

Guide to Research **Compliance** For Principal Investigators & Department Administrators





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Introduction

The administration of academic research has grown more complex over the years. In addition to leading the research that is the core mission of the university, principal investigators (PIs) have ultimate responsibility for compliance with award terms and conditions, federal, state and local regulations, and university policies directly related to their research.

This publication provides an overview of these policies and regulations. It is intended as a supplement to — not a substitute for — the services provided by Extramural Funds Accounting, the Office of Research's Sponsored Programs Office and other campus offices charged with supporting the UC Davis faculty.

Herein you will find:

- Information relating to the most frequently asked questions about award administration
- Key points relating to issues that, in the past, have cost projects funding or been called out by internal and external auditors
- Contact information for the departments that can assist PIs and department administrators with the finer points of award administration and compliance
- Policy references and links to all relevant policies

Our goal is to assist PIs and their support staffs in avoiding common pitfalls in award administration so that they can receive the full value from their sponsored awards and focus on the advancement of knowledge, the development of the next generation of scholars, and service to the worldwide community.

Accounting & Financial Services Extramural Funds Accounting Costing & Policy Analysis <u>Office of Research</u> Sponsored Programs Research Compliance & Integrity

Solicitation of Extramural Funding

At the University of California, all awards must be made to The Regents of the University of California — not to schools, colleges, programs or departments. No official solicitation for extramural support for research or any other sponsored activity, such as training, public service programs or special projects, may be made in the name of the university without prior approval of the Board of Regents or an authorized officer of the university. At UC Davis, the chancellor has delegated such authority, within the limits set forth by the regents, to the vice chancellor for research, as well as to the executive associate vice chancellor for research and the director of Sponsored Programs.

University of California employees who receive any part of their salary through the university, or whose activities use any university resources or facilities, must submit proposals for extramural support through Sponsored Programs. This ensures that all extramurally funded projects conducted by university employees, or with the use of university resources or facilities, have proper signature authority and comply with relevant university policies and guidelines. UC has put this policy in place to protect faculty and the university.

Sponsored Programs assists the campus research community in its efforts to secure extramural funding while promoting proper stewardship of those funds. When processing a proposal and resulting award, Sponsored Programs reviews all documents to ensure that project complies with relevant university policies and guidelines. The staff in Sponsored Programs is available to assist with questions relating to university policy and proposal preparation.

Key Points

University policy requires that proposals be submitted through an authorized campus-based contracts and grants office. At UC Davis, this is Sponsored Programs in the Office of Research.

Research awards are made to The Regents of the University of California.

Who to Contact

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Additional Information

Policy on Eligibility to Undertake Sponsored Research <u>http://manuals.ucdavis.edu/PP</u> <u>M/230/230-02.pdf</u>

Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the university ucop.edu/raohome/cgmemos/9 5-01.html

Eligibility to Serve as Principal Investigator

At UC Davis, the individual responsible for the design, scientific conduct, administrative conduct and reporting of a research, training or public service project supported by extramural funding is known as the principal investigator (PI) and sometimes as the project director. The PI must personally participate in the project to a significant degree. A person who is not actually making a significant contribution to the subject project or research may not be designated as a PI.

To be eligible to hold the designation of PI on a project, the faculty member must work at least 50 percent of full time in any combination of the following six appointments:

- Members of the Academic Senate, including emeriti
- Appointees in the Agronomist series, including emeriti
- Appointee in the Adjunct Professor series at 50 percent or more of full time
- Appointee in the Clinical Professor series at 50 percent or more of full time
- Appointee in the Professional Researcher series at 50 percent or more of full time
- Appointee in the Cooperative Extension Specialist series at 50 percent or more of full time
- A combination of any of the above appointments that total 50 percent or more of full time

Emeriti members of the university retain the PI eligibility that they held prior to their retirement.

With the approval of the vice chancellor for research, UC Davis does allow some exceptions to the PI eligibility policy. Exceptions must be endorsed by the individual's department chair and the appropriate dean or vice chancellor. The vice chancellor for research may also approve exceptions to allow students, postdoctoral fellows, and other individuals to submit proposals for research or training as a principal investigator. Exceptions are approved on a case-by-case basis, and the majority of exceptions are valid only for the specific project listed in the PI exception request.

Key Points

At UC Davis the terms principal investigator, or PI, and sometimes project director, designate the individual responsible for a project supported by extramural funding.

The PI must personally participate in the project to a significant degree.

Eligibility to serve as a Pl is contingent upon certain appointments, listed to the left.

Exceptions to PI eligibility requirements must be endorsed by the department chair and dean and approved by the vice chancellor for research.

Who to Contact

Sponsored Programs proposals@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Additional Information

Policy on Eligibility to Undertake Sponsored Research <u>http://manuals.ucdavis.edu/PP</u> <u>M/230/230-02.pdf</u>

Award Terms & Conditions

Understanding all funding source requirements and restrictions is critical. If the terms of an individual award are stricter than federal guidelines and university policy, the award terms take precedence. For example, travel expenses are allowable under either, but may be specifically excluded or limited by your specific award.

Some important terms and conditions to be considered when managing an award include:

Budget

The PI works with his or her department administrator to prepare a budget and justification for the project. The budget must be in accordance with allowable costing principles, including application of the appropriate facilities and administrative rate (F&A rate, previously called the indirect cost rate). As the project progresses, the grant budget should be compared to actual expenditures on a regular basis.

Modest re-budgeting is generally allowable without approval of the awarding agency. The award terms and conditions should be consulted before re-budgeting to ensure that prior approval is not required. Absent specific award terms to the contrary, re-budgeting of more than 25 percent generally represents a change of scope requiring pre-approval from the granting agency. Significant rebudgeting of key personnel effort indicates a change in scope that requires pre-approval from the granting agency.

Performance period

Expenses must be incurred during the performance period of the award to be allowable. Some agencies allow pre-award spending 90 days prior to the start date of the award. Uniform Guidance now requires prior written sponsor approval for pre-award expenses on a federal award (for more on Uniform Guidance, see additional sections: Cost Principles, F&A Costs, Administrative Costs, and Cost Sharing). If you are unsure whether pre-award spending is allowed, consult your assigned analyst or contracts and grants officer in Sponsored Programs for guidance.

Pre-approvals

Some agencies require pre-approval for certain types of expenses. For example, foreign travel may require sponsor approval as might the carry-forward of unspent funds remaining at the end of a budget period.

Key Points

The terms of an individual award do not take precedence over federal guidelines and university policy unless they are more restrictive.

The PI and department administrator must each thoroughly understand what the agency expects in managing the project. These are spelled out, in detail, in the award terms and conditions.

Costs disallowed by the Office of Management & Budget (OMB) or the university are never allowable, regardless of the award terms.

Every award should be reviewed for specific restrictions such as re-budgeting and unallowable expenses.

Who to Contact

The Awarding Agency

Pl's Department Administrator

Sponsored Programs <u>awards@ucdavis.edu</u> Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8721

Pre-award spending

Spending prior to receipt of an award is generally discouraged. However, in some situations, funding is delayed when the project is ready to commence. If a delay in funding is anticipated, an advance account can be requested. Advance accounts must be requested through Sponsored Programs, and the PI or department chair must guarantee that, if the proposal is not awarded, all pre-award expenses will be funded by departmental or other discretionary funds.

Post-award spending

Expenses incurred after the end of an award period are not allowable. If there is reason to believe a project will not be completed by the end date of the project period, a request for a no-cost extension should be submitted to the sponsor, through Sponsored Programs. The award agreement may indicate a specific timeframe for submission of the nocost extension, which must be met or the request may be denied.

Program income

Program income is defined as gross income, earned by an award recipient, that is directly generated by a supported activity or earned as a result of the award. Examples of program income include fees from services performed or registration fees for conferences sponsored by an award. Most federal agencies identify the method for accounting for program income in the award agreement or have regulations that address the default method for accounting for program income.

If program income is anticipated as part of a proposed project, it should be disclosed in the project proposal. If program income arises during the life of the award that was not anticipated at the proposal stage, the PI's department administrator and Extramural Funds Accounting must be notified so that the proper method to account for the income can be established. All program income and related expenses must be reported to the sponsoring agency along with the award financial activity.

Additional Information

UCOP Contract and Grant Manual, Chapter 2 http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter2/index.html

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 <u>http://www.ecfr.gov/cgibin/text-</u> idx?tpl=/ecfrbrowse/Title02/2cf r200_main_02.tpl

UC Davis Policy on Advance Account Requests: http://manuals.ucdavis.edu/pp m//230/230-06.pdf

Responsible Conduct of Research

Federal regulations require all research institutions to have policies and procedures for handling allegations of research misconduct, protecting whistleblowers, and educating all personnel in the responsible conduct of research. For projects funded through the U.S. Public Health Service, the institution and principal investigators must formally certify the integrity of their research.

Allegations of research misconduct are reported through the campus Office of Research Compliance and Integrity. The research integrity officer is responsible for investigating research misconduct and ensuring that investigation reports are submitted to the federal Office of Research Integrity in a timely manner.

Definitions

- *Research*. All basic, applied and demonstration research in all fields of science, engineering and mathematics, including, but not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, and statistics, and research involving human subjects and animals.
- *Research misconduct*. Fabrication, falsification, or plagiarism in the proposal, performance, or review of research, or in reporting research results.
- *Fabrication*. Making up data or results and recording or reporting them.
- *Falsification*. Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- *Plagiarism*. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Proving Research Misconduct

A finding of research misconduct requires proof of <u>both</u> of the following:

- Fabrication, falsification or plagiarism that constitutes a significant departure from accepted practices of the relevant scholarly community.
- Misconduct committed either intentionally <u>or</u> knowingly <u>or</u> recklessly.

The allegation of misconduct must be proven by a preponderance of the evidence.

Key Points

In accordance with federal regulations, UC Davis has policies and procedures in place for educating researchers in the responsible conduct of research, handling allegations of research misconduct, and protecting whistleblowers.

