



## 2013-2014 Request for Proposals

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## I. Basic Information

### I.1. Purpose

The purpose of the current round of the Creative and Novel Ideas in HIV Research Awards program (CNIHR) is to create a mechanism via the U.S. National Institutes of Health (NIH) Centers for AIDS Research (CFARs) to fund developmental projects to bring insight and new ideas from early stage investigators with expertise in other disciplines to HIV research. The intent of this program is to attract both international and U.S.-based early stage investigators from outside the field of HIV research to help address key scientific questions in HIV research, including emerging issues of long-term survival with HIV infection, prevention of HIV transmission and research toward a cure.

### I.2. Eligibility

Eligible applicants include junior investigators who have either completed their first terminal research degree (e.g. PhD, MD, DVM, MMed + postdoctoral fellowship or formal research training and experience) or medical residency within the last ten years from the concept proposal deadline (i.e. 16 October 2003), and who have a faculty or equivalent position (e.g. assistant professor, senior lecturer, etc.) in good standing at an academic institution or have a comparable position in a not for profit organization or institution with a primary mission of research. U.S. Federal Government employees are ineligible to apply. Some U.S. Government contractors may also be ineligible therefore potential applicants should check with their organization to determine whether external funding is allowed. (See [Section VI.1](#) for more information about eligible organizations and institutions.)

Post-doctoral trainees are eligible to apply IF they have completed their training and will have a faculty or comparable position prior to the full proposal submission deadline of Monday, February 10, 2014; a letter of intent from the investigator's institution indicating the commitment to a faculty or comparable position by the deadline must be included in the concept proposal submission. If the applicant does not have the faculty or comparable position at the time of full proposal submission, their application will be removed from the pool as ineligible.

Applicants must have not yet been engaged in HIV research (as defined by any previous grant, contract, sub-award or publication in HIV or SIV research).

Eligible Principal Investigators (PIs) include: Investigators with the skills, knowledge, and resources necessary to carry out the proposed research. They can be from any relevant discipline. Eligible PIs are invited to work with their institution/organization to develop their application. Applicants from all countries (unless excluded because of regulations applicable to embargoed countries – see link: <http://www.treas.gov/offices/enforcement/ofac/programs>) are encouraged to apply.

If unsure about your eligibility, first read the Frequently Asked Questions ([FAQs](#)) on the CNIHR website. If you still have questions, please contact us at [info@cnihr.org](mailto:info@cnihr.org).

### I.3. Types of Projects

Research topics could include any aspect of HIV and HIV-related research, but may not include prospective human interventional trials (e.g. clinical trials of new drugs, treatments, or devices; or off-label use of a licensed drug). Studies of animal models, stored samples from existing cohorts, small pathogenesis studies or *in vitro* trials are acceptable. If an applicant is considering a study involving approved drugs and/or standard-of-care, the applicant is encouraged to contact the review administrator to determine whether the proposed project would be eligible for funding at [info@cnihr.org](mailto:info@cnihr.org).

Applicants are strongly encouraged to integrate sex and gender considerations into their research design when appropriate. For more information about the inclusion of the role of sex and gender into your CNIHR project, please see the CNIHR website ([www.cnihr.org/sexandgender](http://www.cnihr.org/sexandgender)),

### I.4. Funding Available

Awards will be funded for 1-2 years, up to \$150,000 (direct costs) per year plus applicable indirect costs. Second year funding is contingent upon demonstration of satisfactory progress during year one. International awardee institution's indirect cost rate is limited to 8%. Awarded funds may be used for salary, technical support, laboratory supplies, equipment, and travel to a scientific conference or other training activities directly related to the proposed research project. Successful applicants will be expected to contribute at least 25% of their time to the CNIHR project. Salary support for the CNIHR effort can be budgeted in the CNIHR project or can come from another source, e.g., an institutional start-up package. Generally, funds may not be used to purchase computers unless they can be justified as key to the conduct of the study (data collection, tied to equipment, etc). Additionally, funds may not be used to offset losses of funding incurred through non-renewal of grant funds or through decreases in grant funds due to across-the-board cuts.

