Guide to Sponsored Research Procedures at USC
Winter 2024

The following is a reference tool that highlights some of the important USC policies related to sponsored projects. Please refer to this guide both in the proposal preparation stage and throughout the course of your research.

Contact the Office of Research and Innovation (http://research.usc.edu/, or 213-740-6709) for general questions on research within USC, and contact the USC Office of Culture, Ethics and Compliance (http://ooc.usc.edu/, or 213-740-8258) for any general questions on research compliance.

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I.   Proposal Submission

Externally sponsored proposals must be submitted through the Department of Contracts and Grants (DCG) or, for industry-sponsored clinical trials, through the Clinical Trials Office (CTO).

For externally sponsored projects, except for industry-sponsored clinical trials, proposals are submitted through Cayuse SP prior to submission to the sponsor: https://usc.app.cayuse.com/. Cayuse SP is the system of record to verify that all necessary approvals have been obtained and that investigators have agreed to all terms and conditions associated with the research. Industry-sponsored clinical trials are submitted through the OnCore system (https://sc-ctsi.org/resources/ctms). Regardless of sponsor, clinical trials and clinical research projects with associated billable clinical procedures or other items that are billable to insurers require a Coverage Analysis and, therefore, must also be submitted to OnCore to engage CTO to perform this service.

For further information on submitting proposals, contact the Department of Contracts and Grants: (213) 821-6622 (UPC and HSC); (310) 822-1511 (Marina); or (858) 964-4644 (ATRI). For further information regarding clinical trials, contact the Clinical Trials Office at (323) 442-7218.

A.   <u>Who May Be a Principal Investigator on Sponsored Research Projects at USC</u>

All tenured, tenure track, and Research, Teaching, Practice, and Clinical (RTPC) faculty may serve as Principal Investigators on Sponsored Research Projects at USC. Retired faculty may be called back and asked to serve as Principal Investigators as described in Chapter 10 of the Faculty Handbook. Adjunct and voluntary faculty may not serve as Principal Investigators.

The following may serve as Principal Investigators if a specific waiver is granted upon recommendation by the appropriate department chair(s), appropriate dean(s), and the Senior Vice President of Research and Innovation or designee:

- Part-time faculty
- Research Scientists, Senior Research Associates, and Research Associates
- Postdoctoral Research Associates and Postdoctoral Teaching Associates

Postdoctoral Research Associates and Postdoctoral Teaching Associates, as defined by USC's Postdoctoral Scholars Policy, can also serve as co-principal investigators on sponsored projects without a waiver. To review the Postdoctoral Scholars Policy, please visit https://policy.usc.edu/postdoctoral-scholars/.

In addition:

1) All investigators must have current grants management training (verified at time of award).
2) All investigators supported by federal agencies requiring annual conflict of interest disclosures and/or conflict of interest training must have satisfied these requirements.

3) All investigators supported by federal agencies must have a signed "present assignment" of intellectual property to USC and must have agreed in writing to promptly disclose inventions resulting from their research (verified at time of award).

B. **Institutionally Limited External Competitions**

Some competitions sponsored by outside agencies restrict the number of applicants a university can nominate. In such cases, potential applicants must go through an internal review process and receive approval from USC administration prior to submission to the sponsoring agency. Deadlines for USC internal reviews are typically a month or more in advance of the sponsor's own deadlines.

Researchers intending to apply for an institutionally limited competition should contact Research Initiatives and Infrastructure at rii@usc.edu as soon as an announcement is released.

Further information on institutionally limited competitions can be found at https://rii.usc.edu/limited-submissions/.

C. **Regulatory Research Committees**

If your proposal is subject to review by a regulatory research committee, committee approval is required before research can commence. Investigators should contact the applicable committees soon after a proposal is submitted and/or when funding is likely to obtain guidance and avoid possible delays in starting research. The Department of Contracts and Grants (DCG) and Clinical Trials Office (CTO), as applicable, are authorized to restrict access to an award until all necessary approvals are obtained. The USC regulatory research committees are as follows:

- Human Subjects: **Institutional Research Board (IRB)**. The IRB oversees research involving a living individual about whom an investigator conducting research obtains: (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Visit https://hrpp.usc.edu/irb/ or call (323) 442-0114.

- Stem Cells (Adult or Embryonic): **Stem Cell Research Oversight Committee (SCRO)**. The SCRO provides oversight of all issues related to the derivation and use of stem cells, including but not limited to Human Embryonic Stem Cell (hESC) research. Contact Qilong Ying: qying@med.usc.edu or visit https://stemcell.keck.usc.edu/research/scro/.

- Animals: **Institutional Animal Care and Use Committee (IACUC)**. The IACUC oversees procedures related to research and testing of animals. Visit https://iacuc.usc.edu/ or email iacuc@usc.edu.

- Biological Agents and Regulated Carcinogens: **Institutional Biosafety Committee (IBC)**. The IBC is responsible for oversight of the use of all potentially hazardous biological agents, including infectious agents, human and non-human primate materials,

chemicals used in biomedical research, recombinant DNA and studies involving human gene transfer. Visit http://ehs.usc.edu/research/bio/ibc/, call (323) 442-2200, or e-mail biosafety@usc.edu.

- Radioactive Materials: **Radiation Safety Committee (RSC)**. The RSC is responsible for ensuring that radioactive materials and radiation-producing devices are used safely and in accordance with State and Federal regulations. Visit http://ehs.usc.edu/research/rad/, call (323) 442-2200, or e-mail radsafety@usc.edu.

    - The Laser Safety subcommittee within the RSC is charged with developing and recommending University policies related to the safe use of lasers and laser-related work at USC, as well as monitoring compliance with State and Federal regulations pertaining to the safe use of lasers. Visit http://ehs.usc.edu/research/laser/, call (323) 442-2200, or e-mail radsafety@usc.edu.