Research misconduct includes fabrication, falsification, or plagiarism in any phase of a research project, including the proposal, performance and review, or in the reporting of research results.

Anyone who witnesses or experiences possible research misconduct should immediately consult with the research integrity officer.

Allegations of research misconduct are reported through and investigated by the campus Office of Research Compliance and Integrity.

NSF-funded students and postdoctoral scholars must receive formal training related to the responsible conduct of research.

All NIH-supported training programs must include specific topics related to the responsible conduct of research.

USDA NIFA awards require program directors, faculty, undergraduate and graduate students, postdoctoral researchers, and any staff participating in the funded project to undertake appropriate training and oversight in the responsible and ethical conduct of research. Research misconduct <u>does not</u> include honest error, differences of opinion, or authorship credit disputes. (See Ethics in Authorship below.)

Investigating Research Misconduct

The process for handling allegations of research misconduct at UC Davis involves the following steps, which are subject to specific timeframes as detailed in PPM 220-05:

- 1. *Preliminary assessment*. Does the allegation meet definitions? Is there sufficient evidence to go forward?
- 2. *Inquiry*. Initial fact-finding to determine if the allegation of misconduct warrants an investigation.
- 3. Investigation. A formal examination/evaluation of all relevant facts.
- 4. *Reporting.* The institution must report to the federal Office of Research Integrity (ORI) when an investigation is initiated and when the outcome of the investigation is determined. The institution must notify the ORI at *any* stage in the event of:
 - an immediate hazard or public health issue
 - an immediate need to protect federal funds or equipment
 - a possible criminal violation
 - a risk of premature public release of allegations

Role of the Complainant

The *complainant* is the person (or persons) who reports possible misconduct or makes a formal charge of misconduct. The complainant has a duty to report allegations of potential misconduct in good faith, meaning there must be a reasonable basis for the allegations and not merely a suspicion. The complainant is required to cooperate with the inquiry and investigation process while maintaining confidentiality during the process. Complainants have a right to protection against retaliation related to their good faith allegations.

Role of the Respondent

The *respondent* is the person (or persons) against whom an allegation of research misconduct is directed or the person(s) whose actions are the subject of the inquiry. The respondent has a reasonable duty to cooperate in the investigation process. Rights of the respondent include timely notification of allegations after sequestration of evidence, confidentiality, and the opportunity to respond to allegations, present evidence and review and comment upon the investigation report. Respondents also have a right to restoration of their reputation if no misconduct is found.

Who to Contact

If you see or experience possible research misconduct:

UC Research Integrity Office Hotline (877) 384-4272 http://www.ucop.edu/ethicscompliance-auditservices/compliance/researchcompliance/researchintegrity.html

OR

U.S Department of Health and Human Services Office of Research Integrity <u>ori.dhhs.gov</u>

Additional Information

Responsible Conduct of Research Program www.research.ucdavis.edu/rcr

UC Davis Scientific Misconduct Policy PPM 220-05 <u>manuals.ucdavis.edu/ppm/220</u> /220-05.pdf

UC Davis Whistleblower Policy PPM 380-17 manuals.ucdavis.edu/ppm/380 /380-17.pdf

UC Davis Graduate Student Guide gradstudies.ucdavis.edu/student s/handbook

NIH Training Requirements grants.nih.gov/grants/guide/not ice-files/NOT-OD-10-019.html

NSF Training Requirements edocket.access.gpo.gov/2009/ pdf/E9-19930.pdf

Sanctions for Research Misconduct

The sanctions for findings of research misconduct can include any or all of the following:

- Retraction of publications, certifications
- Suspension/debarment
- Job-related discipline up to and including termination
- Imprisonment for criminal acts

Education Requirements

The America Competes Act and NIH regulations require that students and postdoctoral scholars receiving funding from the NSF complete formal training related to the responsible conduct of research. All NIH-supported training programs must also include specific topics related to the responsible conduct of research.

Completion of the UC Davis Responsible Conduct of Research (RCR) fulfills these requirements. The RCR Program provides graduate students, postdoctoral scholars, faculty, staff and NSF-funded undergraduate students with information, training, and tools to address the increasingly complex ethical issues that they will confront during their careers.

Ethical Considerations in Authorship

Author contribution means having a "considerable degree of involvement with the development of the work, the generation/interpretation of data, drawing of conclusions and/or actual writing of the paper." To be included as an author, each author must have made a substantial intellectual contribution to the work beyond providing instruction, lab space or equipment, financial support, or dissertation guidance. Each author accepts responsibility for the contribution and scholarly conclusions and understands the methodology, the relationship to other similar research and significance and implications of the contribution. Graduate students should familiarize themselves with the guidelines for authorship detailed in the UC Davis Graduate Student Guide.

Conflict of Interest

A conflict of interest is a situation in which the conduct of research could be compromised, or appear to be compromised, by a related financial interest on the part of the PI or other investigators. Financial interest is any personal benefit of significant monetary value, including, but not limited to:

- Salary or other payments received for services
- Equity interests, such as stocks, stock options or other ownership interests
- Intellectual property rights, such as patents, copyrights and royalties from such rights, other than royalties received through the university
- Appointment to a position as an officer, director, agent or employee of a business entity

Rules regarding conflict of interest apply to all investigators on the project as well as to their spouses, domestic partners and dependent children.

On projects sponsored by private sector organizations, any financial interest in the sponsor within 12 months prior to the date of the funding offer and during the project timeframe, constitutes a potential conflict of interest.

University policy prohibits faculty, staff, managers or officials from engaging in any activities that create a conflict of interest between official university activities and any personal interest or obligation.

Because conflicts of interest can arise in the course of an individual's interactions outside the university, the presence of an actual, apparent or perceived conflict of interest does not automatically constitute wrongdoing. However, any such potential conflicts of interest must be disclosed and managed, and the university has a formal procedure for doing so in compliance with federal and state regulations. It requires investigators to:

- Disclose their financial interests and the interests of their spouse/domestic partner and dependent children on the appropriate disclosure form(s).
- Provide updates as the amount or nature of interest changes during the period of performance of supported research.

This process is intended to protect investigators, their sponsored research and other educational and professional activities in which they are engaged, and the university.

Key Points

Pls and other investigators may not have, or appear to have, any personal financial interest in a research project.

University faculty, staff, managers or officials shall not engage in any activities that create a conflict of interest between their official university duties and any other interest or obligation.

This policy applies to investigators and to their spouses, domestic partners and dependent children.

Any potential conflict of interest must be disclosed.

Association of UC Davis's name or logo with commercial interests in the public eye may lead to a conflict of interest.

Who to Contact

Director of Research Compliance & Integrity, Office of Research Phone: (530) 754-7754 Fax: (530) 754-7894 http://research.ucdavis.edu/cont act-us/research-complianceintegrity/

Human Subjects and Conflict of Interest

Research involving human subjects poses special concern with regard to conflict of interest. For example, the research may potentially involve drugs, equipment, materials or methods in which the investigators or their domestic partner or dependent children have a financial interest. Such interests may appear to compromise the rights and well-being of the research subjects, as well as the integrity of the related research and must be disclosed. For this reason, potential conflicts of interest in research with human subjects are subject to careful scrutiny. Disclosure of conflicts of interest related to humansubjects research is included in Institutional Review Board (IRB) procedures and on form HRP 211 Application for Initial Review.

Use of the University Name and Logos

Association of the UC Davis name or logo with commercial interests may lead to a conflict of interest. For example, in the course of consulting or research, faculty members may provide professional evaluations of products or services. However, care must be taken to avoid identifying the university with their opinions or conclusions in any public or private reports that may support their own outside financial interests. Faculty must also avoid implying an endorsement on the part of the university.

Additional Information

Office of Research Compliance & Integrity http://research.ucdavis.edu/offi ces/rci/

Policy on Individual Conflicts of Interest Involving Research <u>http://manuals.ucdavis.edu/PPM/23</u> 0/230-05.pdf

Procedures for Reporting, Reviewing, and Managing Conflicts of Interest in Research <u>manuals.ucdavis.edu/PPM/230/230</u> -05a.pdf

Disclosing Financial Interests in the Consent Form <u>http://research.ucdavis.edu/resource</u> <u>s/forms/#Forms-</u> <u>FinancialConflictsofInterest</u>

All other applicable university, state and federal policies and regulations governing conflict of interest are referenced and linked in <u>http://manuals.ucdavis.edu/PPM/23</u> 0/230-05.pdf

Technical Progress & Final Reports

Required reports include:

Technical Reports

The PI is responsible for submitting all required technical reports to the award sponsor and the Office of Research. Report content requirements are spelled out in the grant terms and conditions, and typically include:

- Identification information (project title, grant/contract number, PI contact information, period of performance including authorized extensions, etc.)
- Significant results of the project
- Technical difficulties and solutions
- List of publications, including articles in progress
- A discussion of milestones and/or deliverables

Final Invention Reports

The PI submits final invention reports to the Office of Research technology licensing office, which submits final invention reports to sponsors. The report describes any new technology developed with support from the award, whether or not it has been disclosed to the campus technology transfer office (Innovation*Access*).

Equipment Inventory Report

The UC Davis Equipment Management office prepares and submits equipment inventory reports that detail all equipment acquired under the award.

Key Points

Complete and accurate reporting, per the reporting schedule associated with each award, is the PI's responsibility.

Sponsors can and do suspend funding in cases where progress or final reports are not submitted in a timely fashion.

Check the sponsor's report formatting requirements and adjust your submission timing based on those requirements.

Copies of reports, or report transmittal letters, should be forwarded to your representative in Sponsored Programs. Sponsored Programs accepts reports electronically, via email.

