Request for Proposals

Impact Grants: Gaining Insights from the Clinic

REGISTRATION DEADLINE: Friday, April 6, 2018 12:00 PM Eastern Time
Registration is REQUIRED (click here)

LOI SUBMISSION DEADLINE: Wednesday, April 11, 2018 3:00 PM Eastern Time

Goal
The goal of this RFP is to generate practical, implementable information that will facilitate the design and interpretation of broadly generalizable HIV cure clinical research.

Specific areas of interest

1. Identify pre-ATI predictors of post-treatment control (PTC) or delay to rebound
2. Diversify the HIV cure clinical study population

Funding Opportunities

1.1: Meta-analysis of data from completed clinical trials (1 year; Total Costs: $100,000)

1.2: Addition of study arm to an existing clinical trial (4 years; Total Costs: $300,000)

1.3: Addition of reservoir and outcome (PTC or delay to rebound) analyses to an existing clinical trial (4 years; Total Costs: $100,000)

2.1: Addition of a recruitment and retention intervention to an existing clinical trial (4 years; Total Costs: $50,000)

2.2: Characterization of clinical case studies (1 year; Total Costs: $75,000)

2.3: Characterization of the reservoir in LMIC settings (2 years; Total Costs: $50,000)

Eligibility

Researchers holding a doctoral degree and affiliated with a nonprofit research institution are eligible to apply. Areas of interest 1.1, 1.2, 1.3, 2.1, and 2.2 are open to investigators from any region of the world. Area of interest 2.3 is open only to principal investigators based in low-, lower-middle-, or upper-middle-income economy countries as defined by the World Bank.

Detailed Information about Funding Opportunities

Eligibility Information

Letter of Intent Requirements

Important Dates, Submission, Review and Approval Pipeline

Grant Policies

Funding Opportunities

All performance periods are to start October 1, 2018

Total costs include indirect costs at a 20% maximum

1.1: Meta-analysis of data from completed clinical trials (1 year; Total Costs: $100,000)

- items **D and E** (see below) are required as applicable

Existing clinical trials are trials that are already fully funded (by amfAR or others) and have received all necessary institutional and regulatory approvals.

1.2: Addition of study arm to an *existing clinical trial* (4 years; Total Costs: $300,000)

- items **A, B, C, D and E** (see below) are required

1.3: Addition of reservoir and outcome (PTC or delay to rebound) analyses to an *existing clinical trial* (4 years; Total Costs: $100,000)

- items **A, B, C, D and E** (see below) are required

2.1: Addition of a recruitment and retention intervention to an *existing clinical trial* (4 years; Total Costs: $50,000)

- must be conducted in the context of an existing curative clinical trial
- must propose an intervention hypothesized to increase participant recruitment and retention over a control group included in the design
- items **A, B, C, D and E** (see below) are required

2.2: Characterization of clinical case studies (1 year; Total Costs: $75,000)

- must include case studies, outside the context of a clinical trial, of unexpected post-treatment control or delay-to-rebound outcomes
- analyses of biological samples taken after, and ideally before, treatment interruption
- amfAR can provide non-binding advice to physicians interested in finding academic collaborators. Such requests to amfAR must be made more than three weeks prior to the LOI receipt date deadline. (Email grants@amfar.org) If you are qualified to conduct cure research-relevant assays on clinical samples and wish to be included on amfAR's list of potential academic collaborators, please contact amfAR at grants@amfar.org.
- items **D and E** (see below) are required

2.3: Characterization of the reservoir in LMIC settings (2 years; Total Costs: $50,000)

- principal investigators must be based in a LMIC setting
- biological samples or study participants must be based in a LMIC setting
- the majority of the funding should be allocated to activities in a LMIC setting. Qualifying low-, lower-middle- or upper-middle-income economy countries (LMIC) as defined by the World Bank.
- study participants not readily available in HIC incl. e.g.: those with coinfections such as TB, helminths, etc.; treatment initiation at CD4<200; pediatric/adolescent; female
- Items **D and E** (see below) are required

Requirements

A. The Background and Rationale section of the research plan must include a description of the existing clinical trial and timeline. The study protocol may be provided as an addendum.

The addenda must include:

B. Documentation that the existing trial is already funded and that all necessary institutional (e.g., IRB) and regulatory (e.g., FDA or equivalent non-U.S. agency) approvals have been received.

C. Documentation that the trial investigators are willing and able, as applicable, to (1.2) add another study arm, (1.3) share samples, or (2.1) incorporate the proposed intervention.

D. Describe the procedure and provide a timeline for obtaining all necessary institutional approvals (e.g., IRB, IBC) required for the research proposed in the application. If the institutional approval(s) have already been obtained, include documentation.

