Guide to Research at USC
Summer 2016

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

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I.   Proposal Submission

All externally sponsored contracts and grants proposals and research service agreements must be submitted through the Department of Contracts and Grants (DCG) or, for industry-sponsored clinical trials, through the Clinical Trials Office (CTO). To facilitate this process, for non-industry sponsored clinical trials, USC has developed TARA (Total Access for Research Administration), a web-based system that streamlines all aspects of research administration. Proposals are submitted through the Kuali-Coeus (KC) component of TARA: https://kc.usc.edu/kc-prd/portal.do. KC is the system of record to verify that all necessary approvals have been obtained, and to verify that investigators have agreed to all terms and conditions associated with the research. Industry-sponsored clinical trial proposals are submitted through the OnCore system (http://sc-ctsi.org/ctms/). Regardless of sponsor, clinical trials 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) 740-7762 (University Park Campus), or (323) 442-2396 (Health Sciences Campus). For further information regarding clinical trials, contact the Clinical Trials Office at (323) 442-7218.

A.   Who May Be an Investigator

All tenured, tenure track, and non-tenure track faculty, and research scientists (with the exception of lecturers, adjunct, and part-time clinical faculty) may act as Principal Investigators. Voluntary faculty may not serve as Principal Investigators. Retired faculty may be called back and asked to serve as Principal Investigators as described in Section 10 of the Faculty Handbook. Postdoctoral Research Associates and Postdoctoral Teaching Associates, as defined by USC's Postdoctoral Scholars Policy, may act as co-principal investigators on sponsored projects, but may not be principal investigators unless a specific waiver and approval is granted upon recommendation by the Department and approval of the appropriate Dean. To review the Postdoctoral Scholars Policy, please visit http://postdocs.usc.edu/files/2011/09/Postdoctoral-Scholars-Policy-rev-9-19-11.pdf.

B.   Institutionally Limited External Competitions

Some grant 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 sponsoring agency's own deadlines.

Researchers intending to apply for an institutionally limited competition should contact the Office of Research at (213) 740-6709, or at vice.president.research@usc.edu as soon as an announcement is released.

Further information on institutionally limited competitions can be found at
http://research.usc.edu/for-investigators/funding/competitions/.

C.   Regulatory Research Committees

If your proposal is subject to review by a regulatory research committee, committee approval is required before research can commence and before an account is established. Investigators should contact the applicable committees before, or soon after a proposal is submitted, to avoid delays in starting research. The Department of Contracts and Grants 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) data through intervention or interaction, or (2) identifiable private information. Visit http://oprs.usc.edu/ or call (323) 223-2340 (Health Science Campus); (213) 821-5272 (University Park Campus).

- 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 David Hinton: dhinton@usc.edu or visit http://www.uscscrocommittee.com/.

- Animals: **Institutional Animal Care and Use Committee (IACUC)**. The IACUC oversees procedures related to research and testing of animals. Visit http://dar.usc.edu, or call (323) 442-1689.

- 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, known regulated carcinogens, recombinant DNA and studies involving human gene transfer. Visit http://adminopsnet.usc.edu/department/environmental-health-safety/uscs-institutional-biosafety-committee-ibc, call (213) 821-8194, or e-mail safety.committees@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. 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://adminopsnet.usc.edu/department/environmental-health-safety/radiation-safety-laser-safety, call (213) 821-8194, or e-mail safety.committees@usc.edu.

- Select Agents (as identified at http://www.selectagents.gov/): **Institutional Biosafety Committee (IBC)**. Approval must be obtained from the IBC prior to receiving or using

any Select Agent in isolated form above exempt quantities. Visit http://adminopsnet.usc.edu/department/environmental-health-safety/uscs-institutional-biosafety-committee-ibc, call (213) 821-8194, or e-mail safety.committees@usc.edu.

- Chemical Safety: **Chemical Safety Committee (CSC)**. The Chemical Safety Committee is responsible for enforcing 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. Visit http://adminopsnet.usc.edu/department/environmental-health-safety/chemical-safety, or call (323) 442-2200.

- Research Safety: **Research Safety Oversight Committee (RSOC)**: The RSOC is responsible for oversight of USC's Research Safety Programs and for facilitating and encouraging the development of strong culture of safety in teaching and research laboratories, establishing and promulgating written institutional policies and guidelines, determining acceptable levels of risk for the institution, and providing guidance to the Office of Environmental Health and Safety, the Department of Risk Management, and individual academic departments. Contact the Department of Environmental Health and Safety at (323) 442-2200 for more information.

