

NCIRE Principal Investigator Manual

— INTRODUCTION —

The Northern California Institute for Research and Education, Inc. (NCIRE) has a robust Principal Investigator (PI) community that we support. To better assist you in running your program through NCIRE, we have created this NCIRE PI Manual as a resource to help you do business efficiently with NCIRE in compliance with our policies and procedures.



NCIRE

Northern California Institute for Research and Education, Inc.

TABLE OF CONTENTS

| | |
|---|-----------|
| ACCOUNTING SERVICES | 6 |
| Types of Invoices..... | 6 |
| Collection on Outstanding Invoices..... | 7 |
| Business Travel Reimbursement Process..... | 7 |
| Instructions on completing the Travel Reimbursement form: | 7 |
| Supporting documentation to include with Travel Reimbursement form: | 8 |
| Subject Payments | 9 |
| NCIRE offers three methods for Subject Payments:..... | 9 |
| A. Subject Payment Check Request | 9 |
| B. Greenphire ClinCard System (Debit Cards) | 10 |
| C. Tango Reward Link® program (Electronic Gift Cards) | 11 |
| Subject Petty Cash Request and Payment | 12 |
| Payroll | 13 |
| Timekeeping System – Timesheet Submission and Approval | 13 |
| Payroll Cost Transfer Request and Process | 13 |
| Year-End W-2 Reporting | 14 |
| Annual Fixed Assets Inventory Check..... | 14 |
| Office of Sponsored Research..... | 16 |
| Office of Sponsored Research Industry Overview | 16 |
| Getting Started | 16 |
| PI Eligibility | 16 |
| Confidential Disclosure / Non-Disclosure Agreement (CDA/NDA) | 16 |
| Collaborative Research and Development Agreement (CRADA) | 17 |
| CRADA Agreement Templates..... | 18 |
| VA Conflict of Interest Form 450 | 18 |
| CRADA Negotiations and Signatures | 18 |
| CRADA Signatory Process | 18 |
| Research Budget..... | 19 |
| Research Budget – Clinical Trials | 19 |
| Initial Research Budget Review | 19 |
| Final Budget Review | 19 |
| Key Industry Rates and Fees as of 10/1/2025 (subject to change) | 20 |
| Payment Schedule..... | 20 |
| Holdback..... | 20 |
| Payments and Invoices..... | 20 |
| Completion of an Industry Sponsored Project | 21 |
| Office of Sponsored Research Federal & Foundation Overview | 21 |
| Pre-Award Roles and Responsibilities | 21 |
| Principal Investigator Responsibilities | 21 |
| Office of Sponsored Research Responsibilities | 22 |

| | |
|--|-----------|
| Pre-Award: Grant Submission Process Eligibility..... | 23 |
| Initiating Grant Applications..... | 24 |
| Submitting application to NCIRE for review and approval | 24 |
| Post-Award Roles and Responsibilities | 25 |
| Principal Investigator Responsibilities | 25 |
| Office of Sponsored Research Responsibilities | 27 |
| Just-In-Time..... | 28 |
| Post-Award..... | 29 |
| Direct/Admin Project Numbers..... | 29 |
| Direct/Admin Project Financial Statements | 30 |
| Acumatica: NCIRE Project Reports | 30 |
| Subaward Agreements | 30 |
| Budget Projections | 30 |
| Reporting Requirements | 31 |
| Formal Requests | 31 |
| Close-out | 31 |
| Subawards/Subcontracts | 32 |
| Subcontract vs Independent Contractor | 32 |
| Initiating and Routing a Subcontract – “subIN” vs “subOUT” | 32 |
| General Office of Sponsored Research Information (Applicable to all NCIRE Administered Projects)..... | 33 |
| Financial Conflict of Interest (FCOI)..... | 34 |
| Research and Development Approval (R&D Approval)..... | 34 |
| R&DC Approval..... | 34 |
| Full ACOS Approval..... | 34 |
| Administrative Approval (Admin Approval) | 34 |
| ACOS Approval Process | 36 |
| R&DC Meeting..... | 36 |
| Institutional Review Board | 36 |
| VA Central Institutional Review Board | 37 |
| Single IRB | 37 |
| IRB Full Committee Review | 38 |
| IRB Expedited Review..... | 38 |
| Exempt Certification..... | 39 |
| IRB Continuing Review | 39 |
| IRB Study Closeout | 39 |
| IRB Closeout and Data Analysis | 39 |

HUMAN RESOURCES.....42

| | |
|---|-----------|
| Recruitment and Hiring Process..... | 42 |
| Without Compensation (WOC) Appointments..... | 44 |
| Visas..... | 45 |
| H-1B Visa | 45 |
| J-1 Visa..... | 46 |
| Optional Practical Training (OPT) | 46 |
| Changes to Existing Employment..... | 47 |
| Promotions | 47 |
| Salary Adjustments..... | 48 |
| Performance Reviews, Merit Increases and Special Contributions Awards..... | 48 |
| Performance Management | 48 |

| | |
|--|-----------|
| Merit Increases..... | 49 |
| Special Contribution Award Guidelines..... | 50 |
| Benefits, Fringe Rate, and Leaves | 51 |
| The Family Medical Leave Act (FMLA)..... | 51 |
| California Family Rights Act (CFRA) | 52 |
| San Francisco Paid Parental Leave Ordinance..... | 52 |
| Other workers' leave rights, including leave related to: | 53 |
| Fringe Benefits Rates | 53 |
| Affordable Care Act (ACA) | 54 |
| Employer Mandate Overview..... | 54 |
| Personnel Agreements with the VA and UCSF | 55 |
| The Intergovernmental Personnel Act (IPA)..... | 55 |
| Joint Personnel Agreements (JPA)..... | 56 |
| Background and Requirements: | 57 |
| Types of JPAs | 58 |
| Employee Relations | 58 |
| Employee Terminations | 59 |
| INFORMATION TECHNOLOGY (IT) | 61 |
| Request IT Support | 61 |
| Getting a Computer | 62 |
| Desktop and Laptop Configuration | 62 |
| Server Configuration | 63 |
| Software Installation..... | 63 |
| Remote Access..... | 64 |
| Computer Equipment Disposal | 65 |
| PROCUREMENT..... | 66 |
| General Procurement Requirements | 66 |
| Purchases above the Micro-Purchase Threshold | 67 |
| Purchases Above the Simplified Acquisition Threshold..... | 68 |
| Procurement Processes | 70 |
| Procurement of Specialty Goods and Services..... | 72 |
| International Orders..... | 72 |
| Material Transfer Agreements (MTA's)..... | 72 |
| Institutional Alliance and Affiliate Transactions..... | 72 |
| Receiving | 73 |
| Returning Goods to a Supplier | 75 |
| Warranty and Vendor Repairs..... | 75 |
| In-House Repairs | 76 |
| Warranties..... | 76 |
| Heavy and Oversized Goods..... | 76 |
| Mission Bay Location | 77 |
| Facility Access..... | 77 |

| | |
|---|-----------|
| Group shared CO2 system (3rd floor) | 77 |
| Deliveries (NCIRE, SFVAMC, UCSF) | 77 |
| Courier service..... | 77 |
| Hazardous waste | 77 |
| Safety and compliance | 78 |
| Building issues | 78 |
| Housekeeping services | 78 |
| Appendix | 79 |
| JPA Process Chart | 79 |
| IPA Chart..... | 80 |
| Promotion Request | 81 |
| Salary Adjustment Request | 82 |
| PI IPA Checklist | 83 |

ACCOUNTING SERVICES



Accounts Receivable

Revenue Sources

NCIRE's revenue is generated from five primary sources. Federal/State grants account for 85% of NCIRE's total revenue. The remaining 15% of the revenue stream is generated from Industry Studies, Private Foundations, Donations, and Interagency Personnel Agreements (IPAs).

Types of Invoices

NCIRE generates five types of invoices as follows:

- NIH/DoD grants – NCIRE's Federal grants are funded via a cost-reimbursement payment mechanism. Twice a month a system allocator is run to capture expenses posted to each federal project for the period beginning at the end of the prior allocator cut-off date through the current allocator cut-off date, and allocates revenue based on each project's indirect cost rate. Funds are then drawn from NCIRE's line of credit with the Federal Payment Management System the following day.
- Subcontracts/Pass-through grants – NCIRE bills the Prime sites for research grant expenditures incurred by PIs on a monthly basis (typically at the close of each accounting period).
- Intergovernmental Personnel Agreement (IPA) – NCIRE bills the VA for payroll and benefits expenditures incurred by NCIRE employees who are funded by their PIs' VA grants.
- Industry Studies (CRC) – NCIRE bills the Industry Sponsors for clinical research services provided by PIs per contracts. Billings are triggered by the completion of study milestones.
- VMU Core Service (Veterinary Medical Unit) – Based on a monthly billing log provided by the VMU, PIs who use the animal facility for animals per diem and procedure services receive expenditure recharges posted to their grants via an internal journal entry, debiting PI's accounts for expenses and crediting VMU for revenue.

NCIRE's invoices are all deemed collectible as receivables are predominantly from federal agencies such as, NIH, DoD, VA, etc., that follow standard payment schedules.

Collection on Outstanding Invoices

NCIRE's collection process begins when an account is 60 days past due. The collection process is as follows:

- Upon completion of each month-end accounting close, the accountant runs an Accounts Receivable Aging Report to identify past due invoices.
- If an invoice is over 60 days past due, the accountant will reach out to the Accounting/ Finance contact provided by the sponsor to inquire about the status of the payment.
- The accountant notifies the CFO and the Grants Specialist of any unusual circumstances related to the delinquent accounts.

If you have questions regarding revenue or payments to your accounts, please contact our Sr. Accountant, Jean Wong, at jean.wong@ncire.org or 415-221-4810 ext. 23752.

Business Travel Reimbursement Process

It is NCIRE's policy to further medical science by promoting research. NCIRE funds may be used to reimburse for travel expenses associated with furthering research and research education.

A Business Travel Reimbursement request/form cannot be submitted prior to travel except for NCIRE employees' pre-approved airfare. The Travel Reimbursement form should be completed and submitted with supporting documentation upon return from travel, within 45 days after the meeting has taken place for domestic travel, and within 60 days for international travel.

Instructions on completing the Travel Reimbursement form:

1. Date – the date the reimbursement form is submitted to NCIRE
2. Name – the name of the traveler who is being reimbursed
3. Location – city, state, or country traveled to
4. Title of Meeting – indicate the title of the meeting and the dates of the meeting.
5. Explain how this travel was related to your research
6. NCIRE account to be charged – if unsure, please consult with your PI or Grants Specialist
7. Breakdown of Expenses – use a separate line for each day of travel, indicating the cost, if any, for each category (airfare, lodging, meals, ground transportation, etc.).
8. Sum the expenses for the day – The total at the bottom right should show the total amount to be reimbursed for the entire trip.
9. Traveler's Signature – signed by the person who traveled to the meeting
10. Authorized Signature – signed by PI or person authorized to sign on behalf of the PI.
Please note that an authorized signer may not sign for his or her own reimbursement.

11. Indicate preference in handling the check – provide your phone extension for pick-up at the NCIRE front desk, send via inter-office mail, or send to home address (include physical address).

Supporting documentation to include with Travel Reimbursement form:

1. **A copy of the meeting program** – it should include the name of the meeting, location, and dates of the meeting.
2. **Airfare** – provide a copy of the airfare receipt and itinerary showing the dates, times, locations traveled to/from, and amount paid. Economy seating should be used whenever possible.
3. **Lodging** – provide an itemized hotel receipt showing detail of charges for each night stayed and payment for the lodging.
4. **Meals** – indicate if meals should be charged per diem or if the meals reimbursed should be itemized. Alcohol expenses are not reimbursable under any circumstance.
 - a. **Per diem** – daily meals will be reimbursed following the GSA rates for the city and state where the meeting was held (<https://www.gsa.gov/travel/plan-book/per-diem-rates>) or for international travel (https://aoprals.state.gov/web920/per_diem.asp). The first and last days of travel are calculated at 75% of the daily rate.
 - b. **Itemized** – actual amounts incurred must be supported by itemized receipts for each meal/expense. The amount reimbursed should not exceed the per diem amount as published by the GSA.
5. **Registration** – Include the registration receipt indicating the amount that was paid or charged.
6. **Ground Transportation**
 - a. Submit all itemized receipts for public transportation, taxi fares, and ride shares for reimbursement.
 - b. When your personal vehicle is used, indicate the addresses that is traveled to and from and include a copy of Google maps to show the distance traveled for calculations for reimbursement.
 - c. Rental cars should only be used when it is more economical compared to the use of taxis or other types of transportation.
7. **Other** – any expenses other than the items mentioned above, please include itemized receipts and details of these expenses.
8. **International travel** – submit the reimbursement form for expenses in U.S. Dollars.
 - a. Include copies of credit card statements showing expenses converted to U.S. Dollars (<https://www1.oanda.com/currency/converter/>)
 - b. If expenses were paid in cash, provide a receipt (describe what was the expense) and a copy of the currency conversion for the amount for the date that the expense was incurred.

Please Reference Policy: [Accounting – Chapter 2 – Business Travel Reimbursement.pdf – User \(sharepoint.com\)](#) for detailed information regarding this process.

If you have questions regarding business travel-related expenses, please contact our Accounts Payable Specialist, Clara Tong at clara.tong@ncire.org or 415-221-4810 ext. 23098.

Subject Payments

Subject payments are used to enhance recruitment by providing an incentive to research subjects for their participation and time commitment in a research study or clinical trial. Depending on sponsor guidelines, some NCIRE-administered grants and Industry Studies may allow research subject payment costs on the project.

NCIRE offers three methods for Subject Payments:

- A. Subject Payment Check Request
- B. Greenphire ClinCards (Debit Cards)
- C. Tango Reward Link® program (Electronic Gift Cards)

A. Subject Payment Check Request

1. On the day of a subject visit, a Subject Payment Form made payable to the research subject should be prepared. The form can be found on the NCIRE Accounting SharePoint site in the Forms area. The following information must be included on the request:
 - a. Date of test
 - b. Subject's name
 - c. Home address (for tax reporting purposes)
 - d. Social Security Number
 - In lieu of a Social Security Number, a completed and signed IRS Form W-9 indicating "Applied For" will allow for payments to be made up to 60 days after signature date.
 - e. Amount of Payment
 - f. NCIRE account number to be charged
 - g. Title of project
 - h. Advance check option
 - In exceptional cases, subject payments may be prepared in advance of a visit. Five business days' notice is required, and checks would be available for pick up at the NCIRE front desk.
 - Unclaimed advance checks should be returned to the NCIRE front desk unless the subject has another visit in the near future.
 - i. Delivery method
 - Checks may be mailed to subjects or held at the NCIRE front desk for pick-up

- j. Authorized signature
 - Authorized signers include the PI and those designated by the PI on the Subject Payment Authorization Form. A blank authorization form can be found in the Forms area of the NCIRE – Accounting SharePoint site.
- k. Subject Signature
 - Subject signatures are waived for advance requests or remote visits
- l. Signed W-9's for new subjects or subject address changes should be attached or forwarded ASAP

2. The Subject Payment Form should be submitted to the Accounting Department for processing. It can be submitted in person to the NCIRE front desk or submitted via secure email (UCSF Secure or NCIRE encrypted) to invoices@ncire.org.
3. Questions about how to properly complete the form and requests for additional information should be directed to by e-mail at invoices@ncire.org.
4. Payment Timing
 - a. The Accounting Department processes Subject Payment Forms for research subjects as a priority. Assuming Subject Payment Forms are complete and appropriate documentation has been provided, payment will be issued within 7 to 10 working days of receipt.
 - b. RUSH payments need to be identified on the form and will be processed within 3 working days. Research subjects should not be directed to contact the Accounting Department directly.

B. Greenphire ClinCard System (Debit Cards)

Greenphire ClinCard System makes subject payments via reloadable debit card payment system.

ClinCard Benefits:

- Participants receive instant payment after a visit
- Coordinators can load and reload cards issued to participants
- Coordinators can send text/emails reminders to participants
- Eliminates the manual handwritten yellow checks and outstanding check follow up
- Eliminates lost checks, stop payments, and re-issue



New/Current Projects

1. To initiate subject payments via ClinCards, please email the following documents/information to invoices@ncire.org IRB Approval Letter (IRB Modification is required for debit card reimbursements)
 - a. Blank Informed Consent form
 - b. ACOS Approval Letter
 - c. Principal Investigators authorization for Study Coordinator(s) to issue ClinCards for the project
 - d. NCIRE Project Number
 - e. Number of ClinCards requested (less than 200)
 - f. Milestone Dollar Amount(s); including travel reimbursement
2. Onboarding - Training provided by Accounts Payable Specialist, Linda Huang.
 - a. ClinCard Reference Guide
 - b. Study Coordinator's email access to ClinCard portal
 - c. Onboarding via Zoom – add study details, milestone payment schedule
3. NCIRE will notify you when ClinCard(s) are ready for pick-up. ClinCard(s) will be available for pick-up at NCIRE front desk (Bldg. 210, 1st floor).

**** We suggest adding following language to the consent form:**

You will receive the payment/reimbursement through a Greenphire ClinCard. The Greenphire ClinCard is a MasterCard Debit Card that can be used anywhere MasterCard is accepted. The funds will generally be available within 3-5 business days after you complete each study visit. It will be provided to you through your study coordinator by NCIRE. In order for Greenphire to support this reimbursement process, NCIRE will need to process certain information about you. This information will be collected by the study coordinator and entered into the Greenphire's business system. Your study coordinator will collect your Subject ID, Name, Address, Date of Birth, Social Security Number (or a completed and signed W-9) and the title of this study to allow them to set you up in the ClinCard system. Your personal information will be kept on the Greenphire business system, and it will be kept completely confidential and will not be shared. Your personal information will be removed from the Greenphire platform after the study is over and the money on the card has been used.