Who to Contact

Sponsored Programs <u>awards@ucdavis.edu</u> Phone: (530) 754-7700 Fax: (530) 754-8229

Additional Information

Intellectual Property Management http://research.ucdavis.edu/pg c/ipm

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 http://www.ecfr.gov/cgibin/textidx?tpl=/ecfrbrowse/Title02/2cf r200_main_02.tpl

Cost Principles

UC Davis and its PIs are jointly responsible for stewardship of sponsored research funds in compliance with federal cost principles established by the Office of Management & Budget (OMB). Prior to December 26, 2014, these principles were described in *OMB Circular A-21* and incorporated into university policies and procedures for administering research awards. The new *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200* ("Uniform Guidance"), replaced several OMB circulars, including A-21. UC is adjusting policies and practices, at both the system and campus levels, to conform to the Uniform Guidance.

Adherence to all cost principles is required to properly and appropriately account for the expenses of conducting research at UC Davis. The consequences of failing to comply with costing principles may range from disallowance of specific incurred costs to termination of the award to federal sanctions, depending on the particular cost and circumstances in question.

Allowable costs

The key concept of cost principles is "allowability." For a cost to be allowable on a specific sponsored award, it must meet all three of the following criteria:

- *Reasonable*. It is necessary for the performance of the project and the cost is what a "prudent person" would pay for the particular goods or services obtained.
- *Allocable.* The project that pays the cost is the project that benefits from it. Expenses shared across multiple projects benefit all projects proportionately, when benefit can be clearly allocated, or reasonably, when proportionate value cannot be readily determined due to the inter-relationship of the work involved.
- *Consistently treated.* The university consistently designates that type of cost as either direct or indirect when incurred for the same purpose in like circumstances.

Additionally, the cost must not be explicitly excluded by federal guidelines or the terms and conditions of the award. Some expenses that may directly benefit a project may be prohibited by the award sponsor and, thus, are not allowable on the award.

Key Points

All UC Davis personnel responsible for initiating or approving financial transactions must be familiar with cost principles, particularly the concept of allowable costs.

The consequences of non-compliance with cost principles may include disallowance of specific incurred costs, termination of the award or federal sanction.

Who to Contact

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721

Costing Policy & Analysis Phone: (530) 752-4621 Fax: (530) 757-8510

External Audits

Federal, state, and local agencies, as well as private sponsors, have the right to perform financial and administrative reviews of their awards made to the university. The UC Davis campus utilizes an external audit coordinator to facilitate and support external audit activities by:

- Acting as a liaison, the main point of contact, for both the campus and the external auditors
- Managing and coordinating financial and administrative information and data requests
- Assisting in resolving questions and issues
- Reporting outside audit activities to campus leadership
- Following up on agreed-upon corrective actions

If contacted by an external agency or sponsor with an audit request, contact external audit coordinator Amy Holzman at (530) 752-9169 or <u>amholzman@ucdavis.edu</u>.

Additional Information

UCOP Contract and Grant Manual, Chapter 6; Financial – General http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter6/index.html

Business and Finance Bulletin, A-47, University Direct Costing Procedures <u>ucop.edu/ucophome/policies/bf</u> <u>b/a47.pdf</u>

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 <u>http://www.ecfr.gov/cgibin/text-</u> idx?tpl=/ecfrbrowse/Title02/2cf r200_main_02.tpl

Facilities & Administrative (F&A) Costs

The university, as a publicly funded institution, must conduct its activities, including sponsored projects, on a "no profit, no loss" basis. Direct costs in project budgets do not fully reimburse the institution for all of its costs. For example, salaries of those individuals involved in administrative services are generally not part of the direct costs. In addition, facility costs, general office supplies, or copying expenses are seldom included in budgets, yet those expenses are reasonable and necessary and must be borne by the institution. Accordingly, the university is required to cover all expenses associated with projects conducted for extramural sponsors.

The Uniform Guidance defines F&A costs as "those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved" (§200.56).

As a recipient of federal funds, UC Davis is required to negotiate a F&A cost rate agreement with the Department of Health and Human Services (the UC Davis cognizant federal audit agency) to establish F&A cost rates for use with UC Davis extramural awards. The university negotiates "predetermined" F&A cost rates. These rates are final and not subject to upward or downward adjustment based upon actual costing experience.

The UC Regents' policy on full cost recovery imposes a duty on all university administrators and PIs to perform sponsored projects on a full cost recovery basis — to ask for and obtain indirect costs from all sponsors. Regents' Standing Order 100.4(m), which authorizes the president to negotiate and approve all indirect cost rates, also incorporates the authority to approve exceptions to the approved rates. Thus, university policy allows for indirect cost rate exceptions to be granted under certain circumstances, as described below.

An exception may be based on sponsor policy. Nonprofit sponsors sometimes restrict reimbursement of indirect costs to less than the full applicable rate. Sponsor restrictions may be by statute, bylaws or policy of nonprofit entities. For governmental sponsors, it may also be by codified agency regulations or program terms published in the sponsor's solicitation or announcement. However, according to the Uniform Guidance, reducing F&A costs on federally funded awards is generally inappropriate.

Key Points

The UC Regents' policy on full cost recovery imposes a duty on all university administrators and Pls to perform sponsored projects on a full cost recovery basis to ask for and obtain indirect costs from all sponsors.

Requesting a reduced F&A rate on a federally funded award is generally inappropriate.

Who to Contact

Pl's Department Administrator

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721 For-profit corporations/organizations and foreign governmental entities should reimburse full F&A costs on sponsored projects. The attorney general of the State of California has ruled that reductions of indirect cost rates for such sponsors are improper gifts of public funds for private benefit.

Exceptions based on Campus Vital Interest are extremely rare. If the development of campus research, training or public service programs or infrastructure may best be served by accepting a sponsored award at less than the applicable indirect cost rate, a vital interest waiver may be approved. Such interests must be viewed as vital to a campus, by campus officials, to the extent that funding the proposed project at a loss, by not collecting full indirect costs, is more important to the campus as a whole (not only to the PI or department) than recovering the full indirect costs.

Additional Information

Costing Policy & Analysis http://afs.ucdavis.edu/our_servi ces/costing-policy-eanalysis/index.html

UCOP Contract and Grant Manual, Chapter 6; Financial – General

http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter6/index.html

UC Davis F&A Cost Policy PPM 230-03 http://manuals.ucdavis.edu/PP M/230/230-03.pdf

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 http://www.ecfr.gov/cgibin/textidx?tpl=/ecfrbrowse/Title02/2cf r200_main_02.tpl

Administrative Costs

Salaries and wages of administrative and clerical staff should generally be treated as F&A costs and charged to a department administration account.

The following types of administrative and clerical activities are considered indirect costs. They should not be charged to sponsored projects because they cannot easily be directly identified with specific projects:

- Administration and support services that span multiple departmental activities
- Contracts and grants analysis
- Personnel functions
- Accounting and budgeting functions
- Routine travel planning
- Processing and tracking of routine purchase orders

The development and preparation of proposals, including word processing, data entry, photocopying, scanning and mailing, are indirect costs and should be considered part of the departmental administration budget.

However, the Uniform Guidance permits direct charging of administrative and clerical salaries to federal awards when all of the following criteria are met:

- 1. Administrative or clerical services are integral* to a project or activity
- 2. Individuals involved can be specifically identified with the project or activity
- 3. Such costs are explicitly included in the budget or have the prior written approval of the federal awarding agency
- 4. The costs are not also recovered as indirect costs

If all of these requirements are met, PIs should add a justification statement to proposals in order to facilitate the required agency approval.

*UC Davis has determined that integral means the services are essential, vital, or fundamental to the project or activity and UC Davis has sponsor approval for spending direct costs in this manner.

Key Points

Salaries and wages of administrative and clerical staff should generally be treated as indirect costs and included in the departmental administration budget.

Uniform Guidance permits charging administrative expenses to a project when four criteria are satisfied. In such cases, the expenses must be identified in the proposal budget, supported by a written justification, and approved by the sponsoring agency.

Who to Contact

Pl's Department Administrator

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721

Additional Information

UCOP Contract and Grant Manual, Chapter 7, Budget and Expenditures http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter7/index.html

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 <u>http://www.ecfr.gov/cgibin/text-</u> <u>idx?tpl=ecfrbrowse/Title02/2cfr</u> 200_main_02.tpl

Expense Categories to Watch

The following categories of expense are frequently misunderstood and tend to be highly scrutinized by auditors. Before approving any expenses in the following categories, check the award terms and conditions and university policy to ensure that the expenses are allowable.

Proposal Preparation Costs

Costs of preparing proposals and applications for acquiring sponsored funding, including copying, mailing, long distance telephone charges, etc., are considered indirect and are not allowable as a direct cost.

Programmatic Salary Costs

Costs related to protocol development and maintenance, managing substances/chemicals, managing and securing project-specific data and coordination of research subjects are allowable direct costs when they are "contributing and directly related to work under an agreement," per the Uniform Guidance. These programmatic costs may be direct charged using the same underlying requirements as other types of direct costs, and are not subject to the prior approval requirements necessary for administrative and clerical salaries.

Participant Support Costs

Under the Uniform Guidance, participant support costs are allowable only with sponsor prior approval. This includes stipends and 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 are not routinely allowed on research projects but can be charged if the project includes an education or outreach component and the agency approves such costs. These costs must be explicitly listed in the proposal budget or approved by the sponsor at the award stage. These costs were previously subject to F&A costs but are now an excluded category. Participant support costs must be excluded from the base when calculating the indirect cost for project budgets.

Computers, Software and Computer Supplies (Computing Devices)

Computing devices under \$5,000 per unit may be direct charged to a project or activity under the following circumstances:

- 1. The machines are <u>essential*</u> and allocable to the project in that they are necessary to acquire, store, analyze, process and publish data and other information electronically, including accessories (or "peripherals") for printing, transmitted and receiving, or storing electronic information.
- 2. The project does not have reasonable access to other devices or equipment that can achieve the same purpose. Devices may not be purchased for reasons of convenience or preference.
- 3. Items costing more than \$5,000 per unit are considered equipment and follow federal equipment rules for when they can be direct charged.
- 4. The costs are constantly treated as either direct costs to an award or an indirect cost.

