



California AIDS Multi-Institutional Clinical Studies 2008 Application Guidelines / Instructions

Overview

For a general summary of CHRP award types, funding caps, review criteria and other information, see our [Call for Applications](#). Below is a general summary of this award type.

A. Award: California AIDS Multi-Institutional Clinical Studies.

B. Type of Research: HIV/AIDS clinical research on critical issues confronting the California HIV epidemic.

C. Maximum Award: The total combined amount for this award may not exceed \$1,000,000 per year in direct costs for three to five participating institutions.

D. Duration of Award: Maximum of three years beginning April 1, 2009.

E. Investigator Eligibility:

A lead investigator at each participating institution must have principal investigator status at that California institution and must commit to the proposed project a minimum of 1.2 person-months of effort (10%) for a 12-month appointment or equivalent effort.

F. Institutional Eligibility: Applicant institutions must be nonprofit academic or research institutions or 501(c)(3) non-profit institutions in California. All participating institutions must have currently active research programs and a record of peer-reviewed research funding in HIV clinical science.

G. Intent of Award: The purpose of this initiative is to provide support for one or two multi-institutional clinical collaborations that will address critical issues confronting the HIV epidemic in California, particularly for those populations most adversely and disproportionately affected by HIV/AIDS. Each award will comprise a collaboration among three to five California institutions. In addition, Research teams will be expected to have the flexibility to reallocate appropriate resources to new and unanticipated clinical research questions that may emerge during the award period.

H. Evaluation Criteria:

Reviewers will evaluate CAMICS applications for:

- The strength of the design, methods, and plans for analyses for the proposed research studies
- Likelihood that the proposed studies will make a significant contribution to advancing science in HIV/AIDS and have an impact on the California HIV epidemic
- Qualifications of the investigators who will be conducting the proposed studies
- The extent to which the participating institutions have complementary and substantive roles in the proposed research and appear to have collaborated in the preliminary studies/activities and planning for the proposed studies
- The reasonableness of the proposed budget and duration of the project in relation to the proposed research
- The extent to which the proposed research infrastructure is in alignment with the proposed research
- The extent to which the research addresses a population or populations that are most adversely and disproportionately affected by the California HIV epidemic, and the potential and methods for recruitment and retention of study participants.

Submission and Deadlines

Before preparing and submitting an application, a Letter of Intent must be submitted online at [proposalCENTRAL](#) and approved by CHRP. Approval of the LOI provides access to the application materials and application submission web pages on proposalCENTRAL.

Letters of Intent are due before noon Pacific Time (3:00 pm Eastern Time) on Tuesday, September 30, 2008.

Complete applications, with the exception of the signed signature pages, are due online before noon Pacific Time (3:00 pm Eastern Time) on Friday, November 14, 2008. After the application is submitted, an automatic verification e-mail will be sent to the applicant.

All times on the proposalCENTRAL web site are in U.S. Eastern Time. Note: Due times at proposalCENTRAL are set to [official U.S. time](#). Computers and telephones often do not display the correct time.

There is no grace period. You will not be able to submit your application after the deadline. Do not submit hard copies of your application.

A complete online application includes entry of all required elements and uploads of all required items in PDF format at proposalCENTRAL. Applicants are responsible for converting documents to PDF format. Do not submit PDF documents with password protection or electronic signature.

Submission of signed signature pages: Print the signature pages from proposalCENTRAL when the application is complete using proposal section 13 (see below). Both the face page and an applications contact page are generated. The face page must be signed by the principal investigator and the signing official at the lead applicant institution. An additional co-principal investigator and the signing official at the co-principal investigator's institution must sign in the "additional signature" fields. Other co-principal investigators and corresponding signing officials must sign over or near the contact information on the contact information pages. The signed document, including the application contacts, may be scanned, saved as a PDF document, and submitted to CHRP by e-mail (chrp@ucop.edu) by **5 p.m. on Friday, Nov. 28**, or received by mail by that time and date using the address below. **No in-person delivery is permitted.**

CHRP's mailing address is:

California HIV/AIDS Research Program
University of California
Office of the President
300 Lakeside Drive, 6th Floor
Oakland, CA 94612-3550

Contact number: 510-987-9855

Alternatively, the signature pages, including the application contacts, may be printed separately at each partnering institution, signed as directed above, scanned to PDF separately, combined into a **single PDF document**, and submitted by e-mail as described above.

Applications without required signatures, with missing sections, which do not meet eligibility requirements, or which do not adhere to these instructions, including required formats (font size, margin size, and page lengths) are subject to administrative rejection by CHRP without peer review. CHRP reserves the right to withdraw administratively applications for which signed signature pages are not received by the above deadline.

