Grant No. P30-AI027763

CFAR FUNDING PROGRAM

CFAR is an NIH Center Grant at UCSF spearheading HIV/AIDS research since 1988

CFAR Director: Monica Gandhi, MD

Co-Directors: Peter Hunt, Mallory Johnson Associate Director: Lauren Sterling

A GUIDE FOR NEW AWARD RECIPIENTS
AND FINANCIAL ANALYSTS

1700 Owens Street, Suite 316, San Francisco, Mission Bay Campus

Congratulations on your CFAR Award!!

Quick timeline summary

REPORTING OUTCOMES

Final Progress report

- -Publications PMCIDs
- -Other grants K to R01
- -Promotions
- -Value added





2-4 WEEKS



[6-8 WEEKS + >]



ONE YEAR BEGINS



End date

Obtain all IRB, compliance, subcontract docs

Start Date

PRE-AWARD

Preliminary Award letter detailing requirements

- -IRB or IACUC compliance
- -NIH Checklist review
- -Budget review
- -Pre-Subcontract docs

SUBMIT NIH CHECKLIST(S) IF NOT PROCEED POST-AWARD

Collect or apply for IRB all other compliance Documents; Complete NIH checklist form (+6 weeks wait)

- Require IRB Docs/FWA numbers
- Completed Checklist sent to NIH for review (+6 weeks)
- -Subcontract docs

POST-AWARD

Final Award letter in place

- -One-year project begins
- -NIH final approval, if apply
- -Subcontract final docs, if apply
- -Funding is released
- -Monitor spending budget
- -6-month milestone report

How your CFAR award budget works

Management of your project #, fund year, etc.

The overall CFAR Grant budget runs from 9/1 to 8/31, which is likely to be different from your 1-year project period.

- This means that you will get a new Chart String for the portion of your project period that is after 9/1.
- The fund year will change every year, project # will also change as switching award cycles this year.

Your CFAR Project Overall: 1/1/20-12/31/2020

Your Proj P1: (1/1/20-8/31/20)

Your Proj P2: (9/1/20-1/31/21)

CFAR Year 30 (9/1/21-8/31/22)

CFAR Year 31 (9/1/22-6/30/23)

Business Unit	Fund	DeptID	Project	Activity Period	Function
SFCMP	4000	*YouProvide	*WeProvide	Example (FY 30) Start: 9/1/21 End: 8/31/22	44



Post-Award Process

You received a Final Award letter and your 1-year project period begins. If international project > you received the final NIH approval = you can finalize the Subcontract agreement between UCSF & other local or foreign institution. Once processed by Contracts and Grants, CFAR funding is released.

I. CFAR Pre-Award Explained

Preliminary Award Letter	Establishes terms of your award, CFAR sends to letter to Awardee No funds available until all IRB/NIH approvals received.	
Instructions for Human Subjects Compliance	Human Subjects IRB or waiver / IACUC - http://irb.ucsf.edu/levels-review; ; Human subjects protection training (CITI) https://irb.ucsf.edu/citi-human-subjects-training	
NIH International Checklist and/or Clinical Checklist	If study takes place in a foreign country (whole or partial) complete the NIH checklist for clearance. Once checklist at NIH it takes approximately 6-8 weeks to receive NIH approval. Brenda and Lauren will assist you to complete form: International Studies Checklist for all CFAR-Supported International Studies	
Review of Budget	CFAR reviews budget together with Awardee, once resolved, budget is finalized	
Subcontract Documents	If award is subcontracted to a non-UCSF institution, you are responsible for making sure expenditures are appropriated. Three additional documents to be submitted to subcontract desk. 1. Scope of Work 2. Letter of Intent – (requires Institutional signature) 3. UCSF Sub-recipient Commitment form (requires Institutional signature)	
Global Programs http://ucglobalprograms.org/	Global Programs provides administrative support for UCSF research in Kenya, Mozambique, Namibia, Tanzania, and Uganda. They can assist in local procurement and payment, and their use may be required depending on the international partner institution (e.g. KEMRI).	