- Select Agents (as identified at http://www.selectagents.gov/): **Institutional Biosafety Committee (IBC)**. Approval must be obtained from the Federal Select Agent Program (FSAP) prior to receiving or using any Select Agents. The agents must be registered with the IBC, and the Biosafety program must coordinate registration with the FSAP. Visit http://ehs.usc.edu/research/bio/ibc/, call (323) 442-2200, or e-mail biosafety@usc.edu.

- Chemical Safety: **Campus-Wide Chemical Safety Committee (CCSC)**. The Chemical Safety Committee is responsible for advising on policies and guidelines related to the use of potentially hazardous chemicals or materials and ensuring that research involving these agents is conducted in a manner that does not endanger the researcher, laboratory workers, the public, or the environment. Call (323) 442-2200 or e-mail labsafety@usc.edu for more detail.

- Research Compliance: **Research Compliance Working Group**. The Research Compliance Working Group comprises key stakeholders involved with research compliance across both campuses and is charged with identifying and prioritizing research compliance risks at USC. As appropriate, the committee makes recommendations to address potential or actual research risks, advises on processes/systems to monitor research compliance on an ongoing basis, and helps improve coordination between administrative units charged with research compliance-related responsibilities. The Working Group meets quarterly. Contact the USC Office of Culture, Ethics and Compliance at compliance@usc.edu for additional detail.

D.   Conflicts of Interest in Research

Any potential conflict of interest related to your research must be identified in Cayuse SP Pre-Award, and also in the iStar system when submitting a protocol for review by the IRB or the IACUC. You must also fully disclose the potential conflict through "diSClose," USC's online disclosure system (https://disclose.usc.edu). Research cannot commence until the **Conflict of Interest Review Committee (CIRC) has reviewed the submission and a decision has been**

made, which may require that you follow a conflict management plan. Conflicts that arise during the course of research must be disclosed when they first appear, and also require an approved management plan. In the case of a conflicting outside relationship that starts after the research has begun, the outside relationship cannot commence until the CIRC review is completed and a decision is made. Call the USC Office of Culture, Ethics and Compliance at compliance@usc.edu for further information.

Investigators supported by Health and Human Service (HHS) agencies (such as NIH, AHRQ and CDC) and/or the Department of Energy are required to submit an annual disclosure of all financial interests related to their institutional responsibilities at USC via diSClose. Annual disclosures must be updated between June 1st and July 31st each year. Additional updates may be required when changes occur during the year. Investigators are not permitted to submit proposals unless their disclosures are up to date and required training has been completed.

Background: http://ooc.usc.edu/conflict-of-interest/conflict-of-interest-in-research/
Policy: https://policy.usc.edu/conflict-of-interest-in-research/

E.   Conflicts of Interest and Commitment

A conflict of interest or conflict of commitment arises when financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment and ability to perform their responsibilities to USC. A conflict of commitment arises when an employee's outside activities conflict with or appear to conflict with their responsibilities to USC. Both types of conflicts should be disclosed through USC's online disclosure system, "diSClose" (https://disclose.usc.edu/). Please note that faculty are not permitted to conduct sponsored research at other institutions (acting as investigator or consultant) without exceptional approval by their dean and the Senior Vice President of Research and Innovation.

You may click below for further information or call the USC Office of Culture, Ethics and Compliance at compliance@usc.edu.

Background: http://ooc.usc.edu/conflict-of-interest/conflict-of-interest-in-professional-and-
                 business-practices/
Policy: https://policy.usc.edu/conflict-of-interest-and-commitment/

F.   Conflicts Due to Foreign and Other External Research Activities

Research sponsors expect that investigators disclose all other sources of research support, both foreign and domestic. This includes positions and scientific appointments at other institutions (foreign or domestic), regardless of the type or position, or whether compensation is received. It also includes reporting of all projects, resources and other support for the research activities of investigators, regardless of whether the support is provided through USC or another institution (foreign or domestic), as well as in-kind support (e.g., office/laboratory space, equipment, supplies, scientific materials, employees), or selection to a foreign "talents" or similar-type program.

This information must be disclosed to sponsors at the time of proposal submission via the current and pending support or other support section of the proposal. After the time of award, disclosure must be made in the annual performance progress report. Substantive changes in project or budget, including the addition of a foreign component to an ongoing grant, require prior sponsor approval. This includes a collaborator at a foreign institution who performs experiments in support of the project, regardless of whether the foreign collaborator receives funding from the grant.

USC requires that any compensated external research activities be disclosed prior to initiation through the diSClose system. USC also requires that all proposed faculty titles outside of the university be submitted for approval in advance through Faculty Affairs, to be approved by the Provost.

Background: https://ooc.usc.edu/compliance-programs/international-activity/international-collaborations-and-disclosure-requirements/

G.   Institutional Conflicts of Interest

USC's Institutional Conflict of Interest (ICOI) policy addresses instances where the financial interests of the University have the potential to cause bias in the conduct of research. Such conflicts occur, for example, where a research project provides a direct benefit to an outside entity through evaluation, validation, trial or test of an invention, product, drug, service, or technology, and the University holds a financial interest in the outside entity. An institutional conflict is considered "significant" if a research project involves human subjects and the university: (1) holds any private equity in the outside entity; (2) has the potential to receive cash payments from existing licensing arrangements with the outside entity; or (3) maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subjects research as a result of technology licensing activities.

Institutional conflicts that are not significant are managed through disclosure of the University's relationship with the outside entity in all publications, proposals, consent documents, and presentations. Significant conflicts are presumed to be unacceptable unless compelling circumstances are present that justify allowing the research to proceed at the University despite the presence of the conflict.