Applicants who have had previous awards from CHRP, the California Breast Cancer Research Program, or the Tobacco-Related Disease Research Program must have all past due fiscal and scientific reports from such awards submitted and approved or new applications are subject to administrative rejection. Any such matters must be resolved before the submission of the new application.

Applicants will be notified of the outcome of their applications by late February or early March, 2009. The anticipated start date for funding is April 1, 2009.

Online Application System

All uploaded files must be in PDF format. For information on PDF conversion, see proposalCENTRAL FAQ and Help files. A list of web-based and software conversion utilities can be found at: <http://www.neh.gov/grants/grantsgov/pdf.html>

***Important:** Do not upload any PDF documents with password protection or electronic signatures.*

Hard-copy items can be scanned to create an image file (e.g. gif or jpg) and then converted to PDF. Be sure that the scan is a high quality image.

For technical assistance with the application submission at proposalCENTRAL, a helpline is available for questions from applicants on weekdays from 5:30 a.m. to 2:00 p.m. Pacific Time. Phone: 1-800-875-2562 or email: pcsupport@altum.com

Application Instructions

Application Contents: To gain access to the application pages and materials on proposalCENTRAL, an applicant must first submit a **Letter of Intent at proposalCENTRAL and the LOI must be approved by CHRP**. Applications will be evaluated on the criteria listed above (Overview, Section H), so it is important to address those criteria in developing a proposal. A complete application consists of the following (maximum length in pages given where applicable):

- A. Signed Signature Pages – proposalCENTRAL generates signature pages from information supplied online after the application is validated (all required items and information uploaded or entered).
- B. Title Page
- C. Applicant Information
- D. Applicant Institution and Contacts
- E. Co-Principal Investigators
- F. Scientific and Lay Abstracts
- G. Budget Summary (Combined)
- H. Organizational Assurances
- I. Narrative Section and Other Attachments:
 - i. Narrative Section
 - Institutional Collaboration and Arrangements – 5 pages
 - Rapid Response Capability – 3 pages
 - Research Proposal – 15 pages for each study
 - References/Literature Cited – 3 pages for each study
 - ii. Human Subjects Description
 - iii. Detailed Budget and Justification (Institution 1)
 - iv. Detailed Budget and Justification (Institution 2)

- v. Detailed Budget and Justification (Institution 3)
 - vi. Detailed Budget and Justification (Other Institutions, if applicable)
 - vii. Biographical Sketch (PI 1)
 - viii. Biographical Sketch (PI 2)
 - ix. Biographical Sketch (PI 3)
 - x. Biographical Sketch(es) (other co-principal investigator(s), if applicable, and key personnel)
 - xi. Appendices – 40 pages maximum- Potential items include:
 - Draft consent forms, for the use of human subjects
 - IRB approval of the project proposed here
 - Supporting manuscripts or articles
 - Letters of support or collaboration
 - Detailed Budget for subcontract(s)
- J. Demographics of Human Research Subjects

Section Explanations: The following numbered explanations correspond to the numbered Proposal Sections seen in the left hand column of the application page at the proposalCENTRAL web site. This page appears when “Edit” is selected under the Manage Proposals tab. Sections 1, 3, 4, 5, 6, 7, 8, 9, and 11 require online entry of information. Section 1 (Title Page) must be completed first. Section 3 allows you to designate others to have access to your application. Section 10 requires multiple uploads of PDF documents. All parts of the application can be edited before submission. After section 1, the remaining sections listed above can be completed in any order, and do not need to be completed in one session. Section 2 provides the templates and additional instructions needed to complete section 10 (the same files are also available within section 10).

1. Title Page (complete online): The project title may not exceed 60 characters and may not include quotation marks.

After entering the title, select “Save”, and select “Next” to continue.

2. Templates and Instructions. These are necessary to complete section 10 (see below). The same documents are also available from within section 10.

3. Access Privileges. Here you can provide access to your application to other parties. You can designate that a given party have “view only” access, if desired. Providing access to collaborating partners is encouraged in order to facilitate joint preparation of the application.

4. Applicant (PI 1 – complete online): The PI representing the institution where the administrative core will be located must take the lead in completing the application on proposalCENTRAL. This individual is called the “Applicant”. ProposalCENTRAL allows the applicant to enable colleagues and staff to access and modify the proposal (see previous **Access Privileges, Section 3**).

Most of these fields populate automatically with data from the applicant’s Professional Profile.

State if you have had any prior business with CHRP such as a grant applicant or a participant on our Advisory Council (f.k.a. Task Force) or any committee. If you used a different name at that time, please specify.

