Grant No. P30-AI027763

CFAR FUNDING PROGRAM

CFAR is an NIH Center Grant at UCSF spearheading HIV/AIDS research since 1988
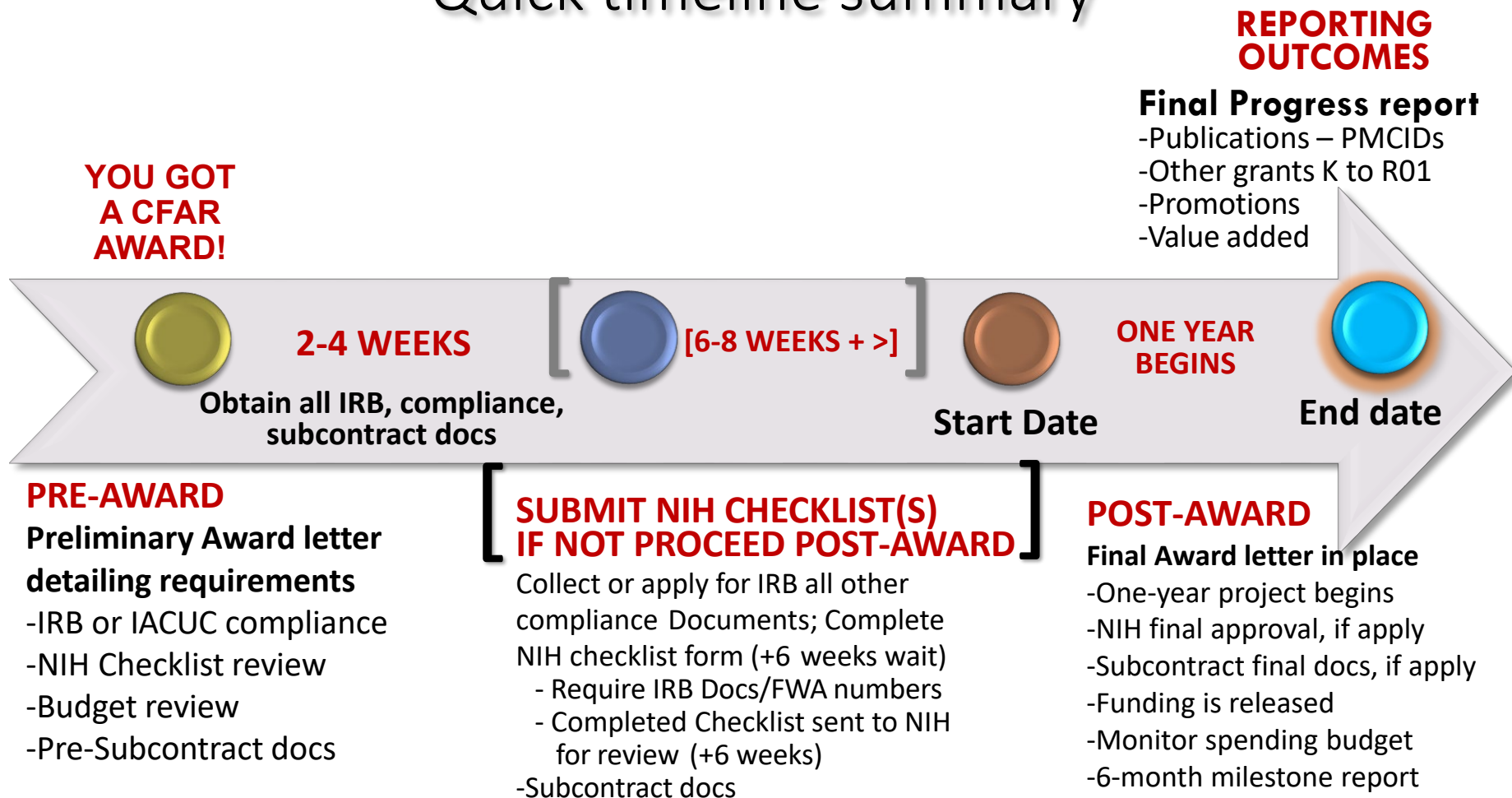
CFAR Director: Monica Gandhi, MD
Co-Directors: Peter Hunt, Mallory Johnson
Associate Director: Lauren Sterling

**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

YOU GOT A CFAR AWARD!

2-4 WEEKS

Obtain all IRB, compliance, subcontract docs

[6-8 WEEKS + >]

ONE YEAR BEGINS

Start Date

End 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 7/1 to 6/30, which will likely differ 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 7/1.
- The fund year will change every year, project # will also change as switching award cycles this year.

Your CFAR Project Overall: 1/1/24-12/31/24

Your Proj P1: (1/1/24-6/30/24) **P2: (7/1/24 – 12/31/24)**

CFAR Year 32 (7/1/23-6/30/24) **CFAR Year 33 (7/1/24-6/30/25)**

Business Unit	Fund	DeptID	Project	Activity Period	Function
SFCMP	4000	*YouProvide	*WeProvide	Example (AP 32) Start: 7/1/23 End: 6/30/24	44

Pre-Award Process

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)

| Preliminary Summary of Special Approvals / Compliance Required	
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 <u>Exempt</u> or <u>Expedited</u> IRB .... >	PI only
IF <u>Full Committee</u> or or INTL/Clinical .... >	All key personnel
STUDY RISK IS EITHER OR BOTH	**BOTH**
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…...........................>	differs from CFAR
IF Subcontract (KEMRI, Vitalant, Gladstone, Other)	
Yes No …...................................>	Subcontract / per institution
at KEMRI ……………………................>	Global Programs budget

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.

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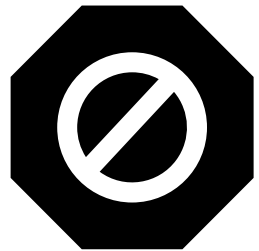
We will be watching your approval dates, but we also expect you to know when your approvals expire and to submit your renewal requests on a timely basis. We cannot pay for any expenses that occur while any of the regulatory approvals are lapsed.

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

--NIH face page
--Sub-recipient commitment form (signed)

--Budget & budget justification

-- IRB approval if required

-- F&A rate agreement (domestic)

-- Advance request if necessary

CFAR Subcontract Review

CFAR will check your Subcontract documents for any edits required before routing them to the UCSF subout desk

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

Subout Desk

Institutional agreements sent to the subrecipient institution for review/signature

UCSF signs the agreement after the subrecipient returns the partially executed agreement

Send invoices to cfarsubaward@ucsf.edu.

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

I. CFAR Pre-Award Explained

Preliminary Award Letter	**Establishes terms of your award, CFAR sends to letter to Awardee (cannot receive funds until all IRB/NIH approvals received domestic or international)**
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).

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

While waiting on approval, gather subcontract docs

After NoA Approval, Start the Subcontract Phase below

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, R01s) and Promotions are imperative for CFAR's return on investment ROI. They keep a running tab on ROIs which are linked to our CFAR.

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"I was close to a breakthrough when the grant money ran out."

- 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!

- 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

- <u>Acknowledge CFAR:</u>
  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. ☺

Acknowledgements and Questions

Questions? Let us know:

- Lauren Sterling
- Brenda Sanchez
- Rado Lee

"There are no stupid questions, so let's also agree there are no stupid answers."

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 Mentoring Program 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