Background: http://ooc.usc.edu/conflict-of-interest/institutional-conflict-of-interest-in-research/
Policy: https://policy.usc.edu/institutional-research-conflict-interest/

H.   Export Controls

The U.S. Government maintains two primary sets of export control regulations that may impact university research. The Export Administration Regulations ("EAR") regulate exports of commercial items with potential military applications (so-called "dual-use" items). The International Traffic in Arms Regulations ("ITAR") regulate exports of items and services specifically designed for military applications.

In addition to these export control regulations, university activities may also be subject to the U.S. Government's economic sanctions against certain countries, entities, and individuals. These economic sanctions programs are administered by the Treasury Department's Office of Foreign Asset Controls ("OFAC").

USC generally does not restrict participation in research to United States citizens, nor does it accept restrictions on a researcher's ability to share the results of their research freely, and will only consider such projects on an exception basis. If you become aware that a sponsor is seeking to restrict participation by a researcher, staff person, or student on the basis of nationality, or restrict publication (other than short review periods to ensure that no confidential or proprietary information has been inadvertently disclosed in an intended publication), you must submit a request for exception to the Office of Research and Innovation. The request is then reviewed by the Office of Research and Innovation in consultation with the USC Office of Culture, Ethics and Compliance and a standing faculty committee, as applicable. For guidance on what the request must address and the conditions that may apply to conducting restricted research, please review USC's International Collaborations and Export Controls policy at https://policy.usc.edu/international-collaborations-and-export-controls/. You may also contact the USC Office of Culture, Ethics and Compliance at compliance@usc.edu for guidance. You may also review more detailed information regarding Export Control regulations on the USC Office of Culture, Ethics and Compliance website at http://ooc.usc.edu/international-activity/research/.

I. Cost Sharing

Cost sharing occurs whenever any portion of project costs are provided at USC's expense rather than at the expense of the sponsor. Mandatory cost sharing is required by the sponsor as a condition of the award, while voluntary cost sharing is not.

There are two kinds of voluntary cost sharing. Voluntary **committed** cost sharing is committed prior to acceptance of the award – either at the time a proposal is submitted or during budget negotiations. Voluntary **uncommitted** cost sharing is not proposed or budgeted for in a sponsored agreement, but generally occurs during the period of performance when research personnel donate additional time or expenses above that proposed to the sponsor or agreed to as part of the award.

For federal programs, the Uniform Guidance states that federal grant programs may no longer consider cost-sharing during the merit review process unless it is statutorily required. Thus, voluntary committed cost-share at the proposal stage will no longer impact the proposal's review.

If a cost sharing commitment is quantified in the proposal or award, regardless of whether it is mandatory or voluntarily committed, the commitment must be identified and approved in writing by the Dean of the relevant school(s) or unit(s) prior to submission of a proposal or acceptance of the award. After the appropriate approval is obtained, the portion of compensation that is cost-shared should be charged to an appropriate school, unit or departmental cost sharing Grant driver

worktag. Call the Office of Financial Analysis at (213) 821-1937 or email ofa@usc.edu for further guidance.

Costs deemed unallowable by the sponsor, including any salary above a sponsor's salary cap, cannot be cost shared. These costs must be charged to an unrestricted school, unit or departmental non-Grant driver worktag/PPG (Program, Project, Gift).

Background: https://fbs.usc.edu/effort-certification/cost-sharing/
Policy: http://policy.usc.edu/cost-sharing/

J.   Graduate Student Tuition Remission

Graduate students participating in research projects may receive a reasonable amount of support (tuition remission and other support) on the basis of the student's participation in a sponsored project. Tuition remission is considered an allowable direct charge for most sponsors, provided that: (1) the student is conducting activities necessary to the sponsored agreement; (2) tuition remission is consistently provided in a like manner to students in return for similar activities conducted in non-sponsored as well as sponsored activities; and (3) during the academic period, the student is enrolled in an advanced degree program at USC and the activities of the student in relation to the sponsored project are also related to the degree program in which the student is enrolled.

The NIH has established a funding cap that limits the amount it awards for a combination of graduate student salary and tuition remission. This cap is determined through reference to the National Research Service Award (NRSA) stipend in effect at the time the grant award is issued. The cap in effect at the time the proposal is submitted applies to the entire life of the competitive segment of the project. Current NRSA levels are posted at https://researchtraining.nih.gov/programs/training-grants.

Tuition charges should be assigned to research grants and other funding sources in proportion to the graduate student's salary allocation during the nine-month academic year.

K.   Student Workers

Students may be hired as student workers on research projects in instances where the work, or student status, does not qualify them to be hired as graduate research assistants.   Student workers do not receive tuition remission and are paid as hourly employees.

Student workers on sponsored research projects must be hired under job code 032024-Student Worker – Research.   The Student Worker – Research title may also be used in other instances when the primary duty of the student is to support research projects, and the student does not qualify to be hired as a graduate research assistant.

L.   Reimbursement Rates

Information on reimbursement rates for indirect costs (also referred to as overhead or Facilities & Administrative Costs) and fringe benefits may be obtained at the Department of Contracts and Grants website: https://dcg.usc.edu/getting-started/proposal-rates-at-a-glance/.

M.   <u>Responsible Conduct of Research (RCR) Training Requirements</u>

All undergraduate students, graduate students, postdoctoral researchers, faculty, and other senior personnel supported by the National Science Foundation (NSF) are required to complete an approved course in Responsible Conduct of Research. To satisfy NSF's RCR requirement, please visit https://sites.usc.edu/ori/responsible-conduct-of-research/ and enroll in USC's online RCR training program, administered by CITI. In addition, trainees supported on certain NIH programs, including training grants, are also required to complete in-person RCR training. To satisfy NIH's in-person training requirement, the Keck School of Medicine has created classroom-based courses on RCR.

Please consult contact Research Integrity, Office of Research and Innovation at gracekri@usc.edu or the Office of Culture, Ethics and Compliance.

II. Award Establishment

A. Pre-Award Authorizations (Advance Funding)

Pre-award authorizations enable investigators to incur costs on a sponsored project before the university has received an award.