Ten to twelve grants are anticipated to be awarded in conjunction with the XX International AIDS Conference, which will be held in Melbourne, Australia from 20-25 July 2014.

I.5. Travel Support

Additional support will be provided for each grantee and their mentor to attend conferences convened by the International AIDS Society during their award period (e.g. the XX International AIDS Conference, 20 - 25 July 2014 and the 8th IAS Conference on HIV Pathogenesis, Treatment and Prevention in Summer 2015). Travel support will be provided only for mentors whose mentees are attending the CNIHR meeting at the above conferences and will be prioritized for CFAR-affiliated mentors.

I.6. Webinars and Additional Information

The CNIHR program will produce four live webinars between August and October 2013 which will be recorded and posted on the CNIHR website: Two will be focused on answering questions about eligibility and scientific questions and two will focus on scientific and application/administrative questions. For more details, please see the CNIHR [website](http://www.cnihr.org). Recordings of the webinars will also be posted on the CNIHR [website](http://www.cnihr.org) (www.cnihr.org).

For other questions, please first read the [FAQs](#) on the CNIHR website. If they were not answered by the FAQs, please contact us at [info@cnihr.org](mailto:info@cnihr.org).

## II. Overview and Timeline

The competition will be administered in a two-phase process: the Concept Proposal phase and the Full Proposal phase. The Concept Proposal phase is open to all eligible candidates. To be eligible to compete in the Full Proposal phase, the applicant must first successfully compete in the Concept Proposal phase.

Table 1 below describes the timeline for the CNIHR funding program.

RFA Release. ....	June 2013
Eligibility and Scientific Webinars.....	August – September, 2013
Application/Administrative and Grantsmanship Webinars.....	August – October, 2013
<b>Concept Proposals Due.....</b>	<b>October 16, 2013</b>
Estimated Review Date.....	November & December, 2013
Estimated Notification Date.....	December 18, 2013
Assistance with finding a CFAR Mentor Deadline.....	January 13, 2014 (invited applicants only)
<b>Full Proposals Due.....</b>	<b>February 10, 2014</b>
Estimated Review Date.....	April 14-18, 2014
Estimated Award Date.....	April 21, 2014

### III. Concept Proposals

**Concept Proposals are due October 16, 2013.**

#### III.1. Application Instructions

Concept Proposals will be submitted electronically in one Adobe PDF file via the CNIHR website (<http://www.cnihr.org>). Applications must be in English. Applicants will certify in the online application that they have not received funding for HIV research, published in the HIV research field, and are not currently engaged in the conduct of research in this field. ***Please note that applications that do not adhere to the instructions will not be considered.***

The Concept Proposal should include (in this order in a single Adobe PDF file):

1. CNIHR Concept Proposal Cover Page (Download: [MS Word](#) or [PDF](#)).
2. Biographical Sketch for the CNIHR applicant (PHS 398 Format - Download: [MS Word](#) or [PDF](#)) omit section A, unless providing a description of factors that may have reduced productivity per [NIH NOT-OD-11-045](#)
3. Two-page proposal outlining the hypotheses, specific aims, brief preliminary data (if any), and brief research design.
4. If applicable, letter of intent from the investigator's institution indicating the commitment to a faculty position by February 10, 2014 (see [section 1.2.](#) above).

#### III.2. Review Process and Criteria

A Scientific Selection Committee (SSC) will review the Concept Proposals. Criteria for selection in the Concept Proposal phase are primarily based upon the scientific merit, investigator, significance, approach, and innovation. For descriptions of these criteria, see page 5: Review Process and Criteria.

Researchers whose proposals are selected for the full proposal competition phase will have eight weeks to prepare and submit a full proposal.

Email for all questions is [info@cnihr.org](mailto:info@cnihr.org).

