CFAR03 Program
Supplemental Request for Applications in Pediatric/Adolescent HIV/AIDS
expires 07/31/13

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CFAR03 Developmental Grant Program
Supplemental Request for Applications in Pediatric/Adolescent HIV/AIDS

The Center for AIDS Research at Emory University (CFAR) and Children's Healthcare of Atlanta (Children's) are collaborating on a request for applications for research in **pediatric/adolescent HIV/AIDS**. Applications and awards will be administered through the CFAR03 mechanism of the CFAR Developmental Core.

The CFAR03 mechanism is intended to help move researchers toward independent investigator status in pediatric/adolescent HIV/AIDS research at the National Institutes of Health (NIH) by funding projects whose findings will strengthen the competitiveness of NIH applications.

The CFAR03 mechanism is modeled on the NIH R03 program and provides support for research projects that can be accomplished in a short period of time (1 year) with limited resources ($40K). There are two cycles of funding available through this supplemental RFA. Cycle A (November 1, 2012 deadline) is reserved for new applications and Cycle B (May 1, 2013 deadline) is reserved for resubmitted applications.

It is anticipated that this supplement will be re-issued on an annual basis from 8/13-7/31/17.

NOTES

- Submission of a CFAR03 application does not preclude concurrent submission of an NIH application containing substantially the same research proposal. Should both applications be funded, the CFAR award must be returned.
- CFAR03 awards may not be used to supplement research currently being funded by NIH or to provide interim support of projects under review.
- Like NIH, the CFAR03 program accepts only one resubmission of an application.
- Within one year of the conclusion of funding for a project made under this RFA, a grant application drawn from work done as a part of, or as a result from, this project must be submitted to an extramural grant agency. (See "Plans for a future NIH application" on p. 6 for additional notes regarding this requirement).

SCOPE

Examples of projects in support of pediatric/adolescent HIV research that might be funded include:

- Pilot or feasibility studies for emerging research opportunities in pediatric HIV/AIDS;
- Secondary analysis of existing data;
- Small, self-contained research projects;
- Development of research methodology or research technology.

NOTE: Some clinical studies are not allowed (see Appendix A for more information)**.**

ELIGIBILITY

INCLUSION CRITERIA:

- Faculty appointment at Emory University or Morehouse School of Medicine;
- Meets the definition of an NIH "New Investigator" **in HIV/AIDS.** Specifically, prior funding as an NIH independent investigator is permitted only as long as that funding has not been in HIV/AIDS.
- Exception: Investigators with prior independent NIH AIDS funding are eligible if they have not been the PI on any NIH AIDS grant within the last five years.

EXCLUSION CRITERIA:

- Individuals who have a current CFAR03 award are not eligible for additional funding while that award is still active. Individuals who are past recipients of a CFAR03 award are not eligible for additional funding that may be considered to be related to, or an extension of, that previously funded CFAR03 research. It is up to the applicant to demonstrate that a proposed project meets this requirement.
- Clinical and Post-doctoral Fellows are not eligible for funding under this RFA.

APPLICATION DEVELOPMENT PROCESS

PRE-SUBMISSION STEPS *NEW APPLICATIONS* (Accepted in Cycle A: Deadline = November 1)

1. **Contact the Developmental Core**. Applicants should contact Dr. Dennis Liotta (404/727-6602), Dr. Ralph DiClemente (404/727-0237), or Dr. Kimberley Hagen (404/727-8855), to discuss whether a proposed project matches the mission and objectives of the Emory CFAR.

2. **Establish eligibility for inclusion in the CFAR Research Career Mentorship Program (CRCMP)**. Applicants ***without prior independent funding from NIH*** are automatically enrolled in the CFAR Research Career Mentorship Program.

   As part of the program, a CRCMP participant ("you") is required to:
   Deadline for steps a-g: September 17, 2012

   a. **Identify an Application Committee** that consists of two or more mentors who will assist in the development of an application's content, consult as needed on the funded research, and assist as needed in writing at least one publication based on the research. Any research collaborators named in the application are also considered to be part of your Application Committee. The Committee Chair should have a successful track record of independent NIH funding.

   b. **Attend an orientation meeting** to review the application development process and the Application Committee's duties. This meeting may be in person or by conference call and should include you, your Application Committee Chair, and one or more members of the Developmental Core leadership. Call Dr. Kimberley Hagen (404-727-8855) to schedule this meeting.

   c. **Meet with your Application Committee** to review the pre-proposal (described below), gather feedback about the proposed specific aims and methods, and discuss the application preparation time line. **Send an email to Dr. Kimberley Hagen documenting that this meeting occurred**.

   d. **Contact the CFAR Biostatistics and Biomedical Informatics Core** to discuss the proposed research methodology and data analysis plans. Call Kirk Easley at 404-712-9642 to make an appointment. *A letter approving your proposed data collection and analysis plans, signed by either a Director or Associate Director of the Biostatistics & Biomedical Informatics Core, must be included in the application packet.*

   e. **Present your research proposal for feedback** to a group of senior scientists, at least two of whom are not a part of your Application Committee.