^{*}PIs are responsible for determining whether or not the device is essential and to what extent the cost of the device is allocable to the sponsored project. PIs and departments should maintain documentation that describes how the proposed computing device meets the above requirements.

Equipment

Equipment is defined by the federal government and the university as tangible, nonexpendable property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit (including tax, shipping and installation). However, when the terms of an award set a lower dollar threshold for equipment — \$1,000 for example — the PI's department must track it as if it falls under the university's definition of equipment. (See UC Davis Supplies and Equipment Policies, http://manuals.ucdavis.edu/PPM/contents.htm#350.)

Important considerations before purchasing equipment on a sponsored project:

- General-purpose equipment is unallowable as a direct cost, except with the prior written approval of the sponsor.
- If a piece of purchased equipment will benefit more than one sponsored agreement or activity, the cost should be distributed to all benefiting activities using a reasonable method of allocation.
- Budgeted equipment is generally purchased in the beginning of a project unless the scope of work is such that the equipment is essential during a later period of performance. If the equipment purchase is to be made within 60 days of the award end date, the justification must be reviewed and approved by Sponsored Programs before purchase.
- Maintenance and repair costs to keep project-specific equipment whether existing or purchased with project funds in operating condition may be allowable within the timeframe of the project performance period, however, per university policy, they are not included in the value of the equipment but rather expensed as non-capital transactions. As with equipment purchases, if the maintenance agreement or repair cost benefits more than one sponsored agreement or activity, the cost must be allocated to the various projects and activities proportionately based on the benefit directly received by each.

Food

The allowability of food expenses can be a source of confusion. Food is generally not allowable as a charge to a sponsored project. However, meal costs incurred during the course of travel are generally allowable as are meals provided as a working portion of a meeting taking place over an extended period of time. The rules for allowability of food expenses are included in UC Davis Entertainment Policy PPM 330-80 (http://manuals.ucdavis.edu/PPM/330/330-80.pdf).

Travel

Before charging travel to an extramural project, PIs and their department administrators should review all relevant travel policies — sponsor, program, federal, university and campus — and follow the most restrictive, noting any special requirements such as pre-trip approval. Reviewing the Fly America Act, which restricts travelers to American Flag air carriers when traveling on federal funds unless exception criteria are met, is especially important. Travelers should also be familiar with export control requirements when traveling internationally. (See UC Davis Travel Policy, <u>http://manuals.ucdavis.edu/PPM/300/300-10.pdf</u>.)

Tuition Remission

Some sponsors do not allow student fees or tuition remission as a direct charge to projects. Check the award terms and conditions or agency guidelines if you are employing a graduate student on your project. Because tuition remission is a required benefit for all graduate student employees, an alternate, non-restricted funding source such as general funds or donations will need to be identified to pay these charges. (See also:

GSR Buy-Down Information, <u>http://afs.ucdavis.edu/our_services/contracts-e-grants/policies/gsr-buy-down.html</u>)"

Memberships and Subscriptions

Memberships and subscriptions are normally considered to be indirect costs because their benefit to research and academic endeavors generally cannot be specifically assigned to individual awards. If memberships are required for attendance at a professional technical meeting related to the funded project, the membership cost may be allowable provided it was specifically budgeted and justified in the project proposal. The Uniform Guidance permits costs of membership in civic or community organization to be direct charged with prior approval by the federal awarding agency or pass-through entity.

Administrative Salaries and Expenses

Refer to the previous section on <u>administrative costs</u> for guidance on administrative and clerical salaries.

Office Supplies, Telecommunication Charges, and Postage Charges

Office supplies, postage/mailing costs, and local telephone line charges (including cell phones) are normally treated as indirect costs and included in the departmental administration component of the F&A rate. They may only be charged to projects as direct costs in unlike circumstances, such as research based upon large-scale mail or telephone surveys. Long-distance charges that are specifically identifiable to a project may be directly charged.

Printing Charges

Costs related to publication or sharing of research results can be charged to a federal award after the period of performance but before the end of the closeout period.

Recharge Activities and Service Centers

Costs of recharge activities and service centers are allowable as direct costs to a sponsored project in which such costs are required under the scope of the project. All usage must be accounted for and services must be charged to all users based on actual usage using uniform, non-discriminatory rates. The rates must be based on the direct costs of providing the service. Rates must be approved within the university policies and appropriately revised based upon review of the actual direct expenses and charges to users. Charging a tax on projects is prohibited. In other words, a programmer's time could be directly recharged based on hours worked on the project, but three percent could not be charged to all extramural projects in a department to pay for programming services.

Visa Costs

The Uniform Guidance allows short-term, non-immigration visa costs for a specific period and purpose as direct costs to federal awards. The person connected with these visa costs must be critical, necessary and clearly identified as directly connected to the work performed on the federal award. Because this is being classified as a recruiting cost, only the initial visa cost is allowable. J-1 and H-1B visas are for a specific period and purpose; therefore, these visa types are generally allowable if the specific conditions are met.

Cost Transfers

A cost transfer is the movement of an expense from one account to another. This may be necessary to correct an error, to move or split costs into accounts that did not exist when the original transaction was made, or for other reasons associated with a department's financial operation. Transfers should be the exception, not the rule. Cost transfers must meet the guidelines for allowability, allocability, reasonableness and consistency. More stringent criteria apply for cost transfers to be allowable on federally funded projects.

PIs and co-investigators are responsible for reviewing their monthly reports of expenditures for allowability and allocability and to identify errors and omissions for resolution in a timely manner.

With the knowledge and approval of the PI, department staff may initiate a cost transfer. All cost transfers must be:

- *Timely*. The transfer must be recorded in the general ledger within 120 days from the close of the month in which the original charge posted to the ledger.
- *Fully explained and justified.* The reason why the original charge was incorrect and why the charge is allowable and allocable to the new account must be documented.
- *Fully documented*. The transfer transaction must contain a reference to the invoice, payroll, or other disbursement document(s) that were the basis of the original direct charge.

A high frequency of cost transfers can imply that financial transactions are not being properly reviewed and recorded when originally incurred. For this reason, cost transfers are highly scrutinized by auditors to determine the reason for the correction and the allowability of the charge to the project.

Initiating a cost transfer

Once an expense has been recorded, it is appropriate to initiate a cost transfer only in the following situations:

- To correct an erroneous recording.
- To record a change in the original decisions made as to the use of goods or services.
- To redistribute certain high-volume, low-value charges that may be shared among several projects under the jurisdiction of the department.
- To redistribute payroll costs based on the after-the-fact verification of effort reported through the campus effort reporting system.

Key Points

Cost transfers should be rare occurrences.

Cost transfers must meet the rules for allowability.

Cost transfers are highly scrutinized by auditors. They must be recorded in a timely manner and fully justified and documented.

Who to Contact

Pl's Department Administrator

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721

Additional Information

UC Davis Expenditure Adjustments Information <u>http://afs.ucdavis.edu/our_servi</u> <u>ces/contracts-e-</u> <u>grants/policies/cost-</u> <u>transfers.html</u>

UC Davis Policy and Procedure Manual, Chapter 330-63, Expenditure Adjustments http://manuals.ucdavis.edu/PP M/330/330-63.pdf

UC Davis PI Ledger Review Instructions http://afs.ucdavis.edu/our_servi ces/contracts-egrants/procedures/pi-ledgerreview.html

University of California, Business and Finance Bulletin A-47 <u>http://policy.ucop.edu/doc/34</u> <u>20326/BFB-A-47</u>

UCOP Contract and Grant Manual, Chapter 7 http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter7/index.html

Cost Sharing

Cost sharing is the portion of the project expense borne by the university and not by the sponsoring agency. It includes *all* contributions, including cash and in-kind, that a recipient makes to an award. Shared costs are typically paid from departmental or discretionary funds or provided by a third party.

There are three types of cost sharing:

- *Mandatory cost sharing.* Costs that the university must contribute toward the project in order for an award to be made.
- *Voluntary committed cost sharing.* Costs associated with a project and identified in the proposal, for which funding is not being requested from the sponsor.
- *Voluntary uncommitted cost sharing.* Any cost associated with a project and not funded by the sponsor, which has not been identified in the proposal, or in any other communication to the sponsor as a commitment of the university.

Mandatory or voluntary committed cost sharing must be disclosed to the sponsor in the proposal. (Note that the National Science Foundation has specific policies prohibiting voluntary committed cost sharing in proposals. Refer to the NSF Grant Proposal Guide when submitting proposals to this agency.) Cost sharing disclosed to the sponsor in the proposal constitutes a promise that university funding will be provided to directly support the project. Once an award is made, the cost sharing documented in the proposal becomes a binding commitment.

According to the Uniform Guidance, voluntary committed cost sharing cannot be used as a factor during the merit review of proposals. UC Davis strongly discourages cost sharing unless such a commitment is required by the sponsor. If cost sharing is mandatory, this must be noted in the request for proposals issued by the award agency. The PI and department administrators are responsible for identifying the accounts that will pay for cost sharing, and for ensuring that those costs are tracked and reported properly.

Using unrecovered indirect costs (when solicitation limits recovery of indirect costs to less than the full negotiated rate) to offset a cost share component in proposals that require mandatory cost sharing requires agency prior approval. If unrecovered indirects are included in proposal budgets, they must be specifically requested in the budget justification section.

Key Points

Cost sharing is the project expense borne by the university or by a third party.

Cost sharing should only be proposed when the award sponsor has specified cost sharing as a condition of receiving the award.

Cost-shared expenses are paid from departmental, discretionary or third-party funds.

Failure to fulfill a proposed cost sharing obligation may result in reduction of the sponsor's award.

The PI is responsible for identifying the account that will pay for the cost sharing, and for tracking and reporting the costs appropriately. Failure to fulfill the cost sharing obligation may result in the reduction of the amount of the sponsor's award.

