without actual or apparent conflicts of their willingness to participate in the conduct or review of research.
- Written confirmation from supervisors, including department chairs and/or Deans, of their agreement to monitor the conduct of research.
- Documentation supporting the investigator’s claim that “compelling circumstances” exist to allow research to proceed despite the presence of a Significant Conflict.
- Written confirmation from non-conflicted academic advisors that the academic interests of students involved in research where the investigator has a conflict of interest are adequately protected.

- Disclosures made to sponsors of actual or potential conflicts.
- Informed consent documents that disclose conflicts of interest to human subjects.
- Disclosures made under USC's Conflict of Interest and Ethics policy when a disclosure under the Conflict of Interest in Research policy reveals a potential conflict of commitment.
- Disclosure statements submitted to journal editors, conferences, etc.

Reminder: An Updated Disclosure Must Be Submitted For Any New Or Previously Undisclosed Conflict Of Interest Related To Your Research, Particularly If There Is A Change In Personal, Financial Or Fiduciary Status.

TO PLACE AN "X" ON A BOX TO IDENTIFY YOUR ROLE IN THE RESEARCH OR TO ANSWER A QUESTION "YES" OR "NO", DOUBLE CLICK ON THE BOX YOU WANT TO FILL IN. IN THE DIALOG BOX THAT APPEARS, SELECT THE "CHECKED" OPTION UNDER "DEFAULT VALUE" AND THEN CLICK "OK".

Disclosure Cover Page

Disclosure Number _____
[Number to be assigned by Office of Compliance]

Name of person submitting statement:

Date:

Your campus address, phone number and email:

Role of person submitting statement:

- Principal Investigator
- Co-Investigator
- Research Personnel (defined in FAQ section below)
- Close Relation (defined in FAQ section below)
- Other (Specify):

If you are the PI, have you confirmed that all Research Personnel on your project have identified and disclosed any Conflict of Interest they may have related to this project?

- Yes No (If no, please ensure your Research Personnel have disclosed any actual or potential conflicts of interest they may have and then complete this form.)

Sponsor/Funding Agency:

Name of Outside Entity:

Title of Project:

USC Acct. No.:

HRA Acct. No.:

Grant/Contract No.:

Summary or abstract of the project:

Estimated start date:

Is this an update of a prior disclosure? If so, please provide the prior disclosure number here:

1. Prohibited Conflicts

a. Will you receive any type of **incentive payment, bonus payment or finders fee** related to the research?

Yes No

b. Will publication rights relating to the research be restricted in any way **and** do any of the following also apply to you?

- Hold a private equity interest in the outside entity
- Have publicly traded-equity interest in excess of \$10,000, or .5% of the outside entity's valuation (except when managed by a third party such as a mutual fund),
or
- Hold a management role in the outside entity.

Yes No

c. Will you, or have you, received any **gifts, gratuities or special favors** from a prospective sponsor of your research (in excess of \$50)?

Yes No

If you answered yes to question 1a, 1b, or 1c, the proposed relationship is a prohibited conflict under USC's policy and cannot be managed. Please do not proceed with this research without consulting with the Vice Provost for Research Advancement or the Office of Compliance. For your information, prohibited conflicts must be reported to certain sponsors such as the National Institutes of Health and the National Science Foundation.

2. Disclosure

For the questions you answer “yes”, please provide specifics on page 7.

- a. Do you maintain an **ownership interest** in the research sponsor (for example, stocks, stock options, warrants, or other ownership interests), or a recipient of research funding?

Yes No

- b. Do you have a **management role** (for example, director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in the research sponsor or a recipient of research funding?

Yes No

- c. Do you have a **management role** (for example, director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in an entity that holds or is negotiating a license of any invention related to the proposed research?

Yes No

- d. Do you maintain any **ownership interest** (for example, stocks, stock options, warrants, or other ownership interests) in an entity that holds or is negotiating a license of any invention related to the proposed research?