C. Tango Reward Link® program (Electronic Gift Cards)

1. The Tango Reward Link® program (<https://www.tangocard.com/solutions/reward-link>) provides a variety of popular gift card options. Tango issues points to the research subject which can be redeemed for gift cards. Please note, a separate Tango account is required for each research project. To initiate subject payments via Tango, please contact Accountant, Linda Huang at linda.huang@ncire.org or at ext. 23069. The following documents will be required to initiate a Tango account:
 - a. ACOS Approval Letter
 - b. IRB Approval Letter
 - c. Blank Informed Consent Form
 - d. Subject Payment Authorization Form

- e. Tango Fund Request Form
2. Each Tango account is replenished monthly by Accounting Department based on its monthly spending.
3. To comply with IRS regulations, PIs are required to submit a summary report at the end of each calendar year. The following information must be included:
 - a. Subject's name
 - b. Subject's mailing address
 - c. Total amount paid to each subject during the calendar yearPIs are responsible for collecting and providing a subject's Social Security Number (SSN) upon NCIRE Accounting's request. It is strongly recommended that subjects' SSN be collected at enrollment.
4. Tango accounts must be closed by the project end date.

If you have any questions regarding Tango, please contact Accountant, Linda Huang at linda.huang@ncire.org or ext. 23069

Subject Petty Cash Request and Payment

A petty cash fund is approved and established for specific PIs, only for providing on-site payments to research subjects who do not have bank accounts or for emergency payment purposes. Petty cash funds are not the preferred method of payment.

A petty cash fund limit is \$250 per request however, if a higher dollar amount is needed for the research study, written justification is required for the CFO's review and preapproval.

To set up a petty cash account, the following documents are required:

1. ACOS letter
2. CHR approval letter
3. Blank consent form created by the PI's office and to be signed by subjects
4. PI's authorization

For initial request, submit a "Subject Petty Cash Form" with PI or authorized administrator's approval.

For petty cash replenishment, submit both "Subject Petty Cash Form" and "Petty Cash Ledger" with PI or authorized administrator's approval.

Petty cash account must be closed by the end of the project cycle. Any remaining cash must be returned to NCIRE Accounting department. Any questions regarding petty cash requests and payment, please contact invoices@ncire.org or Controller, Jian Pu at jian.pu@ncire.org.

Payroll

Timekeeping System – Timesheet Submission and Approval

Timesheet Submission: Timesheets are due on the designated due date at the end of each pay period. Leading up to the due date, the UltiPro system will send two reminder emails on Thursday and Friday. If an employee submits a paper timesheet, the timesheet should be signed by their supervisor and emailed to payroll@ncire.org before the due date.

The Payroll Administrator will review all open and incomplete timesheets on the due date prior to sending out a final reminder email to those who did not submit their timesheet. Each employee is responsible for submitting a timesheet by the due date in order to get paid; late timesheets will not be processed in the current payroll cycle but will be processed in the following pay period. If incorrect information is found on a timesheet, the Payroll Administrator will contact the employee immediately to review and correct (if needed) his or her timesheet prior to payroll processing.

Timesheet Approval: PI/Supervisors will be prompted to review and approve their employees' timesheets via UltiPro at the end of each pay period; the approval reminder will be sent automatically by UltiPro. The PI/Supervisor will receive two more approval reminder emails if their employees' timesheets remain unapproved.

PI and Supervisors are responsible for approving their staff's timesheets every pay period. Once a payroll cycle is complete, the Payroll Administrator will reach out to the approvers for pending/outstanding timesheet approval. It is critical that NCIRE's time and effort reporting requirement is satisfied for internal control and incompliance with Uniform Guidance. PI and Supervisor's approval of timesheets are used as physical evidence of certification of hours worked, which ensures compliance with the requirements of Federal/State/Private funds NCIRE manages.

Payroll Cost Transfer Request and Process

(Listed on NCIRE Intranet – Accounting Policies & Procedures Manual)

The PI's office completes, reviews, signs and dates the Personnel Funding Change Notice Form (PFC) and submits the PFC to NCIRE Payroll Administrator to request a payroll cost transfer.

The Payroll Administrator will forward the PFC to the assigned Grants Specialist for review and approval. The Grants Specialist will review the PFC to verify that the grant being charged is active and has available funds.

The Payroll Administrator then processes the PFC by updating the payroll data accordingly. If retroactive cost transfers are involved, a copy is then provided to the Accounting Specialist for journal entry preparation.

The Accounting Specialist will prepare journal entries for the cost transfer accordingly. Journal entries will only be posted to the current fiscal year and accounting period.

The average turn-around time for a payroll cost transfer to be processed is 7 to 10 days. Payroll cost transfers become effective the beginning of the first pay period after receipt of the request. Questions regarding payroll cost transfers should be directed to Sr. Accountant, Jean Wong at jean.wong@ncire.org or your Grant Specialist.

Year-End W-2 Reporting

In mid-December, the Payroll Administrator will send a reminder email to all NCIRE employees to verify and confirm their personal information including their official name, mailing address, and Social Security Number (SSN) to ensure their personal information will be listed correctly on their W-2 Form.

To ensure that all employee's annual salaries are reported accurately on their W-2 forms, the Payroll Administrator will send a reminder email to ask all employees to submit their last pay period timesheets on time. Timesheets received after the DUE DATE will be reported on next year's W-2 and be excluded as current year's income. The Payroll Administrator will follow the year-end checklist provided by UltiPro to verify employee's W-2 information and then submit the W-2 form print request to UltiPro in early January. UltiPro will then issue W-2 forms in mid-January and send original W-2's to NCIRE's Core Office for distribution. W-2 information is available on UltiPro and can be downloaded. Also, original W-2 forms will be mailed to employee's home address by the end of January.

If you have any questions on the W-2 form or did not receive one, please contact NCIRE payroll at payroll@ncire.org.

Annual Fixed Assets Inventory Check

Annual inventory check is part of NCIRE's audit requirements. In general, it is performed between June and September. In June, Accounting department sends emails to PIs or their lab staff to schedule appointments to inspect NCIRE purchased equipment. An inventory check form listing the details of the equipment such as acquisition date, vendor, cost, current location, etc. is provided in the email request for PI's reference. All PI's NCIRE equipment regardless of NCIRE funding sources are listed on this form.

By verifying an equipment's physical location and condition and checking its tag number as per NCIRE record, both the PI/lab staff and the Accounting staff will sign off on the Inventory Check form to complete the process. The signed form will then be filed within Accounting for audit compliance.

For off campus equipment, email confirmation from PI research group is required. Any questions regarding the process of NCIRE's annual inventory check should be directed to Accountant, Linda Huang at linda.huang@ncire.org.



Office of Sponsored Research Industry Overview

NCIRE Office of Sponsored Research's mission is to foster and maintain mutually beneficial relationships with Industry Sponsors, the San Francisco VA Health Care System (SFVAHCS) and provide first-rate, responsive, and timely service to our Principal Investigators (PI).

NCIRE, with the assistance of the VA's Office of General (OGC) Specialty Team Advising Research (STAR) Attorney, will negotiate a Cooperative Research and Development Agreements (CRADA)—the VA's version of a clinical trial agreement (CTA)—with industry on behalf of our PI's. Our goal is to bring funding and materials into the SFVAHCS research labs to support NCIRE/SFVAHCS/Industry research relationships.

Most NCIRE/SFVAHCS/Industry collaborations are unique and need to be treated as such. Working with VA Policies and Procedures is challenging; helping the potential sponsors by way of education and explaining the background of the VA policies ensures a healthy negotiation between the three institutions. NCIRE and the SFVAHCS strive to be as flexible as possible in negotiating CRADA agreements while at the same time understanding our PI's research needs while honoring the VA's Mission.

Getting Started

PI Eligibility

Prior to entering into an Industry collaboration, the PI must have an Active R&D PI Status. To obtain SFVAHCS PI status, please contact SFVAHCS R&D Office.

Initial Discussions

Once a PI is interested in participating in collaboration with an Industry Sponsor, the PI should contact NCIRE Office of Sponsored Research to review the potential project's feasibility.

This initial meeting will help establish the communication between the PI, NCIRE, and the potential Sponsor.

Confidential Disclosure / Non-Disclosure Agreement (CDA/NDA)

PI's contemplating a collaborative project with an Industry partner may wish to exchange proprietary information with the Industry partner, which either one or both parties require to be kept confidential. The party disclosing proprietary information will usually require the receiving party to sign a Non-Disclosure Agreement (NDA), also referred to as a Confidential Disclosure Agreement (CDA).

For NDA and CDA associated with NCIRE, please forward a copy of the proposed NDA/CDA to NCIRE OSR Team for a formal review with our VA OGC STAR Attorney. NDA/CDA are reviewed and negotiated by the VA's OGC STAR Attorney and once it is approved, it will be forwarded to the SFVAHCS' Associate Chief of Staff – Research (ACOS-R) for review and signature. The ACOS-R will sign the approved NDA/CDA representing the SFVAHCS. The PI may sign as a Read and Understood, but not as a representative of the SFVAHCS. The partially-executed NDA/CDA will be returned to the sponsor for full execution.

NCIRE is not a signatory on the NDA/CDA; however, NCIRE falls under the SFVAHCS's umbrella to access confidential information.

Collaborative Research and Development Agreement (CRADA)

A Collaborative Research and Development Agreement (CRADA) (also known as a Clinical Trial Agreement (CTA) in non-VA Settings) is an agreement between NCIRE, SFVAHCS and Sponsor for the purposes of funding and conducting research to be performed at the SFVAHCS. A CRADA is required by the VA to be used as the agreement of choice; VA/NCIRE cannot use a Sponsor's template agreement.

CRADA Agreements generally include terms governing areas such as:

- Terms and conditions
- Scope of work to be conducted, including reporting and other deliverables
- Intellectual property
- Indemnification
- Care of data and confidential information exchanged during the research
- Publication of the research results
- Rights and procedures to terminate the project
- Payment obligations and schedule
- Budget for the research project

CRADA Agreement Templates

At the beginning of the CRADA negotiations, it is very important to determine the correct CRADA Template to use with the Sponsor as each template has different purpose. The CRADA Templates are as follows:

- Clinical Trial (CT) CRADA Phase 1 – 4
- Basic Science CRADA
- PI Initiated (PII) CRADA
- Device CRADA
- Data CRADA
- Materials Transfer (MT) CRADA

The CRADA Template type usually follows the type of work to be performed. If there is not an exact fit to any of the CRADA Templates, NCIRE and the VA OGC STAR Attorney will help develop a hybrid CRADA to match the proposed scope of work.

VA Conflict of Interest Form 450

The PI of record will be required to complete the VA Conflict of Interest Form 450. The completed FCOI form will be submitted to the STAR Attorney for review along with the proposed CRADA. If a conflict is identified, the VA COI Form 450 will be forwarded on to VA Ethics for further review. An updated FCOI is required annually thereafter for the life of the CRADA.

CRADA Negotiations and Signatures

CRADA negotiations are coordinated by NCIRE and reviewed between NCIRE, Sponsor, and VA OGC STAR Attorney. Once the appropriate CRADA model is supplied to the Sponsor, the Sponsor's legal team will review the CRADA and makes necessary changes (with track changes) and return it to NCIRE.

NCIRE will review the Sponsor's edits and forward the redlined CRADA onto the VA OGC STAR Attorney for further review.

CRADA negotiations will continue until all 3 parties are in agreement. Upon the final approval of the VA's STAR Attorney's Concurrence Memo, the CRADA may proceed for finalization to include, but not limited to, the Statement of Work, Budget, and Payment Schedule.

CRADA Signatory Process

The CRADA signatory process is as follows: Sponsor, PI (as a Read and Understood), NCIRE Executive Director, and finally the SFVAHCS Medical Center Director or designated ACOS-R.

On average the signatory process will take 5 – 7 business days to complete once the semi-executed CRADA arrives at NCIRE. The fully executed CRADA will be returned back to the Sponsor.

Research Budget

NCIRE Office of Sponsored Research will work with the PI and study staff to help develop, review, and approve an Industry sponsored budget.

A Research Budget (non-clinical trial budget) consists of funding from the Sponsor to cover but not be limited to salaries and wages, supplies, equipment, services, etc., for a predefined scope of work.

Research Budget – Clinical Trials

A clinical trial budget consists of per subject/per visit amount and various invoiceable items, often a mix of invoiceable clinical procedures and administrative and institutional costs. Per subject/per visit, the amount consists of clinical procedures and personnel-related costs, not always clearly separated.

Initial Research Budget Review

PI and Study Coordinator will initially review the Sponsor's initial proposed budget for feasibility, technical and personnel resources, personnel costs, and study-specific items. NCIRE Office of Sponsored Research will assist in the initial review.

Research budgets for the PI and Study Coordinator should include the following elements:

- Personnel costs (percentage of effort)
- Costs of clinical procedures and services to be covered by the external funding source (research patient care costs)
- Materials and supplies
- Equipment
- Subject compensation and travel
- Services by vendors

Final Budget Review

NCIRE OSR will review the final budget to ensure that the proper IDC rate is applied and ensure applicable Start-up Costs, IRB Fees, Pharmacy Fees, Annual Renewal Fees, Close-out Fees, etc. are included in the final budget.

Key Industry Rates and Fees as of 10/1/2025 (subject to change)

- NCIRE's Industry Indirect cost (IDC) rate is 40% for Industry Funded Projects
- NCIRE's Fringe Benefits Rate 39.38%
- Annual Cost of Living escalation 3%
- NCIRE Administrative Review Fee \$2,000
- NCIRE VA OGC STAR Review Fee \$1,320
- NCIRE Administrative Closeout Fee \$2,000

Payment Schedule

A Payment Schedule is a proposed payment plan for work performed. Payments can be connected to deliverables, milestones, calendar, etc.

NCIRE's goal is to front load agreements to provide our PI's with an influx of funds to get their new projects up and running.

An example of a front-loaded project is as follows:

Based on a \$100,000 budget for 10 subjects:

\$35,000 Due upon CRADA execution and IRB Approval
\$25,000 Due upon the 5th Subject Enrolled
\$25,000 Due upon the 10th Subject Enrolled
\$15,000 Upon Study Completion and Closeout

Holdback

A Holdback is a percentage a sponsor holds back from a payment. The balance of the holdback is usually paid after the completion of the study. NCIRE does not allow holdback allowances.

Milestone/Subject payments to the NCIRE as stipulated in a CRADA are considered earned revenue and cannot be subject to a holdback percentage by the payor. Milestone/Subject payments made in full are required in order to sufficiently fund the internal costs incurred in support of the milestone completion. These internal costs include coverage for study procedures, personnel effort, administrative infrastructure, and pass-through costs. Specific site responsibilities are addressed in the CRADA/Scope of Work.

However, in the event NCIRE does not complete the contractual responsibilities, the payor may consider withholding Close-out fees until completion of said responsibilities.

Payments and Invoices

During the performance of the Industry sponsored project, milestones will be met and completed. Upon meeting those milestones, the PI's study team will notify NCIRE OSR of the completion of the milestone. For example, milestones may be the following: completion of the IRB submission, enrollment of the first subject, completion of the interim report, final report submitted for publication, etc. NCIRE OSR will work with NCIRE Accounting to generate an invoice to the sponsor for the work completed.

All payments must be sent directly to NCIRE.

NCIRE
4150 Clement Street, MS 151NC
San Francisco, CA 94121
Attention Accounts Receivable

Completion of an Industry Sponsored Project

Upon completion of an Industry Sponsored project, NCIRE OSR will verify all milestones have been completed and/or the study has been closed by the sponsor. NCIRE OSR will verify that all invoices have been paid and all funds from the sponsor have been received. The industry project will be closed and the residual funds will be transferred into a 394 Admin Account (subject to the 394 residual policy) to support general research.

Office of Sponsored Research Federal & Foundation Overview

Northern California Institute for Research and Education, Inc. (NCIRE) is a VA-affiliated nonprofit research corporation (NPC) that supports over 200 researchers some of whom have joint VA/University appointments. Our broad portfolio of sponsor projects receives generous support from the National Institutes of Health (NIH), the Department of Defense (DoD), private foundations, and individual donors, making us the leading NPC devoted to Veteran's health in the U.S. NCIRE Office of Sponsored Research (OSR) team is here to provide you with pre- and post-award research administrative support. The OSR team is a liaison between you and your funding agencies. We help ensure each NCIRE-administered sponsor project complies with funding agency policies while also adhering to both NCIRE and VA policies.

Pre-Award Roles and Responsibilities

NCIRE Office of Sponsored Research (OSR) coordinates submission of proposals and acceptance of awards for federal and non-federal grants and contracts. The successful proposal development and submission process is a collaborative effort between the PI and NCIRE OSR.

Principal Investigator Responsibilities

The researcher must have active SFVA PI status prior to submitting any application. This status allows an individual to perform research on SFVAHCS property. To obtain PI status, please contact SFVAHCS R&D Office. All research administered by NCIRE, including individual grants, agreements, and contracts, requires review and approval by the R&D Committee BEFORE any research can commence. The PI must be a UCSF faculty member in good standing and be able to submit proposals for support. The PI must certify that over 50% of the project's direct recurring costs are directly associated with work physically taking place at the SFVA campus or approved alternate sites other than UCSF.

During the proposal development and submission phase, the PI is responsible for:

- Initiating contact with NCIRE Office of Sponsored Research (OSR).
- Identifying the funding opportunity and providing a copy to OSR.
- Reading and understanding the funding opportunity guidelines and eligibility requirements.
- Confirming their funding agency is participating in the announcement.
- Identifying subrecipients, if applicable.
- In conjunction with OSR, collecting subcontract package(s) and other required documents from subrecipient(s).
- In conjunction with OSR, developing the project budget; and for internal records, providing to OSR for their review and verification, applicable rates used for UCSF salaries, core services, and clinical billables. Costs for supplies and other expenses are projected based on fair market costs and quotes.
- Complying with NCIRE's policies and procedures regarding the review and approval of proposal submissions.
- Submitting applications to OSR two weeks prior to submission due date; or 4 weeks prior if applications include subcontract(s).
- Ensuring that all the information in the proposal is presented in a manner that is complete, accurate, and developed using the practices commonly accepted within the scientific community.
- Complying with the sponsor's application requirements.
- Ensuring that all required forms and certifications are completed in a timely manner; such as, but not limited to, Financial Conflict of Interest (FCOI) disclosures and PI Assurances.
- Collecting Just in Time (JIT) documents from all applicable parties and submitting to OSR for review and submission.
- Ensuring that all work and activities will be performed as described in the proposed project, if the application is chosen for an award.

Office of Sponsored Research Responsibilities

The initial contacts for proposal development are NCIRE Grants Specialists who work with PIs and project teams by providing assistance throughout the application process.

The NCIRE Office of Sponsored Research (OSR) is the sole authority for contacting the awarding agency regarding the negotiation and acceptance of award.