Per federal regulations, cost-shared expenses must meet the same criteria as direct-charged expenses:

- Readily verifiable in the university's records (i.e. ledger expenses) or documented in writing, if provided by a third party.
- Necessary and reasonable to achieve the project objectives.
- Allowable under applicable cost principles.
- Not paid by another award, except as specifically authorized by the agency.
- Provided for in the approved budget when required by the awarding agency.
- Incurred within the performance period of the award.

Tracking, reporting, and certifying cost sharing

The PI, departmental administrative staff, and Extramural Funds Accounting staff share responsibility for tracking, reporting and certifying cost-shared expenses.

Pre-award:

The PI prepares a cost share pledge by:

- Clearly documenting cost sharing in the proposal budget justification.
- Omitting from the proposal text any normal university resources necessary for the project which are not offered as voluntary committed cost sharing. If deemed necessary, this type of information should be narrative in nature and must not include quantifiable financial information.
- Obtaining signed documentation from each funding source that has promised to contribute. Letters of funding commitment from third parties must be on the contributor's letterhead.
- If the contribution is from the university, a signed letter from a provost, dean or department chair, or the authorized official's signature on the Sponsored Programs datasheet, is acceptable.
- Submitting all signed documentation with the proposal package to Sponsored Programs.

Post-award:

• Department administrators are responsible for recording and tracking cost share expenses in the Cost Share Tracking System. The PI is responsible for ensuring that all cost share contributions are captured correctly and that cost sharing obligations are met in a timely manner.

Who to Contact

Pl's Department Administrator

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721

Additional Information

UC Davis Cost Sharing Help http://afs.ucdavis.edu/systems/ cost-share-system/index.html

http://afs.ucdavis.edu/systems/ effort-commitmentsystem/index.html

UCOP Contract and Grant Manual, Chapter 5 <u>http://ucop.edu/research-policy-analysis-coordination/resources-tools/contract-and-grant-manual/chapter5/index.html</u>

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 http://www.ecfr.gov/cgibin/textidx?tpl=ecfrbrowse/Title02/2cfr 200 main 02.tpl Notify Sponsored Programs immediately if there is any possibility that a cost sharing commitment will not be fulfilled. This includes situations in which a PI transfers to another institution during the performance period of a project, because the sponsor may hold UC Davis responsible for fulfilling all, or a proportionate share, of any cost sharing commitment associated with the project.

The PI and/or the department administrator must submit cost share contribution reports to Extramural Funds Accounting for submission to the sponsor in accordance with the reporting terms defined in the award agreement.

Effort Reporting

Effort reporting is the method of certifying to the federal granting agencies that the effort required as a condition of the award has actually been completed. Effort reporting is required by OMB Circular A-21*, which requires certification of effort spent by all employees whose salaries are charged directly to federal and federal flow-through funds, as well as for reporting committed cost sharing (but not uncommitted cost sharing) on federally funded projects.

Effort is expressed as a percentage of the total amount of time spent on all work-related activities for which the university compensates the individual. If cost sharing applies — whether mandatory or voluntary committed — UC Davis is required to track the cost-shared effort and certify that the campus has satisfied its commitment to the project. Any voluntary uncommitted cost-shared effort over and above what was originally specified in the project proposal, is not tracked, reported or certified.

Certifying Effort

An effort report must be certified for each employee whose salary (or portion thereof) is charged to a federally sponsored award and/or for any employee who has cost sharing commitments on the project.

PIs and other faculty in professorial, professional research, and management positions who are paid on federal or federal flowthrough funds are required to certify their own effort. Effort for other employees must be certified by the PI or other responsible official. The certifier must have firsthand knowledge of the work performed and the amount of effort expended on that project.

At UC Davis, effort reporting and certification is conducted annually. The annual effort reporting period aligns with the federal fiscal year of October 1 through September 30. Effort reports are issued on or around November 15 (approximately 45 days after the end of the reporting period). The deadline for certifying effort reports is January 28 (120 days after the end of the reporting period).

*The University of California and UC Davis will evaluate alternative methods for meeting new Uniform Guidance requirements.

Key Points

Effort reporting is only required on federally funded projects.

When the sponsoring agency mandates cost sharing, UC Davis must track and certify the costshared effort and expenditures.

Those who certify effort must have firsthand knowledge of the work performed and effort expended.

Effort reports are issued on or about Nov. 15, and certification is typically due Jan. 28.

Who to Contact

Pl's Department Administrator

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721

Additional Information

Cost Sharing Help http://afs.ucdavis.edu/systems/c ost-share-system/index.html

Effort Reporting Help http://afs.ucdavis.edu/systems/ef fort-reporting-system/index.html

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 http://www.ecfr.gov/cgi-bin/textidx?tpl=/ecfrbrowse/Title02/2cfr 200_main_02.tpl

UCOP Contract and Grant Manual, Chapter 7 http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter7/index.html

Developing & Monitoring Sub-Recipient Relationships

As the prime recipient of a grant, UC Davis may collaborate with other institutions, known as sub-recipients, that carry out a portion of the project. Sub-recipients can receive funding in the form of a subaward from the prime award.

Determining whether the relationship with an outside provider will be considered a sub-award or a vendor procurement transaction is important. Therefore, before developing a proposal, the PI should discuss any necessary outside providers with his or her department administrator or Sponsored Programs representative.

If the relationship is appropriately characterized as a sub-recipient relationship, the sub-awards are processed by Sponsored Programs. Only the first \$25,000 of a sub-award expense is subject to the UC Davis F&A charge when the indirect cost base is modified total direct costs. F&A charges are not applied to sub-award expenses incurred by other UC campuses.

Sub-recipients must comply with all terms and conditions of the prime award. The PI is responsible for monitoring the sub-recipient for compliance with award terms and conditions and for satisfactory performance of their portion of the project, including the completeness and acceptability of work performed, reasonableness of expenditures, and fulfillment of cost sharing commitments. PIs should understand that federal awards can be at risk if they sign an invoice authorizing payment of funds to a sub-recipient without first thoughtfully evaluating the sub-recipient's progress.

Sub-awards are monitored using one, or a combination of, the following mechanisms:

- *Reporting*: Review of financial and performance reports submitted by the sub-recipient.
- *Contact*: Regular contact with sub-recipients about program activities and progress.
- *Invoice review*: Invoices are approved by the PI and processed for payment by departmental administrators.

Key Points

Sub-recipients are collaborating institutions that participate in a portion of a project and receive funding as a sub-award from the prime award.

The terms and conditions governing the relationship depend on whether the provider is a subrecipient or a vendor.

Only the first \$25,000 of a subaward expense is subject to the UC Davis F&A charge when the indirect cost base is modified total direct costs.

Pls are responsible for carefully monitoring and accurately reporting the performance of their sub-recipients.

Who to Contact

Pl's Department Administrator

Sponsored Programs proposals@ucdavis.edu awards@ucdavis.edu Phone: (530) 754-7700 Fax: (530) 754-8229

Extramural Funds Accounting Phone: (530) 757-8523 Fax: (530) 757-8721

Additional Information

UCOP Contract and Grant Manual, Chapter 7 http://ucop.edu/research-policyanalysis-coordination/resourcestools/contract-and-grantmanual/chapter7/index.html

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200 <u>http://www.ecfr.gov/cgi-bin/textidx?tpl=ecfrbrowse/Title02/2cfr2</u> 00 main 02.tpl

Research Involving Humans or Animals

UC Davis has both legal and ethical obligations to ensure that human and animal subjects used in research are treated responsibly.

Research Involving Humans

Federal regulations (Common Rule 45 CFR 46) and UC Davis policy require that the Institutional Review Board (IRB) review and approve all research involving human subjects before any human studies commence. This includes projects related to the investigation of new drugs; medical, radiological, engineering, physiological, behavioral, sociological, and nutritional studies; projects involving human tissues or blood; as well as images, questionnaires, interviews, and other procedures.

Projects involving anonymous data and human tissue that were collected for purposes other than the newly proposed research may not fit the definition of research involving human subjects. If you have questions about whether research involves human subjects, you should contact the IRB administration.

All personnel who participate in studies involving human subjects must successfully complete an IRB training course. In addition, all studies approved by the IRB require continuing review. Failure to ensure that a project is reviewed/approved by IRB in a timely manner may lead to suspension of the project and any grants related to the study.

Prior to beginning a study involving human subjects:

- Apply to the IRB for review and approval. This requirement applies to all projects, even when federal regulations exempt certain research from full IRB review.
- Complete the online human subjects training course approved by the IRB. This requirement applies to PIs, associate investigators, student investigators, study coordinators, visiting scientists, consultants, laboratory technicians and all assistants who will have direct contact with human subjects of research. Training must be renewed as determined by IRB. The PI is responsible for ensuring compliance with training requirements.

Key Points

The Institutional Review Board (IRB) must review and approve all research involving human subjects before the project commences, even if federal regulations permit certain research to be exempt from full institutional board review.

Institutional Animal Care and Use Committee (IACUC) must review and approve all research studies and teaching exercises involving the use of vertebrate animals before research procedures are performed.

Advance training is required for most research personnel in advance of conducting human and animal research.

Who to Contact

Institutional Review Board (human subjects) Phone: (916) 703-9151 Fax: (916) 703-9160

Additional Information

Research Involving Human Subjects (UC Davis Policy) http://manuals.ucdavis.edu/pp m/contents.htm#240

Research Involving Animals

All research, teaching or testing that involves the use of vertebrate animals must be approved by the UC Davis Institutional Animal Care and Use Committee (IACUC) before the activities are performed. This includes off-site contract work such as polyclonal antibody production. Any significant changes to an approved project must be approved by the IACUC in advance of implementation. The IACUC can assist PIs in complying with all applicable federal, state, local and institutional regulations regarding animal care and use. An approved Animal Care and Use Protocol must be in place before animals are ordered.