Sponsors participating in the Federal Wide Research Terms and Conditions supplementing uniform guidance allow receipts of grants and cooperative agreements issued under the federal guidance to incur project costs up to 90 days before the official start date of the award without prior approval.

Pre-award authorizations require approval from the investigator's dean (school of primary appointment) and a programmatic justification because the Dean's worktag/PPGG (Gift, Grant, Program, Project) is at risk until the award is received. For further information, visit the Department of Contracts and Grants website at https://dcg.usc.edu/, or call (213) 821-6622 (UPC and HSC); (310) 822-1511 (Marina); or (858) 964-4644 (ATRI).

B. Award Creation

Upon award acceptance, the Department of Contracts and Grants processes the award in Cayuse SP. Once finalized, the Cayuse Award contains a summary of the award information, including award terms and conditions. It is important to review the Award and its terms and conditions to understand your obligations. Once processed in Cayuse SP, Sponsored Projects Accounting finalizes a set-up in the University's financial system, Workday Financials. Until the Grant driver worktag is established, the PI cannot charge costs directly against the award. For further information on award establishment, visit the Department of Contracts and Grants website at https://dcg.usc.edu/, or call (213) 821-6622 (UPC and HSC); (310) 822-1511 (Marina); or (858) 964-4644 (ATRI). For more information on Worktag/PPGG (Gift, Grant, Program, Project) establishment, visit the Sponsored Projects Accounting website at https://fbs.usc.edu/sponsored-projects-accounting/creating-an-award-award-line-and-grant-worktag/, or call (213) 740-5381. Industry-sponsored clinical trials are activated by the Clinical Trials Office (CTO) through OnCore.

C. Division of Overhead for Multi-School Projects

In instances involving collaboration between researchers in more than one school, the Lead Unit, who is responsible for the oversight and monitoring of the award, will be established as the master worktag. The Lead Unit is typically in the school of the Principal Investigator's primary appointment. Satellite Grant driver worktags should be established in the school of any Co-Principal Investigator or Co-Investigator(s) primary appointment so that indirect costs may be allocated in proportion to the research costs accrued in that school. For information on how to request set up for Multi-School or Multi-PI project, refer to https://dcg.usc.edu/training-resources/cayuse-sp-pre-award-resources/. For further information on how to establish a satellite Grant driver worktag, visit Sponsored Projects Accounting's website at

https://fbs.usc.edu/sponsored-projects-accounting/creating-an-award-award-line-and-grant-worktag/ or call (213) 740-5381.

D.   Intellectual Property Assignment

Researchers are obligated to assign all rights to intellectual property created, developed, or reduced to practice: (1) while conducting research at USC; (2) through the significant use of university facilities, funds, resources, or supplies; or (3) pursuant to a sponsored or other written agreement to transfer ownership to USC. Researchers also must promptly report any potentially patentable inventions to USC through the USC Stevens Center for Innovation. Invention disclosures are made online via Sophia, USC's web-based system for disclosure and tracking of invention disclosures and related patents and agreements (https://stevens.usc.edu/researchers/invention-disclosure-process/). All invention disclosures are examined by the University to determine whether a particular invention is patentable and whether the University desires to seek patent protection. For additional guidance on commercialization of technology, please see https://dcg.usc.edu/wp-content/uploads/2021/06/Commercialization-of-Technology-at-USC-memo_3-2-17.pdf or consult with USC Stevens Center for Innovation at https://stevens.usc.edu.

The Department of Contracts and Grants verifies that all named project personnel have completed the IP assignment process prior to establishing new awards from federal sponsor. In addition, all graduate research assistants complete the IP assignment at time of hire, as do research staff (within Workday).

III. After Research Commences

A. Effort Reporting

Faculty and research staff are responsible for reporting and certifying percentage effort charged to a sponsored project promptly. Certification includes making corrections and adjustments if there are differences between estimates and actual effort. All twelve-month faculty and exempt employees must certify their effort quarterly, while all nine-month faculty and RAs must be certified once each semester. For RAs, the PI on the award is responsible for certifying each of their effort(s). In the event an RA is split between multiple departments, each PI will certify the effort on the award. Non-exempt staff effort is certified bi-weekly via the university's timekeeping systems. The Principal Investigator is responsible for confirming that the faculty and staff members working on the sponsored project have certified promptly and that the time and effort charged appear reasonable.

To assist in the completion of effort reporting, USC has implemented a web-based effort certification system called eCert, through which all effort may be certified.

Certification processes are overseen by USC's **Office of Financial Analysis**. Visit https://fbs.usc.edu/effort-certification/, call (213) 821-1937 or e-mail eCert@usc.edu, or contact your own department coordinator for further guidance.

B. Salary Charging

Institutional activities such as proposal writing, committee service, and teaching may not be charged to sponsored projects. Therefore, no more than 95% of any researcher's salary may be charged to sponsored projects. In exceptional circumstances, more than 95% may be charged, but the researcher must demonstrate that their institutional effort is solely dedicated to existing sponsored projects.

Also, certain sponsors limit the total amount of salary they will support. For example, NSF normally limits total salary support to no more than two months of a principal investigator or co-investigator's salary in any one year. Any compensation over two months must be disclosed in the proposal budget, justified in the budget justification, and approved by NSF in the award notice.

Please consult the USC Office of Culture, Ethics and Compliance for additional guidance.