## IV. Full Proposals

**Full proposals are due Monday, February 10, 2014. Only researchers whose proposals were selected from the concept proposal competition phase are invited to submit full proposals.**

Applicants who are chosen to submit a full proposal and do not already have a relationship with a CFAR are **required** to establish a mentor relationship with a CFAR-affiliated investigator. This can include senior international investigators affiliated with CFARs. Resources regarding potential CFAR-affiliated mentors are provided on the CNIHR [website](#) and on the [NIH CFAR webpage describing which CFARs are collaborating with international institutions](#). Resources for mentors and collaborators can be found on the CNIHR website.

Applicants who are unable to find a mentor through these resources must contact the CNIHR program at [info@cnihr.org](mailto:info@cnihr.org) on or before January 13, 2014 to receive assistance in identifying a CFAR mentor.

In addition to the CFAR mentor, applicants are allowed to include another mentor (can be non-CFAR-affiliated). Travel support to IAS conferences will be prioritized for CFAR-affiliated mentors.

Successful awardees will be eligible for and encouraged to access CFAR Core services from collaborating CFARs. For more information about CFARs and CFAR Core services, see the NIH CFAR website (<http://www3.niaid.nih.gov/LabsAndResources/resources/cfar/>).

### IV.1. Application Instructions

Full Proposals will be submitted electronically in one Adobe PDF file via the CNIHR website (<http://www.cnihr.org>). The full proposal will be on the forms used commonly for NIH grant applications ([PHS 398 forms](#)) and should follow a modified NIH investigator initiated grant application (R01) format

For detailed instructions on how to fill out the forms see: <http://www.niaid.nih.gov/ncn/grants/app/default.htm> with the following modifications. The Research Plan (Specific Aims through Approach) is limited to 4 pages (Bibliography and References Cited sections do not count toward the page limit). No appendices are allowed. Do not submit Targeted/Planned Enrollment Tables. Applications must be in English. **Please note that applications that do not adhere to the instructions will not be considered.**

The Full Proposal should include (in this order in a single Adobe Portable Document Format (PDF) file):

1. CNIHR program-provided Full Proposal Cover Page (Download: [MS Word](#) or [PDF](#).)
2. Face Page: (Download: [MS Word](#) or [PDF](#)) Institutional sign-off and eRA Commons ID required. \*See below,
3. Project Summary Page: (Download: [MS Word](#) or [PDF](#))
4. Detailed budget for 12 month period: (Download: [MS Word](#) or [PDF](#))
5. Complete budget and justification: (Download: [MS Word](#) or [PDF](#))
6. Checklist including institutional indirect (F&A) costs: (Download: [MS Word](#) or [PDF](#))
7. Resources page (Download: [MS Word](#) or [PDF](#))
8. Biographical Sketch for the CNIHR applicant (Download: [MS Word](#) or [PDF](#)) omit section A, unless providing a description of factors that may have reduced productivity per [NIH NOT-OD-11-045](#).
9. Other Support for the CNIHR applicant (Download: [MS Word](#) or [PDF](#))
10. Research Plan (Maximum 4 pages for **a-d** below). Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).
  - a. Specific Aims (suggested length ½ page)
  - b. Significance (suggested length 1 page)
  - c. Innovation (suggested length ½ page)
  - d. Approach (suggested length 2 pages)

*All research plans will undergo a biostatistical evaluation as part of the review process, therefore applicants are strongly encouraged to consult a biostatistician in the preparation of their application.*

11. Description of the Research Environment (suggested length ½ page). Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).
12. Bibliography and References cited (as needed) Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).