- Research Compliance: **Research Compliance Committee**. The Research Compliance Committee is comprised of key stakeholders involved with research compliance across both campuses, and is charged with identifying and prioritized 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 Committee meets quarterly. Contact the Office of Compliance at (213) 740-8258 for additional detail.

D.   Conflicts of Interest in Research

Any potential conflict of interest related to your research must be identified in KC 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 on-line disclosure system. Research cannot commence until a decision is made by the **Conflict of Interest Review Committee (CIRC)**, 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 makes a decision. Call the Office of Compliance at (213) 740-8258 for further information.

Investigators supported by Health and Human Service (HHS) agencies (such as NIH, AHRQ and CDC) 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-interest-research
Policy: http://policy.usc.edu/research-conflict-interest/

E.   Conflicts of Interest in Professional and Business Practices and Conflicts of Commitment

A conflict of interest and ethics arises when financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment and ability to perform his or her responsibilities to USC. A conflict of commitment arises when an employee's outside activities conflict with or appear to conflict with his or her responsibilities to USC. Both types of conflicts should be disclosed through USC's on-line disclosure system, "diSClose" (https://disclose.usc.edu/). You may click below for further information or call the Office of Compliance at (213) 740-8258.

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

F.   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/institutional-conflict-interest-research
Policy: http://policy.usc.edu/institutional-research-conflict-interest/

G.   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 also may 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 his or her research freely. 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), please contact the Contracts and Grants Officer assigned to your Lead Unit and the Office of Compliance at (213) 740-8258. You may also review more detailed information regarding Export Control regulations on the Office of Compliance website at http://ooc.usc.edu/export-controls.

H.   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. It generally occurs when research personnel donate additional time above that proposed to the sponsor or agreed to as part of the award.

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. If the committed cost sharing arises during the conduct of the supported activity, the Principal Investigator must notify his or her Dean and obtain written approval as well. 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 account. Call the Office of Financial Analysis at (213) 821-1937 for further guidance.

Costs deemed unallowable by the sponsor, including any salary above a salary cap, cannot be cost shared. These costs must also be charged to an unrestricted school, unit or departmental account.

Background: http://research.usc.edu/dcg/proposal-development/cost-sharing/
Policy: http://policy.usc.edu/cost-sharing/

I.   **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 http://grants.nih.gov/training/nrsa.htm.

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.

J.   **Reimbursement Rates**

Information on reimbursement rates for indirect costs and fringe benefits may be obtained at the Department of Contracts and Grants website (http://research.usc.edu/dcg/proposal-development/rates-at-a-glance/). Current minimum graduate assistant and postdoctoral scholar stipend rates may be found at https://research.usc.edu/files/2011/07/minsal_for_gra_and_postdocs-Fall-2014.pdf.

K.   **Responsible Conduct of Research (RCR) Training Requirements**

All students, including undergraduates, graduate students, and postdoctoral scholars supported by the National Science Foundation (NSF), are required to complete training in the Responsible Conduct of Research (RCR). In addition, students supported on certain NIH programs, including training grants, are also required to complete in-person RCR training.

To satisfy NSF's RCR requirement, please visit http://research.usc.edu/policies/rcr/ and enroll in USC's on-line RCR training program, administered by CITI. To satisfy NIH's in-person training requirement, individual schools, including the Keck School of Medicine and USC Dornsife, have created classroom based courses on RCR. Please consult your school for information.

II.   Award and Account Establishment

The **Department of Contracts and Grants** negotiates the terms of all sponsored research agreements with external sponsors, including non-industry sponsored clinical trials. The Clinical Trial Office negotiates industry-sponsored clinical trials.

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.

Pre-award authorizations require approval from the investigator's dean (school of primary appointment) and a programmatic justification, because the Dean's account is at risk until the award is received. For further information, visit the Department of Contracts and Grants website at http://research.usc.edu/dcg/, or call (213) 740-7762 (University Park Campus), or (323) 442-2396 (Health Sciences Campus).

B.   Award and Account Creation

Upon award acceptance, the Department of Contracts and Grants processes the award and identifies an account number in Kuali Coeus (KC). Once finalized, an Award Synopsis is available, which contains a summary of the terms and conditions of the award. It is important to review the Award and its terms and conditions to understand your obligations. Once processed in KC, Sponsored Projects Accounting establishes an account in the University's financial system, KFS. Until the account is established, the PI cannot charge costs against the award. For further information on award establishment, visit the Department of Contracts and Grants website at http://research.usc.edu/dcg/, or call (213) 740-7762 (University Park Campus), or (323) 442-2396 (Health Sciences Campus). For more information on account establishment, visit the Sponsored Projects Accounting website at http://fbs.usc.edu/depts/spa/page/6742/policies-information/, 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, should establish the master account. The Lead Unit is typically in the school of the Principal Investigator's primary appointment. Satellite accounts 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 further information on how to establish a satellite account, visit Sponsored Projects Accounting's website at http://fbs.usc.edu/depts/spa/page/6742/policies-information/, or call (213) 740-5381.