Yes No

- e. During the last twelve month period have you received **personal payments** for service (including consulting, appointments, and speaker fees, but excluding travel reimbursement) from the sponsor or any other organization that might have an economic interest in the outcome of this research?

Yes No

- f. If you answered yes to Question e, is the amount of these payments equal to or more than \$10,000?

Yes No

If no, please return form as described in the instructions on the cover page.

- g. Do you anticipate that you will receive **personal payments** for service (including consulting, appointments, and speaker fees, but excluding travel reimbursement) in the next twelve months from the sponsor or any other organization that might have an economic interest in the outcome of this research?

Yes No

- h. If yes, will the amount of these payments be equal to or greater than \$10,000?

Yes No

If no, please return form as described in the instructions on the cover page.

If you answered yes to any question on page 5 or 6, please provide specifics here*:

*Please see page 1 for examples of the types of documents you should submit to support your disclosure. All consulting relationships must also comply with USC's Intellectual Property policy. The policy can be reviewed at:
<http://policies.usc.edu/policies/intellectualproperty040301.pdf>.

3. Determination of Significant Conflict of Interest

- a. Does the project involve human subjects **and** did you answer yes to any question in section 2?

Yes No

If yes, have you submitted an application with the IRB?

Yes No

If yes, IRB Application No:

If no, when will the application be submitted?

- b. Do you intend to use **students** that are enrolled in a course you teach or who you are otherwise supervising in an academic capacity to perform services for a company in which you or your Close Relation has an **ownership interest, management role, or receives any type of remuneration**?

Yes No

- c. If you are or will be involved in a sponsored research agreement with an outside entity, do you hold:

- Any private equity interest (*e.g.*, stocks, stock options, or other ownership interests)?
- Publicly traded equity in excess of \$50,000 in a research sponsor or licensee?
- Management Role (for example, director, officer, scientific, or technical appointment or any other role with significant decision-making authority) in a research sponsor or licensee?

Yes No

If you answered yes to any of questions 3a-c, then you also hold a significant conflict of interest.

If you hold a significant conflict, please explain the compelling circumstances that justify your participation in the research project on the next page.

Compelling circumstances justifying my participation in this research project*:

*Please see page 1 for examples of the types of documents you should submit in support of your compelling circumstances.

Management Plan

Please use the following page to propose a management plan to ensure objectivity in your research. All management plans shall contain, at a minimum, these elements:

- All relevant **publications, proposals and presentations** must contain a statement disclosing support received from, or financial interests in, any source outside of USC;
- All **informed consent documents** in the context of human subjects research must disclose support received from, or financial interests in, any source outside of USC. Conflicted Investigators and/or Research Personnel are not permitted to consent human subjects;
- The Investigator and/or Research Personnel and their Close Relations will not participate in any **intellectual property negotiations**, or other contractual negotiations, between USC and the outside entity;
- Investigators must **notify students** of the presence of a Conflict of Interest if the student is to perform as a research assistant on the research, along with a notification to the student and his or her advisor of the student's rights, and the appointment of a third party faculty member as a monitor of the situation.

Examples of additional elements to include in the management plan are provided in USC's *Conflict of Interest in Research* policy. Please be as specific as possible in your recommendations. Please provide your management plan on page the next page.

Please provide your management plan here*:

* Please see page 1 for examples of the types of documents you should submit in support of your management plan.

Frequently Asked Questions

What is a Conflict of Interest?

A "Conflict of Interest" is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research. Conflicts of Interest include non-financial as well as financial conflicts, because non-financial interests can also come into conflict with a researcher's primary commitment to maintain scientific objectivity. Investigators should consider not only situations that are unacceptable, but also gray areas that might create the appearance of a Conflict of Interest.