5. Applicant Institution and Contacts (complete online): Include key information for the applicant PI’s Signing Official (Grants Officer) and Fiscal Contact. Do not use generic e-mail addresses (e.g. contractsandgrants@medfield.edu).

6. Co-Principal Investigators and Contacts (complete online): Enter information for each co-principal investigator, including a signing official (Grants Officer) and a fiscal contact. The “Applicant PI” and associated key officials should not be entered here as that information was previously submitted in Sections 4 and 5 above. There is to be one co-principal investigator from each of the additional 2-4 participating institutions, except for institutions where subcontractors and consultants will be located, if applicable. For other key personnel, including subcontractors or consultants, choose “other” from the drop-down menu and specify the role in the text box. Enter these individuals from all institutions here. Do not use generic e-mail addresses (e.g. contractsandgrants@medfield.edu). Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

7. Scientific and Lay Abstracts (complete online): Provide a brief description of the proposed study’s long term objectives and specific aims, making reference to the potential impact and/or significance to HIV/AIDS research and attentiveness to the needs of California. Describe concisely the study methods for achieving these goals, highlighting the innovative aspects of the proposed study. The scientific abstract should be directed to Program Officers and Reviewers. The lay abstract should be directed to community reviewers and is designed for publication and distribution to audiences who are less familiar with scientific matters. *Each abstract is limited to 4,500 characters, including spaces.*

Because the abstracts are entered into text boxes, special characters such as Greek letters, superscripts, subscripts or italics are not permitted.

Keywords: Choose a minimum of three keywords that best categorize the proposed research.

Research Area: From the Research Area List (also shown below), choose the research areas that best describe the focus of your proposal (more than one area can be selected using “control click”, or they can be added individually):

- 01 Vaccine Development
- 02 Antiviral Strategies/Therapeutics

- 03 Molecular Biology of HIV
- 04 Pathogenesis of HIV
- 05 Basic Immunology
- 06 Molecular Biology of OI/Malignancies
- 07 Pathogenesis of OI/Malignancies
- 08 HIV Immune Response
- 09 Diagnosis of HIV and AIDS-Related Diseases
- 10 Treatment for HIV and AIDS Related Diseases
- 11 Clinical Epidemiology
- 12 Behavioral Epidemiology
- 13 Precursors and Contexts of Transmission
- 14 Determinants of Health Care-Related Behavior
- 15 Prevention Interventions
- 16 Prevention Evaluation
- 17 Health Services
- 18 Health Policy

8. Budget Summary (complete online): Provide summary budget information for each project year for all the collaborating institutions combined. The maximum term for the project is 3 years. For a three-year award, Period 1 will be 04/01/2009 to 03/31/2010, Period 2 will be 04/01/2010 to 03/31/2011, and Period 3 will be 04/01/2011 to 03/31/2012. The grant award is limited to \$1,000,000 per year plus indirect costs. Include any equipment costs under "Supplies and Expenses". Also, include infrastructure costs in "Supplies and Expenses".

University of California institutions are not eligible for indirect costs. Non-UC institutions are eligible for indirect costs up to 25% of eligible direct costs. Be sure that the amounts are the appropriate sums of those entered in the Detailed Budgets (Section 10).

9. Organizational Assurances (complete online): Indicate whether human subjects, or animal subjects are to be involved in the proposed research. This information is required for all applications, *whether or not* the proposed research involves such subjects.

Documentation of Institutional Review Board (IRB) approval is not required at the time of submission. Please begin your assurance process as soon as possible. The project must be submitted to the appropriate IRB(s) before or within 21 days of notification that an award has been made. If an award is made, CHRP will request verification of approval (see "Pre-Award Requirements" below for details). Funding will not be released until appropriate verifications have been received. If all reasonable efforts are not made to obtain IRB approval(s) in a timely fashion, funds may be reallocated to other potential grantees' proposed research projects.

10. Narrative Section and Other Attachments This section requires multiple PDF uploads as outlined below. The required items can be uploaded in any order, and do not need to be uploaded in a single session. For each template that is provided, you must fill out the document header. *The minimum font size is 11 point, (8 point for figures and graphics). The minimum margin size is 1/2 inch. There is no required font style, but Times New Roman or Arial are recommended.*

Narrative Section (template provided – upload single PDF): This section includes:

- Institutional Collaboration and Arrangements – 5 pages
- Rapid Response Capability – 3 pages
- Research Proposal – 15 pages for each study
- References – 3 pages for each study

Combine all sub-sections, in the above order, into a single file with each sub-section starting on a new page. Page formats and limitations for each section must be strictly observed. Number the pages (bottom center) starting from 1.