E. Describe the procedure and provide a timeline for obtaining all necessary regulatory (e.g., FDA or equivalent non-U.S. agency) approvals required for the research proposed in the application. If the regulatory approvals have already been obtained, include documentation.

Funding will be rescinded if documentation of items D and E are not submitted to amfAR within 3 months following the performance period start date.

Questions about the intended scope of this RFP may be sent to grants@amfar.org. Phone calls will not be accepted.

Eligibility

- Principal Investigators (PIs) must hold a doctoral-level degree and be affiliated with a nonprofit research institution; it is not required that PIs hold a faculty-level position.
- Applications are accepted only from nonprofit research institutions. Collaborating institutions (subawardees) may be for-profit entities. The PI must be affiliated with (e.g., on the faculty of) the applicant institution.
- PI's for Area of Interest 2.3 must be based in an LMIC and the majority of funding must support activities in the LMIC.
- PIs for Areas of Interest 1.1., 1.2., 1.3, 2.1 and 2.2 may be from any region in the world.
- The PI will be expected to coordinate the development, implementation and analysis of the project as a whole, and be responsible for overall financial management and the preparation and submission of required reports.
- amfAR does not require an institution signature on Letters of Intent. However, institution signature is required at the application stage.

Letter of Intent (LOI) Requirements

LOIs must include the following:

Entered on the **Details tab** in the portal:

- Abstract (maximum 2,000 characters/spaces)
- Clinical research implementation statement (maximum 2,000 characters/spaces)
- Hypothesis/specific aims (maximum 1,700 characters/spaces)
- Timeline (maximum 450 characters/spaces for each year)

Uploaded to the **Attachments tab** in the portal:

- 5-page research plan with the following sections in this order:

  A. Background and Rationale: Concisely describe the background and rationale for the project and how it addresses either: *identifying pre-ATI predictors of post-treatment control (PTC) or delay to rebound; OR diversifying the HIV cure clinical study population*. If your LOI addresses specific area of interest 1.2, 1.3, or 2.1, include a description of the existing clinical trial and timeline in this section.

  B. Preliminary Studies: Summarize the investigator's preliminary studies.

  C. Experimental Design Proposed: Clearly and concisely describe the experimental design and the procedures to be used. Include, where applicable, sample size, power analyses and other relevant statistical analyses.

  D. Pitfalls/Alternatives: Describe potential difficulties or pitfalls that might arise and alternate strategies you would employ to achieve the specific aims and research goals.

  Figures and Legends should be embedded throughout the research plan. Figure legends should be concise and in a font size large enough to be easily read in printed copies of the LOI.

- Literature Cited (not counted toward research plan's page limit)
- Biographical sketches for all key personnel
- Addenda: The Addenda should begin with a face page titled "ADDENDA" and a list of the contents. Required:

  [Requirement A—description of existing clinical plan and timeline—is included in the research plan.]

  B. LOIs addressing specific areas of interest 1.2, 1.3, and 2.1 are required to include documentation in the addenda which demonstrates that the existing trial is already funded and that all necessary institutional (e.g., IRB) and regulatory (e.g., FDA or equivalent non-U.S. agency) approvals have been received.
  C. LOIs addressing specific areas of interest 1.2, 1.3, and 2.1 are also required to include documentation in the addenda which demonstrates that the trial investigators are willing and able, as applicable, to (a) add another study arm, (b) share samples, or (c) obtain incorporate the proposed intervention.
  D. All areas of interest: describe the procedure and provide a timeline for obtaining all necessary institutional approvals (e.g., IRB, IBC) required for the research proposed in the application. If the institutional approvals have already been obtained, include the documentation.

E. All areas of interest: describe the procedure and provide a timeline for obtaining all regulatory (e.g., FDA or equivalent non-U.S. agency) approvals required for the research proposed in the application. If the regulatory approvals have already been obtained, include the documentation.

Grant funding will be rescinded if documentation of items D and E are not received by amfAR within 3 months following the performance period start date.

Optional:

- Protocol for an existing clinical trial on which the proposed research builds.
- Additional Letters of Support/Collaboration.

Please arrange and upload all necessary documents, approvals, and letters (with a cover page listing all contents) as a single PDF.

- Signature Page

Deadlines and Other Important Dates

Registration Deadline: Friday, April 6, 2018, 12:00 PM Eastern Time - REQUIRED

- Applicants will receive portal user name/password, URL to start their LOI, LOI instructions and templates within one business day following registration.
- Note that the amfAR office will be closed on Friday, December 22, 2017; Monday, December 25, 2017; Friday, December 29, 2017; Monday, January 1, 2018; Monday, January 15, 2018; and Monday, February 19, 2018. Materials will be sent on the first business day following those closures.