III. After Research Commences

A. Effort Reporting

Faculty and research staff are responsible for reporting and certifying percentage effort charged to a sponsored project in a timely manner. 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 RA's must be certified once each semester. For RA's, 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 to the effort on the award. Non-exempt staff effort is certified bi-weekly via the university's time keeping 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 http://fbs.usc.edu/depts/ofa/page/4118/policies/, call (213) 821-1937, 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. Generally speaking, therefore, no more than 95% of a researcher's salary may be charged to sponsored projects. In exceptional circumstances, more than 95% may be charged, but the researcher must demonstrate that his or her 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 2 months of a principal investigator or co-investigator's salary in any one year. Any compensation in excess of two months must be disclosed in the proposal budget, justified in the budget justification, and be specifically approved by NSF in the award notice.

Please consult the Office of Compliance for additional guidance.

C. Cost Transfers

A cost transfer is a mechanism used to transfer payroll and non-payroll transactions from one sponsored account to another when a sponsored account was erroneously charged. This 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 account necessitated by a delay in finalizing contract negotiation on a sponsored account. 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 http://fbs.usc.edu/depts/spa/, or call (213) 740-5381 for more information.

D.   Subrecipient Monitoring

All subcontractors must sign a subcontract that includes a detailed statement of work. Investigators must monitor subcontractors to ensure that they are complying with the terms of the award. These monitoring duties include confirming that the subcontractor is satisfying the statement of work, and that the invoices submitted by the subcontractor are reasonable, allocable, and allowable on the project. For assistance on issues related to subrecipient monitoring, please contact the Department of Contracts and Grants (http://research.usc.edu/dcg/) or the Office of Financial Analysis (http://fbs.usc.edu/depts/ofa/).

E.   Program Income

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

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 account, 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 USC eMarket.

Furthermore, for sponsored-project funded independent contractor projects, Business Services (Purchasing Services and Disbursement Control) is required to perform a cost analysis on each independent contractor's proposed pricing to confirm reasonableness. If 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.

Prior approval is required from federal sponsors in order to incur participant support costs and must be listed as a separate category on the budget at both the proposal and award stage. Any re-

budgeting of participant support costs to another budget category also requires approval from the federal sponsor. Finally, NSF does not allow the charging of overhead on participant support costs. For non-federal sponsors, award specific guidelines should be consulted before rebudgeting 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 or not 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. Particular care must be taken to appropriately allocate expenses and purchases close in time 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 contact may not be directly charged to a sponsored research account. Examples of indirect costs include facilities, salaries of administrative and clerical personnel, telephone charges, general office supplies, and computer equipment.

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-Salary Charges

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

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. For information regarding a sponsor's guidelines and/or restrictions on an Award, please reference the Award and terms conditions in Kuali Coeus. Consult with the Office of Financial Analysis or the Office of 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 http://policy.usc.edu/files/2014/02/Expenditure-Manual.pdf.

I.   Rebudgeting

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 rebudgeting and can be processed through SPA's Budget Reallocation system.

Award terms and conditions should be reviewed to determine rebudgeting authority. Sponsors have various policies and may require prior approval before rebudgeting. If a particular rebudgeting request reflects a change in research scope or objectives, prior approval from the sponsor is almost always required. Sponsors define change in scope differently; the NIH requires that any rebudgeting 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.

I.   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 from a project that involves multiple schools. In particular, 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 (http://fbs.usc.edu/depts/ofa/; (213) 821-1937 for additional guidance.

J.   Recharge Centers and Specialized Service Facilities

USC schools, academic departments, and other university divisions may establish Recharge Centers and Specialized Service Facilities 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 CORES software to bill charges to accounts. Visit https://research.usc.edu/cores/ 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 (http://fbs.usc.edu/depts/ofa/; (213) 821-1937) 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.

Background: http://fbs.usc.edu/depts/ofa/page/5643/rechargeservice-centers/
Policy: http://policy.usc.edu/recharge-centers/

K.   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.

L.   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:

- 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).

M.   Material Transfer Agreements (MTAs)

A Material Transfer Agreement (MTA) is a research contract between a provider and a recipient of tangible research materials and data which governs the terms and conditions under which the materials and/or data may be used. MTA's 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 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/mta-cda for guidance.

N.   Non-Disclosure Agreements (NDA/CDA)

Non-disclosure agreements (NDA/CDA's) 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.