   f. **Submit a letter of intent**.
   The letter of intent should include:

      - RFA title, project year, and application cycle – e.g. CFAR03, YR14-B
      - A preliminary title for the project
      - Contact information, including:
        - PI(s): name, work phone, cell phone, and email
        - Application Committee members: names, work phones, and email
        - Co-investigators, and proposed collaborators, if any: name and email
      - A list of people who would be well qualified to review the application
      - A list of individuals who should not review the application and why.

   g. **Submit a pre-proposal**
   The *pre-proposal (limit = 1 page, single spaced) should include:*

      - A one to three sentence background of the research problem
      - Research Question(s) or Hypotheses
      - Specific Aims
      - A brief description of the proposed approach.

Deadline for step h: October 15, 2012

h. **Send at least one draft of the application narrative to your Application Committee for scoring**. There are two forms available through the Developmental Core website for use in scoring preliminary drafts. One is a checklist and one is for comments. It is up to the applicant to decide whether to have committee members use one or both forms when providing review of drafts. **A statement that this review occurred should be submitted in the application cover letter**. *Note: This is an important step as it helps the applicant identify in advance the specific strengths and weaknesses of the proposed application*.

PRE-SUBMISSION STEPS -- *RESUBMITTED APPLICATIONS* (Accepted in Cycle B: Deadline = May 1)

1. **Mentorship Program participants must meet with their Application Committee** to review the Summary Statement (pink sheets) received after the prior submission and discuss needed changes to the application. **A statement that this meeting occurred should be included in the application cover letter.**
2. **Submit a letter of intent and pre-proposal.**
   These may be resubmissions of a previously submitted LOI and/or Pre-proposal or may be revised versions, as appropriate. See section "f" above for details of what should be included in each document.
   Deadline: March 15
3. **Mark changes in the application per NIH standards.** Mark substantial scientific changes in the text of the revised application by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction (see below). The narrative should incorporate research completed since the prior version of the application was submitted.
4. **Include a one page Introduction, per NIH standards**, that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the pink sheets received after the previous submission.
5. **Prior to resubmission, Mentorship Program participants must send at least one draft of the revised application to their Application Committee for scoring and comments.** Committee members should use the "CFAR03 Pre-submission Review Comment Form," available on the Developmental Core website, when scoring resubmission draft(s). **A statement that this review occurred should be submitted in the application cover letter**. *This is an important step as it not only provides the applicant with feedback on how well a revised application responds to pink sheet comments, it also helps identify the specific strengths and remaining weaknesses of the revised application*.

SCHEDULE / DEADLINES

CYCLE A: New Applications

LOI & Pre-proposal due	**September 17**
Application due	**November 1**
Study Section held	Normally held the first week in December
Funding announcement	Normally announced the first week in January

CYCLE B: Resubmissions

LOI & Pre-proposal due	**March 15**
Application due	**May 1**
Study Section held	Normally held the first week in June
Funding announcement	Normally announced the fourth week in June

APPLICATION INSTRUCTIONS

Applications should be submitted on SF424 (R&R) electronic forms.

Applicants who have never filled out a Grants.gov SF424 form should watch the following tutorial first: http://www.grants.gov/assets/CompletingaGrants.govApplication.html

The Funding Opportunity Announcement (FOA) used for CFAR03 applications is **PA-11-262**. This is the FOA for investigator-initiated applications for the NIH Small Research Grant Program (R03) upon which the CFAR03 is based. Click this link to access PA-11-262.

The necessary forms for applying for a CFAR03 may be downloaded from PA-11-262 by clicking the "Apply for Grant Electronically" button under "Required Application Instructions" and saving the forms to your hard drive.

Note: If the user has an acceptable version of Adobe Reader installed but is still receiving an error message when opening the Application Package, right click on the download link, choose "Save Link As" to save the Application Package to a computer hard drive, and then open it directly from Adobe Reader.

Instructions for completing the application may be found in the NIH *PHS SF424 (R&R) Adobe Forms Version B Application Guide* (NIH Instructions), downloadable via **PA-11-262**.

All attachments must be submitted as NIH-compliant pdf files. See NIH Instructions sections 2.3.2 and 2.6.

After completing the application forms, do NOT submit the package through Grants.gov. Instead, put the saved pdf file in your CFAR Dropbox folder (see Application Submission Procedure, p. 8).

NIH Forms: CFAR03-specific Instructions:

With the exceptions detailed below, follow the NIH Instructions for filling out a CFAR03 application.
NOTE: Unless otherwise indicated, fill in ALL form fields, not just the required ones.