During the proposal development and submission phase, the Office of Sponsored Research will provide assistance with the following:

- Initiating a kick-off meeting to discuss each application.
- Reviewing the funding opportunity with the PI.
- Confirming proposal eligibility and obtaining approval to submit an application that disallows the use of NCIRE's current federally negotiated F&A rate.
- Working with PIs to define timelines for deliverables and submission.
- Advising the PI of proposal requirements and sponsor guidelines.
- Identifying any potential risks related to compliance with the sponsor's guidelines or policies.
- Discussing possible challenges should the proposal be recommended for funding (e.g. converting UCSF personnel to NCIRE personnel).
- In conjunction with the PI, developing and ensuring accurate project budgets.
- Notifying Procurement of potential Independent Contractors and anticipated acquisition of goods and services (excluding subcontracts) in excess of \$50,000.
- Collaborating as necessary with subrecipients for compliance paperwork, budget documents, and other required documentation.
- Initiating and monitoring compliance and regulatory reviews of all applications.
- Ensuring adherence to institutional, sponsor and governmental guidelines.
- Submitting proposals in accordance with sponsor's guidelines.
- Reviewing and submitting Just in Time (JIT) documents.
- Negotiating awards and contracts.
- Issuing the project number.

Pre-Award: Grant Submission Process Eligibility

Prior to submitting a grant application (as a prime awardee or a subrecipient), the PI must obtain SFVAHCS PI status.

NCIRE uses Cayuse (<https://ncire.cayuse424.com/>), a system-to-system (S2S) solution, to prepare and submit applications to Grants.gov. If you are a new user, please contact your NCIRE Grants Specialist for Cayuse login information. If you are unsure of who your Grants Specialist is, please send an email to cgawards@ncire.org and one will be assigned to you.

To submit to other funding agencies that do not use Grants.gov, please work with your Grants Specialist. In some cases, separate agency specific registrations are required. Please allow for additional time as registration may take time.

Initiating Grant Applications

PIs submitting through NCIRE must notify their Grants Specialist at their earliest convenience of their intent to submit and provide a copy of the funding opportunity. This is essential as each funding agency has unique guidelines and NCIRE needs sufficient time to review agency specific requirements. Completed grant applications are due to NCIRE Office of Sponsored Research (OSR) at least two weeks prior to submission deadline; or 4 weeks prior if applications include subcontract(s).

Proposals funded by private industry should be submitted through NCIRE Clinical Research Center Office. Please contact NCIRE Associate Director of Compliance & Contracts.

Submitting application to NCIRE for review and approval

All applications must be reviewed and approved by NCIRE Office of Sponsored Research (OSR) prior to submission; otherwise, it may be forfeited. PIs must submit application components to their Grants Specialist in accordance with the established timeline below.

| Application Review/Submission Timeline | |
|---|--|
| 4 Weeks Before Sponsor Deadline (if applicable) | NCIRE applications with subcontracts – Subcontract packages from each subsite are due. Subcontract budgets and justification need to be reviewed, approved, and finalized by NCIRE prior to finalizing prime budget. |
| 2 Weeks Before Sponsor Deadline | Initial review excluding research plan. Final budget, justification, and/or other required documents are due to OSR. |
| 1 Week Before Sponsor Deadline | Second review excluding research plan. |
| 3 Business Days Before Sponsor Deadline | Final research plan due. |
| 2 Business Days Before Sponsor Deadline | Grants Specialist submits application. |

If the above timeline cannot be met, the Grants Specialist will make every effort to submit the application; but cannot guarantee a Sponsor and NCIRE compliant application or an on-time submission.

NCIRE OSR is the sole authority for contacting the awarding agency regarding the negotiation and acceptance of awards. PIs and their staff are asked to contact their Grants Specialist to direct their concerns regarding negotiations of their grants or contracts. NCIRE will contact the awarding agency and keep the PI advised.

All NCIRE administered projects including individual grants, subaward agreements, and contracts require ACOS approval by R&D committee BEFORE any research may begin. Please see ACOS Approval Process section for more details regarding ACOS approval.

Post-Award Roles and Responsibilities

NCIRE Office of Sponsored Research (OSR) coordinates the post-award administration of awards for federal and non-federal grants and contracts. The successful administration of a project is a collaborative effort between the PI and NCIRE OSR.

Principal Investigator Responsibilities

The administrative and fiscal responsibility for management of a sponsored project rests with the PI named in the award or agreement. Primary responsibility for the overall conduct of a project rests with the PI.

Principal Investigators are responsible for:

- Maintaining PI status and complying with the applicable VA Research Committees for the project to be administered by NCIRE (Handbook 1200.17).
- Ensuring that all the information in the application, award, and technical/progress report is presented in a manner that is complete, accurate, and developed according to the practices commonly accepted within the scientific community.
- In conjunction with the Grants Specialist, resolving any issues to lift restrictions and/or special terms and conditions as noted in the award notice.
- Initiating ACOS approval process and ensuring all required forms and compliance certifications are completed in a timely manner; including, but not limited to, VA Safety Committee forms, and VA R&D Committee forms.
- Conducting the work according to the research protocol or Scope of Work (SOW) that was submitted with the original proposal or as subsequently modified and approved by the sponsor in agreement with the PI.
- Ensuring that all work meets the highest ethical standards and is conducted without real or apparent conflicts of interest.
- Ensuring all work performed is conducted in compliance with applicable federal, state, and local laws and with SFVA, NCIRE, and UCSF (if applicable) policies.
- Submitting reports to Office of Sponsored Research in accordance with the sponsor's requirements at least 1 week prior to due date.

- Reviewing and complying with all terms and conditions of the award.
- Communicating to NCIRE any special circumstances that may be encountered.
- Notifying NCIRE immediately when deviations from the approved Scope of Work or budget may be necessary.
- Managing the project's budget to ensure incurred expenses are reasonable, allocable and appropriate.
- Ensuring all expenditures comply with OMB Uniform Guidance and the sponsor's approved budget.
- Managing the project's budget to avoid overspending.
- Authorize selection and manage activities of subrecipient(s) and consultants to ensure performance in accordance with the contract.
- Monitoring subrecipient(s) activities and expenditures for compliance with approved SOW, timelines, budget and other deliverables. PI will advise OSR if there are concerns or compliance issues with the subrecipient.
- Reviewing and approving subrecipient invoices in a timely matter.
- Participating in the development of budget projections and providing OSR with relevant details in real-time.
- Reviewing budget projections developed by OSR. Identify and initiate changes to staffing or other expenditure allocations.
- Initiating cost transfers, payroll allocation forms, Joint Personnel Agreements (JPA), and Intergovernmental Personnel Acts (IPA).
- Ensuring senior key personnel effort commitments are fulfilled and if applicable, notifying NCIRE to request prior approval for significant reduction in effort.
- Reviewing and returning quarterly certification to NCIRE, attesting to the accuracy of the Project Account Statements—certifying that time and effort, and all other costs are reflected correctly on the expenditure report.
- Managing project personnel in compliance with applicable federal and state laws and VA and NCIRE policies.
- Maintaining all project-related records that support the deliverables, including records of subrecipient(s); and confirming all records are maintained through the record retention period.
- Ensuring that all requests for project/grant reimbursements are submitted to NCIRE within the timelines established by NCIRE policy.
- Ensuring that appropriate credit is attributed to the VA for its contributions to medical and scientific research. (Please refer to VHA Handbook 1200.19 for additional information and guidance).
- Completing and submitting annual Financial Conflict of Interest (FCOI/COI) disclosures (based on projects). Notifying NCIRE immediately following the identification of a significant financial interest that may conflict with the work to be carried out and comply

with all applicable regulations in managing, reducing, or eliminating any domestic/foreign conflict.

- Ensuring compliance with federal regulations, and research conduct policies, including those relating to:
 1. Protection of Human Subjects – Ensuring the protection of the rights and welfare of human research participants, obtaining IRB approval, and ensuring the research team is current on and trained compliance with IRB policies and procedures, federal and state regulations, and other relevant NCIRE/VA policies.
 2. Clinical Trials – Maintaining current and accurate records in the www.clinicaltrials.gov database.
 3. Care and Use of Animals – Ensuring animal research is approved by IACUC and that all aspects of animal care and use are conducted according to the approved protocol.
 4. Conflicts of Interest – Adhering to the COI policies related to the training and requirements.
 5. Scientific Misconduct – Managing the scientific integrity of the project. Communicating any allegations of fraud or scientific misconduct to the appropriate office in a timely matter. Ensuring all project personnel are trained in the responsible conduct research.
 6. Patents and Inventions – Maintaining records of program assets and intellectual property. Adhering to sponsor's invention reporting requirements and the VA policies regarding the disclosure of inventions.

Office of Sponsored Research Responsibilities

When an award is received, an NCIRE Grants Specialist is assigned to the project to provide the PI with grant management support. Typically, one Grants Specialist will manage all accounts and projects associated with a particular PI. Should more than one Grants Specialist be involved (for example, when the PI has two different types of accounts such as an industry sponsored program and a federal award), both Grants Specialists will work closely to ensure the PI has an overall picture of all financial resources and requirements.

NCIRE Grants Specialists are responsible for:

- Negotiating terms and conditions in compliance with NCIRE and VA policies.
- Receiving and reviewing award documents from sponsoring agencies.
- Executing award documents on behalf of NCIRE and returning to Sponsor when applicable.
- Analyzing the award documents for critical and relevant terms, conditions, and requirements. Communicating to the PI any special award terms and conditions requiring special administrative oversight and documenting correspondences.
- Reviewing approved budget(s) for accuracy.

- Issuing project numbers and working with NCIRE Accounting to monitor those funds.
- Ensuring VA R&D Committee and ACOS approval is in place prior to activating the new project.
- Providing training and support to PIs and their designated staff to monitor and comply with grants and contracts management requirements.
- Informing and advising the PI of the Sponsoring agency's regulations and reporting requirements.
- Monitoring the project's budget to ensure incurred expenses are reasonable, allocable and appropriate. Working with the PI to ensure compliance with Sponsor restrictions or other factors.
- Monitoring the project's budget, to ensure spending is appropriate and to avoid overspending.
- Monitoring expenditures and ensuring compliance with the Sponsor's approved budget and NCIRE policies.
- Providing financial projections to PI. Work proactively to monitor project budget and expenses. Meeting with PI to review project portfolio and discuss actual/projected expenses and spending analysis to prevent over/under-spending.
- Reviewing and approving cost-transfers, payroll allocations forms, JPA, and IPA.
- Managing any post-award budget revisions and if applicable, obtaining sponsor approval.
- Acting as a primary point of administrative contact for the sponsoring agency.
- Notifying and reminding the PI and program staff of deadlines to ensure compliance.
- Ensuring that technical progress, fiscal and other required reports are submitted to the sponsor on time.
- Working with NCIRE Accounting to prepare and review financial reports.
- Reviewing and maintaining the official copies of proposals, award documents, and all required reports.
- Initiating, negotiating, and administering all subaward agreements.
- Reviewing subrecipient invoices for fiscal compliance.
- Reviewing and submitting all official correspondence and requests to the sponsoring agency; including but not limited to, technical reports, final reports, requests for budget revisions, prior approval requests, or no-cost extensions.
- Responding and complying with audit requests for information.
- Closing out accounts.
- Maintaining records in accordance with record retention policies.

Just-In-Time

When your research project is being considered for funding—sometimes referred as “Just-In-Time” (JIT)—please work with your NCIRE Grants Specialist to gather all requested documents. Your Grants Specialist will review all documents before submitting to the Sponsor agency.

A general list of requested JIT documents for NIH grants consists of (but not limited to):

1. FCOI disclosure for all applicable Key Personnel
2. Updated and signed Other Support pages
3. IRB approval and human subjects training certificates, if applicable
4. IACUC approval, if applicable

A general list of requested JIT documents for DoD grants consists of (but not limited to):

1. FCOI disclosure for all applicable Key Personnel
2. Updated/revised budget
3. Copies of quotes, service agreements, etc.
4. Salary verifications
5. Updated list of current and pending research support

Post-Award

Direct/Admin Project Numbers

Once an award notice or subaward agreement has been received by NCIRE Office of Sponsored Research (OSR), your Grants Specialist will issue a project number for direct costs per the award budget and if applicable, an admin project number for indirect costs.

Direct costs are those that can be attributed to a specific sponsored project or other cost objective, or costs that can be assigned to such an activity relatively easy and with a high degree of accuracy. Expenses charged to a direct project should only be those that can be directly attributed to that project.

Indirect costs are those that are incurred for a common or joint purposes. These expenses cannot be readily attributed to a specific research activity and are charged to an admin project. Admin funds may only be used to support general VA/NCIRE research activities. The admin account will earn 5% admin revenue of every qualifying direct dollar spent on the project. Admin funds should be used in proportion to the associated direct project. Note admin funds expire three months after the associated direct project end date; and any unused funds will be returned to NCIRE.

Examples of appropriate usage of direct and admin funds:

- Dr. Smith hires an SRA and charges 45% of the SRA's effort on Direct Project 1000 and 45% on Direct Project 2000 based on the SRA's effort on the two projects; and charges the remaining 10% on Admin Project 1001 because the SRA allocates time assisting Dr. Smith with preparations for a future grant submission.
- Travel costs for a scientific conference were charged to Direct Project 1000 because the Dr. Smith presented an abstract from data collect from Direct Project 1000.

- Travel costs for a scientific conference were charged to Admin Project 1001 because the Dr. Smith attended a conference that is related to her field of research, where she networked with other attendees for future collaboration.

Project numbers will only be activated and provided to you when either ADMIN or FULL ACOS approval has been obtained and all applicable compliance documents (e.g. FCOI) have been received. Please see ACOS Approval Process section for more details regarding the ACOS approval.

Direct/Admin Project Financial Statements

Copies of your account balances, transaction reports, and commits reports can be reviewed and downloaded from Acumatica.

Acumatica: NCIRE Project Reports

Acumatica is an online tool for PI's and their authorized administrators to look up real time account information such as project expenses, budget and balances. Please contact NCIRE IT for an Acumatica login ID and password.

The below Acumatica weblink can be found on NCIRE's Intranet under Accounting and Finance and is also provided in Accounting's month-end close email notifications sent to the research group.

Acumatica: <https://ncire.acumatica.com/>

Reports included Project Balances, Detailed Transactions, and List of Commitments. All reports can be downloaded to Excel.

If you have questions regarding new user set-up or how to retrieve reports, please contact NCIRE Controller, Jian Pu at Jian.Pu@ncire.org.

Subaward Agreements

Please see the Subaward section below for more information.

Budget Projections

Your Grants Specialist will provide budget projections for your direct project(s) on a quarterly basis. It is highly encouraged that you schedule time with your Grants Specialist to review them together.

Reporting Requirements

Please do not submit reports (e.g. technical, financial) to the sponsor without a Grants Specialist's review and approval. All reports should be routed to your Grants Specialist for review and submission.

Formal Requests

All communications to the Sponsor agency should be conducted through Office of Sponsored Research (OSR). This includes requests for (but not limited to): No-Cost-Extension (NCE), budget revisions, carry-forward approval, etc.

Close-out

Three months prior to your award end date, a conversation between you and your Grants Specialist should be initiated. Your Grants Specialist will assist you with:

- Preparing a final budget projection to ensure the project closes in good financial standing
- Planning out the next steps for personnel changes
- Preparing for the close-out of subaward agreements (if applicable)
- Completing sponsor reporting requirements

Should you have questions, please feel free to contact your NCIRE Grants Specialist. If you are unsure who your assigned Grants Specialist is, please email cgawards@ncire.org.



Subawards/Subcontracts

Subcontract vs Independent Contractor

Collaborators working on NCIRE-administered projects must be categorized correctly to ensure the correct mechanism is used. Below is a table differentiating between Subcontracts and Consultant/Independent Contractor (IC).

| Subcontracts | Independent Contractors |
|---|---|
| Subrecipient's PI will take a significant role in programmatic decision making and assist the PRIME PI in achieving the project's goals and objectives. | Does not participate/collaborate in project design/proposal development. |
| | Provides routine goods and/or services to other customers or clients |
| Subrecipient collaborates and has responsibility for programmatic decision making. | Provides goods or services developed according to the specifications of the PRIME PI |
| Subrecipient provides a scope of work and budget as part of the proposal preparation. | Provides personnel services that are primarily advisory in nature |
| Subrecipient completes work promised and analyzes results found. | Provides other ancillary services related to the sponsored project per the instructions of the PRIME PI |

Once the correct mechanism has been identified, please work with your NCIRE Grants Specialist to initiate the contract. If you are unsure about who your Grant Specialist is, please send an email to cgawards@ncire.org and one will be assigned to you. If you believe you need to speak to someone about initiating an Independent Contract, please reach out to Procurement at procurement@ncire.org.

Initiating and Routing a Subcontract – “subIN” vs “subOUT”

The “subIN” process is initiated when a PRIME entity contacts the NCIRE PI and/or their Grants Specialist in preparation of an application submission well before the application due date. “SubIN” is the term used when referencing NCIRE as the subrecipient of funding being passed down through a PRIME awardee from a sponsor. Thus, subIN is synonymous with funds coming into NCIRE. The PRIME entity will dictate what documents they will need from NCIRE in support of completing their application.

Typically, the NCIRE PI will be responsible for building a detailed budget and justification, preparing a Scope of Work (SOW) for their role on the project, providing an updated Biosketch and Other Support document, if applicable. The NCIRE PI may also be asked to provide a List of Equipment document and a Facilities and Other Resources document, as well as other items

deemed necessary. Once finalized, all documents should be forwarded to your Grants Specialist for review, approval, and ultimate submission to the PRIME entity. Generally, NCIRE will also be expected to provide a Letter of Intent, which will be counter-signed by both the NCIRE PI and the NCIRE Chief Executive Officer prior to submission.

Once the PRIME entity has been awarded, they will contact the NCIRE PI and/or Grants Specialist to establish the subaward agreement. The Grant Specialist, working in collaboration with the NCIRE PI, will review the agreement and negotiate terms of the agreement when necessary. Once a subaward agreement is fully-executed, the Grant Specialist will set-up a NCIRE project number. NCIRE project number(s) will be activated and released to the NCIRE PI when ACOS approval has been obtained and any outstanding compliance documents (e.g. FCOI) have been submitted to OSR.