C. Cost Transfers

A cost transfer is a mechanism used to transfer payroll and non-payroll transactions from or to a sponsored Grant driver worktag. The Worktag/PPGG (Gift, Grant, Program, Project) to which the cost is transferred may itself be a sponsored Worktag/PPGG (Gift, Grant, Program, Project), but only if the cost is allowable. A cost transfer can occur for a variety of reasons, including a clerical or bookkeeping error, an inappropriate initial allocation of a charge to one project when the charge benefits several projects, or an initial charge to a non-sponsored Worktag/PPGG (Gift,

Grant, Program, Project) necessitated by a delay in finalizing contract negotiation on a sponsored Worktag/PPGG (Gift, Grant, Program, Project). Cost transfers should be made within 90 days of when the error is discovered, and no later than 15 days after the termination date of the budget period. If the cost transfer is related to salary, investigators must certify the changed effort accordingly. All cost transfers must be fully documented. USC's Sponsored Projects Accounting (SPA) oversees the cost transfer process. Visit https://fbs.usc.edu/sponsored-projects-accounting/transfers-of-costs/, or call (213) 740-5381 for more information.

D.   Subrecipient Monitoring

All subcontractors must sign a Supplier Contract agreement that includes a detailed statement of work. Investigators must monitor subcontractors to ensure they are complying with the award terms. These monitoring duties include confirming that the subcontractor is satisfying the statement of work and reviewing and approving invoices submitted by the subcontractor to ensure costs are reasonable, allocable, and allowable on the project. For assistance on issues related to subrecipient monitoring, visit https://dcg.usc.edu/getting-started/subawards/ or contact the Department of Contracts and Grants (https://dcg.usc.edu/).

The university creates a separate Grant Driver Worktag to monitor subrecipient activity. For more information, visit https://fbs.usc.edu/sponsored-projects-accounting/types-of-awards-and-award-lines/.

E.   Program Income

Program income is gross income earned by a grantee directly generated by the sponsored project or activity or earned by the award, other than income resulting from royalties or licensing fees. All program income must be reported on the financial status report.

The university creates a separate Grant Driver Worktag to monitor Program Income activity. More details are available here: https://fbs.usc.edu/sponsored-projects-accounting/types-of-awards-and-award-lines/.

F.   Use of Consultants

Before an independent contractor (e.g., consultant) provides professional advice or service that will be paid for by a sponsored project, the PI and Department must confirm allowability and ensure compliance with the terms and conditions of the award. If allowable, the requisition can be processed through Workday.

Furthermore, for sponsored project-funded independent contractor projects, Business Services (Procurement and Payment Services) is required to perform a cost analysis on each independent contractor's proposed pricing to confirm reasonableness. If the costs proposed by the independent contractor are significantly higher than the cost analysis, the independent contractor cannot be engaged until further review.

G.   Participant Support

Participant support costs are direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences or training projects. Participant support costs do not include honoraria for guest speakers, expenses for the PI, project staff or collaborators to attend project meetings, conferences, or seminars, payments to GRAs or other employees, or payments made to research subjects as an incentive for recruitment or participation in a research project. The university creates a separate Worktag/PPGG (Gift, Grant, Program, Project) to monitor participant support budget categories and costs to conform to these requirements.

Prior approval is required from federal sponsors to incur participant support costs and must be listed as a separate category on the budget at the proposal and award stage. Any re-budgeting of participant support costs to another budget category also requires approval from the federal sponsor. Finally, federal sponsors do not allow the charging of overhead on participant support costs. For non-federal sponsors, award-specific guidelines should be consulted before re-budgeting participant support costs.

H.   Expenses and Purchases

All expenses and purchases funded by a sponsored project must directly and fully benefit the project. Principal Investigators are responsible for determining whether an expense or purchase is required on a particular project and to what extent the cost is allocable to the sponsored project. If the expense or purchase will benefit more than one award, it must be allocated in proportion to the amount each award will benefit. Care must be taken to appropriately allocate expenses and purchases close to the end date of an award (e.g., last 60 days). If you are not certain how to appropriately allocate a particular expense, please contact the Office of Financial Analysis for assistance.

Indirect costs that are not directly attributable to a particular grant or contract may not be directly charged to a sponsored research Worktag/PPGG (Gift, Grant, Program, Project). Examples of indirect costs include facilities, salaries of administrative and clerical personnel, telephone charges, general office supplies, and computer equipment, except as specified below. Please contact the Office of Financial Analysis at (213) 821-1937 or email ofa@usc.edu for assistance.

Payroll/Salary Charges

There are certain situations where administrative and clerical salaries may be direct charged, but the salaries must be integral to the project on which they are charged, the individuals to be charged must be specifically identified with the project or activity, and the personnel must be specifically identified in the budget.

Non-Payroll/Salary Charges

All expenses and purchases funded by a sponsored project must comply with the sponsor's guidelines and the University's Purchasing policies and procedures. For example, international

travel funded by a sponsored project must comply with the Fly America Act: https://www.gsa.gov/policy-regulations/policy/travel-management-policy/fly-america-act. For information regarding a sponsor's guidelines and/or restrictions on an Award, please reference the Award terms and conditions in Cayuse SP. Consult with the Office of Financial Analysis or the USC Office of Culture, Ethics and Compliance before attempting to direct charge administrative or clerical salaries or computer equipment to an award. To review USC Purchasing's policies and procedures, please visit https://policy.usc.edu/usc-policies/policies-by-topic/expenditures-and-procurement/.

Computing devices may be charged directly if they are noted in the budget, essential to the project, and the cost is appropriately allocated, consistent with the overall percentage use of the computer on the project.

I.   Re-budgeting

The budget is the financial expression of the project or program as approved during the award process. After a sponsored project has been awarded, the PI may determine that the approved budget allocations are not consistent with actual project needs. In that instance, the PI may request that funds be reallocated from one spending category to another in a way that better reflects project requirements. This process is called re-budgeting and can be processed through Workday. More information can be found here: https://fbs.usc.edu/sponsored-projects-accounting/award-budget-plan/.