II. Post-Award Process

Final Award Letter Release of Funds	Final award letter with project period (one year) starts post-award process > Funds are released	
No Cost Extensions	NCEs - Require CFAR Director's approval and are not recommended.	
Payroll/Purchasing/ Travel	Payroll, Purchasing and Travel changes should be made in the local department (Subcontracts with CFAR Admin)	
Budget > Charges	All charges must be REASONABLE , ALLOCABLE , CONSISTENTLY TREATED , AND ALLOWABLE . See <u>Contracts and Grants accounting guidelines</u> .	
Re-budgeting	You have the authority to rebudget up to 25% total costs without approval. If you require significant rebudget, contact Lauren Sterling . Be sure to spend funding consistently throughout the life of award. See next slide, 'How your budget works.'	
Advances	No advances permitted while waiting for NIH approval.	
Global Programs http://ucglobalprograms.org/	If applicable, Once final award letter sent, final budget and justification will be sent to Global Programs. They will act as the middle-man between KEMRI and UCSF expediting payment costs for your award.	
(At UCSF) PI Review of Expenses/General Ledger Verification	You as the PI are responsible to review your grant expenses regularly (at least quarterly). Please meet regularly with your financial administrator to review the expenses posting on your grant, as they are responsible for completing monthly general ledger verification for your project.	

If any of your IRB/IACUC approvals lapse, you must stop all work on your project!

We will be watching your approval dates, but we also expect you to know when your approvals expire and to submit your renewal requests on a timely basis. We cannot pay for any expenses that occur while any of the regulatory approvals are lapsed.

NIH Cost Principles + Unallowable Costs

NIH's Cost Principles

- Reasonable a prudent person would have paid that price
- Allocable directly benefits the grant and is assigned (at least in part) to the grant
- Consistent costs treated the same regardless of funding source
- Conforming/Allowable meets the terms and conditions of the award (see right)



Types of unallowable costs may include:

- Stipend payments
- Alterations and renovations
- Patients care costs
- Entertaining expenses which include alcohol
- Food
- TRAVEL (please check with us)

Summary of Subcontract Process

Subcontract Documents:

- --Scope of Work
- --Sub-recipient Letter of Intent
- --Sub-recipient commitment form
- --Budget Foreign and Domestic to be reviewed
- ? Advance (only if necessary)

CFAR Subcontract Review

CFAR will check your Subcontract documents for institutional signatures

Budget / justification finalized

If KEMRI budget, Awardee and Financial administrators work with Global Programs to finalize international budget

Subout Desk

Institutional agreements drawn

Account is set up

Chartstring is set up

One year begins

No carryforwards allowed

Account
setup;
Project date
set; Final
Award letter
sent!



Pre-Award Process Details

You received a Preliminary Award letter advising you of your award instructions for the compliance process. If international work, it will requires completing the International checklist form and pre-subcontract documents (UCSF vs institution agreement). Other Budget essentials discussed. Note: you cannot begin your study until all approvals have been received!

Compliance Checklist:

This checklist determines the IRB documents your project requires (see your award letter)

This effective determines the IND documents your	project region es (ess year arrans retter)
Preliminary Summary of Special Appro	
HUMAN SUBJECTS/SPECIMENS / DATA	REQUIRED APPROVALS
IF fully de-identified data or specimens>	Self Certification Form
IF Exempt Review>	Exempt certification approval
IF Minimal Risk>	Expedited Review approval
IF Above Minimal Risk>	Full committee Review approval
HUMAN SUBJECTS CERTIFICATES TYPES	
IF Exempt or Expedited IRB or INTL/Clinical>	PI only
IF <u>Full Committee</u> or includes Vulnerable Populations	All key personnel
>	
STUDY RISK IS EITHER OR BOTH	вотн
Above Minimal Risk;>	NIH Clinical Checklist, AND
OR Vulnerable Populations>	Study Specific Research Protocol + Consent Docs
IF DOING INTERNATIONAL RESEARCH >	NIH International Checklist
IF Animal Research>	IACUC Approval
Not at UCSF>	UCSF IACUC MOU
IF YOU HAVE A CURRENT T32 AWARD	
Yes / No If yes>	Confirm T32, and no salary
	Provide your T32 budget
IF YOU HAVE A CURRENT K-AWARD	Confirm Salary <25% plus specific aims for K
Yes No If yes>	
IF Subcontract (KEMRI, Vitalant, Gladstone, Other)	
Yes No>	
at KEMRI>	
at NEWKI	Giobai Frograms budget