The “subOUT” process requires the NCIRE PI to alert their Grant Specialist when they plan to include subrecipient(s) within their proposed application. “SubOUT” is the term used when referencing NCIRE as the PRIME awardee, where NCIRE will act as a pass-through entity to award funding to a subrecipient. Thus, subOUT is synonymous with funds going out of NCIRE. The NCIRE PI will need to obtain and forward a subaward package from each subrecipient site. A complete subcontract package contains the following documents:

- Subrecipient Questionnaire
- Statement of work
- Detailed budget
- Budget Justification
- Biosketch for all key personnel
- Facilities and other resources
- Equipment
- Letter of Intent
- Current F&A rate agreement letter
- Copy/URL to most recent annual audit

Once the application is funded, the Grants Specialist will work with the NCIRE PI to initiate a subaward agreement.

General Office of Sponsored Research Information (Applicable to all NCIRE Administered Projects)

Financial Conflict of Interest (FCOI)

For all NCIRE administered research projects, Investigators must disclose financial interests prior to review and approval by the Research & Development (R&D) Committee. Investigators must complete the Disclosure Form at time of proposal submission, when an award is funded, annually thereafter in conjunction with submission of non-competing continuation awards and no-cost extensions, and at any time when a disclosure needs to be made. NCIRE will advise the R&D Committee when disclosures are not in place at the time of the initial award or if the annual disclosure is not completed. If a Principal Investigator/Key Personnel disclosure form is missing or incomplete; it will delay the activation of an NCIRE project number.

Research and Development Approval (R&D Approval)

VA Research is defined as research conducted on the SFVAHCS Campus by a Principal Investigator (PI) who has Active PI Status. The PI serves on compensated, without compensation (WOC), or joint-personnel appointment (JPA) usually between UCSF and NCIRE.

All research projects that will be performed at the SFVAHCS must have R&D Approval with an Associate Chief of Staff (ACOS) Approval Letter stating the project title and protocols that will be used for that specific project.

R&DC Approval

There are two types of ACOS approvals:

- Full ACOS Approval
- Administrative Approval

Full ACOS Approval

Full ACOS approval allows work on the project to begin. When a project achieves Full ACOS approval, it includes all required subcommittee reviews and has been approved at an R&DC Committee meeting.

Administrative Approval (Admin Approval)

Admin approval is given to a project for the purpose of releasing funds for start-up administrative costs. These activities are usually in preparation to start a study (e.g. recruitment, purchase equipment). No research may be conducted with Admin Approval.

Admin approval is not approval to conduct research activities beyond the administrative tasks. To submit for admin approval, the project must have a fully-executed Pink Sheet (Request for R&D Committee Approval form) with all three signatures (PI, Service Chief, and ACOS-R) and a grant/subcontract or CRADA application.

Please note, a project with admin approval will still need to obtain Full ACOS Approval before the PI can begin conducting research. Research may not start until Full R&DC Approval is granted and an ACOS for R&D Approval Letter has been generated.

ACOS Approval Process

NCIRE provides a dedicated Analyst to facilitate the ACOS R&D review process for NCIRE-administered projects. The NCIRE Analyst will assist with coordinating the review process alongside the PI's study team. NCIRE's goal is to make this approval process as efficient as possible between the various committee reviews. Please contact the NCIRE Office of Sponsored Research (OSR) for further details.

The "Request for R&D Committee Approval" form (aka Pink Sheet) is the first step to initiating the ACOS R&D approval process. A completed Pink Sheet must be submitted to NCIRE at the same time the grant application was submitted. The Pink Sheet identifies the resources and committee reviews required for the project to start at the SFVAHCS.

The ACOS for R&D at the SFVAHCS will determine if a project meets the definition of VA Research and will sign and approve all Pink Sheets.

SFVAHCS Research Subcommittees include, but are not limited to, the following (depending on the project scope):

- Animal Research and Care (IACUC)
- Biosafety Subcommittee (IBC)
- Committee of Research Safety (SRS)
- Human Research Protection Program (HRPP)
- Radiation Safety
- Privacy Office

R&DC Meeting

Once all the required subcommittee approvals are obtained, the project is then placed on the R&DC Agenda for full R&D Committee Approval. The R&DC Meeting meets on the first Thursday of each month.

After a project is approved, an ACOS Approval Memo will be generated and sent to the PI/PI's admin team.

Institutional Review Board

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

The IRB is responsible for reviewing all research prior to its initiation (whether funded or not) involving human participants. The IRB is concerned with protecting the welfare, rights, and privacy of human subjects. The IRB has the authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy.

NCIRE and the SFVAHCS are required to use the University of California San Francisco's IRB as the local IRB of record.

NCIRE and the SFVAHCS also have the ability to use external IRBs such as Advarra, Sterling IRB and WCG IRB (formerly WIRB) if certain conditions are met. Please contact the SFVAHCS's HRPP Program for more information.

VA Central Institutional Review Board

For research studies with multiple VA sites, NCIRE and the SFVAHCS have the ability to use the VA's Central IRB (VA cIRB).

The purpose of the VA cIRB is two-fold. First and foremost, its purpose is to enhance the quality of human research protection in multi-site human research projects by performing appropriate ethical and scientific review, while ensuring local issues are addressed. The second is to enhance the efficiency of these reviews across participating sites.

Single IRB

A Single IRB (sIRB) review uses one IRB to accomplish IRB review and approval for all the institutions/sites conducting the study/trial.

With the newly implemented Common Rule, NCIRE and the SFVAHCS can also use a sIRB as long as it fulfills the sIRB requirements.

The revised federal Common Rule contains a new requirement for single IRB review for collaborative, non-exempt human subjects research that involves multiple institutions. This applies to all federally funded or supported research.

In addition, the sIRB mandate is an NIH policy that requires certain types of NIH-supported studies. It involves multiple sites where each will conduct the same protocol involving non-exempt human subjects research to use a single IRB to accomplish IRB review and approval for all domestic participating sites. The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible. Per VA policy, if a commercial IRB is being considered, NCIRE is not allowed to directly pay commercial IRBs because it would be construed as the NPC negotiating/working on behalf of the VA. This would be seen as avoiding the acquisition law.

NIH Policy sIRB

This is distinct from the Common Rule requirement and applies to most grants and contracts submitted to NIH on or after January 25, 2018 that involve multi-site, non-exempt human subjects research. The policy defines multi-site research as a subset of collaborative research

that requires the use of a single IRB. It is important to identify when a project must comply with the NIH policy. Specific NIH requirements must be present in the grant or contract applications for studies subject to this policy that do not apply to studies under the broader Common Rule requirement.

The mandates do not apply to the following types of participating sites in multi-site research:

- Many Veteran's Affairs (VA) sites due to strict VA policy. For each study, you must check with the VA Human Research Protection Program Office to understand whether they qualify for an exception.
- Foreign sites (though domestic sites of the same study must be reviewed by a sIRB).

Sites involving tribal nations.

- Sites for which review by the proposed sIRB is prohibited by a federal, tribal, or state law, regulation, or policy.

IRB Full Committee Review

These studies are reviewed by the IRB committee at a convened meeting.

Full committee review is required for:

- Greater than minimal risk studies or
- Studies that are a minimal risk but do not fit in an expedited review category

IRB Expedited Review

Expedited review studies are typically reviewed by a small number of IRB reviewers.

Expedited review is appropriate for studies that, according to 45 CFR 46.110 and 21 CFR 56.110:[\[MF1\]](#), involve no greater than minimal risk AND fit into one (or more) of the following nine specific expedited review categories:

1. **Category 1:** Approved drug or device being used for its approved indication
2. **Category 2:** Blood sampling (limited amounts)
3. **Category 3:** Noninvasive specimen collection
4. **Category 4:** Noninvasive, routine clinical procedures, such as MRI or EKG (no sedation, general anesthesia, x-rays or microwaves)
5. **Category 5:** Use of data or specimens collected for non-research or research purposes (e.g. chart reviews)
6. **Category 6:** Collection of data from voice, video, digital, or image recordings. So that risks related to the invasion of privacy and breach of confidentiality are no greater than minimal.
7. **Category 7:** Low-risk behavioral research
8. **Category 8:** A continuing review of inactive research or studies that are essentially complete

9. **Category 9:** A continuing review of other minimal risk research studies

Exempt Certification

DHHS regulations in 45 CFR 46.104 (Common Rule) identify several different categories of minimal risk research as being exempt from the federal policy for the protection of human subjects. Federal HIPAA regulations, California state law, and UCSF institutional policies further limit exempt research categories. Full category details can be found here: <https://irb.ucsf.edu/levels-review#exempt-categories>.

IRB Continuing Review

If you continue working on a study beyond its expiration date, you must submit the study to the IRB for continuing review approval. The IRB re-reviews the study to determine if it is appropriate for the study to continue as is or with modifications. Most studies must undergo continual review annually.

IRB Study Closeout

You must submit a Study Closeout Report for ALL types of studies. The report updates the IRB on the study's conduct and outcomes, including any risks or problems that may have arisen since the last continuing review and may need to be disclosed to the study participants or others.

Do NOT close out a study if any of the following conditions apply. These studies must remain active and receive ongoing IRB review and approval.

- Any of the following activities are ongoing:
 - Local enrollment,
 - Local research-related interventions or
 - Local participant follow-up
- Data analysis or manuscript preparation that involves use or access to individually identifiable information.
- Biological specimens containing individually identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research continues. If specimens were transferred to a separate repository that has ongoing IRB approval, then the study may be closed.
- You have not received permission from the study sponsor to close the study with the IRB.

IRB Closeout and Data Analysis

If you are planning to close your study, but would like to continue to review the data sets from the study and avoid paying annual IRB charges, you must:

- Formally closeout the Study with IRB

- De-identify the datasets
- Start a new unfunded study with an amended title

As of **7/1/2024**, the IRB Fee Schedule is as follows. NCIRE is listed under the UCSF Affiliated Institutions:

| | Initial Full Committee Reviews | Renewal of Full Committee Reviews (Continuing Review) | Initial Expedited Reviews | Renewal of Expedited Reviews (Continuing Review) | Modifications, Personnel Changes, Enrollment Exception Requests |
|---|--------------------------------|---|---------------------------|--|---|
| Protocols funded by private industry (institutional indirect costs are not included in this rate) | \$3930 | \$2140 | \$1540 | \$1540 | \$290 |
| Protocols submitted by UCSF affiliated institutions , e.g., <ul style="list-style-type: none"> • Gladstone • NCIRE • Vitalant • SFDPH • See full list of UCSF affiliates | \$4960 | \$2700 | \$1950 | \$1950 | \$370 |

Fee Chart 2: Fees for Multi-Site Studies where UCSF is the sIRB* (UCSF is serving as the single IRB of Record for all participating sites)

Important information about this table:

- These fees will be implemented on new sIRB studies submitted to the IRB for Initial Review on or after October 1, 2024. Studies that have IRB approval prior to October 1st and then add relying sites on/after October 1st will not be subject to these fees.
- These fees are for each relying site.
- These fees are additional to the costs of the review for the UCSF study site, which are outlined in Table 1. Examples of how the fees from Tables 1 and 2 may be combined for sIRB studies will be added to the IRB website shortly.

| | Initial Full Committee Reviews | Renewal of Full Committee Reviews (Continuing Review) | Initial Expedited Reviews | Renewal of Expedited Reviews (Continuing Review) | Modifications, Personnel Changes, Enrollment Exception Requests |
|---|--------------------------------|---|---------------------------|--|---|
| Protocols submitted by UCSF affiliated institutions , i.e., <ul style="list-style-type: none"> • Gladstone • NCIRE • Vitalant • SFDPH <ul style="list-style-type: none"> • See full list of UCSF affiliates (Primary site is UCSF affiliated institution) | \$1550 per relying site | \$720 per site | \$1430 per site | \$720 per site | \$170 per affected site |
| Protocols submitted by UCSF (Primary site is UCSF) | \$1230 per relying site | \$570 per site | \$1130 per site | \$570 per site | \$130 per affected site |

Fee Chart 3: Fees for Studies Relying on an External (Non-UCSF) IRB Studies that use external IRBs first need to obtain permission from the UCSF IRB. This review process will be charged the expedited review rate from Table 1. These fees should be budgeted into the clinical trial agreement.

| | Initial Full Committee Reviews | Initial Expedited Reviews | Modifications, Personnel Changes |
|---|--------------------------------|---------------------------|----------------------------------|
| Studies where the UCSF researchers rely on an external (non-UCSF) IRB | \$1540 | \$1540 | \$290 |

Current IRB Fees can be found here: <https://irb.ucsf.edu/irb-review-fees>



NCIRE Human Resources Department provides comprehensive workplace services dedicated to supporting our PI community. Working in strategic partnerships with each PI we recruit, develop, and retain a highly skilled, diverse, and engaged workforce. We also offer comprehensive guidance and support in benefits administration, compensation, affiliate personnel contracts, employee relations, diversity, employee recognition, employee communications and organizational development.

Recruitment and Hiring Process

The NCIRE recruitment and hiring process is a method in which a PI with Human Resources assistance, identifies a laboratory need, creates a position to fill that need, targets and recruits from the available talent pool, and eventually selects and hires the most qualified candidate.

Below are the individual steps in the NCIRE hiring process.

If you are not sure what type of position you need in your laboratory, we are here to help. Please reach out to a member of the NCIRE Human Resources team and we can assist you with your workforce planning needs. Once your job need(s) are identified and the position type is solidified, then email the below information to a Human Resources Representative to create a job requisition:

- Position Description
- Type of position (full-time, part-time, intermittent, temp)
- Hours per week
- NCIRE Project number
- Percentage effort
- Primary PI
- Supervisor

Once the position information is sent to the Human Resources Representative, a job requisition is created in the recruiting system for the PI and Grants Specialist to approve. Once approved, the position will be posted on all required sites. PI's who would like their position posted on any specific job board or site should communicate their request via email to their Human Resources Representative. All charges related to job postings are charged back to the NCIRE Project number on which the job requisition was approved. Please note that all job postings must be publicly listed for a minimum of three days before an offer of employment can be made.

Once applicants begin applying, all candidates must be reviewed and dispositioned (categorizing why an applicant was not selected) within the recruitment system by the hiring manager. This is a crucial step for NCIRE to remain compliant with the Office of Federal Contract Compliance Programs (OFCCP) and the Equal Employment Opportunity Commission (EEOC). All qualified applicants should be interviewed, and the best qualified candidate for the position should be selected.

Once a candidate is selected, the PI or Hiring Manager should submit to Human Resources the following documents:

- New Hire Form
- Tour of Duty
- Position Description
- Telephone references (at least two)

Forms must all be completed and signed by both the Hiring Manager and Principal Investigator and returned to Human Resources. Please note that NCIRE Human Resources cannot move forward with an official offer until all forms are completed, submitted and the candidate is entered by you or your staff into Research and Development Information System (RDIS). Once the HR paperwork is received, NCIRE Human Resources will phone the selected candidate and communicate the approved job offer. Only NCIRE Human Resources is authorized to make an official job offer on behalf of the organization. ****Please keep in mind it typically takes a minimum of two weeks to fully onboard a new hire prior to their start**

**** NCIRE cannot move forward with employee's onboarding steps if the employee is not entered into RDIS per VA requirements.****

Please note that all employees working for NCIRE must have a "Without Compensation" (WOC) appointment granted by the SFVAHCS, in progress before they may start employment. There are more details regarding the WOC process and the importance of this distinction in the next section. NCIRE Human Resources will facilitate and schedule the required appointments for your employee to start the WOC process once the RDIS profile is completed by the PI or their staff. Delay in making the RDIS profile may significantly delay your selected applicant's start date.



****NCIRE hiring process timeline can vary based on the SFVAHCS HR's availability to process VA Without Compensation (WOC) appointments. All NCIRE employees must be processed for a WOC appointment prior to beginning employment.****

Without Compensation (WOC) Appointments

All NCIRE employees are required to have what is known as a Without Compensation (WOC) Appointment with the SFVAHCS. Individuals requiring WOC appointments include, but are not limited to, all NCIRE employees (and individuals paid by a JPA contract) working at the SFVAHCS. The WOC appointment gives NCIRE employees the ability to work on the SFVAHCS research, computer systems and have access to NCIRE administered VA approved research materials, while being covered under Federal Tort Claims Act (FTCA). Under the FTCA, the federal government acts as a self-insurer, and recognizes liability for any negligent, or wrongful acts, or omissions of its employees acting within the scope of their official duties. The United States is liable to the same extent an individual would be in like circumstances. **Employees may start employment with NCIRE but are not authorized to work on research until their WOC letter is signed. They may shadow and train but they may not perform actual research until the VA has issued an approved WOC letter.**

In order to obtain a WOC appointment, Human Resources works with the SFVAHCS HR Department and new hire before their start date to initiate the process. Once the WOC letter is approved HR will provide the PI and employee with the signed WOC Letter. This along with required federal documents, if approved, provides the NCIRE employee access to the campus and VA services mentioned above for up to a maximum of three years (variations may apply) and allows the employee to begin research activity.

Before completion of your employee's WOC term, NCIRE Human Resources will reach out to begin the renewal process with your employee. It is critical that your employee comply with the request to complete the WOC Renewal process, as not doing so can deactivate your employee's status to work in your lab and on campus. An NCIRE employee working on campus without an active WOC is not sanctioned by the VA and creates a tremendous legal liability for NCIRE and the PI they work for. Employees that do not have an active WOC are no longer protected under the FTCA and are not authorized to continue work on any VA research project until their WOC status is renewed. Please encourage your employees to always comply with requests from NCIRE and VA Human Resources to update information as requested for their WOC appointment.

Per VA regulations, employees on an H-1B visa are not eligible for WOC appointments. As a result, the employee must be on an Intergovernmental Personnel Act (IPA) Agreement once eligible to receive access to the campus and VA services mentioned above. More information regarding personnel agreements with the VA can be found on page 51

Visas

H-1B Visa

The H-1B status is a nonimmigrant classification used by a citizen of another country who will be employed temporarily in the United States in a specialty occupation. An individual is allowed to remain in the U.S. in H-1B status for a total of 6 years. U.S. citizenship and Immigration Services (USCIS) only adjudicates the status for a maximum of 3 years at one time.

