



2015-2016 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 other disciplines to HIV research. The intent of this program is to attract both international and U.S.-based early stage investigators excelling outside the field of HIV research to help address key scientific questions in HIV research.

I.2. Eligibility

Applicants are expected to have the skills, knowledge, and resources necessary to carry out the proposed research, but may not have been engaged in any past or current HIV or SIV research. Disqualifying research experiences include (but are not limited to) authorship on any HIV/SIV research papers; serving as an investigator on an HIV/SIV grant (including postdoctoral fellowships); and receiving an HIV/SIV grant, subaward, or contract. Eligibility of all applicants will be assessed at both the concept proposal and full application phases, and will be considered on a case-by case basis. If you have questions, please contact us at info@cnihr.org.

Eligible Principal Investigators (PIs) can be from any relevant discipline. Eligible PIs are encouraged to work with their institutions throughout the concept proposal phase and will be required to have institutional sign-off on their application if invited to submit a full proposal. 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.

Applicants are expected to maintain their eligibility until the award start date.

Degree time limit requirement:

Applicants must have either completed their first terminal research degree or their medical residency within the last ten years from the concept proposal deadline (i.e. 30 October 2005). Examples include PhD; MD; DVM; MMed + postdoctoral fellowship/other formal research training (5 year maximum time limit for research training); or MD + medical residency (not fellowship).

Extensions to this 10 year time period will be considered for reasons that can include medical issues, disability, family care responsibilities, extended periods of clinical training, natural disasters, and active duty military service and require supporting documentation. The extension time allowed will be equivalent to the time away from research or research training. The CNIHR program will follow NIH guidelines for the extension of the Early Stage Investigator period (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-034.html>.) Please contact the CNIHR Program (info@cnihr.org) in order to request an extension.

Job title and institutional requirements:

In order to be eligible, junior investigators must be faculty or equivalent (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. (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 Thursday, February 11, 2016; 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.

Restrictions:

Applicants who have a K or a similar type of mentored award from NIH or another federal agency should review the [FAQs](#) to learn more about potential restrictions and additional CNIHR and NIH requirements.

U.S. Federal Government employees are ineligible to apply since federal funds are used to support the CNIHR program. Some U.S. Government contractors may also be ineligible and potential applicants should check with their organization to determine whether external funding is allowed.

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.

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 your proposed study design involves testing a biomedical or behavioral intervention (including approved drugs and/or standard of care), please contact the CNIHR program administrator to determine whether the proposed project would be eligible for funding at 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 (<http://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. Non-U.S. institutions' indirect cost rates are limited to 8%. Awarded funds may be used for salary, technical support, laboratory supplies, equipment, and travel to scientific conferences 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 announced in conjunction with the 21st International AIDS Conference, which will be held in Durban, South Africa from July 17-22, 2016.

I.5. Travel Support

Additional support outside of the grant will be provided for each award recipient to attend CNIHR networking meetings at NIH (dates TBD), and for both grantees and their mentors to attend the Conference on Retroviruses and Opportunistic Infections (CROI) in both 2017 and 2018. Travel support will be provided only for mentors whose mentees are attending the CNIHR meetings at the above conferences and will be prioritized for CFAR-affiliated mentors. Support for awardees to attend other program affiliated meetings in 2017 and 2018 will also be provided based on the availability of funds.

I.6. Webinars and Additional Information

The CNIHR program will produce four live webinars in October 2015 which will be recorded and posted on the CNIHR website. Two will be focused on answering questions about eligibility and scientific questions, and will be on October 8th, 2015 and two will focus on grantsmanship and application/administrative questions, and will be hosted on October 22nd, 2015. For more details, please see the CNIHR [website](#).

For other questions, please first read the [FAQs](#) on the CNIHR website, and if additional information is needed please contact us at 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.....	July 2015
Eligibility and Scientific Webinars.....	October 8, 2015
Application/Administrative and Grantsmanship Webinars.....	October 22, 2015
Concept Proposals Due.....	October 30, 2015 *Extended from 10/16*
Estimated Review Date.....	November & December, 2015
Estimated Notification Date.....	December 18, 2015
Assistance with finding a CFAR Mentor Deadline.....	January 15, 2016 (invited applicants only)
Full Proposals Due.....	February 11, 2016
Estimated Review Date.....	April 11-15, 2016
Estimated Notification Date.....	April 22, 2016
Earliest Award Start Date*	June 1, 2016

*Award start date is contingent upon the availability of funds and when all NIH approvals and regulatory documents are received.