LOI Submission Deadline: Wednesday, April 11, 2018, 3PM Eastern Time (no extensions will be granted)

Application Invitation: Late May, 2018 (TENTATIVE)

Application Submission: Early August, 2018 (TENTATIVE)

Notice of Decision: Late September, 2018 (TENTATIVE)

Performance Period Start: October 1, 2018

Submission, Review and Approval Pipeline

1. Interested applicants must register online to obtain portal link, username/password and complete information about Letter of Intent requirements.

   Click here to register.

2. LOIs are submitted online.
3. Letters of Intent (LOIs) are reviewed by amfAR staff to ensure that (a) eligibility requirements are met; (b) proposed research is responsive to the RFP and in line with amfAR objectives.

   LOIs that meet those criteria proceed to peer review.

4. LOIs are reviewed by leading HIV experts and scored on the following criteria:
   - Expected impact on HIV cure clinical research
   - Appropriateness of the proposed work with respect to available funds

- Competency and track record of members of the team

5. Applicants with the highest scoring LOIs are invited to submit full applications. Full applications are reviewed by members of amfAR's scientific advisory committee and discussed during an in-person meeting to assess the merit of each application with respect to:
    - Expected impact on HIV cure clinical research
    - Innovation and novelty in the proposed work
    - Competency and track record of members of the team
    - Possible scientific or budgetary overlap
6. Successful applications, chosen based on review scores, comments and amfAR priorities are recommended to amfAR's Board of Trustees for approval.
7. The board of trustees has sole authority to approve grant funding.
8. Grant agreements must be fully executed within 60 days following the notice of grant award.
9. Documentation of all necessary institutional (e.g., IRB, IBC) and regulatory (e.g., FDA or foreign equivalent) approvals must be submitted within three months following the notice of grant award.

amfAR Grant Policies

TO WHOM GRANTS ARE MADE

Grants are awarded to nonprofit institutions; they are not awarded to individual investigators. Accordingly, an application, if solicited, must bear the signature of an official authorized to sign for the institution and, if requested, the applicant institution must submit proof of its nonprofit status. Applications are neither requested nor accepted from for-profit entities. Institution endorsement or signature is not required for Letters of Intent.

By accepting an amfAR grant, the recipient institution will accept full responsibility for the conduct of the investigation and for the acts of the investigator(s). Both are under the direction of the institution and are subject to its medical and scientific policies. Similarly, project personnel compensated with funds awarded by the Foundation are employees of the recipient institution; they are not amfAR employees.

Investigators and other personnel need not be U.S. citizens, and there are no restrictions as to age, color, creed, gender, medical condition, handicap, national origin, parental status, political affiliation, race, religion, marital status, or sexual orientation.

Members of the Foundation's board of trustees are not eligible investigators for Foundation-supported research. Members of the Scientific Advisory Committee (SAC) are eligible. Members of the board of trustees and SAC must comply with the Foundation's policies regarding the avoidance of conflicts of interest.

Additional eligibility requirements may be stipulated in an RFP or other solicitation for submission of a proposal or application.

AVAILABILITY OF FUNDS

All amfAR grants are awarded contingent upon the availability of funds and without guarantee of subsequent or continued funding.

ALLOWED USE OF FUNDS

In general, a **grant** is applied to direct costs of salaries for professional and technical personnel, laboratory supplies and equipment, travel, and the publication of findings. For-profit organizations may receive sub-awards or subcontracts supported with grant funds contingent upon amfAR's prior written approval.

Funds are not awarded for the following:

- Major construction or the remodeling of facilities (minor alterations are allowed with adequate justification);
- The direct cost of support services and facilities generally available at a sponsoring institution (occupancy costs, utilities, maintenance, telephone, office furniture and supplies, etc.) except when directly allocable, and essential to carrying out the proposed research;
- The purchase, lease, rental, or servicing of office equipment
- Funding for dissertation research

Recipient institutions agree not to promote or engage in violence, terrorism, or the destruction of any state, and to take prudent measures to insure that they do not provide support through sub-grants or other financing to any entity that engages in those activities.

Indirect Costs—Foundation grants are not meant to cover the total cost of a proposed research project. A grantee institution is expected to provide the necessary physical facilities and administrative services, as well as other supporting services normally available at a sponsoring institution. Expenses generally considered to be indirect costs may be budgeted as direct costs only when required for the operation of remote sites deemed necessary and leased or rented exclusively for conduct of the funded research. Such requests will be carefully assessed for appropriateness and are subject to peer review and administrative approval. Indirect costs are allowed at a maximum rate of 20% of direct costs excluding subawards to support discrete component project(s) under the direction of co-investigators at other institutions. However, such subcontracts may include indirect costs at maximum rate of 20% of direct costs to be paid to the subawardee. The maximum indirect rates for Mathilde Krim fellowships grants are 10% for phase I and 15% for phase II.