Institutional Collaboration and Arrangements: Provide a narrative that describes collaborative activities and arrangements planned for the research project or projects. Describe the salient features of the setting or context in which the research project will be undertaken and how these features may have an impact on the research process and outcomes. Describe the substantive and complementary roles of each institution. Describe the research capacity of the participating institutions in the context of the proposed research, including infrastructure and special resources, either in place or planned. Describe any training activities, such as participation by medical fellows, postdoctoral fellows, or graduate students in the proposed research, if applicable. Describe any role to be played by new investigators, if applicable. If warranted by the proposed research, describe the role, activities and general composition of a data safety monitoring board. *Limit to 5 pages.*

Rapid Response Capability: Start on a new page, and provide a description of the capability of the collaborating institutions and personnel to reallocate resources to address unanticipated critical clinical research questions should any arise during the award period that warrant a rapid response. Highlight research areas in which the collaborating research team has particular strength, and special enabling resources. *Limit to 3 pages.*

Research Proposal: Start on a new page and limit to 15 pages for each study. It is expected that either one or two substantive research studies will be proposed. Be sure to address the evaluation criteria set forth in the application instructions. Provide a clear and concise description of the proposed study or studies. Use sections as listed below. Specify the research problem or hypothesis and specific aims. Explain the supporting rationale for the study or studies in the context of the current literature and unpublished findings, if applicable. Describe how it involves unexplored and new areas of knowledge in HIV/AIDS and the potential impact on the field. Provide details of the research design and methods. Include an explanation of how the research may lead to an expanded research effort in the future, including specific grant mechanisms and funding agencies. Specify how the study is attentive to the needs of the State of Cali-

fornia. A timeline at the end of the research design and methods section will demonstrate how the aims are interrelated, prioritized, and feasible. *Limit to 15 pages for each study.*

References/Literature Cited: Include complete titles for each citation. *Limit to 3 pages for each study.*

Human Subjects Description (template provided – upload PDF):

1. Detailed description of the involvement of human subjects in the project.
2. Identify the sources of research material specimens, records, or data.
3. Characteristics of the subject population, especially underserved or under-researched groups (Enter numbers in Proposal Section 11).
4. Describe the plans for recruiting subjects and documenting consent.
5. Describe any potential risks—physical, psychological, social, legal, or other.
6. Describe the procedures for protecting against, or minimizing, any potential risks.
7. Discuss why the risks are reasonable relative to the anticipated benefits.

Detailed Budgets and Justifications (template provided – upload PDFs): Complete a detailed budget and justification separately for each of the collaborating institutions covering the entire award period. Use whole dollar amounts.

Item 1, Personnel: Enter total personnel costs for each grant period. To calculate personnel costs, use the tables at the bottom of the page. List all key personnel for the appropriate institution as in Proposal Section 6, or PI 1 entered in Proposal Section 4, if applicable, whether or not salary and benefits are requested. Do not list subcontractors here. Additional rows may be added to the tables, if necessary. Each of the Co-Principal Investigators must allocate a minimum of 1.2 person-months effort (10%) for a 12 month appointment or equivalent effort. Award funds may not be used to increase or supplement total approved compensation beyond 100% full-time equivalent.

The salary requested should not exceed that commensurate with effort and the annual salary. CHRP accepts effort without pay.

CHRP is adopting the NIH policy of reporting effort in person-months. Enter the appropriate person-months under “Effort in Person-Months”. To convert percent effort into person-months, use the following resources:

http://grants.nih.gov/grants/policy/person_months_faqs.htm and
http://grants.nih.gov/grants/policy/person_months_conversion_chart.xls

Item 2, Consultant/Contractual Costs: Enter direct costs and explain in the Budget Justification. Do not include any indirect costs here. Provide amounts for subcategories in the Budget Justification, if applicable. If indirect costs are requested for a non-U.C. institution issuing a subcontract, or for a non-U.C. institution receiving a subcontract, follow the rules on the detailed budget form. Include subcontract personnel costs here, and clarify in the budget justification including names and affiliations of key subcontract personnel. Do not include subcontract personnel costs in the key personnel tables.

Item 3, Supplies and Expenses: Provide the total cost of supplies and expenses, including equipment and infrastructure. Equipment is defined as non-expendable, tangible property that is free standing and has a normal life expectancy of one year or more. Special permission must be obtained from CHRP to purchase equipment that costs more than \$5,000 per item. The cost of equipment purchases of \$5,000 or more per item must be subtracted from the direct costs before calculating indirect costs for non-U.C. institutions (see item 6 below).