13. Protection of Human Subjects (if applicable; maximum 1 page). Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).
14. Vertebrate Animals (if applicable; maximum 1 page). Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).
15. CFAR Mentor's Letter of Support
16. Biographical Sketch for the CFAR Mentor (PHS 398 Format - Download: [MS Word](#) or [PDF](#)) omit section A
17. CFAR Mentorship Agreement. To ensure that the awardee and CFAR mentor have a clear understanding of their roles, responsibilities, and research goals, each awardee and mentor will be asked to develop a brief written agreement that describes the following: 1) Expectations for the mentoring experience; 2) Expectations regarding the time and frequency of meetings; 3) Timetable for the project; and 4) Expectations about collaboration on this project (i.e., authorship on presentations and publications).
18. Other Mentor's Letter of Support (if applicable)
19. Biographical Sketch for the Other Mentor (PHS 398 Format - Download: [MS Word](#) or [PDF](#)) omit section A (if applicable)
20. Letters of Support (letters of support from collaborators essential to the proposed project must accompany the application).

\*eRA Commons ID. The eRA Commons is an online interface where institutional signing officials, principal investigators, trainees, and post-docs at institutions can access and share information about research grants. The NIH uses your eRA Commons ID to track grant information about investigators. Please see the CNIHR website [FAQs](#) and the eRA Commons FAQ ([http://era.nih.gov/commons/faq\\_commons.cfm](http://era.nih.gov/commons/faq_commons.cfm)) for more information and instructions on how to obtain an eRA Commons ID. The request process can take several weeks, so it is important to begin the process quickly after an invitation to submit a full proposal is received.

#### IV.2. Budget Development Guidelines and Restrictions

1. Travel to the required International AIDS Society conferences is provided by the International AIDS Society, and should not be included in the budget. Budgeting for travel to other conferences to present CNIHR project research results is allowable and encouraged.
2. Requested support for project collaborators who are NOT at the same institution as the awardee must be listed as consultant costs. If the collaborator cannot accept consultancy fees, a subcontract must be issued to their institution. These costs must be listed in the detailed budget as consortium costs with applicable indirect costs included.
3. Requested support for equipment and technology, including computers, must be fully justified in the budget justification with a clear connection to the scientific aspects of the project and not for general office use.
4. Tuition, fees and stipends for graduate students are allowable within the following guidelines:
  - a. Total compensation (salary, fringe, and tuition/fees) cannot exceed \$39,264. ([NOT-OD-12-033](#))
5. Costs associated with Institutional Review Board (IRB) review of human research protocols, or Institutional Animal Care and Use Committee (IACUC) review of animal research protocols, are not allowable as direct charges unless such costs are not covered by the organization's Facilities and Administrative (F&A) agreement.
6. All costs must conform to the NIH Grants Policy Statement (GPS) and applicable U.S. Office of Management and Budget OMB circulars for necessity and reasonability, allocability, conformance and consistency, as well as allowability. Please follow the link below to section 7.2 cost principles section of the [NIH Grants Policy Statement](#).
7. Please refer to the Funding Available ([section I.4](#)) for further information regarding allowable costs.

### IV.3. Review Process and Criteria

#### Written Reviews:

Each application will be assigned to a minimum of two non-conflicted reviewers with relevant expertise.

The evaluation criteria for full proposals include:

- Scientific Merit of the proposal and its likelihood to provide information that can significantly advance our understanding of HIV and/or provide preliminary data that is likely to lead to independent research grant funding.
- Significance – What will be the potential effect of these studies on the concepts or methods that drive the field of HIV research? Does the study address an important problem consistent with the objective to advance our understanding of HIV? If the aims are achieved, how will scientific knowledge be advanced?
- Investigator – Are the PI, mentor(s), collaborators, and other researchers well suited to the project? Does this person have appropriate experience and training? If the project is collaborative, do the investigators have complementary and integrated expertise?
- Approach – Are the conceptual framework, design, methods, and statistical analysis plan adequately developed, well integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternatives? Does the study design account appropriately for differences by sex or gender?
- Innovation – Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- Environment – Do the proposed methods take advantage of the unique environment and unique populations where appropriate? Are useful collaborative arrangements between resources in the institution(s) utilized where appropriate and described adequately? This criteria only applies to the Full Proposal phase.

The reviewers are asked to summarize the strengths and weaknesses of the proposal based on all of the above criteria. Each project is scored according to the [NIH scoring system](#) using scientific merit as the metric for success. All full applications will also undergo a biostatistical review.