O.   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. Please visit the Office of Compliance web-site at http://ooc.usc.edu/international-travel for more detailed guidance, or call (213) 740-8258 for assistance. In case of travel emergencies, contact USC's travel emergency hotline at (213) 821-1042, or visit http://procurement.usc.edu/travel/emergencies/.

P.   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 NIH website at http://publicaccess.nih.gov/index.htm, or the Norris Medical Library website at http://www.usc.edu/hsc/nml/lib-information/nih.html.

Q.   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 Office of Compliance at (213) 740-8258.

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. 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 is charged with fiscal oversight of the project closeout process. Visit http://fbs.usc.edu/depts/spa/, or call (213) 740-5381 for more information.

B. <u>Intellectual Property</u>

Under USC's Intellectual Property policy (http://policy.usc.edu/files/2014/02/intellectual_property.pdf) and consistent with both federal and state laws, all intellectual property (e.g., patentable inventions) 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.   Scientific Integrity

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

Investigators are expected to conduct research with the highest ethical standards. Allegations of plagiarism, fabrication, and falsification are taken seriously. USC's policy on scientific misconduct (http://ooc.usc.edu/scientific-integrity) defines the university process for investigations into such allegations.

A.   Data Management

Data can include laboratory notebooks, notes, preliminary analyses, 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.

The National Science Foundation requires all funded projects provide a data management plan to facilitate sharing of research data, and the National Institutes for Health requires data management plans for larger projects. Resources on creation of data management plans can be found at https://research.usc.edu/dcg/proposal-preparation/.

B.   Authorship

Generally speaking, 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 http://www.usc.edu/academe/acsen/Documents/Resolutions/URC_on_Authorship_and_Attribution_passed%20with%20resolution.pdf.

VI.   Education Requirements

Educational and training resources are available to USC investigators and research administrators as on-line or in-person courses. The "USC Research Training Finder" http://sc-ctsi.org/training-matrix/) (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.   Kuali Financial System Training

Certain applications within the Kuali Financial Systems (KFS) require mandatory training. Training resources as well as an overview and user guides are all available. For further details, go to http://fbs.usc.edu/depts/kuali/page/3549/about-usc-kuali/.

B.   Grants Management Training

Prior to establishment of an award, all principal investigators , co-principal investigators, and other researchers and research administrators seeking sponsored account access must complete grants management training, which provides information on appropriate grants management, including financial management, reporting, compliance, effort allocation, and research ethics. Please visit https://research.usc.edu/grants-management-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 Office of Compliance at (213) 740-8258 or complian@usc.edu. Details on USC's RCR program can be found at http://research.usc.edu/policies/rcr/.

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 on-line training on the requirements of federal regulations and USC policy, as well as on diSClose, USC's on-line disclosure system. Details on training can be found at http://ooc.usc.edu/conflict-interest-research.

E.   Human Subjects Education

All key personnel engaged in human subjects research must complete the CITI on-line human subjects education course. Go to: http://oprs.usc.edu/education/citi/, or contact the **Office for Protection of Research Subjects** at (213) 821-1154, or oprs@usc.edu.

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://adminopsnet.usc.edu/department/environmental-health-safety/radiation-safety-laser-safety, 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://adminopsnet.usc.edu/department/environmental-health-safety/uscs-institutional-biosafety-committee-ibc, or call (323) 442-2200.

I.   Research Advancement

The Office of Research offers courses in grantsmanship, including specialized courses on proposal writing for foundations, corporations, NIH, and Department of Defense. Information can be found at http://research.usc.edu/for-investigators/training/, or call 213-740-6709.

J.   GCP

The Office for Protection of Research Subjects (OPRS) administers training in how to adhere with Good Clinical Practice (GCP) standards, which are the international, ethical, and scientific standards expected in design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Compliance with GCP provides regulators assurance that data are reported, results are credible and accurate, and that the rights, safety, confidentiality, and well-being of trial subjects are protected. Beginning January 1, 2010, GCP training is required for all USC PIs and Key Personnel conducting Full Board clinical trial research. For more information, please visit http://oprs.usc.edu/education/good-clinical-practice-gcp-training/.

K.   Research Administrators Forum (RAF)

The RAF, which meets approximately three times per year and is sponsored by the Office of Compliance, provides research administrators from both campuses an opportunity to network and share information related to research administration and compliance, discuss issues, and learn about university policies and procedures as well as changes in laws and regulations that may apply to them. The RAF was established in response to a recommendation from faculty and staff members to give administrators more opportunities to share experiences with peers and learn about the research administration issues that affect their job responsibilities.

Anyone interested is encouraged to attend. Please call the Office of Compliance at (213) 740-8258 or email complian@usc.edu to be added to the invitation list.