For an H-1B filing, the sponsoring U.S. employer must file a Labor Condition Application (LCA) with the U.S. Department of Labor (DOL) confirming several facts, including the payment of prevailing wages for the position and the working conditions offered. It is required by the DOL that, prior to the request, a Notice of Filing must be posted at the work location for the beneficiary. The purpose of this is for the sponsoring employer to attest to the following:

- Non-displacement of U.S. workers both in the employer's workforce, and/or secondary displacement of U.S. workers in the general workforce;
- Fair recruitment and hiring of U.S. worker applicant(s) who are equally or better qualified than the H-1B nonimmigrant(s).

This notice must include information on the position, title location and wages. Once a request has been submitted to and approved by the DOL, the employer must then file an H-1B petition that includes the DOL certified LCA.

Determinations for H-1B sponsorship are made on a case by case basis. Different factors contribute to the decision, such as business necessity, position, background of candidate (if and how it compares to other applicants), candidate's current immigration status (if applicable), continued need and current funding. The PI must also certify that they have not been able to find a more qualified US candidate to fill the position (VASFHCS requirement).

Once it has been determined that you would like to pursue a candidate that requires a H-1B visa the following steps must be taken:

- PI/Supervisor reaches out to HR to begin H1B initial process/extension
- HR forwards Visa Requisition Form for PI/Supervisor to complete to verify funding for legal and filing fees associated with the visa
- Office of Sponsored Research (or accounting in certain circumstances) reviews available funding
- If approved, NCIRE HR contacts immigration attorney to begin process

J-1 Visa

A J-1 visa is a nonimmigrant visa issued by the United States to research scholars, professors and exchange visitors participating in programs that promote cultural exchange, especially to obtain medical or business training within the U.S. All applicants must meet eligibility criteria, and English language requirements.

The J-1 Visa must be sponsored by either a university, private sector or government program. Our academic affiliate, University of California, San Francisco (UCSF) sponsors J-1 Visa's for NCIRE as needed. Inviting an international scholar to UCSF as an employee is governed by U.S. immigration law and regulations and UCSF policy. All J-1 visa requests must meet UCSF guidelines to qualify for the program as well as meet minimum salary regulations. The PI will also be required to certify to the SFVAHCS HR that during the recruitment efforts, no U.S. candidate was as skilled as the international scholar.

Request for a J-1 employee must be made through NCIRE Human Resources. UCSF will not process a J-1 Visa for NCIRE without written confirmation from NCIRE HR that funding for the position is available per the specifics of the program. Once funding is approved at NCIRE then NCIRE HR issues a letter to UCSF confirming finances and provide details of the exact appointment to UCSF HR, who then works with UCSF's International Student Scholar's office to issue the J-1 Visa. UCSF International Student Scholar's office requests a minimum of four months advanced notice for J-1 Visa requests.

Optional Practical Training (OPT)

Optional Practical Training (OPT) is 12-month work authorization available to F-1 international students who have been full-time students for at least one year and plan to seek temporary employment in the United States in their fields of study to gain experience. This is the last work authorization that a student can obtain that will not require employer sponsorship.

The F-1 students will remain in F-1 status under the I-20 sponsorship of their home school but will be issued an Optional Practical Training (OPT) card to work within the United States for a duration of 12 months in their designated field. The student may not be hired or work in any capacity (including as a volunteer) until the OP/EAD card is issued and received by the student and until the EAD card start date on the card has been reached. The 12 months of OPT must be used all at once, it cannot be broken up.

Principal Investigators must be aware that the person is a student and that they are working on an OPT/EAD as a temporary employee. It does not grant a student the permission to permanently stay and work in the country. **The maximum length of time that NCIRE may employ an OPT individual is 12 months, and it must be the first 12 months of the OPT/EAD.** Please note that NCIRE is an E-Verify company and eligible for the STEM OPT 24-Month Extension program.

Changes to Existing Employment

Promotions

Managing promotions is a dynamic way PI's can drive their research program forward. A promotion is a way to add more responsibilities to an employee and is also a significant form of boosting employee motivation and morale. Higher morale results in more productivity and prevents your department from losing valuable talent. There are two types of promotions that are processed at NCIRE.

The first and most common is a job series-based promotion.

This is also sometimes known as a "natural" promotion, which means the promotion is the "natural" next step in the career growth for that job holder. This type of promotion occurs when someone has excelled in their current job and has shown that they are ready for the next logical step within their job series.

An example of a job series-based promotion would be a Research Assistant I moving to a Research Assistant II. The Research Assistant II position is the natural next step of growth from a Research Assistant I position. Series based promotions usually are non-competitive, meaning it is not related to a job posting.

The second type of promotion is a competitive promotion.

A competitive promotion is when a PI wants to create a new job within his/her group for a specific individual, but it is not within the individual's job series. Since it is not a natural progression within the job family, a job requisition must be created and posted to provide all individuals interested in the opportunity a fair chance.

For example, if a Staff Research Associate I would like to apply for an Administrative Analyst II position, it would be considered a competitive promotion process, meaning a job recruitment would need to be open in the same manner as any other recruitment for a new hire. The job must be posted for a minimum of three days, and all qualified candidates must be considered.

Things to remember for a non-competitive, job series "natural" promotion:

A non-competitive promotion must have a written justification and a job description attached. To assist you with the process, Human Resources has created the Promotion Request form, which covers all the pertinent information required.

The Promotion form can be found in the appendix (page 76).

Things to remember for a competitive promotion:

- The job must be initiated by the PI or Supervisor based on organizational objectives and must be open as an official job posting through Human Resources
- The posting must be up for a minimum of three days, and all qualified applicants who apply must be considered for the position, and the most qualified should be selected.
- If your employee turns out to be the most qualified out of the applicants and for a higher-level position for which he or she had applied, that will then complete the competitive promotion process
- An updated signed job description would be required

Salary Adjustments

NCIRE is committed to ensuring fair and equitable compensation practices and maintaining competitive salaries for all employees. It is an important responsibility that salaries within your area of supervision are fairly administered and in compliance with NCIRE's Affirmative Action Program and non-discrimination policies.

There may be instances in which an employee's salary may be changed without an associated change in job. This is referred to as a salary adjustment. Salary adjustments may be necessary during the year to reflect current market rates, to retain key contributors, or reward performance of individuals who have shown major growth or taken on additional duties within a position and role.

Requests for salary adjustments must be made in writing with pertinent information provided for the reason the salary adjustment is being requested. A template [salary request memo](#) can be found in the appendices of this manual to assist you.

Performance Reviews, Merit Increases and Special Contributions Awards

Performance Management

Performance management is fundamental to the effectiveness of any organization as all workplaces rely on the success of their employees within the roles to move the organization's objective forward. Each employee impacts and adds to your own laboratory's growth or decline. Collectively, a workforce that performs at high levels can help your laboratory and research program grow.

Performance management consists of two parallel processes:

1. The informal, day-to-day management of individuals and teams by their immediate manager.
2. The formal framework within appraisal process which the performance of individuals and teams is assessed and improved.

The two processes are mutually supportive and depend on the same factors for success.

They involve:

- Monitoring individual or team performance against accepted benchmarks or standards
- Feedback on performance - both praise (positive reinforcement) and feedback highlighting unsatisfactory performance
- Ensuring that negative feedback is delivered in an objective manner and is accompanied by an explanation of why performance is unsatisfactory
- Affording an opportunity for the employee to provide an explanation as well as the means to improve in the future
- Coaching, training or other support to address poor performance
- Follow-up monitoring to check that the performance has improved, with the improvements reinforced with positive feedback
- Recourse to formal procedures, such as the disciplinary or capability procedure, where the poor performance continues and represents serious cause for concern

Those with responsibility for managing people can make or break a team. Engaging with your laboratory in both informal and formal performance management is vital.

NCIRE aides in the process by having a formal performance appraisal each year. The Annual Performance Appraisal stresses the importance of effective and frequent feedback between managers and employees, and the appraisal should be a natural conclusion to this ongoing process. The employee's self-assessment along with the PI/Manager's evaluation of the work, will serve as talking points regarding performance and plans for the coming review period. The Annual Performance Appraisal(s) are to be completed and sent to HR each year by 7th pay period or roughly by the middle of March. Each year HR will provide you with specifics on dates.

Merit Increases

A merit increase is a pay raise that NCIRE encourages PI's to provide to all their employees annually during the performance appraisal period. As the name implies, employees earn merit increases based on the value of their skills and contributions to the department. NCIRE provides the opportunity for merit increases in the range of 3% to 5% on an annual basis, depending on what percentage is approved by NCIRE's Board of Directors.

NCIRE encourages all PI's to budget for a minimum of 3-7% increase per year, per employee, to plan for this expense. Merit increases motivate employees to work harder to meet their

performance goals as well as assists employees to counterbalance the cost-of-living increases, which impacts an employee's ability to remain in the geographic area. In addition, regular merit increases are part of NCIRE's generous benefits package and encourages talented employees to stay with our organization over leaving for another.

Please note that increases will not be granted to employees whose performance has been rated as unsatisfactory overall, or if an employee is on a performance improvement plan. PI's who do not have adequate funding to provide a merit increases may waive them, if the funding situation is confirmed by their Grants Specialist to Human Resources.

To be eligible for a merit increase, an employee must be employed with NCIRE by December 31st of the prior year, proceeding the April review period.

Special Contribution Award Guidelines

The Special Contribution Award Program provides an opportunity for managers to recognize the outstanding work achievement of any regular full-time or part-time employee who has gone above and beyond his or her position description requirements or who has demonstrated outstanding corporate citizenship, teamwork or leadership towards the improvement or enhancement of a department project or activity, work process(es) or institutional objective(s). Award options can either be a one-time cash payment, time off award (or combination thereof) that does not increase the employee's base salary or salary-based benefits. Temporary and casual employees are excluded from the special contributions.

The justification for the award must include a detailed description of the employee's work achievement and specifically how this achievement contributed to the improvement of the department or institution. The explanation will be compared to the employee's position description in the personnel file. Special Contribution Awards must be approved by the appropriate Grants Specialist, Human Resources Manager, and in special circumstances, the Executive Director before the value of the award can be determined and communicated to the employee. A letter of recognition will be sent together outlining the cash payment or time-off award. A copy of the letter will be placed in the employee's personnel file. The following guidelines apply to this award:

- The employee must be in good standing with NCIRE without any active performance improvement plans
- An employee can receive up to 6% of the base pay as a Special Contribution Award
- Special contributions may be granted in cash, time-off or a combination of both as long as the total value is no more than 6% of the employee's annual base pay
- Managers may give one or multiple special contributions to employees throughout the fiscal year as long as the awards are linked to specific achievements that are above and beyond the employee's day-to-day responsibilities and the total award for all requested special contributions does not exceed the 6% maximum

- Awards must be commensurate with the employee's contribution
- Special Contribution Awards should not be given in lieu of merit increases or promotions
- Nominations must be submitted in the fiscal year of the outstanding achievement or contribution occurred
- Only one award per achievement is permitted

Guidelines for Time-Off Awards:

- Time-off awards to full-time employees will be granted and used in 8-hour increments. Time off awards for part-time employees will be prorated accordingly (i.e., 6-hour workday will result in a 6-hour time off award).
- The total value of the time-off awarded may be up to and not exceed 6% of the employee's annual base pay.
- It is encouraged that time-off awards be used within 90 days after the approval and must be used within the fiscal year in which the award was earned.
- Time-off awards may not be converted to cash payments.
- Approved time-off awards may transfer with an employee who has changed jobs within NCIRE, however the above noted guidelines would still apply.
- Time-off awards are not paid out upon termination, they are use or lose awarded days

Benefits, Fringe Rate, and Leaves

The Family Medical Leave Act (FMLA)

The Family and Medical Leave Act (FMLA) is a federal law which became effective in 1993. The law's stated purpose is to help employees balance their work and family responsibilities by taking reasonable unpaid leave for certain family and medical reasons.

FMLA Applies to the following Employers:

- Private sector employers who employ 50 or more employees for at least 20 work weeks in the current or preceding calendar year – including joint employers and successors of covered employers
- Public agencies, including local, State, and Federal employers, and local education agencies (schools)

In order to be eligible to take leave under the FMLA, an employee must:

- Work for a covered employer;
- Have worked 1,250 hours during the 12 months prior to the start of leave
- Work at a location where the employer has 50 or more employees within 75 miles
- Have worked for the employer for 12 months

A covered employer must grant an eligible employee up to a total of 12 work weeks of unpaid, job-protected leave in a 12-month period for one or more of the following reasons:

- For the birth of a son or daughter, and to bond with the newborn child;
- For the placement with the employee of a child for adoption or foster care, and to bond with that child;
- To care for an immediate family member (spouse, child, or parent – but not a parent “in-law”) with a serious health condition;
- To take medical leave when the employee is unable to work because of a serious health condition; or
- For qualifying exigencies arising out of the fact that the employee’s spouse, son, daughter, or parent is on active duty or call to active-duty status as a member of the National Guard, Reserves, or Regular Armed Forces.

FMLA eligible employees of covered employers can take unpaid, job-protected leave for specified family and medical reasons with continuation of group health insurance coverage under the same terms and conditions as if the employee had not taken leave.

An employer has several obligations to an employee who uses FMLA leave, including:

- The obligations to maintain the employee's health benefits during leave
- To follow certain rules regarding other employee benefits and compensation
- To reinstate the employee to his or her same position (or an equivalent position) upon return from FMLA leave.

California Family Rights Act (CFRA)

California Family Rights Act (CFRA) is similar to FMLA and generally mirrors FMLA closely in terms eligibility, time off and continuation of medical benefits. CFRA is only available for those that reside in California. These types of leaves typically run concurrently, however there are some major differences:

- FMLA applies to self, spouse, child and parents whereas CFRA also covers domestic partners and domestic partner's child.
- FMLA includes pregnancy related disability leave within the 12 weeks of leave which CFRA does not; however, CFRA does guarantee a 12 week leave after childbirth irrespective of any disability.
- FMLA requires the employers to maintain the group health benefits being provided to the employees; however, CFRA requires the employers to maintain all group benefits being provided to the employees, not just health benefits.

San Francisco Paid Parental Leave Ordinance

The San Francisco Paid Parental Leave Ordinance (SF PPLO) requires employers, who have employees working in San Francisco, provide Supplemental Compensation to employees who are receiving California Paid Family Leave (PFL) benefits to bond with a new child, so that the employees receive up to 100% of their normal weekly wages during 6 weeks of parental leave.

NOTE: There are two different parental leave benefit laws that employees may access:

1. PFL program, paid by the State of California's Employment Development Department (EDD)
2. SF PPLO, paid by Covered Employers

In order to receive SF PPLO benefits, an employee will have to apply for both the PFL benefits (by applying to EDD) and the SF PPLO benefits (by submitting the documentation to the employee's employer).

PFL is completely separate from both the FMLA and CFRA. PFL provides up to 8 weeks of partial wage replacement from the state to workers who take time off to bond with a new child or to care for a seriously ill family member. PFL is a state benefits program that provides eligible employees with up to 60% or 70% (depending on income) of their weekly wages for up to 8 weeks to bond with a newborn, newly adopted or foster child.

Under the SF PPLO, employers are required to provide employees who are receiving state PFL for new child bonding with "Supplemental Compensation" equal to the difference between the employee's PFL benefit amount and the employee's normal gross weekly wages, such that the employee receives up to 100% of their weekly wages. Subject to a weekly maximum benefit amount, for up to 8 weeks.

Other workers' leave rights, including leave related to:

- The Uniformed Services Employment and Reemployment Rights Act
- California's Military Leave law
- Workers' Compensation
- Jury Duty
- Witness Duty
- Victims of Crime, including domestic violence
- Child Activities (such as school-related activities)
- Voting

If an employee comes to you and asks for a leave of absence for any reason, please contact Human Resources at ncirehr@ncire.org and we will help you and your employee navigate the various leave process.

Fringe Benefits Rates

NCIRE believes benefits are an essential tool in attracting and retaining top talent to support your research goals. NCIRE reviews group plan benefits annually and works on providing a comprehensive total rewards program to protect our staff and their families while keeping costs in-line with the market.

Fringe benefit rates differ for various categories of employees, such as full time, part-time, and temporary. Fringe benefits costs include: payroll taxes, workers' compensation, vacation accrual, long term disability insurance, life insurance, and AD&D, group medical, dental, and vision plans.

It is crucial for budgeting purposes to include fringe benefits costs when hiring staff and budgeting. We recommend that you budget a minimum of 39.38% for fringe benefits for full-time employees, 24% for part-time employees, and 12% for intermittent (on-call employees). All employees are eligible for certain mandatory benefits regardless of the number of hours worked, such as workers' compensation and paid sick leave.

All rates are expressed as a percentage of salaries. Therefore, to calculate fringe benefit costs, multiply the requested salary by the applicable benefit rate. Please note that the actual cost may be lower or higher, depending on your employee's choices and circumstances. Things that impact the benefit rate are plan selection, coverage election, and waiver of benefits. The percentages stated above are recommended estimates.

Please note that the offering of benefits within certain employment groups must be consistent. We have certain employees that are benefit eligible, and we must offer coverage to those who are hired within those eligible categories. Pls may not influence the benefit choices of their employees, nor may they ask specifics about the coverage their employee have selected.

Please refer to your project ledger to see actual fringe costs for your staff members. If you need assistance with reading your ledger, please contact a member of NCIRE's accounting staff.

Affordable Care Act (ACA)

The Affordable Care Act (ACA) is a health care reform law enacted in March 2010 and its purpose is to make health insurance accessible and affordable to all. It provides employees with better health security by setting up modifications that expand coverage and lower health care costs. It also ensures more choice and increases the quality of care for all.

Employer Mandate Overview

Employers must offer health insurance that is affordable and provides minimum value to 95% of their full-time employees and their children up to the end of the month in which they turn age 26 or be subject to penalties.

Employees are considered full-time at NCIRE if they work 30 hours or more per week on a regular basis. These employees are eligible to participate in NCIRE's benefit plan which offers a collection of benefits consisting of medical, dental, vision, flexible spending, and life insurance. Eligibility is affected when a designated full-time employee transitions to intermittent status or part-time status. In these cases' we may be required to continue medical benefit coverage until

a specific date. That specific date depends on complex factors related to what is known as the Standard Measurement period.

The Standard Measurement period is a 12-month look back period where the employee's hours are tallied and calculated to determine the average number of hours. During this period, if it is determined that the employee has averaged 30 hours or more, the employee must be made an offer of medical coverage. Employees that switch from a full-time status to a part-time or intermittent status may still be eligible to continue to receive medical benefits via your grant by the rules that govern the ACA. To determine if you will be responsible for your share of the cost of your employee's medical benefits, even if the employee is working on intermittent or part-time status, please reach out to a member of the Human Resources team prior to requesting a status change.