Award terms and conditions should be reviewed to determine re-budgeting authority. Sponsors have various policies and may require prior approval before re-budgeting. If a particular re-budgeting request reflects a change in research scope or objectives, prior approval from the sponsor is always required. Sponsors define change in scope differently; the NIH requires that any re-budgeting in one budget category over 25% of the total costs awarded requires sponsor approval, while the NSF does not use a dollar threshold. Significant re-budgeting (i.e., when the cumulative amount of transfers among direct cost categories for the current budget period exceeds 25% of the total award, or $250,000, whichever is less) will be flagged for further assessment as to whether the re-budgeting, in fact, amounts to a change in scope requiring sponsor approval. If sponsor approval is required, please contact the Department of Contracts and Grants to submit the request to the sponsor.

J.   Interdepartmental Consulting

University faculty are not eligible to receive additional compensation for consulting within the university. Faculty time should be budgeted for inter-school projects in the same manner that faculty time is budgeted for single-school projects. There should be no distinction between how a faculty member is compensated for a project that involves a single school and a project that involves multiple schools. Interdisciplinary research, even in the form of interdepartmental consulting on a sponsored project, is not an overload activity and is considered part of a faculty member's regular workload and compensation. Please contact the Office of Financial Analysis at https://fbs.usc.edu/financial-analysis/or (213) 821-1937; ofa@usc.edu for additional guidance.

K.   Recharge Centers and Specialized Service Facilities

USC schools, academic departments, and other university divisions may establish Recharge Centers to provide goods and/or services to university activities, programs, and organizations. In some instances, they are established to provide specialized services to a few users, such as animal care facilities, but they may also be used to provide commonly used goods or services, such as telecommunications centers or computer centers. A Specialized Service Facility usually provides services involving the use of complex or highly specialized services. Recharge Centers are expected to use FBS software to bill charges to the Program driver worktag. Visit https://fbs.usc.edu/financial-analysis/recharge/ for additional detail on how to establish a recharge center.

Regardless of which type of facility is established, billing rates must be designed to recover no more than the allowable cost of goods and services provided. In addition, all users, including those supported by federal awards, must be tracked in order to ensure the appropriate rate is determined and that users are billed at the same rate for similar goods and services.

The Office of Financial Analysis provides guidance and oversight to assist in the establishment of such facilities and costing assistance to ensure that services provided are charged in an appropriate manner. For more information, click below, or contact the Office of Financial Analysis at https://fbs.usc.edu/financial-analysis/ or (213) 821-1937; ofa@usc.edu.

Background: https://fbs.usc.edu/financial-analysis/recharge/
Policy: http://policy.usc.edu/recharge-centers/

L.   When to Notify Regulatory Research Committees

Investigators must inform regulatory research committees of any changes that relate to studies under their jurisdiction, such as:

- Adverse events
- Changes to study personnel
- Protocol changes
- Changes in funding sources

If you are unclear as to whether to report a change, consult the applicable committee.

M.   When to Update Conflict of Interest Disclosure

Any change in a financial or other interest related to research must be updated in diSClose and disclosed to the CIRC, regardless of whether a disclosure was made at the outset of the research. These include changes in the following:

- Percentage of ownership in outside entities with a financial interest in research;
- Amount of consulting performed on behalf of an outside entity;
- Role of an investigator in an outside entity (i.e., from consultant to managerial role).

N. Material Transfer Agreements (MTAs) and Data Transfer Agreements (DTAs)

A Material Transfer Agreement (MTA) is a research contract between a provider and a recipient of tangible research materials and related data which governs the terms and conditions under which the materials and/or data may be used. A Data Sharing Agreement (DTA) is a research contract between a provider and recipient of data which governs the terms under which the data may be used. MTAs and DTAs protect the intellectual and other property rights of the provider and may also address issues such as publication, limitation(s) on the use of the research materials, inventions and results from the use of the research material, indemnification, and liability issues.

USC Stevens is responsible for reviewing MTAs and DTAs to ensure compliance with these requirements and acting as the authorized university representative for purposes of signing the MTA. Please visit USC Stevens at https://stevens.usc.edu/researchers/request-an-mta-dta-cda/ for guidance.

O. Non-Disclosure Agreements (NDA/CDA)

Non-disclosure agreements (NDA/CDAs) are contracts that protect proprietary information (which may include inventions and USC's intellectual property) and define the permitted use and distribution of non-public information you either provide or receive – such as the status or results of research, unpublished patent information, planned research – to and from non-profit institutions and for-profit entities. Non-disclosure agreements are not intended for use in transferring tangible material or in transferring research data for use in the conduct of research, for which an MTA or Data Transfer Agreement (DTA) should be used.

Non-disclosure agreements are permitted in limited circumstances as a necessary step toward initiating funded research projects or licensing technology. USC Stevens is responsible for reviewing NDAs related to licensing, the Department of Contracts and Grants is responsible for NDAs related to sponsored research, and the Clinical Trials Office is responsible for NDAs related to industry-sponsored clinical trials. Investigators and research staff should never independently sign an NDA or CDA (or other contractual agreement) on behalf of the university.

P. International Travel

Travel outside the United States for research-related reasons can present a range of legal and safety issues under US law and university policy, depending on where you are going, who is traveling, what you are taking with you, who you will be working with on your trip, and what information you intend to take with you. Travel to certain destinations may be restricted or prohibited under Department of Treasury regulations, and items you take with you are subject to export control regulations and may require a license prior to travel. Please review the International Collaborations and Export Controls policy (https://policy.usc.edu/international-collaborations-and-export-controls/) and contact the USC Office of Culture, Ethics and Compliance at compliance@usc.edu for guidance. In case of travel emergencies, contact USC's

travel emergency hotline at (213) 821-1042 or visit https://sites.usc.edu/procurement/travel-expense/travel-safety/travel-emergencies/.

Q.   NIH Public Access Policy

The NIH Public Access Policy mandates that journal articles that arise from NIH funding be submitted to PubMed Central for open access upon acceptance by the journal. Also, all NIH applications, proposals, and progress reports must include the PubMed Central reference number when citing an article that is authored or co-authored by the investigator or arose from the investigator's NIH award. It is important to comply with this requirement to ensure that your research can continue to be funded by NIH.