Prior to beginning a study involving animals:

- Submit a protocol to the IACUC for approval. This can be done online at <u>https://iacuc.ucdavis.edu/protocol</u>.
- Complete the Animal Care and Use 101 course, which is accessed through the campus Learning Management System: http://safetyservices.ucdavis.edu/tr/animalCareAndUseTraining
- Participate in the Occupational Health Program by completing the online risk assessment form and health history questionnaire: <u>http://safetyservices.ucdavis.edu/tr/occupationalHealthTraining</u>

Who to Contact

UC Davis IACUC Office (animal subjects) Phone: (530) 752-2364 Fax: (530) 752-4994 E-mail: iacuc-staff@ucdavis.edu

Environmental Health & Safety (if biological agents, controlled substances or hazardous materials or are to be used) Phone: (530) 752-1493 Fax: (530) 752-4527 E-mail: <u>ehsdesk@ucdavis.edu</u>

Additional Information

Policy on Care and Use of Animals in Research and Teaching http://manuals.ucdavis.edu/pp m/290/290-30.pdf

Research Involving Human Anatomical Specimen and/or Tissues

All UC Davis researchers who wish to use human anatomical specimens or tissues for education or research <u>must</u> submit an application to the UC Davis Anatomical Materials Review Committee (AMRC) and receive approval from the AMRC before commencing the research or education efforts.

UC Davis policy defines "anatomical specimens" and sets forth the standards and procedures for the procurement, inventory, use, management, transfer, transportation and disposition of human anatomical specimens to support the appropriate educational and research use of human anatomical materials by faculty, staff, students and residents.

The Human Anatomical Specimen and Tissue Oversight Committee (HASTOC) was established to provide a uniform approach and process for the development of and adherence to the UC Davis policy on anatomical specimens. As part of its charge, HASTOC serves as the UC Davis Anatomical Advisory Board.

Arrangements for the procurement or donation of anatomical specimens from a source other than the Donated Body Program or UCDHS Department of Pathology & Laboratory Medicine must be approved by the AMRC prior to receipt. The AMRC meets monthly to review and take action on requests to use human anatomical specimens. Application forms can be obtained by contacting the UC Davis Donated Body Program at (916) 734-9560.

Who to Contact

Director of Research Compliance & Integrity Office of Research Phone: (530) 754-7754 Fax: (530) 754-7894 http://research.ucdavis.edu/pol iciescompliance/humananatomical-specimen-tissueoversight

Additional Information

UC Davis Donated Body Program <u>http://www.ucdmc.ucdavis.edu</u> <u>/bodydonation/</u> (916) 734-9560

Research Involving Human Stem Cells

All UC Davis activities involving human stem cell research shall be conducted in compliance with the applicable university, state, and federal regulations governing such research, including any restrictions on the use of federal funds for such research. This is regardless of the type of stem cells or whether the stem cells are adult or embryonic.

UC Davis researchers who intend to conduct research involving human stem cells must submit an application to the UC Davis Stem Cell Research Oversight Committee (SCRO) and receive approval from the SCRO Committee <u>before</u> commencing any research efforts. Additional approvals must be obtained from the Institutional Biosafety Committee (IBC) or other committees such as the Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) as appropriate. Researchers must also obtain any necessary Material Transfer Agreements (MTA) of the human embryonic stem cells being used for the research.

Researchers may not distribute human embryonic stem cells or their derivatives without the specific written approval to do so from the appropriate entity. Researchers must obtain *all* applicable authorizations for the research *prior* to review by the SCRO Committee.

Key Points

Human stem cell research cannot commence until approved by the SCRO Committee.

Researchers must obtain all applicable authorizations for the research prior to SCRO review. This includes, as appropriate, IBC approval, IACUC approval, IRB approval, and an MTA.

All SCRO protocols are subject to renewal. Protocol approval periods depend on the appropriate level of review.

Who to Contact

Director of Research Compliance & Integrity Office of Research Phone: (530) 754-7754 Fax: (530) 754-7894

Additional Information

UC Davis Office of Research Compliance & Integrity http://research.ucdavis.edu/pol iciescompliance/stem-cellresearch/

UC Davis Policy on Human Stem Cell Research <u>http://manuals.ucdavis.edu/PP</u> <u>M/220/220-02.pdf</u>

California Institute for Regenerative Medicine (CIRM) www.cirm.ca.gov/

National Institutes of Health Stem Cell Information <u>http://stemcells.nih.gov/</u>

Biosafety

A Biological Use Authorization (BUA) from the Institutional Biosafety Committee (IBC) is required for any activity involving recombinant DNA or biohazardous agents or materials, before the materials may be acquired and before the research activity may be commence. If the project involves the use of animals, IACUC approval, which is contingent on IBC approval, is also required. Human gene transfer projects require IRB approval, which is contingent on IBC approval. The specific types of projects that require BUA review are listed on the biological safety website.

Training Requirements

New PIs are advised to attend Biological Use Authorization Basics (BUA) training and orientation. This is an optional, instructor-led course that details the BUA requirement and provides guidance for completing the BUA application.

The following courses are mandatory prerequisites for PIs and laboratory staff working with specific biohazards:

- *General Biological Safety*. For work at Biological Safety Level 2 (BSL2) with human and non-human primate source materials including cell lines, or with Risk Group 2 human infectious agents.
- *Safe Use of Biological Safety Cabinets*. For researchers and staff who own or use biological safety cabinets.
- *Biological Safety for Research Involving Animals*. For work with animals experimentally or naturally infected with zoonotic or human disease agents including viral vectors.
- *Biological Safety for Plant Research*. For work with plant pathogens or recombinant plants in laboratory or greenhouse environments.
- *Safe Handling of rDNA Materials.* For research staff who handle rDNA materials other than plant, including transgenic animals, recombinant vectors and other rDNA constructs.
- *NIH Guidelines Training*. Mandated for PIs who work with rDNA.
- *Human Gene Transfer Studies at UC Davis.* For PIs and clinical coordinators of human gene therapy (transfer) studies.

Key Points

This information is only an overview of biosafety requirements. Detailed requirements and links to all relevant policy and guidelines may be found in the Biosafety section of the Safety Services website.

A Biological Use Authorization (BUA) from the Institutional Biosafety Committee (IBC) is required for any research or other work that involves recombinant DNA or other biohazardous agents or materials.

For projects involving human subjects, approval of the Institutional Review Board (IRB) is also required.

For projects involving vertebrate animals IACUC approval is also required.

IRB or IACUC approval is contingent upon first obtaining a Biological Use Authorization.

Training is required before investigators or their staff may work with specific types of biohazards.

The biological safety staff in Environmental Health & Safety is the primary resource for information, training, consultation and compliance with biological safety requirements. The Biological Safety program also offers customized training in select agents, BSL3 laboratory practices, plant biosafety at BSL1-P/BSL2-P and BSL3-P, and other specialized biological safety topics.

The safety of research often comes down to individual behavior. To avoid injury, illness or fatalities, all required protective clothing and equipment must be utilized when working with biological agents. Utmost care should be given to understanding and following correct material-handling and equipment-operation procedures, and a zero-tolerance policy for lapses in sound safety practice should be enforced.

Who to Contact

Biological Safety Office Phone: (530) 752-1493 Fax: (530) 752-4527

Additional Information

Biological Safety http://safetyservices.ucdavis.edu/p s/bis

Safety Services http://safetyservices.ucdavis.edu

Biological Use Authorization Application <u>http://safetyservices.ucdavis.edu/p</u> <u>s/bis/f_p/bua/bioUseAuthorizatio</u> <u>n_BUA</u>

Biosafety Rules and Practices FAQ http://safetyservices.ucdavis.edu/p s/bis/faq/faqs

Cal OSHA Bloodborne Pathogen Standard <u>http://www.dir.ca.gov/title8/519</u> <u>3.html</u>

NIH Guidelines http://osp.od.nih.gov/officebiotechnologyactivities/rdna/nih_guidelines_oba. html

Radiological and Laser Safety

A UC Davis Use Authorization is required prior to use of radioactive materials, radiation-producing (x-ray) machines, high intensity light sources or lasers. Usage must be approved by the appropriate radiation use committee. In some cases, the use committee may need to review and approve not only material or equipment, but a particular proposed use.

The Office of Environmental Health and Safety (EH&S) assists PIs in complying with all applicable regulations and use authorization requirements.

Prior to beginning a study involving these types of materials or equipment, the PI must:

- Submit a Use Authorization application to EH&S for review and approval.
- Complete all required training associated with the particular material or equipment.

The safety of research often comes down to individual behavior. All required protective eyewear, clothing and equipment must be utilized when working with radioactive materials, radiation and lasers. Utmost care should be given to understanding and following correct materialhandling and equipment-operation procedures, and a zero-tolerance policy for lapses in sound safety practice should be enforced. This is critical to avoid injury, illness and fatalities.

Key Points

Use authorization is required for all projects involving radioactive materials, radiation-producing (xray) machines, high intensity light sources or lasers.

Specific use of such materials or equipment may also require approval.

The Environmental Health & Safety unit reviews and approves use authorizations for radiation safety.

Who to Contact

Environmental Health & Safety Phone: (530) 752-1493 Fax: (530) 752-4527 E-mail: ehsdesk@ucdavis.edu

Additional Information

Radiological Safety Application http://safetyservices.ucdavis.ed u/ps/rs

Safety Training http://safetyservices.ucdavis.ed u/tr

Controlled Substances

The UC Davis Controlled Substance Program oversees the special requirements and procedures applicable to the procurement, storage, use, transfer, disposal and inspection of controlled substances at all locations that are the responsibility of the UC Davis administration.

All research studies involving the use of controlled substances must be registered with the Office of Environmental Health and Safety (EH&S) before any controlled substance may be purchased.

Prior to beginning a study, the PI must contact EH&S to request a new authorization. The authorization process includes inspection of the proposed storage location. An EH&S specialist will provide the PI with all of the necessary forms for proper documentation of each controlled substance acquisition, use and disposal.

Additionally, all personnel who will be handling controlled substances must complete controlled substances training.

The UC Davis Policy and Procedure Manual, section 290-70, provides detailed information on PI responsibilities and procedures for purchase, use, storage and disposal of controlled substances.