#### Review Committee:

The review committee (comprised of senior members of the CFARs, IAS and other eminent scientists with relevant expertise in the field of HIV) will convene a formal review within nine weeks of receipt of applications. Those applicants who are selected for funding will be notified immediately. All applicants will receive written critiques in order to enhance their ability to benefit from other funding opportunities.



## V. Award Requirements

### V.1. Pre-Award Requirements

1. **Human Subjects and Animal Care Approvals:** Animal Care and Institutional Review Board approvals, if applicable, must be obtained prior to **receipt** of an award, but are not required to submit an application. Prior to funding, a copy of all [Institutional Biohazard](#), Animal Care and Institutional Review Board (IRB) approvals must be forwarded to the post-award administrator.

Prior to receipt of an award involving human subjects, IRB approval from all participating sites and human subjects training certification for all key personnel will be required. Proposals involving either international sites or clinical research above minimal risk will require additional clearances from NIH. If the project involves human subjects and the institutional IRB has deemed the study “greater than minimal risk”, the awardee must submit a Clinical Research Checklist before funding is released. For the definition of minimal risk, see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>. It is recommended that if your study is minimal risk or below, you apply for independent approval by the applicable IRBs – this would avoid the need to get additional approval from NIH for domestic studies.

For more information about human subjects approval, see: <http://www.hhs.gov/ohrp/> and <http://funding.niaid.nih.gov/researchfunding/sci/human/pages/default.aspx>.

For more information on animal care approvals, see: <http://grants.nih.gov/grants/olaw/olaw.htm> and <http://funding.niaid.nih.gov/researchfunding/sci/animal/pages/default.aspx>.

2. Proposals involving either international sites or clinical research above minimal risk will require additional clearances from NIH.

### V.2. Post-Award Requirements

1. Awardees will be required to submit yearly progress reports to the CNIHR program and make an oral or poster presentation at meetings in conjunction with the International AIDS Conference and the International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention.
2. Toward the end of year one, mentors are expected to submit a brief report to the CNIHR program describing the progress of the CNIHR project and advising whether sufficient progress has been made to award the second year of funding.
3. CNIHR support must be acknowledged in all publications derived from the CNIHR award. Sample language is “This award program was made possible by a partnership between the International AIDS Society, the NIH-funded Centers for AIDS Research, and the U.S. National Institutes of Health.”
4. In the event that other pending support is funded which overlaps with or reduces the principal investigator’s effort on this project, the PI must immediately notify the post award administrator. The CNIHR awardee’s funding status will be reviewed and if it is determined that the PI is unable to meet the specific aims of the proposal, the CNIHR award will be revoked.
5. If for any reason the awardee is unable to fulfill the requirements or adhere to the policies of the CNIHR awards program, at the discretion of the CNIHR program officials, the award may be revoked.
6. After the project is completed, the CNIHR awardee will be surveyed annually to provide information about publications, collaborations, and future grants related to the CNIHR project.



## VI. Appendix

### VI.1 Types of Eligible Organizations and Institutions\*

#### U.S.-based

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Research Institutes
- Hispanic-serving Institutions with a primary mission of research
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions with a primary mission of research
- Nonprofits with 501(c)(3) IRS (Internal Revenue Service) Status (Other than Institutions of Higher Education) with a primary mission of research
- Nonprofits without 501(c)(3) IRS (Internal Revenue Service) Status (Other than Institutions of Higher Education) with a primary mission of research
- [Small Businesses](#) with a primary mission of research
- Regional Organizations with a primary mission of research

#### Non-U.S.-based

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Research Institutes
- Nonprofit Organizations with a primary mission of research
- [Small Businesses](#) with a primary mission of research
- Regional Organizations with a primary mission of research

*This award program was made possible by a partnership between the International AIDS Society, the NIH-funded Centers for AIDS Research, and the U.S. National Institutes of Health.*