For further information on how to comply with this requirement, please visit the NIH website at https://publicaccess.nih.gov/ or contact a librarian at the Norris Medical Library at medlib@usc.edu.

R.   Clinical Trials Registration and Reporting

The HHS Final Rule for Clinical Trials Registration and Results Information Submission sets forth requirements for registration and reporting results information to ClinicalTrials.gov on FDA-regulated drug, biological, and device product trials and applies to all clinical trials with a primary completion date on or after January 18, 2017. The NIH has a complementary policy requiring registration and reporting results information on all NIH-sponsored clinical trials, regardless of whether the trial is FDA-regulated or not.

Registration of an applicable clinical trial must be submitted no later than 21 days after enrollment of the first participant and requires submission of the full protocol and statistical analysis plan, among several other items. To register a trial, you will need to request a user account in the ClinicalTrials.gov Protocol Registration System (PRS):

- For Cancer Studies, contact the Cancer Center at (323) 865-0432
- For Non-Cancer Studies, contact the Department of Contracts and Grants

The Clinical Trials Office (CTO) at USC requires confirmation of registration prior to approving any Research Order Form (ROF) for the trial.

At the conclusion of the trial, the data that must be reported includes participant flow, demographic and baseline characteristics, primary and secondary outcomes, as well as results of any scientifically appropriate statistical tests and adverse event information. The standard deadline for results information submission is not later than one year after the primary completion date, although delayed submission of results may be certified and granted in certain circumstances.

In addition to reporting of data, as of January 21, 2018, the New Common Rule requires that "any clinical trial conducted by a Common Rule department or agency, one consent form be posted on a publicly available federal website within a specific time frame ("after the clinical

trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol." The consent form must have been used in enrolling participants in order to satisfy this provision. The two publicly available federal websites are ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

In addition, the International Committee of Medical Journal Editors (ICMJE) requires registration for clinical trials as a condition of consideration for publication. ICMJE requires registration of a clinical trial at or before the first participant is enrolled in any approved public registry, which includes ClinicalTrials.gov, and requires a data sharing statement and data sharing plan. For additional guidance, please consult https://clinicaltrials.gov/ct2/manage-recs/fdaaa or call the USC Office of Culture, Ethics and Compliance at compliance@usc.edu.

For more information on clinical research at USC, consult https://sc-ctsi.org/resources/guide-to-clinical-research-at-usc.

S.   Audits

If you receive oral and/or written notice from a sponsor or other outside agency that it intends to conduct an audit or any other type of review of your sponsored project, please immediately contact the Office of Financial Analysis at (213) 821-1937, or the USC Office of Culture, Ethics and Compliance at compliance@usc.edu.

IV. Closeout

A. <u>Reporting</u>

Investigators are required to satisfy all final reporting requirements, which include notifying the sponsor that the research has been completed, submitting final reports, and disclosing project results and expenditures. Timely closeout of awards is critical, as non-compliance may impact and delay the receipt of future awards from a sponsor, in particular federal agencies.

A copy of the final report should be submitted to the Department of Contracts and Grants, along with the completed Final Patent Report, if applicable. Required reports can be identified in the terms and conditions of the Award and the Payments, Reports & Terms tab in Cayuse SP. If required reporting requirements are not met, investigators may be precluded from submitting new proposals until all existing reporting requirements are satisfied.

USC's Sponsored Projects Accounting (SPA) office oversees the fiscal aspect of the project closeout process. Visit https://fbs.usc.edu/sponsored-projects-accounting/financial-closeout/, or call (213) 740-5381 for more information.

It is the responsibility of the Investigator to provide Sponsored Projects Accounting with necessary financial information in order for SPA to process any required financial reporting requirements accurately.

B. <u>Intellectual Property</u>

Under USC's Intellectual Property policy (https://policy.usc.edu/intellectual-property/) and consistent with both federal and state laws, all intellectual property (e.g., patentable inventions and copyrightable materials, including software) resulting from government and industry-sponsored projects, or from substantial use of university resources, must be disclosed to **USC Stevens**. USC Stevens assists faculty, staff and students with intellectual property matters in several ways, including obtaining and maintaining patents, identifying potential licensees and partners, consulting on start-up activities and strategies, and negotiating related agreements. In addition, USC Stevens provides services for transferring technologies to other non-commercial and non-profit research institutes. Visit http://stevens.usc.edu/, or call (213) 821-5000 for more information.

V. Research Integrity

USC offers an online course as part of its Grants Management Training for Faculty that emphasizes research integrity issues, such as conflict of interest, research misconduct, peer review, data management and mentoring. You may access the course via TrojanLearn.

Investigators are expected to conduct research with the highest ethical standards. Allegations of plagiarism, fabrication, and falsification are taken seriously. USC's policy on research and scholarship misconduct (https://policy.usc.edu/research-and-scholarship-misconduct/) defines the university process for investigations into such allegations. If you have questions regarding the research misconduct policy or process for investigating allegations of scientific misconduct, please contact USC's Research Integrity Officer (RIO) in the Office of Research and Innovation: https://sites.usc.edu/ori/

A. Data Management and Sharing

Data can include laboratory notebooks, notes, preliminary analyses, lab meeting slides as well as any other records that are necessary for the reconstruction and evaluation of results of research, regardless of the form or media on which they are recorded. Generally speaking, USC owns all research data created in the course of research conducted at the university.

Both the National Science Foundation and the National Institutes of Health require the submission of data management and sharing (DMS) plans to facilitate the sharing of research data on all grants they sponsor. For guidance on how to prepare and submit a DMS to NIH, please visit https://dcg.usc.edu/nih-data-management/. For guidance on how to prepare and submit a DMS to NSF, please visit https://new.nsf.gov/funding/data-management-plan. You can also contact the Research Integrity Officer (RIO) in the Office of Research and Innovation at https://sites.usc.ed/ori/ for guidance on specific plans.