The safety of research often comes down to individual behavior. All required protective clothing and equipment must be utilized when working with controlled substances. Utmost care should be given to understanding and following correct material-handling and equipment-operation procedures, and a zero-tolerance policy for lapses in sound safety practice should be enforced. This is critical to avoid injury, illness and fatalities.

Key Points

The procurement, storage, use, transfer, disposal and inspection of controlled substances are monitored by the UC Davis Controlled Substance Program.

Authorization is required before purchasing any controlled substance.

Specialized training is required before beginning any study involving a controlled substance.

Who to Contact

Environmental Health & Safety Phone: (530) 752-1493 Fax: (530) 752-4527 E-mail: <u>ehsdesk@ucdavis.edu</u>

Additional Information

UC Davis Policy and Procedure Manual, section 290-70 http://manuals.ucdavis.edu/pp m/290/290-70.pdf

Chemical Safety

All research studies involving the use of chemicals in a laboratory setting require:

- Proper reporting of the chemical inventory
- Proper labeling, storage and disposal methods
- A written Chemical Hygiene Plan that includes standard operating procedures
- Staff training

Additional requirements for the use of campus-recognized chemical carcinogens also apply as appropriate.

Although not required by policy, the following training courses are recommended for all personnel working with chemicals:

- Laboratory Safety
- Hazardous Waste Management and Minimization

PIs and others responsible for chemicals and hazardous waste are required to self-audit chemical inventories on an annual basis and enter results into the Chemical Inventory System maintained by EH&S. This self-audit process is designed to verify regulatory compliance and enables county inspectors to audit the central system rather than visit every laboratory. Failure to comply with applicable regulations could result in fines to laboratories or projects.

The safety of research often comes down to individual behavior. All required protective clothing and equipment must be utilized when working with chemicals. Utmost care should be given to understanding and following correct material-handling and equipment-operation procedures, and a zero-tolerance policy for lapses in sound safety practice should be enforced. This is critical to avoid injury, illness and fatalities.

Key Points

Chemicals used in research must be labeled, stored and disposed of properly.

PIs must self-audit chemical inventories and submit audit information to the EH&S Chemical Inventory System.

Who to Contact

Environmental Health & Safety Phone: (530) 752-1493 Fax: (530) 752-4527 E-mail: <u>ehsdesk@ucdavis.edu</u>

Additional Information

Chemical Inventory System http://safetyservices.ucdavis.ed u/ps/hmhwm/cis

Lab Safety and Chemical Hygiene Plan information http://safetyservices.ucdavis.ed u/ps/cls/clsm

Policy on Hazardous Chemical Use, Storage, Transportation, and Disposal http://manuals.ucdavis.edu/pp m/290/290-65.pdf

Policy on Selection and Use of Protective Clothing and Equipment http://manuals.ucdavis.edu/pp m/290/290-50.pdf

Policy on Hazardous Substances Communication <u>http://manuals.ucdavis.edu/pp</u> <u>m/290/290-27.pdf</u>

Boating Safety

UC Policy 290-82 sets forth the policies and procedures governing the safe use of motorized watercraft (boats) for all research and educations activities. This policy applies regardless of the location of the activity, source of funding, and boat ownership. It does not apply to boats used in UC Davis sponsored sports and recreational activities.

Boats used for UC Davis research and educational activities must always be operated in a safe, legal, and prudent manner, meeting appropriate standards for safety, reliability, and suitability for the environmental conditions under which the boat will be operated. In addition, specific roles, responsibilities, and obligations for boat operators, boat occupants, the boating safety officer, and Fleet Services are set forth in the policy. Additional required procedures and activities, including annual boat safety inspections, trip notifications, and accident and incident reporting are also set forth in the policy.

Related Government Regulations

U.S. Code of Federal Regulations:

- Title 33, Navigation and Navigable Waterways <u>http://www.gpo.gov/fdsys/pkg/CFR-1999-title33-vol1/content-detail.html</u>
- Title 46, Shipping <u>http://www.gpo.gov/fdsys/pkg/CFR-2010-title46-vol1/content-detail.html</u>

California Code of Law:

- Harbor and Navigation Code http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hnc&group=00001-01000&file=650-674
- Vehicle Code
 <u>http://www.leginfo.ca.gov/.html/veh_table_of_contents.html</u>

California Code of Regulations, Title 8, Section 3389, Life Rings and Personal Flotation Devices <u>https://www.dir.ca.gov/title8/3389.html</u>

U.S. Coast Guard Navigation Rules <u>http://www.navcen.uscg.gov/?pageName=navRulesContent</u>

Who to Contact

Office of Boating Safety Phone: (707) 875-1933 E-mail: <u>boating@ucdavis.edu</u> <u>http://safetyservices.ucdavis.ed</u> <u>u/ps/rmwc/rmr/ip/marineProgr</u> <u>am</u>

For chartering boats and insurance requirements: Risk Management Phone: (530) 752-1493

Additional Information

UC Davis Policy and Procedure Manual:

- Section 290-15 Safety Management <u>http://manuals.ucdavis.</u> <u>edu/PPM/290/290-15.pdf</u>
- Section 290-80, Diving Safety <u>http://manuals.ucdavis.</u> <u>edu/PPM/290/290-</u> <u>80.pdf</u>
- Section 370-20, Workers' Compensation <u>http://manuals.ucdavis.</u> <u>edu/PPM/370/370-</u> <u>20.pdf</u>

UC Davis Boating Safety Manual http://bml.ucdavis.edu/wpcontent/uploads/BMLBoatMan.p df

Export Controls

Export controls govern the shipment, transmission, or transfer of certain sensitive items, information or software to non-U.S. persons, as defined by the U.S. State Department International Traffic in Arms Regulations (ITAR) and the U.S. Commerce Department Export Administration Regulations (EAR) or foreign entities.

United States export controls exist to protect the national security and foreign policy interests of this country. Due to concerns about homeland security, proliferation of weapons of mass destruction, terrorism, and unauthorized releases of technology to U.S. economic competitors, the federal government has recently increased its scrutiny of export control compliance by colleges and universities.

Depending on the type of technology and particular country involved, the U.S. government may require an export license prior to transferring certain items to certain countries, foreign nationals or entities, even within the U.S. Most of the items, information or software that members of UC Davis ship or share with colleagues and research partners are not of a nature that would be restricted for these purposes, nor are they destined for countries or individuals subject to U.S. embargoes or sanctions. Nonetheless, UC Davis is required to exercise due diligence in complying with U.S. trade laws while preserving one of the University of California's core values, openness in research.

Definitions

- *U.S. person.* A citizen of the United States, a lawful permanent resident alien of the U.S. (a green-card holder), a refugee, protected political asylee or someone granted temporary residency under amnesty or Special Agricultural Worker provisions. The word "person" includes organizations and entities, such as universities.
- *Foreign person*. Anyone who is not a "U.S. person" as defined above.
- *Deemed export.* Export controls may apply not only when an item, a piece of information or software is sent outside U.S. borders, but also when shared with foreign persons or entities within the U.S. Under the deemed export provisions of U.S. trade laws, an export is "deemed" to take place when sensitive items, information or software are released to a foreign national within the U.S..

Key Points

U.S. export control regulations govern shipment, transmission, or transfer of certain sensitive items, information or software to non-U.S. persons (foreign persons or entities) as defined by U.S. State Department and Department of Commerce regulations. (See Definitions in this section.)

Restricted matter shared with foreign persons or entities within the U.S. is deemed to be exported. Therefore, export controls may apply to restricted items, information or software sent outside U.S. borders or shared with foreign persons or entities within the U.S.

Basic and applied research conducted at an institution of higher learning in the U.S., where the resulting information is in the public domain, is exempted from export controls through the Fundamental Research Exemption.

Publishing and openly sharing data and information that results from research makes it publicly available and exempts it from export controls.

- *Publicly available.* Published information that is generally accessible or available to the public through a variety of channels. This definition includes fundamental research conducted and disseminated by universities (see below).
- *Fundamental research*. Basic and applied research in science and engineering conducted at an institution of higher learning in the U.S. where the resulting information is regularly published and broadly shared within the scientific community. This is distinguished from research with results that are restricted for proprietary reasons or subject to specific U.S. government access and dissemination controls.

The general rule is that only U.S. persons are eligible to receive controlled items, information or software without first obtaining an export license from the appropriate U.S. government agency. Violations of export control regulations can lead to significant personal civil and criminal penalties.

Fundamental research and public domain exemptions

U.S. law recognizes a fundamental research exemption to deemed export license requirements. Information publicly available is also excluded from export control regulations. The University of California maintains an open fundamental research environment in which scientific data and results are publicly available and not subject to federal export control regulations. Qualifying under the fundamental research exemption enables foreign nationals to be a part of the research community and supports the exchange of technical data without being subject to deemed export regulation.

Please note that although the conduct, products, and results of fundamental research may proceed openly and can be shared freely with foreign nationals in the U.S. without concern for deemed export restrictions, export-controlled information or materials provided by a third party may not be openly shared with foreign nationals, even when those individuals may be important contributors to the performance of the fundamental research. For example, a vendor or a research partner may have to disclose the heat and vibration tolerances on a piece of export-controlled hardware being provided

Key Points, continued

Violations of export control regulations can lead to significant personal civil and criminal penalties.

Assessing whether export controls will apply and obtaining an export licenses can be complex and lengthy processes. Licensing requirements should be identified in the proposal/award stage. Office of Research Compliance provides support for assessing export licensing requirements and obtaining export licenses.

To avoid violations, do not accept proprietary information that is marked "Export Controlled." Do not accept restrictions on publications. Do not allow the participation of "foreign persons" in your research without a license in place if required. Do not ship anything outside U.S., before ensuring that you have complied with the applicable licensing requirements. for use in carrying out a fundamental research experiment. Such information is also subject to export control, and generates the obligations discussed here.