OVERLAP

amfAR will not award or continue funding grants for which there is scientific, budget or commitment overlap.

Scientific Overlap—Scientific overlap occurs when substantially the same research is proposed in more than one application; or is submitted to two or more different funding sources for review and funding consideration; or a specific research objective and the experimental design for accomplishing that objective are the same or closely related in two or more currently funded or pending applications or awards for which there is any overlap in the period of performance, regardless of funding source.

Budget Overlap—Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already funded by another source.

Commitment Overlap—Commitment overlap occurs when any project-supported personnel has time commitments (i.e., percent effort) exceeding 100 percent, regardless of how the effort/salary is being supported or funded.

SOURCE OF FUNDS
Funds available to the Foundation are obtained principally from private donations.

REVIEW AND APPROVAL PROCESS
amfAR intends to encourage and support HIV/AIDS research of the highest quality. Therefore, every properly prepared and submitted LOI or application received in response to an amfAR solicitation is peer-reviewed by members of the Foundation's Scientific Advisory Committee (SAC). Each is subject to an overall conformance review by the Foundation staff. Those found to be inconsistent with the guidelines and instructions are eliminated at that time, and the investigator and the applicant institution's grants official are notified. Applications are solicited from investigators whose letters of intent have been recommended by the Foundation's SAC. Unsolicited applications are not accepted for consideration.

The SAC, a volunteer body of scientists who are experts in various fields of HIV/AIDS research, evaluates (1) the scientific merit of LOIs and applications; (2) the relevance of the research to the control of the epidemic or to the benefit of patients with AIDS or HIV/AIDS-related conditions; (3) the qualifications, experience, and productivity of the investigator/sponsor; (4) the facilities available; and (5) the likelihood of success. The SAC's determinations are considered by the amfAR board of trustees, which holds the sole authority to approve project funding.

Submission of an LOI does not guarantee an invitation to submit a complete application. The LOI process is very competitive and only a limited number of proposals are approved for additional review.

Written critiques are not available for LOIs.

CONFIDENTIALITY
Throughout the review and award process, the Foundation respects the privacy of the applicant and endeavors to protect from disclosure any confidential or proprietary information contained in a submitted proposal. However, amfAR has in place no mechanisms to maintain or guarantee confidentiality and, as a not-for-profit corporation, lacks the financial resources to (1) institute such mechanisms or (2) accept liability for the disclosure of information. At the same time, the Foundation does not consider information on an application's project description form (lay-language summary) to be confidential. That information may be made public as a description of the project being funded by amfAR. Submission of an application or LOI is deemed acceptance of these provisions.

REVIEWER CONFLICTS OF INTEREST
A Conflict of Interest (COI) exists when a reviewer (or their close family member) has a professional or financial interest that does, or could be construed to, bias their assessment of an application.

COIs include, but aren't limited to, the following situations.

A reviewer or a close family member (now or in the past year):

1. Collaborates with the applicant
2. Subcontracts or consults with the applicant
3. Works at the same institution* as the applicant

   **Institutions that are part of a large system are considered separate as long as they are operationally and financially independent of each other. For example, UCSF and UCLA are considered separate institutions.*

A reviewer may not review or be present for the discussion and scoring of an application or letter of intent when a COI exists.

HUMAN AND ANIMAL SUBJECTS / BIOHAZARDS

Applicants are required to submit documentation of institutional approvals for research involving human or animal subjects or the use or production of biohazards. Research activity may not begin, nor may expenditures be made, until such approvals are received and forwarded to amfAR. Although these approvals are not required at the LOI stage, they will be required either with full applications or "just in time" for projects approved to receive grant funding.

Restrictions on the Use of Funds Awarded to Foreign Organizations—Unless written authority is obtained in advance from amfAR, funds from grants awarded to organizations outside of the United States (U.S.) may not be used to support (a) services performed in the U.S., or (b) travel to or from the U.S. Authorization to use funds for such purposes may be obtained by providing either of the following sets of documentation: (1) a copy of U.S. Internal Revenue Service (IRS) form W-8EXP bearing a valid International Taxpayer Identification Number or Employer Identification Number and either (a) an IRS determination letter or (b) written opinion of U.S. counsel that the organization is described in IRS Code section 501(c)(3); (2) alternatively, an applicant organization in a country that benefits from an exemption under a tax treaty with the U.S. should provide (a) a completed copy of IRS form W-8BEN and (b) an affidavit stating the treaty provision under which benefits are claimed and asserting facts pertinent to the treaty provision (e.g., facts to establish that the organization would qualify under IRS code section 501(c)(3)). Although these documents are not required at the LOI or application stage, they may be requested if grant funding is awarded.