Although not an all-inclusive list, each of the following is a type of Conflict of Interest that must be disclosed:

- Maintaining a **private equity interest** (e.g., stocks, stock options or other ownership interests not publicly traded) in a research sponsor or licensee, or in a company having an economic interest in the research, regardless of the value of such equity interest.
- Maintaining a **publicly traded equity interest** of \$10,000 or more (except when the ownership interest is managed by a third party such as a mutual fund) or .5% of the valuation of a research sponsor or licensee, or in a company having an economic interest in the research.
- Holding a **management role** (e.g., director, officer, scientific, or technical appointment where the Investigator or Research Personnel has significant decision-making authority) in a research sponsor, licensee, or in a company having an economic interest in the research; or any other instance where the Investigator or Research Personnel has significant decision-making authority within the outside entity.
- Using a **student** to perform services for a company in which the Investigator, Research Personnel, or the Close Relation of either, has an ownership or management role when (1) the student is currently enrolled in an Investigator, Research Personnel, or the Close Relation of either's class; or (2) the Investigator, Research Personnel, or Close Relation of either currently supervise(s) the student in an academic capacity; or (3) the Investigator, Research Personnel, or the Close Relation of either otherwise has the ability to influence the academic progress of the student.
- Maintaining a **financial interest** or **management role** in a research sponsor of the Investigator and/or Research Personnel's laboratory.
- Maintaining a **financial interest** or **management role** in a company who has given, or expressed interest in giving, a major gift to the Investigator and/or Research Personnel's department or school.

- Accepting **personal payments for services (i.e. consulting arrangements, non-managerial scientific or technical appointments), from any sponsor or any organization or individual having an economic interest in the investigator's research, that total \$10,000 or more** when aggregated in any twelve month period.
- Accepting **gifts, gratuities or special favors** from an actual or prospective sponsor of an Investigator's research, other than occasional gifts of nominal or modest value (less than \$50 in value or isolated invitations to meals).¹
- Maintaining a financial interest or management role (see above) in a company that is **negotiating a license** to intellectual property from USC.
- Receipt of **intellectual property rights** (e.g., patents, copyrights or royalties from such rights) from a research sponsor by an Investigator, Research Personnel or the Close Relation of either.

What are my responsibilities with respect to identifying conflicts of interest?

You are responsible for determining whether you or your Research Personnel have actual or potential conflicts of interest or commitment. You should evaluate potential conflicts not only at the outset of your research, but also at any time a change occurs in any financial or non-financial interest during the course of your research. This continuing evaluation can occur at the time a new proposal is submitted, when a new relationship is established with an outside entity, or when a prior relationship with an outside entity changes.

Who are "Research Personnel"?

Research personnel are any USC employee, whether faculty or staff, who contribute to a research activity, whether or not the research is funded, and regardless of status (for example, research associates, technicians, nurse coordinators, administrators, and graduate assistants).

What is a "Close Relation"?

A Close Relation means the spouse, domestic partner, or dependent child of an Investigator or Research Personnel. In addition, a colleague, sibling, parent, or other relation is considered a Close Relation when an Investigator and/or Research Personnel knows that the individual maintains a Conflict of Interest that may be impacted by research the Investigator and/or Research Personnel is conducting.

¹ Investigators and/or Research Personnel who are healthcare providers are subject to additional requirements when accepting gifts, gratuities, or special favors from pharmaceutical companies, medical device companies, health care suppliers, and their employees or agents. For more detail, please review USC's *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*.

What is the extent of my responsibility to determine possible conflicts of interest that may be maintained by Research Personnel?

Under USC's Conflict of Interest in Research Policy, you are responsible for confirming that all research personnel under your supervision and who are involved in proposing, conducting or reporting research on your project have identified and disclosed any potential conflict of interest related to your research, and that any such research personnel comply with any measures put in place to manage the conflict. This can be accomplished through raising the issue at staff meetings, sending out a memo to research personnel under your supervision, or any other reasonable method of communication. You should document all of your efforts to make this assessment.

What types of documents or other information should an Investigator provide in connection with a disclosure?