III. Concept Proposals

Concept Proposals are due **October 30, 2015**. *This deadline has been extended from October 16th, 2015.*

III.1. Application Instructions

Concept Proposals will be submitted electronically via the CNIHR website (<http://www.cnihr.org>). Detailed instructions can be found in the Concept Proposal Submission User Guide located on the Instructions page (<http://cnihr.org/instructions/>). Applications must be in English. **Please note that applications that do not adhere to the instructions will not be considered.**

The Concept Proposal submission on the CNIHR website will include the following components:

1. Basic information (name, position, institution, email contact information) for the PI is required.
2. General information about the project: proposed title, 5 key words; selection of relevant topic areas; and the Biographical Sketch for the CNIHR applicant (new SF424 Format - Download: [MS Word](#), but please submit as PDF) omitting section A, unless providing a description of factors that may have reduced productivity per [NIH NOT-OD-11-045](#).
3. Eligibility confirmation: Applicants will certify in the online application that they meet all eligibility criteria. This includes confirming that they have not received funding for HIV/SIV research, published in the HIV/SIV research field, do not have current or past HIV/SIV research experience in this field, and they meet the degree time limit, job title, and institutional requirements. Applicants will also need to submit a complete list of publications and current and past research funding.
 - a. If applicable (see [section I.2](#) above), the applicant will upload a PDF format letter of intent from their institution indicating the commitment to a faculty position by February 11, 2016.
4. Personnel (optional): This information is not required at the time of Concept Proposal Submission, but is allowed. If any other investigators (e.g. mentor or collaborators) have been identified, contact and affiliation information for those personnel can be added. Additionally, biosketches (SF 424 format) may be submitted for any identified mentors or collaborators, but are not required.
5. Body of Concept Proposal: This includes a Project Summary (50 word maximum), Hypothesis (100 word maximum), Specific Aims (700 word maximum), Preliminary Data if any (250 word maximum), and Research Design (700 word maximum)
 - a. References cited should be included as a PDF upload.

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 section IV.3: 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. Written critiques of the Concept Proposals will not be provided.

Email for all questions is info@cnihr.org.

IV. Full Proposals

Full proposals are due Thursday, February 11, 2016. Only researchers whose proposals are selected from the concept proposal competition phase will be invited to submit full proposals.

All applicants chosen to submit a full proposal 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](#). Additional information and resources for mentors and collaborators can be found on the CNIHR website.

Applicants who are unable to find a mentor must contact the CNIHR program at info@cnihr.org on or before January 15, 2016 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); however program sponsored travel support to the Conference on Retroviruses and Opportunistic Infections and other 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 via the CNIHR website (<http://www.cnihr.org>). The full proposal will be completed on the forms commonly used for NIH grant applications ([PHS 398 forms](#), with the exception of the biosketches which are in SF424 format) and should follow a NIH investigator initiated grant application (R01) format with the modifications listed below.

Components 2-16 below are to be uploaded in PDF 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. Sections 10 a-d of the Research Plan (Specific Aims through Approach) are limited to 4 pages (Sections e-h 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 will include:

1. CNIHR program-requested basic project information to be submitted by webform
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 (new SF424 Format - Download: [MS Word](#)) 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 ½-1 page)
 - b. Significance (suggested length ½-1 page)
 - c. Innovation (suggested length ½ page)
 - d. Approach (suggested length 2 pages)
 - e. Bibliography and References cited (as needed)
 - f. Description of the Research Environment (suggested length ½ page)
 - g. Protection of Human Subjects (if applicable; maximum 1 page)
 - h. Vertebrate Animals (if applicable; maximum 1 page)
11. CFAR Mentor's Letter of Support (PDF document to be uploaded if applicable)

12. Biographical Sketch for the CNIHR mentor (new SF424 Format - Download: [MS Word](#)) omit section A
13. 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).
14. Other Mentor's Letter of Support (if applicable)
15. Biographical Sketch for the other mentor (new SF424 Format - Download: [MS Word](#)) omit section A
16. 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) 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.

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.

IV.2. Budget Development Guidelines and Restrictions

1. Travel to the required CNIHR networking meetings and Conference on Retroviruses and Opportunistic Infections conferences is provided by the CNIHR program 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 should 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 \$42,000. ([NOT-OD-14-046](#))
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 ([section 1.4](#)) for further information regarding allowable costs. Errors in budgets with respect to allowable costs may or may not be eligible for re-budgeting upon review by CNIHR program grants management and the NIH. Supplemental funding, such as the mechanism used to fund the CNIHR program, is considered **new** funding and follows the same rules for award as a competing grant. In most instances, unallowable costs are removed not re-budgeted.

CNIHR awards are supported with funds from the US Federal Government and therefore all awardees must comply with and abide by all federal funding rules and regulations. The awardees institution will be responsible for reimbursing the CNIHR program for costs found to be non-compliant with NIH policies.

IV.3. Review Process and Criteria

Written Reviews:

Each application will be assigned three 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 will be 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/sachrp/sachrpminrisk20080131.html>. 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 annual CNIHR networking meetings or the Conference on Retroviruses and Other Infections. Awardees will also be encouraged to submit abstracts for presentation during the International AIDS Conferences and the International AIDS Society (IAS) Conferences 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. All publications resulting from CNIHR funding must acknowledge the CNIHR grant and comply with the NIH Public Access Policy and be submitted to PubMedCentral to receive a PMCID assignment.
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 or is no longer in compliance with federal funding policies, 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 is 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.