Summary of CFAR NIH International Checklist Process

Int'l Checklist form

FWA numbers (UCSF + foreign)
Foreign budget component
Specific Aims table

+

Documents:

IRB approvals from UCSF and foreign (3-6 weeks)

Human Subjects CITI certificates for key personnel

Internal Review / CFAR & You

CFAR will check your checklist for completion/accuracy (IRBs, FWA#, budget, review of aims table, CITI docs)

Final checklist Sent to NIH

Checklist at NIH queue
IF questions, address them
Resend checklist to NIH with
revisions

Approval wait 3-6 weeks
Requires notice of NIH
approval before project can
begin

After NoA
Approval,
Start the
Subcontract
Phase below

While waiting on approval, gather subcontract docs

Summary of CFAR NIH Clinical Checklist Process

Clinical Checklist form Documents:

IRB approvals (if received)

FWA numbers (all participating institutions)

Human Subjects CITI certificates for key personnel

Consent forms

Study-specific research protocol
Data Safety Monitoring Plan

Internal Review / CFAR & You

CFAR will check your checklist for completion

Review of IRBs, FWA#

Review of HS training docs

Review of Research protocol and consent forms

Final checklist Sent to NIH

Checklist at NIH queue

Update checklist with NIH if revisions requested or IRB approval updates

Approval wait 3-6 weeks

Email notice of approval required

After NoA
Approval,
Start the
Subcontract
Phase below

NoA = Notice of Award NIH

Part III: Completion of Award, Reporting to NIH

Your outcomes matter to CFAR, metrics such as new Publications, Grants (K, RO1s) and Promotions are imperative for CFAR's return on investment ROI. They keep a running tab on ROIs which are linked to our CFAR.

- Provide one-page progress reports as requested by NIH, twice a year.
- Final Progress Report must include all publications directly related to your CFAR training grant along with PMCID numbers! was close to a breakthrough when
- Include pertinent manuscripts in progress.
 http://www.ncbi.nlm.nih.gov/pmc/pmctopmid/
- List any or all subsequent awards received directly related to your CFAR, e.g. K - R01 Awards
- Acknowledge CFAR:

This research was supported by a grant from the National Institutes of Health: UCSF-Bay Area Center for AIDS Research (P30 AI027763).

If you leave UCSF, please provide your contact information. \odot



Acknowledgements and Questions

Questions? Let us know:

- Lauren Sterling
- Brenda Sanchez
- Rado Lee



WHO, WHAT, WHEN, WHERE

WHO: NIH funded since 1988. The UCSF-Gladstone Center for AIDS Research (CFAR) seeks to expand HIV research occurring at the intersections of basic, clinical, and behavioral / epidemiological scientific disciplines.

WHAT: CFAR is the first established funding agency at UCSF, we spearheaded the establishment of the RAP Funding Portal in 2007. We offer these funding mechanisms:

- Mentored Scientist Award \$50k
- Pilot Award Program for Investigators New to HIV \$50K
- International Mentored Scientist Award \$30K
- **Boost Awards** \$50 \$5000 (seed money to develop ideas, gather pilot preliminary data, etc.)

In addition, CFAR operates its own unique <u>Mentoring Program</u> designed for early-career investigators professional development. The Program is Co-directed by Jonathan Fuchs and John Sauceda.

WHEN: Request for Applications (RFAs) occur twice a year, Spring and Fall.

WHERE: CFAR is located at 1700 Owens Street, Suite 316 (Mission Bay)

NIH International Collaborations Map

Our CFAR Awardees have been active in Africa, Central and South America, India, Iran