To assist the CIRC in evaluating a conflict of interest disclosure, the Investigator should provide copies of all documentation and information that supports his or her representations. Although not a complete list, examples of acceptable supporting documentation include:

- Documents that substantiate equity interests in an outside entity.
- Consulting agreements.
- Documents related to intellectual property rights.
- Proposals, including statements of work, on research related to a disclosure.
- Written confirmation from investigators without actual or apparent conflicts of their willingness to participate in the conduct or review of research.
- Written confirmation from supervisors, including department chairs and/or Deans, of their agreement to monitor the conduct of research.
- Documentation supporting the investigator's claim that "compelling circumstances" exist to allow research to proceed despite the presence of a Significant Conflict.
- Written confirmation from non-conflicted academic advisors that the academic interests of students involved in research where the investigator has a conflict of interest are adequately protected.
- Disclosures made to sponsors of actual or potential conflicts.
- Informed consent documents that disclose conflicts of interest to human subjects.
- Disclosures made under USC's Conflict of Interest and Ethics policy when a disclosure under the Conflict of Interest in Research policy reveals a potential conflict of commitment.
- Disclosure statements submitted to journal editors, conferences, etc.

What is considered a "Significant Conflict"?

A "**Significant Conflict**" is a Conflict of Interest that is presumed to be unacceptable unless the Investigator or Research Personnel is able to present **compelling circumstances** that justify allowing the research to proceed despite the presence of the Significant Conflict. Significant Conflicts include, but are not limited to:

- Any Conflict of Interest in research involving **human subjects**, unless the conflict arises from the Investigator or Research Personnel's acceptance of payments for services that are less than \$10,000 when aggregated in any twelve month period.
- Using a student to perform services for a company in which the Investigator, Research Personnel, or the Close Relation of either, has an ownership or management role when (1) the student is currently enrolled in an Investigator, Research Personnel, or the Close Relation of either's class; or (2) the Investigator, Research Personnel, or Close Relation of either currently supervise(s) the student in an academic capacity; or (3) the Investigator, Research Personnel, or the Close Relation of either otherwise has the ability to influence the academic progress of the student.
- Any sponsored research agreement with an outside entity in which the Investigator, Research Personnel or the Close Relation of either:
 - Holds any **private equity interest**;
 - Holds a **publicly traded equity interest in excess of \$50,000** in a research sponsor or licensee, or in a company having an economic interest in the research;
 - Holds a **management role** in a research sponsor or licensee.

What does the CIRC consider sufficient "compelling circumstances" that would allow an Investigator or Research Personnel with a Significant Conflict to remain involved with research?

The CIRC determines on a case-by-case basis whether an investigator has provided "compelling circumstances" that justify allowing the research to proceed despite the presence of a Significant Conflict. Compelling circumstances may exist when an investigator demonstrates that he or she is the only person capable of performing the research due to his or her unique talents or skills. For example, the research may involve experimentation to further develop an early stage discovery that requires the investigator's unique insights and knowledge. In the case of human subjects research, the investigator should also demonstrate a low-risk of harm to human subjects.

We encourage you to contact the Office of Compliance to assist you in articulating the compelling circumstances that may be present in situations where you maintain a Significant Conflict.

What kinds of conflicts of interest are prohibited?

Certain types of conflicts are prohibited under USC policy, as follows:

- Transfer of intellectual property **rights** arising out of research conducted at USC to any outside entity.

- Any incentive payments, bonus payments, finders fees, or any type of payment or incentive based on outcome with respect to the proposal, conduct, supervision, or reporting of research, or with respect to the evaluation of a product or service intended for a commercial market (e.g., a clinical trial for a pharmaceutical company), regardless of the amount of compensation or payments received.
- Any sponsored agreement in which publication rights are restricted for proprietary or other reasons, in combination with the Investigator or Close Relation receiving any form of payment, holding any private equity interest, or holding publicly-traded equity interests of \$10,000 or more (except when the equity interest is managed by a third party such as a mutual fund) or .5% of the outside entity's valuation, or holding a management role;
- Accepting gifts, gratuities or special favors from an actual or prospective sponsor of an Investigator's research, other than occasional gifts of nominal or modest value (less than \$50 in value or isolated invitations to meals).

What is a "Conflict of Commitment"?