Physical exports don't have an exemption

The fundamental research and publicly available exemptions do not apply to tangible items that are carried or shipped outside of the U.S. Required export licenses must be secured for shipment of controlled items into or out of the U.S. In such cases, the items must be analyzed to determine whether they are subject to export controls, and an export license must be obtained from the government. This can be complicated and lengthy process, so please plan accordingly. The Research Compliance & Integrity Unit within the Office of Research provides support to analyze items and obtain export licenses.

Technologies typically subject to export control laws

Export controls are frequently, but not exclusively, associated with items, information or software within the following general areas:

- Chemical, biotechnology and biomedical engineering
- Materials technology
- Remote sensing, imaging and reconnaissance
- Navigation, avionics and flight control
- Robotics
- Propulsion system and unmanned air vehicle subsystems
- Telecommunications/networking
- Nuclear technology
- Sensors and sensor technology
- Advanced computer/microelectronic technology
- Information security/encryption
- Laser and directed energy systems
- Rocket systems
- Marine technology

Complying with export laws

The following strategies should be used to maintain eligibility for the fundamental research exemption and compliance with other requirements of expert control regulations.

- 1. Publish early and often to ensure that all technical data about export-controlled commodities qualify as publicly available.
 - Publish information in journals, books, open websites and other digital media, open conferences and meetings.
 - Make research readily available at university libraries.
 - Release educational information by instruction in catalog courses and associated teaching laboratories of the university.

Who to Contact

Director of Research Compliance & Integrity Office of Research Phone: (530) 754-7754 Fax: (530) 754-7894

http://research.ucdavis.edu/pol iciescompliance/export-controls/

Additional Information

UC policies on publication of research results: <u>http://its.ucdavis.edu/research/publications/</u>

U.S. State Department International Traffic in Arms Regulations (ITAR) http://pmddtc.state.gov/regulati ons_laws/itar.html

U.S. State Department embargoed countries list: <u>http://pmddtc.state.gov/embarg</u> <u>oed_countries/</u>

U.S. Commerce Department Export Administration Regulations (EAR) <u>bis.doc.gov/licensing/exporting</u> <u>basics.htm</u>

- Publish and broadly share information resulting from fundamental research within the scientific community and where no contractual controls (other than short delays to protect intellectual property) have been accepted.
- 2. Make software and technical data you have developed available for general distribution either free of charge or at a price that does not exceed the cost of reproduction and distribution.
 - If the source code of a software program is publicly available, then the machine-readable code compiled from the source code is also considered publicly available and, therefore, not subject to the Export Administration Regulations (EAR). (See EAR 734, Supplement 1, Question G(1).)
 - The cost of reproduction and distribution may include variable and fixed allocations of overhead and normal profit for the reproduction and distribution functions but may not include recovery for development, design, or acquisition, such that the provider does not receive a fee for the inherent value of the software. (See EAR 734, Supplement 1, Question G(2).)
- 3. Ask software providers to identify the export control classification number that controls the software. Then research the applicability of export controls to that software. The software provider could have been overly cautious and the software may not be, in fact, export controlled.
- 4. <u>Do not</u> accept publication controls or access/dissemination restrictions, such as approval requirements of sponsor to publish results, or for use by foreign nationals.
- 5. <u>Do not</u> enter into secrecy agreements, or otherwise agree to withhold results of research projects conducted at the university or which involve university facilities, students or staff.
- 6. <u>Do not</u> accept proprietary information or material that is marked "Export Controlled." Return to the manufacturer any materials it provides to you about export-controlled equipment that is marked "confidential," without using them. Review any confidentiality/non-disclosure agreements to ensure that you and the university are not assuming the burden of restricting dissemination based on citizenship status or securing licenses.
- 7. <u>Do not</u> agree to background checks or other arrangements in which the external sponsor screens, clears, or otherwise approves project staff. University policy allows for background screening conducted by the university when appropriate to the position.

- <u>Do not</u> travel to conduct research or educational activities in embargoed countries without first checking with the Office of Research to ascertain whether a license from the Department of Treasury, Office of Foreign Assets Control, is required. A current list of embargoed countries can be found on the U.S. Department of State website: <u>pmddtc.state.gov/embargoed_countries</u>.
- <u>Do not</u> ship any item outside the U.S. without first checking the U.S. State Department International Traffic in Arms Regulations (ITAR) and U.S. Commerce Department Export Administration Regulations, (EAR) lists to determine if the item (including a commodity, software or technology) is controlled.
- 10. <u>Do not</u> attend meetings where foreign nationals are prohibited from attending.
- 11. <u>Do not</u> sign the DD2345, Militarily Critical Technical Data Agreement, as a condition of attending a conference or receiving materials from the government.
- 12. <u>Do</u> plan ahead.
 - Identify projects that will have deliverables to foreign countries at the proposal/award stage. Contact Sponsored Programs for assistance in anticipating or resolving any issues that may arise so that your research may proceed in a manner that is compliant with export regulations.
 - Determine licensing requirements early and assist Innovation*Access* or the UC Davis Biosafety Committee in securing licenses. UC has never been denied a license, but it can be a lengthy process.
- 13. <u>Do</u> train research staff regarding the shipment of controlled commodities, software and technology.
- 14. <u>Do</u> contact the Research Compliance Office for assistance in securing an export license or to verify a license exception prior to shipment. If a license is not required, maintain records of the determination process.

Roles & Responsibilities

Different campus offices are responsible for various phases of the extramural funding process. The following table demonstrates key proposal and award roles and responsibilities.

PI and Research Staff	PI's Department Administrator and Staff
Develop complete, timely proposals Prepare all required reports and submit to sponsors Understand sponsors' terms and conditions and university policies and procedures related to sponsored project administration Manage and control project funds, including subcontractor funds, to ensure compliance with award terms and conditions and university policy Authorize expenses When applicable, certify personnel effort and approve cost share reports Ensure scientific integrity and manage projects Manage subcontractor progress Ensure that staff have adequate training for research involving human subjects, animals and/or hazardous materials.	 Assist with development of proposals Prepare administrative reports for submission to sponsors Keep PI informed of the financial status of the award and assist in administration of the award Provide the PI with business and accounting expertise Process financial and budget transactions and review project status monthly to ensure only allowable costs are recorded and project expenditures are within budgetary constraints Maintain and monitor effort commitments for faculty Establish appropriate accounting structure to satisfy sponsor financial reporting requirements
Extramural Funds Accounting	Sponsored Programs
Establish awards in the financial system Approve project expenditure accounts and ensure reporting attributes are accurate Prepare financial reports throughout the life of the project Prepare invoices, letter of credit draws, perform collection activities Coordinate effort reporting process Perform post-audit reviews of financial transactions Coordinate financial close out of the award Conduct campuswide training in post-award management	 Review and approve proposals Negotiate awards and sub-awards, and accept on behalf of the Regents Approve and submit post-award reports to sponsors, as required. Review and approve proposal budgets, ensuring compliance with UC and Sponsor policies Advise PIs and their staffs on budget preparation and indirect cost calculation Collect internal approvals and conflict of interest disclosure forms Distribute proposal information to appropriate campus offices such as Environmental Health & Safety, Extramural Funds Accounting and other departments.

Contact Information

Accounting & Financial Services

http://afs.ucdavis.edu/index.html 1441 Research Park Drive Davis, CA 95616 Phone: (530) 757-8501 Fax: (530) 757-8510

Biological Safety Office

http://safetyservices.ucdavis.edu/ps/bis 276 Hoagland Hall Phone: (530) 752-1493 Fax: 752-4527 Biosafety staff e-mails: http://safetyservices.ucdavis.edu/about-us-1/org-chart-pages/biological-safety-org-chart

Costing & Policy Analysis

http://afs.ucdavis.edu/our_services/costingpolicy-e-analysis/index.html 1441 Research Park Drive, Room 101 Phone: (530) 752-4621 Fax: (530) 757-8510

Environmental Health & Safety

Phone: 530-752-1493 Fax: 530-752-4527 E-mail: <u>ehsdesk@ucdavis.edu</u>

Extramural Funds Accounting

http://afs.ucdavis.edu/our_services/contractse-grants/index.html 1441 Research Park Drive, Room 170 Phone: (530) 757-8523 Fax: (530) 757-8721

External Audit Coordinator

Amy Holzman, Internal Audit Services Phone: (530) 752-9169 <u>amholzman@ucdavis.edu</u>

Institutional Animal Care & Use Committee Office

http://safetyservices.ucdavis.edu/ps/a/IACUC ARS Q3 Phone: (530) 752-2364: Fax: (530) 752-4994 E-mail: <u>iacuc-staff@ucdavis.edu</u>

Institutional Review Board

http://research.ucdavis.edu/policiescompliance /irb-admin/ UC Davis Medical Center, CTSC Building 2921 Stockton Blvd., Suite 1400, Room 1429 Sacramento, CA 95817 Phone: (916) 703-9151 Fax: (916) 703-9160 IRB contacts: http://research.ucdavis.edu/contact-us/irb/

Office of Research

http://research.ucdavis.edu/ 1850 Research Park Drive, Suite 300 Davis, CA 95618-6153 Phone: (530) 754-7679 Fax: (530) 754-7894 Office of Research contacts: http://research.ucdavis.edu/contact-us

Research Compliance & Integrity

http://research.ucdavis.edu/offices/rci/ 1850 Research Park Drive, Suite 300 Davis, CA 95618-6153 Phone: (530) 754-7754 Fax: (530) 754-7894 Staff contacts: http://research.ucdavis.edu/contactus/research-compliance-integrity/

Safety Services

http://safetyservices.ucdavis.edu 276 Hoagland Hall Phone: (530) 752-2599 Fax: (530) 752-4527

Sponsored Programs

http://research.ucdavis.edu/proposals-grantscontracts/spo/ 1850 Research Park Drive, Suite 300 Davis, CA 95618-6153 Phone: (530) 754-7700 Fax: (530) 754-8229 Staff contacts: http://research.ucdavis.edu/contactus/sponsored-programs/