Personnel Agreements with the VA and UCSF

The Intergovernmental Personnel Act (IPA)

The Intergovernmental Personnel Act (IPA) Mobility Program provides for the temporary assignment of personnel between state and local governments, colleges and universities, and other eligible organizations and the Federal Government. NCIRE is an eligible organization that provides temporary personnel to PI's working on Federal research projects. This is done via an IPA Agreement.

When used appropriately, the IPA is a strategic tool that can aid to further research by utilizing skilled, and trained personnel already available on campus. When a PI has a VA research project with a "hard-to-fill" research position, where a specific skill set is needed, an IPA with NCIRE may be an ideal situation.

If the PI is aware of a qualified NCIRE employee that has the skill level needed for a VA research position, then the PI may initiate an IPA agreement to "rent" the NCIRE employee's time on the Federal VA Project. PIs can initiate an IPA by reaching out to the VA Research and Development Office (R&D office). Within the R&D office, there is a team of IPA experts that will provide and explain documents needed and a timeline of when to complete.

When completed, the agreement spells out the terms of the contract, confirms funding available and also provided an estimate of work to be performed. A contract may be initiated for a maximum of 2 years, and then may be renewed. Research IPAs and zero-dollar IPAs have no limit to the number of terms. A four-year limit applies to Fiscal IPAs, unless it is justified the position is 100% research-focused with no clinical duties. The justification must be submitted to and approved by the R&D Office before being routed for signatures. When the limit applies, once the 4-year maximum has been reached, the employee must transfer back to an NCIRE project for a minimum of 12 months before being eligible for another IPA agreement.

IPAs may be initiated for employees on H-1B visas to ensure they are covered under the Federal Tort Claims Act (FTCA). Zero-dollar IPAs may be used when the PI does not have an active Federal VA research project. For more information, please consult with your Human Resources Representative.

To ensure the NCIRE employee qualifies for an IPA the following must be true:

- The individual must be employed and charged on an NCIRE project for at least 90 days in a non-time-limited appointment prior to an IPA start date.
- The NCIRE position being placed on an IPA must be for scientific/research position. Administrative personnel are not allowed to be placed on an IPA between NCIRE and the VA. Licensed clinicians are not allowed to be on an IPA using Research funds.
- The PI pay the administrative fee which is 5% of payroll and benefits for each pay period per contract, without a cap on new IPAs, including IPA renewals.
 - The administrative fee must be funded through unrestricted sources.

To initiate an IPA, the Principal Investigator should:

- Contact the Research and Development Office and ask to speak Eva Lau or email her at Eva.Lau@va.gov.
- All Research IPA's must be submitted and approved by the Research and Development Office before being routed for other signatures.

Please note that:

- The IPA is not approved and may not start until all signatures are obtained.
- The IPA must be submitted for processing at least six weeks before its intended start date.
- IPA's may not be backdated.
- The PI is responsible for tracking IPA dates and funding allocations for their employees
- A funding plan must be in place with NCIRE prior to the IPA ending

Joint Personnel Agreements (JPA)

A Joint personnel Agreement (JPA) is a contract and a billing mechanism that is administered by NCIRE, for work done by a UCSF PI on an NCIRE project performed on the SFVAHCS campus. In other words, the JPA is an agreement that details the terms under which a UCSF employee is provided to NCIRE to work on NCIRE projects and activities.

NCIRE reimburses UCSF for salary and benefit costs for the effort allocated on the Joint Personnel Agreement.

The work done by those on a JPA for NCIRE must be done at the SFVAHCS campus or in research space leased by the VA.

All individuals who are paid via a JPA must also have an NCIRE WOC appointment to cover their NCIRE efforts, regardless if they have a WOC appointment via UCSF or a paid appointment with the SFVAHCS. This is required by UCSF and NCIRE and this condition must be met before a JPA will be executed.

UCSF charges NCIRE an administrative fee for processing JPA payroll. This fee is calculated at 26% of total salary plus benefits plus associated JPA costs (i.e. GAEL) per billing period. If the funding source that the JPA individual is being paid from allows NCIRE's full F&A rate, NCIRE will cover the fee using its general administrative funds. If the JPA individual's effort is charged to a funding source that doesn't allow NCIRE's full F&A rate (i.e. industry or private donation account), the JPA fee is paid by the PI's admin funds.

Background and Requirements:

- The need for effort of an UCSF employee (the "Requested Employee") is determined at the time of NCIRE grant (or contract) Proposal Preparation. A JPA is necessary if proposed research-related activities require the effort of UCSF faculty, academic or staff employees. The JPA can only be used for personal related costs, specifically salary, fringe benefits and institutional administrative recovery.
- An individual may only have one comprehensive JPA, regardless of the number of NCIRE based projects or grants for which he/she may provide effort. All effort contributed by the UCSF employee to NCIRE-based projects or grants is consolidated in one comprehensive JPA. The comprehensive JPA is for a maximum of 12 months and must be renewed annually.
- At the time of proposal submission, the UCSF Analyst in conjunction with the NCIRE project's PI, shall negotiate:
 - a) The time period during which the requested UCSF employee will be needed, maximum of 1 year;
 - b) The anticipated average effort per month the requested employee is to work on NCIRE activities;
 - c) UCSF salary and benefits (excluding UCSF overhead) and the corresponding amount of effort to be reimbursed by NCIRE for the contract period shall be in compliance with the following guidelines:
 - d) In consideration of the services to be performed by the employee, compensation is based on hours worked and the approved UCSF salary and benefits of employee authorized for those services at that time.
 - e) Maximum effort per week for an employee with a UCSF faculty and VA appointment may not exceed 60 hours per week. This includes all UCSF, NCIRE, and third party (e.g. VAMC) combined effort. Staff, Postdoctoral scholars or non-faculty academics (e.g. Specialist) may not exceed 40 hours maximum effort per week.

Other Relevant Requirements related to the use of JPAs include the following:

- a) A JPA for a non-faculty employee should only be proposed for a career or “long-term” employee, with a minimum of five years of service credit prior to the initiation of the JPA, and who is vested in the UC Retirement System. The time and service provisions do not apply to faculty and postdoctoral scholars. This means that new hires in the administrative services cannot be on a JPA.
- b) The JPA process is not to be utilized to unduly advantage an employee’s benefits situation. Other than for highly unusual circumstances, concurrent employee (dual employment), by both UCSF and NCIRE is generally not allowable for non-faculty academics and staff employees. Refer to UCSF policy related to affiliate dual employment.
- c) An NCIRE Employee may not be placed on a JPA.
- d) A current UCSF employee may desire to terminate employment with UCSF in order to seek employment with NCIRE. If the employee is considering termination of his/her UCSF employment, the employee’s home department shall advise the employee to contact the UCSF benefits office to obtain relevant employment information so an informed decision regarding termination of UCSF employment can be made.

Types of JPAs

New JPA: This is an agreement that is being submitted for an individual for the first time. The period of the agreement lasts for up to one year.

Renewal JPA: This is an agreement that is being submitted to update an expired agreement. This is also for a period of up to a year.

Modification 1 JPA (Mod 1): When there is a 5% or greater change in an individual’s effort, salary, or end date to the agreement, a Modification 1 is needed.

Modification 2 JPA (Mod 2): This is a funding modification when there is a less than 5% change in effort or salary. Modification 2 is also used when the effort distribution between NCIRE projects changes but total JPA effort does not change.

To Start a JPA

The Principal Investigator should reach out to their UCSF department Analyst to initiate a JPA.

Employee Relations

Employee relations is a term used to describe relations between employers and employees. Employee relations include the processes of developing, implementing, examining and administering the employer-employee relationship. This responsibility is shared organizationally by NCIRE, and by the PI along with their managerial staff.

Sometimes, despite best efforts, workplace conflict may occur. When those instances arise, NCIRE Human Resources is here to guide and assist you.

**** Below are situations where you should always notify Human Resources:**

- Claim of Discrimination
- Allegations of wrongdoing by others
- Claim of Harassment
- Poor performance of employee
- Non-Compliance to rules and regulations
- Excessive absences or tardiness
- Workplace bullying
- Hours & Wage Issues
- Workplace conflict
- Illegal conduct
- Violation of SFVAHCS policy
- Violation of safety rules
- Request for an accommodation
- Request for a leave
- Workplace injury
- A threat of violence

Workplace culture and strong professional relationships are important in fostering an atmosphere that creates high performing team members. To that end, Human Resources will partner with you and help you navigate and apply organizational policies and procedures as it relates to the employer-employee relationship. Our goal is to ensure the best possible outcome for everyone involved in the situation so that we can get your team back to the business of moving your research forward. Please do not hesitate to reach out to Human Resources with any questions.

*** Disclaimer: Please note that the list above is not all-inclusive but is intended to provide general guidance. There are many other situations where contacting Human Resources for assistance is appropriate.*

Employee Terminations

Principal Investigators should notify NCIRE HR at least two weeks before an employee's last day of employment. If the employee will be transferring to UCSF or the SFVAHCS and needs to retain their VA property, the new PI or Supervisor must email and obtain the SFVAHCS R&D office's approval before the employee's exit interview with NCIRE. If the approval is not sent to NCIRE before the exit, per SFVAHCS rules, all VA property must be turned in.

Once NCIRE HR has obtained notice from the PI or the employee an exit interview will be set up between the employee and NCIRE HR. After the appointment has been set up, NCIRE HR will send the employee the appropriate exit documentation and instructions. Per California law, final hard copy paychecks must be provided to an employee on their last day of employment. The PI or Supervisor must approve the employee's final timesheet no later than 72 hours in advance of the employee's exit date. This is to ensure appropriate time for payroll to issue the final check to Human Resources.

On the employee's last day, the employee will return all SFVAHCS property to each SFVAHCS department listed on the Property Return Form and verify with the PI or Supervisor that all research materials have been submitted or returned. This is verified by the PI, or Supervisors' signature on the Exit Property Return list. Once completed the employee should come to NCIRE for their exit interview.

During the exit interview, NCIRE HR will go over their exit documents and answer any questions the employee may have regarding their pay or benefits. At the end of their exit interview, the employee will receive their final paycheck and vacation payout (if applicable). If your employee has a J-1 or an H-1B visa, please note that NCIRE will be withdrawing the visa that we requested on your behalf upon the employee's termination. NCIRE will inform the immigration service of your employee's departure from the organization after the last day of your employee's employment.

INFORMATION TECHNOLOGY (IT)



NCIRE's Information Technology (IT) Department is dedicated to providing technical support to the Research Community at SFVAHCS. We also collaborate with the VA OIT team to ensure all research computers are in compliance with VA OIT policies to minimize interruption to the operations.

Request IT Support

The NCIRE IT Team provides IT support to the Research Community at SFVAHCS. To receive IT support, the requester must have an active status in the R&D Information System (RDIS). To check RDIS status, please contact the R&D Office.

There are multiple methods to submit IT support requests:

1. The most direct method is to contact the NCIRE IT Team by either calling extension 23939 or sending an e-mail to helpdesk@ncire.org.
2. Alternatively, the NCIRE IT Team uses the same IT ticketing system as VA OIT. You can submit a ticket through the VA YourIT Portal (<https://yourit.va.gov/>) or call extension 24949.

A ticket will then be routed to our work queue. Once the ticket is assigned, one of our technicians will contact you to schedule a day and time to work on your request.

Generally, we work on support tickets in the order they are received. The only exception is when the user encounters a complete work stoppage issue. If you encounter other IT issues and need it resolved quickly, you may specify the urgency and reason in the request, and we will do our best to accommodate. Please note contacting our technicians directly doesn't guarantee your IT issue will be addressed immediately as we are currently working on other tickets in our queue. Our technicians will create a ticket on your behalf and will schedule a day and time to work on it.

The NCIRE IT Team only supports computer equipment that has an NCIRE tag and/or a VA EE Tag. We cannot provide IT support on personal computer equipment.

Our standard hours of operation are 8:00am to 4:30pm (PST) Monday through Friday, except for holidays. The NCIRE IT Team doesn't provide after-hours support. If there is a need for after-hours support, please submit a request via direct e-mail to NCIRE IT Director

(keith.chan@ncire.org) at least 3 days in advance. Please note, after-hours support is not guaranteed due to the availability of our staff.

Getting a Computer

A new employee can request a VA computer (desktop or laptop) and up to two monitors. VA OIT has a one-device policy; therefore, either a desktop or a laptop will be provided but not both. If a laptop is requested, a docking station will also be provided for connecting monitors and other peripherals at the desk. Please note only PC desktops and laptops are available at the time of this writing.

To request a new computer, you may contact the R&D Office to submit the request for you. Alternatively, you can use the VA YourIT Portal (<https://yourit.va.gov/>) and submit a New Hire Equipment request by going to “Software & Hardware -> New Hire Equipment” service catalog.

If the hardware specification of the VA computer doesn’t meet the requirement of the software you use, you may purchase a computer using your research funding. The computer must be compatible with the VA Gold Image. Please contact the NCIRE IT Team for a recommendation, and we can also request a quote for you.

All computers purchased through NCIRE will be delivered to the NCIRE IT Team first. Once the configuration is completed, one of our technicians will contact you to schedule a time to deliver the computer to you.

Occasionally, the NCIRE IT Team may have spare computers available. If you need an extra computer for your research group, you may contact the NCIRE IT Team to inquire about availability. Please note that spare computers are not new.

Desktop and Laptop Configuration

All computer equipment must have an NCIRE property tag and/or VA EE tag clearly attached to be serviced by the NCIRE IT Team.

Desktop and laptop computers (both PC and Mac) that are connected to the VA network must be configured using VA Gold Image. There is no exception to this policy.

Desktop and laptop computers that are used off the network (remotely) will not be configured using the VA Gold Image. However, the NCIRE IT team installs encryption and antivirus software on all off-network computers. In addition, the user is required to sign a user agreement before the off-network computer will be released for use.

Desktop and laptop computers must have “keep the hard drive” support option at the time of purchase. If a computer is used off of the network (remotely) and the computer model does not offer the “keep the hard drive” support option, the user must obtain a written authorization from the NCIRE IT Director (keith.chan@ncire.org) before purchasing the computer.

Server Configuration

All servers must be mounted to one of the server racks in the VA server room in Building 207 or the server room on the 4th floor at the Mission Bay location. In addition, all servers must have “keep the hard drive” support option.

An Enterprise Work Request (EWR) is required to join a server to the VA network. It is the user’s responsibility to submit the request. The NCIRE IT Team can provide assistance if you have any questions about the request form. To submit an EWR, you can go to the VA YourIT Portal (<https://yourit.va.gov/>), under the “Data Center & Network -> VA IT Enterprise Work Request” service catalog.

The version of the operating system used on the server must have an “approved” status on the VA Technical Reference Model (TRM) website (<http://trm.oit.va.gov/>). The NCIRE IT Team provides limited support on server issues, and it is the user’s responsibility to maintain the hardware and software. To obtain administrative privilege on a server, please visit the Electronic Permission Access System (ePAS) site (<https://epas.r02.med.va.gov/apps/myva/>) to submit a request.

Software Installation

The user must provide the installation media (CD/DVD or downloaded installation package) and a valid software installation license. If the software is installed on a computer connected to the VA network, it must have an “approved” status on the VA TRM website (<http://trm.oit.va.gov/>). The user is responsible for purchasing software upgrades to comply with the VA TRM requirement. VA OIT scans all networked computers monthly and will remove all non-compliant software. If you need to use a software version that is not compliant with TRM requirements, please contact the NCIRE IT Team to speak about a Plan of Action and Milestones (POAM) submission. A POAM submission form, if approved, will provide an exemption to allow you to use that particular version of the software for up to one year. The hope is this will enable you to plan for an upgrade or switch over to an alternate software.

The NCIRE IT Team does not manage software licenses. It is the user's responsibility to maintain the required software licenses needed for their specific research.

All users must follow the license agreement specific to each software, especially the rule defining the number of computers or users each license provides. Cracked or pirated versions of software and illegally obtained software/licenses are not permitted for use on any system, under any circumstance. The NCIRE IT Team reserves the right to decline a software installation request if there is a legitimate reason to believe the licensing agreement is not being followed, and/or the software/license is not a legal copy.

It is the user's responsibility to purchase a software support contract. The complex nature of most research-specific software can generally only be supported by the vendor's technical support service. If a support contract covers the software, in that circumstance, NCIRE IT Team can assist with coordinating vendor support. If a support contract does not cover the software, the NCIRE IT Team can only provide best effort troubleshooting, but a resolution is not guaranteed.

Remote Access

At SFVAHCS, there are two remote access methods available. To request a remote access account, please visit <https://vaww.ramp.vansoc.va.gov/> (this is an internal site, and you need to access this site using a computer that is connected to the VA network).

VPN access, also known as RESCUE VPN or Cisco AnyConnect VPN, is available if you have a VA issued computer or an NCIRE purchased computer that is configured with the VA Gold Image. With VPN, your computer is connected to the VA network directly, and you can access network resources the same way you do onsite. One consideration is that the computer must have all the required security updates which are regularly and automatically installed through the network. If the computer misses any of the updates, the VPN connection might be rejected, and you will need to bring the computer to the NCIRE IT Team to have the updates installed.

Citrix Gateway (<https://citrixaccess.va.gov>), also known as CAG, is another tool available, and you can access it using any device including your personal computer. Unlike VPN, your computer is not connected to the VA network directly, and therefore VA mandated software and updates will not be installed on your personal computer. There are commonly used VA applications published on the Citrix StoreFront, and you can access VA e-mail, R drive, W drive and other network drives from there. In addition, you may request separately to remotely connect to your office computer. There are limitations with Citrix Gateway as you cannot copy files from Citrix onto your computer and vice versa, and you cannot print to a local printer connected to your computer.