Items 4a and b, Project-Related Travel and Scientific Meetings: Elaborate on each item in the Budget Justification. Describe the nature and purpose of project-related travel, and provide specific meeting information for scientific travel.

Item 6, Indirect Costs: University of California institutions are not eligible for indirect costs. Non-UC institutions are eligible for indirect costs up to 25% of total eligible direct costs, or at the rate established for the institution through a U.S. Department of Health and Human Services (DHHS) negotiated indirect cost rate agreement (or other similarly established rate), whichever is lower. Indirect costs should be calculated at the lower rate and shown on the budget. All direct costs at non-U.C. institutions are eligible, except for equipment purchases more than \$5,000 per item. The cost of equipment purchases more than \$5,000 per item must be subtracted from the direct costs before calculating indirect costs for non-U.C. institutions. If indirect costs are requested for a non-U.C. subcontracting organization, or by a non-U.C. institution issuing a subcontract, follow the rules on the Detailed Budget and Justification form.

Documentation of an institution’s DHHS indirect rate agreement or alternate rate agreement must be submitted upon request if an award is offered to a non-U.C. institution, or if a subcontract to a non-U.C. institution is proposed.

On the included pages, provide a narrative justification of the amounts requested in each category. Limit the justification to 5 pages.

Biographical Sketches (template provided – upload PDFs): Include Biographical Sketches for each of the Co-Principal Investigators and the Key Personnel. Include other support, where applicable. List current and pending research and non-research activities, including paid faculty, clinical, or administrative appointments. Specify possible overlap and the proposed resolution. Limit each biosketch to 6 pages. For calculating effort in person-months, see the links provided above in the instructions for “Detailed Budgets and Justifications”.

Appendices (upload PDF files): Items may include: data collection instruments or draft consent forms, letters of commitment from consultants and/or collaborators, IRB approvals for the project proposed in this application, no more than two reprints or manuscripts, and detailed budgets for subcontracts. While the applicant may submit multiple files, limit the appendix section to 40 pages total.

11. Demographics of Research Subjects (complete online): Provide the numeric breakdown of proposed human subjects according to gender and race/ethnicity.

12. Validate. The web site will run an automatic checklist for all required items including the uploads listed as required in Section 10. Any missing required items will be listed, and if there are no missing required items, you will be invited to proceed.

13. Print Face Page(s) When Application Complete. This procedure generates signature pages (including application contacts) and allows the application to be combined into one PDF document. For instructions on the submission of the signature pages, see "Submission and Deadlines" on page 2 of these instructions.

14. Submit. You must submit before noon Pacific Time (3 p.m. Eastern Time) on November 14, 2008. Submit the signed signature pages according to the "Submission and Deadlines" section of this document.

Pre-Award Requirements

Human Subjects:

Approvals for human research subjects are not required at the time of application. If an award is offered by CHRP, you must supply verification of IRB approval(s). Funding will not be released until satisfactory verification(s) have been received by CHRP. Applicants are encouraged to apply to the appropriate board as soon as possible in order to expedite funding, and you must do so before or within 21 days of notification that an award has been offered. CHRP may request a copy of the IRB application. If all reasonable efforts are not made to obtain appropriate approvals in a timely fashion, funds may be reallocated to other potential grantees' proposed research projects. **IMPORTANT:** Approvals obtained under a different title, investigator, or organization are *not* acceptable, unless they cross-reference the proposed project. If necessary and appropriate, apply for an amendment to an existing approval. Approvals must have specified start and end dates.

Other Requirements:

Upon request, awardees must supply the following information or documents:

1. Verification of Principal Investigator status from an appropriate institutional official.
2. Documentation of 501(c)(3) non-profit organization status, if applicable.
3. Documentation of the DHHS-negotiated (or equivalent) indirect cost rate for non-U.C. institutions.
4. Detailed budgets and justifications for any subcontract(s).
5. Resolution of any scientific overlap issues with other grants or pending applications.

Contacting CHRP

For questions about this document, templates or template instructions, please contact:

Dragana Nikolajevic, MA, MPA
Grants Analyst
510-987-0660
dragana.nikolajevic@ucop.edu

For technical questions about the online application process, contact proposalCENTRAL:

800-875-2562, weekdays from 5:30 a.m. to 2:00 p.m. Pacific Time
pcsupport@altum.com

Program Officer

For other inquiries, contact the program officer for this award type. All applicants are encouraged to contact the appropriate CHRP program officer before submitting an application for any grant mechanism. Contact with the program officers provides feedback that applicants can take advantage of and use in the drafting of their proposals.

Peter Agron, PhD
510-987-9858
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