A "Conflict of Commitment" is a conflict between outside activities and a full-time employee's responsibility to devote his or her primary professional loyalty, time and energy to his or her teaching, research, service, administrative, and clinical duties, as applicable. Refer to USC's *Conflict of Interest and Ethics* policy and the Faculty Handbook for more detail. In addition, Conflicts of Commitment should be disclosed to your supervisor and/or dean.

If I have a financial interest, management role or accept compensation for personal services from an outside company and that outside company wants to apply for an SBIR or STTR grant, can I still participate in the portion of the research taking place at USC?

In these circumstances, you generally cannot act as both the Investigator and/or Research Personnel in the research taking place at USC and that occurring at the outside company. However, assuming adequate measures are in place to manage the conflict, you can act as Investigator and/or Research Personnel at the outside entity if an investigator with no conflict performs the basic research taking place at USC.

What if my research involves human subjects and I receive payments for personal services under \$10,000 from the sponsor?

These types of payments must be disclosed to the IRB in connection with its review of the protocol. The IRB may require the Investigator and/or Research Personnel to disclose this compensation to all human subjects during the informed consent process. The IRB may also refer these arrangements to the Conflict of Interest Review Committee depending on the circumstances.

When I disclose an actual or potential conflict of interest, what types of management recommendations may the university impose?

It is important to remember that cases are individually reviewed, and subtle differences in the nature and magnitude of the financial interest(s), in combination with the investigator's role in the research study, the type of research being conducted and the clarity and completeness of the disclosure, may affect the CIRC's determinations and recommendations. Here are some examples of possible outcomes:

Scenario #1: You are hired by an outside entity to perform consulting services and your compensation will be relatively modest.

If you perform personal services for an outside entity with an economic interest in the outcome of your research, but the total amount of compensation you receive is less than \$10,000 in the preceding 12 months, the CIRC may simply acknowledge your disclosure and not impose any management recommendations.

Scenario #2: Same situation as Scenario #1 but your consulting relationship with the outside entity will result in you receiving more than \$10,000 during a 12-month period.

Since you will receive more than \$10,000 within a 12-month period, the CIRC will more closely scrutinize your disclosure. The CIRC will determine whether your relationship with the outside entity is a conflict of interest that can be managed, reduced or eliminated through the implementation of an effective management plan.

Scenario #3: What if the Principal Investigator has an ownership interest or managerial responsibilities with her research sponsor?

These types of financial interests and management roles are considered "significant conflicts" under USC's Conflict of Interest in Research policy. The CIRC closely scrutinizes such relationships, and only allows the Investigator and/or Research Personnel to participate in the research if he or she can present compelling circumstances that support continued involvement in the research.

The factors considered include:

- The extent of the investigator's equity holdings in the company;
- Whether the investigator is directing the research or, alternatively, has designated an investigator with no financial interest to direct the research;
- Whether the spouse of the investigator is the CEO or other officer;
- Whether the company is a new start-up with no assets or has secured financing;
- Whether the investigator is also serving as a paid consultant to the company;
- The extent to which the research project overlaps with the immediate commercial interests of the sponsor.

Based on the facts of a particular disclosure, the CIRC will determine whether the Investigator and/or Research Personnel can be involved with the research despite the

presence of a Significant Conflict, and if so, require the implementation of an appropriate management plan.

In addition, since the faculty member's primary professional duty of loyalty is to USC, a conflict of commitment may be present if the faculty member is devoting significant time to his or her work with the outside entity.

What should I do if my conflict of interest changes during the award or contract period?

You should submit an updated "*Statement of Outside Interests Related to Research*" for any new or previously undisclosed Conflict of Interest, particularly when there is a change in personal, financial or fiduciary status. For further information, please see Section 6 of USC's Conflict of Interest in Research policy.

What resources are available to me at USC if I have questions about conflicts of interest?

There are a variety of resources available to you at USC to help guide you through the process of determining whether you have a potential or actual conflict of interest, and to assist you in making the appropriate disclosure if in fact you do. These resources include the Vice Provost for Research Advancement, the Office of Compliance and/or your school's Associate Dean for Research.