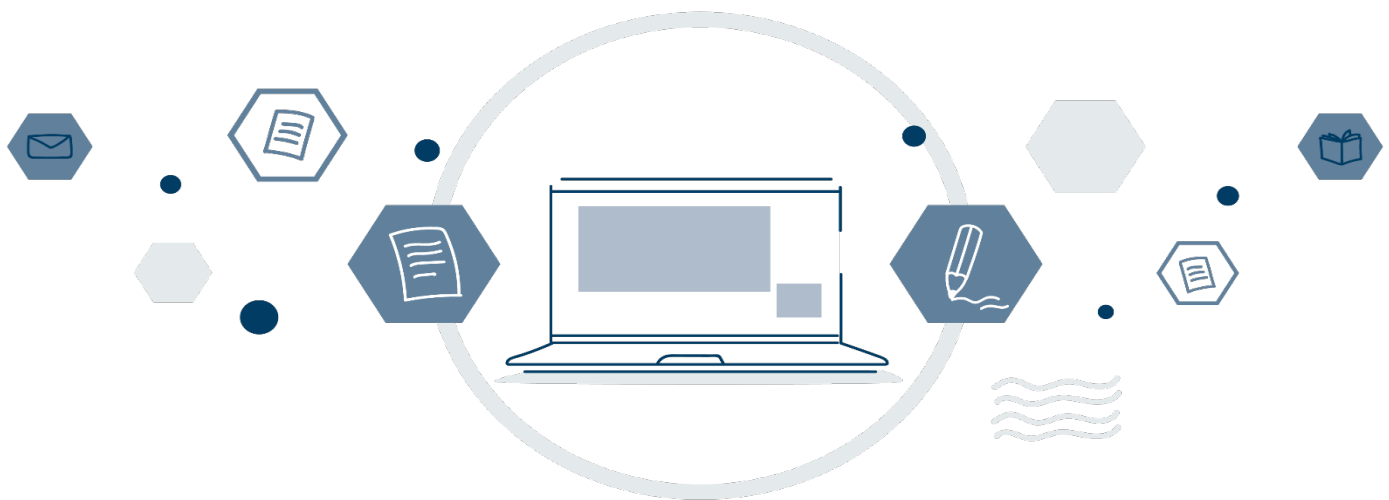
Both remote access methods require the use of a PIV card. In the event you don't have your PIV card with you, or the card reader is not working properly, you may request for PIV exemption by calling the VA Enterprise Service Desk at 1-855-673-4357. They will give you a temporary password to log on.

NCIRE e-mail accounts can be accessed through webmail (<https://outlook.office.com>) without connecting to VPN or Citrix Gateway. The link to webmail is also available on the NCIRE website (<https://www.ncire.org>) under the "Employee Resources" section.

Computer Equipment Disposal

All computer equipment with an NCIRE tag and/or a VA EE Tag are recorded in the inventory system, and we are required to perform an annual inventory check. Therefore, it is important to follow the proper procedure to dispose of computer equipment. Please contact the NCIRE IT Team by either calling extension 23939 or sending an e-mail to helpdesk@ncire.org. Alternatively, you can submit a ticket through the VA YourIT Portal (<https://yourit.va.gov/>) or call extension 24949, and the ticket will be routed to our work queue. Please include the description of the item and the location in the request. Once the ticket is assigned, one of our technicians will contact you to arrange a schedule to pick up the equipment.

If the equipment is a computer or a device with an internal hard drive, we will remove the hard drive before disposal and dispose of the hard drive in accordance with current VA data destruction policy. In addition, we will fill out the VA 0751 form if the equipment has a VA EE tag so that the record will be removed from the VA inventory system.





NCIRE's Office of Procurement is dedicated to providing assistance and support to our Research Community to acquire the goods and services they need to support research.

The Office of Procurement is committed to assisting the NCIRE community with timely and cost-effective procurement of quality goods and services, while complying with the current requirements of 2 CFR 200 "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Award", Subpart D, Sections 200.317-326, as well as the regulations of other agencies, including VA and NCIRE policies relative to purchasing on sponsored awards.

We strive to be a trusted source of procurement resources, education, and information for our campus customers while navigating our institutional requirements.

General Procurement Requirements

The following requirements apply for all purchases:

- Sufficient funds must be available to cover costs.
- A research rationale (justification) must be provided for each research-related procurement; for education activities, the expense must be within the scope of the approved educational activity.
- All procurement for sponsored research projects must be reasonable and necessary for the performance of the project, as well as allowable and allocable under the terms and conditions set forth in the grant.
- It is the responsibility of the person submitting the request to ensure all required back-up documents have been attached to assure timely processing. Documentation is critical to the approval and procurement process.
- Procurement exceeding \$50,000 require 3 competitive bids. If you are unable to obtain 3 bids for an item due to specifications or conditions proprietary to one vendor, you will be required to provide a Sole Source Justification with the purchase order request.
- Procurement exceeding the Federal Simplified Acquisition Threshold (SAT) of \$250,000 require a formal bidding process.
- NCIRE is not exempt from state sales tax. All procurement made with NCIRE administered funds are subject to sales tax.
- Meet the general procurement standards in 2 CFR section 200.318-326.
- Procurement and/or agreements to suppliers will not be made by NCIRE employees and nonemployee PIs who have a real or apparent conflict of interest that has not been

previously reviewed, approved, or mitigated with NCIRE. Procurement that provide personal benefit are not allowed.

- Vendors must be reviewed and approved as eligible to conduct business with NCIRE.
- Suspension and Debarment: Non-federal entities are subject to the non-procurement debarment and suspension regulations implementing Executive Orders 12549 and 12689, 2 CFR part 180. These regulations restrict awards, subawards and contracts with certain parties that are debarred, suspended, or otherwise excluded from or ineligible for participation in Federal assistance programs or activities. NCIRE will review the System for Award Management website (www.sam.gov) for vendor exclusion and debarment status.

Purchases above the Micro-Purchase Threshold

NCIRE is required to conduct all procurement transactions in a manner that provides full and open competition, in accordance with 2 CFR section 200.319 – 323.

Outlined below are necessary steps when acquiring goods and services in excess of \$50,000, but less than \$250,000. Note these general steps may not cover all circumstances. Notifying the Office of Procurement at the onset will allow time to ensure proper steps are completed in order to stay compliant with federal requirements.

Acquisition of Goods and Services in excess of \$50,000 but less than \$250,000:

- I. Requester will initiate a Request for Quote (RFQ) and obtains bids/proposals from three sources. Please note:
 - a. Contracts cannot exceed the current budget period of your funding source.
 - b. Certain transactions may require prior sponsor approval and/or rebudgeting.
 - c. Certain research activities require a subaward agreement.
 - d. Payment to an individual must use the Independent Contractor process to determine eligibility.
 - e. If during this process it is apparent the expense will exceed the SAT of \$250,000, please notify the Senior Manager, Procurement and Logistics immediately to review the RFQ and process to ensure compliance with Federal requirements.
- II. Requester will provide cost reasonableness justification, or if selection is based on other criteria.
- III. If a Sole Source is indicated, Requester to provide a completed PA-200 Source Justification form.
 - a. Sole Sources are:
 - A vendor or a distributor given an exclusive right to sell in a geographic area;
 - A vendor who supplies equipment to a Requester who needs matching or coordinating equipment.
 - b. Sole sources are not:
 - A vendor of personal choice or convenience
- IV. Requester to provide any new vendor's W-9 and remittance address, or a contact for Procurement to obtain those items.
- V. All vendors must not be Federally debarred. (to check, please visit www.sam.gov)
- VI. Requester will provide vendor contract/agreement/SOW for review of language. We recommend a MS Word document version be sent with all relevant information to procurement@ncire.org

for review prior to the requisition being submitted. Procurement will negotiate with the vendor about the contract terms.

- VII. Requester will create a requisition in Acumatica and upload all the RFQ documentation, and any other relevant documents for record keeping and audit purposes.
- VIII. Requester to submit requisition once complete.
- IX. Requisition routes for approvals.
- X. Procurement reviews the documentation and contract, then routes for signature(s) if accepted.
 - a. If the contract has not been reviewed prior to this step, please note that negotiations may delay processing.
 - b. Institutional signature at this threshold is by NCIRE's Chief Executive Officer.
- XI. Once the contract is fully-executed, and a Purchase Order (PO) is issued from the approved requisition, Procurement will forward the fully-executed contract and the PO to the Requester and the vendor. Work may now begin.

This process may expand or contract to include other requirements depending on the type of procurement, funding source, vendor, etc. Please note, any transaction requiring construction has significantly different requirements.

Purchases Above the Simplified Acquisition Threshold

NCIRE is required to conduct all procurement transactions in a manner providing full and open competition, in accordance with 2 CFR section 200.319 – 323.

The Office of Procurement recommends an initial discussion of the proposed transaction to evaluate specific steps required.

Acquisition of Goods and Services in excess of \$250,000

- I. To be compliant with 2 CFR requirements, NCIRE requires three (3) formal bids through the Request for Proposal (RFP) process on all purchases of \$250,000 or more. Requesters must provide the Statement of Work, criteria, specifications, contract period, contract budget and any other relevant information essential to preparing the RFP.
 - a. Bids of \$250,000 or more shall be secured or confirmed in writing by a NCIRE Procurement designee and reviewed and authorized by the CFO or CEO.
 - b. All information necessary to prepare and submit bids/quotations shall be given equally to all suppliers solicited.
 - c. The RFP description or specification must not favor one brand or trade name article, manufacturer or supplier over others.
 - d. The right shall be reserved to accept or reject bids/quotations on each item separately or the bid/quotation as a whole. If the Requester, typically the Principal Investigator or designee, obtains bids from vendors, those bid documents must be submitted with the requisition. NCIRE's Office of Procurement must assure that the vendors submitting bids are as qualified as the vendor of choice.

- II. Procurement by noncompetitive proposals is procurement through solicitation of a proposal from only one source and may be used only when one or more of the following circumstances apply.
- a. The item is available only from a single source:
 - To justify sole source on purchases for goods and services in excess of \$250,000, the requisition must be accompanied by a PA-200 Source Justification form describing the features of a brand or trade name that only that product or service will fulfill, to the exclusion of all others. All such statements become a part of the purchase contract file and must be defensible at time of audit.
 - Reasons must be specific and based on factual information that relates to the use of the item or service in the work or research.
 - Single source vendor quotations will be compared to quotations received from vendors of the same or comparable equipment; the Requester will be asked to prepare justification in terms of paying higher costs for the specified item/service.
 - Sole sources are:
 - A vendor or a distributor given an exclusive right to sell in a geographic area.
 - A vendor who supplies equipment to a Requester who needs matching/coordinating equipment.
 - Sole sources are not:
 - A vendor of personal choice or convenience.
 - b. The public exigency or emergency for the requirement will not permit a delay resulting from competitive solicitation.
 - c. The Federal awarding agency or pass-through entity expressly authorizes noncompetitive proposals in response to a written request from the non-Federal entity; or
 - d. After solicitation of a number of sources, competition is determined inadequate.
- III. For goods or services in excess of \$250,000, NCIRE Procurement will document the industry or markets involved, and/or document their opinion of the reasonableness of the requirement's cost provided. Appropriate documentation includes:
- a. Comparison of the requirement to analogous items or items containing the same or similar components, or
 - b. Consideration of the cost of development or of the singular benefits to be obtained by the Requester, as supplied within the requisition.
- IV. NCIRE Procurement may determine that insufficient evidence has been provided to justify the Requester's instructions to buy from a sole source. In that case, details of the transaction, together with details of possible alternatives, may be sent to the CFO or CEO for specific approval or additional documentation prior to issuing the order.
- V. Once the RFP Process is complete, the Requester must submit a requisition with all documentation attached to generate a purchase order.
- VI. Procurement will provide the purchase order and the fully executed contract to the Requester and vendor once fully executed.

Procurement Processes

- It is the policy of NCIRE to utilize a purchase order system. All procurement requests for supplies and other items must be submitted in the Acumatica requisition system. Please visit the Employee Resources page on NCIRE's website for the link to Acumatica.
<https://www.ncire.org/employee-resources>
- NCIRE staff will review requests to ensure completeness and approve as appropriate to their position and authority.
- Purchases will be delivered to NCIRE campuses. On delivery, the recipient must inspect the purchases and return signed packing slips to NCIRE's office. Any offsite deliveries must be approved.
- When the order is complete and invoice/s received, the order will be paid by NCIRE.
- Requesters must contact NCIRE to verify eligibility of vendors. The Offices of Procurement and Accounting will establish and approve new vendor accounts in advance of the purchase. Please contact Procurement with new vendor information.
- Orders must be requisitioned by PIs or an authorized designee. Designees are authorized by the PI completing the Authorized Access Form. The Authorized Access Form is available on the NCIRE Intranet website in the Procurement tab.
 - Complete the form with all NCIRE project numbers to be delegated and all individuals with the same level of authority.
 - PI wet ink signatures, Adobe certificate signatures, or DocuSign with audit history are accepted.
 - Return this form to authorization@ncire.org or the front desk at NCIRE's Building 210, 1st floor. If returning a physical form it is recommended you retain a copy and email procurement@ncire.org to notify the form was given to the front desk.
 - Indicate in request if any individuals are new and require an Acumatica account.
 - Acumatica accounts do not require access to the VA domain via PIV card.
 - NCIRE Procurement will provide training in the Acumatica environment for requisitions.
- An NCIRE Purchase Order (PO) is required for all procurements. NCIRE's Acumatica requisitioning environment is to be utilized for procurement requests. Manual PA-100 procurement forms are available on the NCIRE Intranet website in the Procurement tab if access to the requisition system is pending.
- Requisitions must be complete, and all documentation must be attached, including any necessary forms and quotations. Special instructions regarding the items or shipping should be clearly indicated. Incomplete information causes delivery of incorrect items and ordering delays or return of the request.
- Vendors must reference NCIRE as the "bill to" party on all quotes and invoices.
- Orders over \$50,000 must have three bids/quotes or include an approved sole source justification.

- Please contact Procurement about orders over \$250,000 for guidance about the formal bidding process.
- Signatures on vendor documentation must be by authorized institutional parties. With the exception of “Read and Understood By” sections, vendor contracts and agreements are signed by NCIRE’s Chief Executive Officer or the Senior Manager, Procurement and Logistics.
- All requests should be submitted to allow several workdays for NCIRE processing and sufficient time for the vendor to deliver the order. Early planning is encouraged for smooth ordering processes. Complex requests should be brought to Procurement’s attention as early in the process as possible. Certain transactions may require additional processing time such as:
 - Orders over the Federal micro-purchase threshold of \$50,000 requiring bids
 - Orders over the Federal Simplified Acquisition threshold of \$250,000 requiring the formal bid process
 - Contracts
 - Independent Contractors
 - Service agreements
 - Material transfer agreements (MTA’s)
 - Data Use Agreements (DUA’s)
 - First orders to a new vendor
 - Orders requiring a medical license
 - International vendors
 - Equipment

Please see sections under the Specialty Procurement section for more information about these categories.

- **Expedited Requests:** Emergency orders (when an unanticipated event has caused the need for an immediate order) should be clearly identified. Detailed accompanying emails to your Grants Specialist and Buyer are appreciated.
- **Change Orders:** If it becomes necessary to change or cancel an order or part of an order, the user department must contact Procurement to initiate the process.
- **Delivery Inspection:** At the time of arrival, all items should be checked for physical damage and the packing slip or bill of lading should be immediately compared to the delivery. If an item appears damaged or is not in working order, it must be immediately reported to the vendor for resolution. NCIRE’s Office of Procurement will contact vendors concerning discrepancies/damage noted by the purchaser. Please see the “Returning Goods to a Supplier” section for additional information.
- **Personal Use:** Equipment purchased for home use is assumed to be for personal benefit and will not be authorized without clear justification of business purpose. Equipment remains NCIRE property and appropriate Offsite Equipment User Agreement paperwork to document the equipment’s location must be submitted and approved by NCIRE.

Please contact your Buyer with questions about requisitions, vendors, or procedures. Please refer to the Procurement section of the NCIRE Intranet for the most current forms. Outdated forms will require revision to the most current version.

Procurement of Specialty Goods and Services

International Orders

International orders require an Acumatica purchase requisition, with a PA-200 Source Justification form outlining the requirement to purchase non-domestic goods and services attached. International vendors must provide a W-8BEN-E form and will be subject to vendor vetting procedures. Items purchased outside of the U.S. may need to be cleared through U.S. Customs.

When ordering from an international vendor, please take into consideration the cost of freight, broker's fees, California Use Tax, and approximately 9% to 12% in duty fees and additional order processing time. Providing your FedEx account number can simplify customs fees.

- Please contact Procurement prior to engaging the vendor and generating the purchase requisition to discuss international procurements.
- Please also refer to the Accounting policy in section 4.02 International Purchases.

Material Transfer Agreements (MTA's)

- All Material Transfer Agreements (MTA's) must be reviewed by NCIRE.
- Most MTA's must go through a review process within the VA Regional Counsel.
- For basic agreements relating to purchased goods shipped to the SFVAHCS location, please contact your Buyer.
- Other types of MTA's should be discussed with your Office of Sponsored Research Grants Specialist.
- Please also refer to the Office of Sponsored Research section of the NCIRE Intranet for policies and procedures.

Institutional Alliance and Affiliate Transactions

Transactions arranged with our institutional alliance, the San Francisco VA Health Care System and our institutional affiliate, the University of California San Francisco are considered internal services. These services such as usage of institutional Cores, clinical services for subjects and subject samples, research and hospital diagnostic equipment are shared institutional resources that are a direct portion of the basis of our affiliate relationships with SFVAHCS and UCSF. These services are provided at internal rates to NCIRE.

Expenses Involving Subjects

Transactions requiring a protocol number are expected to include the appropriate number/s alongside the rationale in the justification of the expense to be approved.

Additional paperwork and credentials may also be required by the vendors such as signed order forms, prescriptions, or a copy of the PI's medical license.

- Human drugs, medical devices, some surgery supplies
 - o VA Research Pharmacist receives orders for the PI's, especially for dispensing in blind studies
 - o External compounding Pharmacies should ship to the attention of the Research Pharmacist in the SFVAHCS Pharmacy location
 - o Sponsors should ship to the to the attention of the Research Pharmacist in the SFVAHCS Pharmacy location
 - o UCSF Investigational Pharmacy when dispensed/formulated there or fees related to study drugs
- Recording devices of subjects for research work require CHR/IRB
 - o Voice recorders (must be VA approved model/s)
 - o Video equipment including baby monitors (cannot store to the Cloud)

Regarding drugs requiring a Drug Enforcement Agency (DEA) license:

Please note that NCIRE is forbidden to purchase certain controlled substances requiring a DEA license.

If the SFVAHCS Pharmacy cannot source the desired controlled substance, the requisition will be rejected by NCIRE.