If you are creating a databank, library, or repository for data or biospecimens with the idea that it will be maintained for further research purposes, including the sharing with researchers beyond the scope of the original research intent, it is your responsibility to ensure that you follow the USC Policy on Biorepositories. The USC policy on Biospecimens and Data Repositories can be found at https://policy.usc.edu/biorepositories/.

B. Authorship

Authorship credit should be given to those who have made significant contributions to the conception and design or analysis and interpretation of data, or both; to drafting of the manuscript or revising it critically for intellectual content; or on final approval of the manuscript. Principal authorship and other publication credits should accurately reflect the relative scientific or professional contributions of the individuals involved, regardless of their relative status. The USC Academic Senate has implemented standards for authorship and attribution of research products, which can be found at https://cpb-us-e1.wpmucdn.com/sites.usc.edu/dist/4/582/files/2022/01/URC_on_Authorship_and_Attribution_10.20111.pdf.

VI. Education Requirements

Educational and training resources are available to USC investigators and research administrators as online or in-person courses. The "USC Research Training Finder" (http://researchtrainingfinder.usc.edu/) helps research team members identify minimum training and certification needed to fulfill federal, state and/or sponsor requirements, as well as identify additional recommended training available at USC.

A.   Workday Financials Training

Certain applications within Workday Financials require mandatory training. Training resources, as well as an overview and user guides, are all available. For further details, go to https://sites.usc.edu/workdayinfo/.

B.   Grants Management Training

Prior to establishment of an award, all principal investigators, co-principal investigators, and other researchers and research administrators seeking sponsored Worktag/PPGG (Gift, Grant, Program, Project) access must complete grants management training, which provides information on appropriate grants management, including financial management, reporting, compliance, effort allocation, and research ethics. Faculty who completed grants management training prior to 2015 must also complete online refresher training addressing these topics. Please visit https://research.usc.edu/training/ for more detail, including instructions on how to access the training.

C.   Responsible Conduct of Research (RCR)

USC's RCR course for undergraduates, graduate students, and post-docs is provided by CITI (Collaborative IRB Training Initiative) for NSF-supported projects and in-person for NIH projects. For more information on how to access the course, contact the USC Office of Culture, Ethics and Compliance at (213) 740-8258 or compliance@usc.edu. Details on USC's RCR program can be found at https://sites.usc.edu/ori/responsible-conduct-of-research/.

D.   Conflict of Interest in Research

All researchers who propose or conduct research sponsored by the Department of Health and Human Services (NIH, CDC, HRSA) must complete training at least once every four years regarding conflicts of interest in research. USC offers online training on the requirements of federal regulations and USC policy, as well as on diSClose, USC's online disclosure system. Both the initial training requirement and the subsequent refresher training requirement must be completed in TrojanLearn. The training is titled "HHS Conflict of Interest in Research." Refresher training must be completed every four years. Additional detail and training instructions can be found at https://ooc.usc.edu/ethics-at-usc/conflict-of-interest/conflict-of-interest-in-research/hhs-required-coi-training/.

E.   Human Subjects Education

All key personnel engaged in human subjects research must complete the CITI online human subjects education course. The human subjects training certificate is valid for three years and can be renewed by completing a refresher course. The course is offered in a social behavioral and a biomedical version. Go to https://hrpp.usc.edu/education_certification/citi-faqs/, www.citiprogram.org, or contact the **Human Research Protection Program (HRPP)** at (213) 821-1154 or HRPP@usc.edu for further information or with questions.

F.   Animal Use

All principal investigators, staff, and students working in laboratory animal facilities and/or handling animals or animal tissues must complete initial training and yearly refresher training thereafter by the **Department of Animal Resources**. Visit http://dar.usc.edu/, or call (323) 442-1689.

G.   Radiation Safety

All individuals who work with or in the vicinity of radioactive material or radiation-producing machines must undergo appropriate training. This training is required by the **Radiation Safety Committee** and administered by **Environmental Health and Safety**. Visit http://ehs.usc.edu/research/rad/, or call (323) 442-2200.

H.   Institutional Biosafety

All investigators and laboratory personnel who engage in research involving potentially hazardous biological agents, including but not limited to infectious agents, human and non-human primate materials (including established cell lines), known regulated carcinogens, select agents, recombinant DNA and studies involving human gene transfer must undergo appropriate training. This training is required by the **Institutional Biosafety Committee** and administered by **Environmental Health and Safety**. Visit http://ehs.usc.edu/research/bio/, or call (323) 442-2200.

I.   Research Advancement

Research Initiatives and Infrastructure offers courses in grantsmanship, including specialized courses on proposal writing for foundations, corporations, NIH, and the Department of Defense. Information can be found at https://rii.usc.edu/cer/ or call 213-740-6709.

Furthermore, the USC Office of Research Strategy and Development offers a variety of support services for faculty preparing large, interdisciplinary, multi-school proposals. These services range from proposal conceptualization to writing and administrative support. The office also maintains and strengthens ties between USC investigators and federal research sponsors, tracks current and emerging funding priorities among federal agencies, and helps faculty initiate or expand sponsored research programs. For more information, please visit https://rsd.usc.edu/.

J.   Good Clinical Practice (GCP)

Good Clinical Practice (GCP) is the internationally recognized ethical and scientific standard expected in the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Compliance with GCP denotes that the data and results are credible and accurate, and the rights, safety, confidentiality, and well-being of trial subjects are protected. GCP training is required for all USC PIs and Key Personnel conducting Full Board clinical trial research. Additionally, GCP refresher training must be taken every 3 years, beginning June 1, 2017. For more information, contact HRPP: (213) 821-1154; https://hrpp.usc.edu/education_certification/.