Receiving

The purpose of the Receiving Department is to receive and inspect materials and equipment, deliver materials and equipment to the ordering department and return goods or materials to vendors that were originally ordered on an NCIRE purchase order. Receiving also assigns tags and facilitates obtaining SFVAHCS EE tags.

- Upon delivery, the recipient must initial and date the packing slip from received items provided by the Receiving Department.
- If there are any issues with a delivery, the Receiving Department will contact the original buyer and end-user.
- It is the responsibility of the recipients to inform Receiving and Procurement if deliveries require scheduling. There is no storage capability for large items. If the VA movers are required the recipient must coordinate scheduling with the LEAF work order system.

- Please note that we do not have access to freezers to store goods that cannot be delivered immediately.
- Current inbound shipping issues experienced by all USA customers affect our location especially because the SFVAHCS warehouse facility closes at 3pm.
 - Planes arrive late, pushing back the entire delivery process.
 - The early morning overnight priority deliveries are sometimes split by the carriers, and the second truck does not arrive before the warehouse closes.
 - Standard overnight seems to now be slated as delivery by 4:30pm, which is after SFVAHCS warehouse closes.
- Any clearly damaged or leaking package will be refused by the SFVAHCS Warehouse due to their receiving policy.
- Pandemic and Holiday specific issues:
 - Many carriers are still not requiring signature due to COVID procedures; therefore it is more difficult to track and get accurate data.
 - Persistent delays from the global shortage of air transit and staffing remain as significant factors for shipping exceptions.
 - Holiday drivers may not always know our location's special circumstances for closing time and consolidated delivery point.
 - Holiday seasons will stress carrier ability to deliver on time.
- The Mission Bay location might have deliveries occur during hours when no NCIRE staff is present. The building has multiple tenants, so the carriers might leave items near the service elevator, and if misdelivered, some tenants may leave a package near the passenger elevators.

Recommendations for NCIRE shipments:

- Order sensitive items with plenty of time to route for approvals so we can purchase early in the week.
- Provide us with contacts in your labs and when people are likely to be there. Provide additional contact info in the event we need to reach you or your team if no one is available for delivery. Do you have colleagues that could help you out in a pinch? Let us know who we could ask to store a temperature sensitive item for you in the event you are not around to receive.
- Ask Sponsors sending medication or colleagues/collaborators providing samples on ice to send early in the week and use FedEx Priority overnight (10:30am delivery type) or UPS morning or noon delivery.
- Avoid the “saver” options for anything temperature sensitive since it has later delivery times (~5pm from both carriers) beyond when the SFVAHCS warehouse is open to receive.
- If you have an NCIRE purchase that has a delivery exception, please let NCIRE Procurement team know about your experience, since we do not always know it did not arrive on the expected day, or that ice has melted. Especially if vendors have repeated issues please let

procurement@ncire.org know as we might be able to help identify what is causing the problems.

- Make a note of any dry ice products in the “Notes to Buyer” and if you are willing to pay for the earlier overnight delivery type. Please be aware that many vendors do not list the temperature requirements for shipping, the shipping level, or allow us to select a different level, especially our punch out vendors and any third party shippers.
- Many vendors do not provide shipping notices at all. We also find that backorder notices are not always given. Your Buyer can assist with investigating late or missing orders.

Having personal items delivered through NCIRE, UCSF, or SFVAHCS Receiving Departments, is prohibited. Receiving assumes no obligation in these cases for the reporting of damage claims, concealed damage, or for incorrect shipments.

Returning Goods to a Supplier

Returns of goods or materials originally ordered with an NCIRE purchase order require approval by the Office of Procurement. Procurement will contact the vendor to set up a return and obtain Return Material Authorization.

Occasionally it becomes necessary for a department to return materials to the vendor for credit or exchange. NCIRE Procurement coordinates the following types of returns:

- Incorrect items returned in exchange for correct items.
- Defective or damaged items.
- Over shipments.
- Excess material ordered by the department.
- Goods are no longer required.

Once the return has been authorized by the vendor, Procurement will contact the end-user and will schedule a time to pick up the item(s) for return.

Warranty and Vendor Repairs

Warranty repair orders must reference the original purchase order number. The following information must be indicated on the requisition in addition to the standard required information:

- Description of equipment. Include brand, model and serial number.
- Estimated cost of repair or warranty.
- Purchase order number of the item originally purchased against (if available).
- Number of cartons being shipped to the vendor.
- Complete shipping address. Provide street address, no P.O. Boxes
- Weight of package (if known)
- Whether the department wants the equipment insured; if so, the value must be provided. If more than one package is being shipped, the value of each package must be indicated.

All items must be properly packed, and each package must be completely sealed and labeled for shipment. Some vendors require that a repair authorization number be assigned to the repair job prior to shipment. If the requesting department has obtained the return number, indicate on the purchase requisition. If the materials need to be picked up for return, please contact your designated buyer to make arrangements with Receiving to pick this up.

If the requesting department requires the material to be picked up, contact your designated Buyer or note on the purchase requisition, the building/room number for the package(s) to be picked up.

In-House Repairs

In-house repairs are defined as repairs performed on-site by a vendor on a per call basis and charged at a time and material rate. These types of repairs are not covered under maintenance contracts unless otherwise specified under the maintenance contract.

Departments must obtain a purchase order number before scheduling service for an in-house repair. Each service call requires a new purchase order number.

Warranties

Many purchased items are delivered with a manufacturer warranty card or certificate. When necessary, it is the user department's responsibility to complete the card and return it to the vendor immediately for proper certification. The originating department should retain all warranty information. In the event a repair service is required during the warranty period, the warranty information must be included on the paperwork submitted to Procurement.

Heavy and Oversized Goods

The Office of Procurement has the responsibility for determining where incoming goods are to be shipped at the time of order placement with the vendor.

Procurement must notify the Material Handlers when ordering heavy equipment or equipment larger than the elevators. Space and weight restrictions may require for equipment to be delivered directly to a location by the vendor or the SFVAHCS movers. Personnel may need to be on hand to allow entry. Please advise your Buyer if any of these conditions apply to your order.

- Freezers and Refrigerators
- Large office furniture
- Items requiring forklift or pallet jack equipment

Mission Bay Location

Facility Access

Departments may request new key cards through the SFVAHCS Research & Development (R&D) office and approved by SFVAHCS Engineering. Once approved, Alexandra (Building Management) will contact us when the card is ready to be picked up at the 1700 Owens Street front desk.

Group shared CO2 system (3rd floor)

The CO2 manifold is located on the 3rd floor in room 349. The CO2 is shared with Endocrine, Orthopedic, and Dermatology labs. If a PI wishes to be added, they will need to establish departmentally their contribution to the expense, then submit a new requisition for an NCIRE issued purchase order indicating the percentage. The combined purchase orders cover the shared CO2 charges. Orders are placed by NCIRE Procurement with our current vendor Airgas.

Deliveries (NCIRE, SFVAMC, UCSF)

Deliveries are received by NCIRE Procurement in room 349.

Receiving's intake includes NCIRE, UCSF and SFVAHCS orders.

Receiving will document the items coming in and will deliver to the 3rd and 4th floors.

There are many entities that share space in the building. Please address mail and/or packages to 1700 Owens Street, including the correct affiliation (NCIRE, SFVAHCS or UCSF), followed by "Receiving, Rm. 349" to ensure delivery by the carriers to the correct location.

SFVAHCS and UCSF deliveries: Packing slips (if available) and tracking numbers will be recorded, filed and will be delivered to its destination. Packages with missing information (name, room number, phone number) will remain in Room 349, until the end-user claims it.

Courier service

Incoming and outgoing interoffice mail is scheduled with the courier every Wednesday.

Outgoing mail to the VA may be dropped off in Room 349 by 1PM. Interoffice mail goes directly to SFVAHCS mailroom for processing.

Hazardous waste

The SFVAHCS's Hazmat cage is located on the ground level of 1700 Owens St. Hazardous waste is picked up every month by an outside company contracted by the SFVAHCS. Contact James Greenwell at James.Greenwell@va.gov (415) 221-4810 x24177 to schedule a pickup request.

Safety and compliance

Address any issues or concerns to the appropriate SFVAHCS Contacts:

Radiation Safety (Steve Fong) Stephen.Fong@va.gov 415-221-4810 x 24950

Safety Specialist (James Green) James.Greenwell@va.gov 415-221-4810 x24177

Biosafety (Michael Kim) Michael.Kim2@va.gov 415-221-4810 x22229

Research Safety Office (Rakita Singh) Rakita.Singh@va.gov 415 221-4810 x24122

Building issues

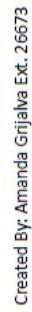
Minor maintenance can be addressed to the onsite SFVAHCS engineer. Anything that is behind the wall, can also be addressed to the building's engineering team or their management (Alexandria). Contact info will be provided upon request.

Housekeeping services

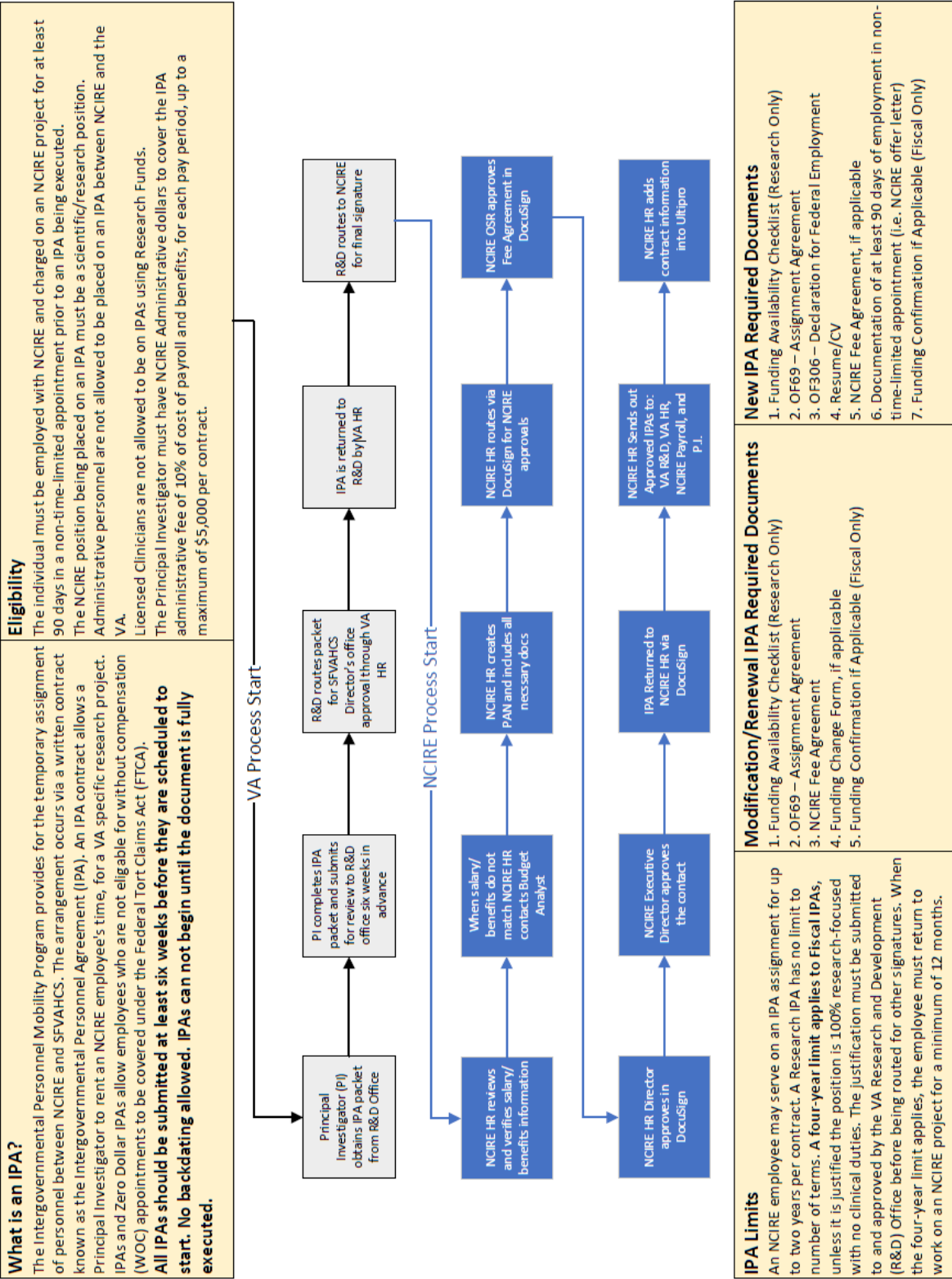
Housekeeping services are contracted by the SFVAHCS Environmental Management Services (EMS). They service all SFVAHCS areas, except for the VMU. Any questions can be directed to the EMS office at the SFVAHCS.



JPA Process Chart



IPA Chart





Promotion Request

Date (Enter)

To: Lydia Blednyh, Human Resources Director
From: Principal Investigator, (Enter)
Subject: Requested Promotion of (Employee first and last name)

Current title: (Enter current title)

Requested title: (Enter new title)

Requested Effective Date: (Effective date must be at the start of NCIRE pay period)

Proposed Increase from: \$(Enter) to \$(Enter)

New Positions exemption Status: ☐ Non-Exempt (hourly) ☐ Exempt (salaried)

(Please phone HR if unsure of exemption status)

Justification for promotion:

(Employees name) level of work experience has recently increased to include (List increased duties and accomplishments). (Employees name) has been given more responsibility (List responsibilities). These tasks are all consistent to that of (List new title). I am requesting a promotion for (Enter employees name) effective (Enter date, must be at the beginning of a NCIRE pay period).

Please let me know if you have any other questions.

A promotion request must a proposed job description attached at the time of submission. The proposed job description should clearly demonstrate a higher level of responsibility.



Salary Adjustment Request

Date (Enter)

To: Lydia Blednyh, Human Resources Director
From: Principal Investigator, (Enter)
Subject: Requested Salary adjustment for (Employee first and last name)

Employee's Current Title: (Enter current title)

Requested Effective Date: (Effective date must be at the start of NCIRE pay period)

Proposed Increase from: \$(Enter) to \$(Enter)

Reason: (i.e. market rate, retention, increased duties, equity)

Justification for Salary Adjustment:

(Employees name) level of work experience has recently increased to include (List increased duties and accomplishments). (Employees name) has been given more responsibility (List responsibilities). These tasks are all consistent to that of (List new title). I am requesting a promotion for (Enter employees name) effective (Enter date, must be at the beginning of a NCIRE pay period).

Please let me know if you have any other questions.



PI IPA Checklist

For an NCIRE employee to qualify for an IPA of any kind, the following must be true:

- ☐ The individual must be employed at and charged to an NCIRE project for at least 90 days in a non-time-limited appointment prior to the requested start date of an IPA.
- ☐ The NCIRE position being placed on an IPA is a scientific/research position, not administrative personnel. Licensed clinicians are not allowed to be on an IPA using Research funds, in accordance with [VA Handbook 5005](#) (Staffing) Section C on IPAs. Under section C.2. (Policy), "Under no circumstances should IPA agreements be used as a mechanism for hiring clinical staff or as a substitute for scarce medical specialist, sharing, commercial item or other clinical service contracts. Nor is it appropriate to use IPA agreements for administrative and support positions.
- ☐ The Principal Investigator must have NCIRE administrative funds to cover the IPA fee of 5% of payroll and benefits each pay period, with no cap. This must be paid by an NCIRE administrative account. Confirm funding with grants specialist.

New IPAs that are through the R&D office must have the following documents:

- ☐ R&D IPA Funding Availability Checklist
- ☐ IPA Agreement OF 69
- ☐ Resume or CV (N/A if extension only)
- ☐ OF 306 for Federal Employment Declaration
- ☐ Documentation of at least 90 days of employment in a non-time-limited appointment (i.e. NCIRE Offer Letter)
- ☐ NCIRE Personnel Funding Change Form
- ☐ NCIRE IPA Fee Agreement

Modification and Extensions IPAs must have the following documents:

- ☐ R&D IPA Funding Availability Checklist
- ☐ IPA Agreement OF 69
- ☐ NCIRE Personnel Funding Change Form (if applicable)
- ☐ NCIRE IPA Fee Agreement

For IPAs that are funded via SFVA Fiscal Budget Office, the following are required for a completed package:

- ☐ Routing Sheet
- ☐ Email from VA Fiscal confirming funding availability for length of IPA
- ☐ IPA Agreement OF 69
- ☐ OF 306 for Federal Employment Declaration
- ☐ Resume or CV (N/A if extension only)
- ☐ Documentation of at least 90 days of employment in a non-time-limited appointment (i.e. NCIRE Offer Letter)
- ☐ NCIRE Personnel Funding Change Form (if applicable)
- ☐ NCIRE IPA Fee Agreement
- ☐ Approval from Gregory Green, Director, Research Operations if applying for four-year limit waiver

Final Considerations

- Remember for all the above scenarios, there is a 2-year limit per contract. Research IPAs and zero-dollar IPAs may be renewed as needed via a new 2-year contract with no maximum renewal limit. Please note that a 4-year limit applies to Fiscal IPAs, unless it is justified the position is 100% research-focused with no clinical duties, and a waiver is approved via the R&D Office. When the 4-year limit applies, the employee must be moved back onto a NCIRE-administered project for a period of no less than 12 months.
- Effective October 1, 2025, the IPA administrative fee will be 5% of payroll and benefits for each pay period, per contract, without a cap. The fee is to offset administrative costs associated with processing and maintenance. The fee must be funded through unrestricted sources. Investigators sponsoring IPAs should have active awards and a direct connection to NCIRE.
- IPA must be submitted, at minimum, six weeks before the requested start date. IPAs submitted less than six weeks in advance will be rejected and a new start date will be assigned to meet the requirement. If the IPA is not approved in the six-week window, the IPA will be assigned a new future dated start date as retroactive dates are not allowed. To avoid this scenario, it is strongly recommended you submit your IPA documents ten to twelve weeks in advance.
- The PI and Employee must sign all IPA documents within a week of submission to the R&D Department.
- Principal Investigators are responsible for managing their renewals in a timely manner. Renewals should be sent three months before the end of the current IPA. Alternatively, if the employee is moving off the IPA and onto a NCIRE-administered project, a Personal Funding Change form must submit a minimum of two weeks

before the current IPA expires.