SF 424 (R&R) FACE PAGE (NIH Instructions section 4.2)

2. Applicant Identifier: Insert the applicant's 7-digit Emory employee ID number
3. Date Received by State / State Application Identifier: Leave blank
4. a) Federal Identifier: Insert RFA title, project year, and cycle – e.g. CFAR03 Supplement, YR14-B
4. b) Agency Routing Identifier: leave blank.
5. Organizational DUNS: See OSP fact sheet: http://www.osp.emory.edu/links/fact/index.cfm
6. Employer Identification: Insert 'Entity Number' from OSP fact sheet
7. Type of Applicant: "O: Private Institution of Higher Education"
12. Proposed Project: The actual dates of support will be established after Emory OSP releases a Smartkey and Project Number for a given award but this is a required field on SF424 forms so use the following dates as filler: Cycle A: 01/15/13, 01/14/14; Cycle B: 07/15/13, 07/14/14.
13. Congressional District: See OSP fact sheet
15. Estimated Project Funding: Assign total amount to "Non-Federal Funds."
16. Choose "No"
19. This section normally collects contact information for someone from OSP (i.e. one of Emory's "Signing Officials"). For the purposes of a CFAR03, this section should include contact information *for the person who is responsible for post-award grant management*, should this application be funded. This will probably be the PI's departmental grant administrator or his/her designate.
20. Leave blank

The following sections have no CFAR-specific instructions:

PROJECT/PERFORMANCE SITE LOCATIONS (NIH Instructions section 4.3)
OTHER PROJECT INFORMATION (NIH Instructions section 4.4)
SENIOR/KEY PERSON PROFILES (NIH Instructions section 4.5)
PHS 398 COVER PAGE SUPPLEMENT (NIH Instructions section 5.3)
398 CHECKLIST (NIH Instructions section 5.6)

PHS 398 RESEARCH PLAN (NIH Instructions, section 5.5)

Format all documents per NIH rules (see NIH Instructions section 2.6).

Internet website addresses (URLs) should not be used to provide information necessary to the review because reviewers are not obligated to view the Internet sites.

File names for each section should follow the following heuristic: "PI Last Name.SectionName.pdf." For example:

- Doe.SpecificAims.pdf (Note: Limit=1 page)
- Doe.ResearchStrategy.pdf (Note: Limit=6 pages)

5. Progress Report Publications List: N/A. Do not include

14. Letters of Support: Include the following:

- Letters signed by the Core Director of each CFAR Science Core that will provide services for the proposed project. Each letter should clearly describe specific service(s) to be provided and the amount / limits of those services. (Provide a separate letter for each Core used);
- Letters from named research collaborators and consultants. For paid consultants, letters should include rate/charge for consulting services;
- A letter from the PI's Department Chair or Division Director;
- Mentorship Program participants only:
    - A letter signed by the Director or Associate Director of the Biostatistics and Biomedical Informatics Core, approving the proposed data collection and analysis plans.

NOTE: Because submitted letters must be hand signed, this attachment alone may be created by *scanning* signed letters into a single pdf file instead of using pdf conversion software.

16. Appendix: At a minimum, include the following two required Appendices

- **CFAR Scientific Core Statement**: Include **either**:
    1. A description of the CFAR Core facilities to be used (limit: 1 paragraph per Core);
    2. A statement that no CFAR core exists that can provide access to equipment, services, expertise, training, or materials needed for the proposed study (NOTE: *Applications will be marked down on review if, in the opinion of the reviewers, the applicant is overlooking opportunities to collaborate with / seek appropriate research support from the CFAR Cores*); or
    3. A statement explaining any other reason why the applicant is not planning to use any of the CFAR cores.

  Applications without one of the above 3 statements will not be considered for funding

- **Future Plans for NIH Applications** (Limit = 1 page). Describe how the findings from the proposed research will be useful for future NIH applications. Outline the remaining experiments, if any, that need to take place prior to an eventual NIH application based on this work. Because **it is a requirement of this RFA that an extramural grant application (not necessarily to NIH) be submitted within one year of the conclusion of funding**, please describe the proposed funding mechanism(s) and, if applicable, how any non-NIH-funded work will support a later NIH application.

  Given that 30% of an application's score will be based on the proposed project's potential to contribute to a future NIH application, the importance of this Appendix cannot be overstated.

The following additional items **may** be included in the Appendix:

- Surveys, questionnaires, and other data collection instruments;
- Informed consent documents;
- Up to 3 of the following types of publications:

- **Manuscripts and/or abstracts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
- **Manuscripts and/or abstracts that are published, but for which a free, online, publicly available journal link is not available:** The entire article should be submitted as a PDF attachment.
- **Patents directly relevant to the project:** The entire document should be submitted as a PDF attachment;

The following items **may not** be included in the Appendix:

- Articles not yet accepted for publication.
- Photographs or color images of gels, micrographs, etc., **are no longer accepted as Appendix material**. These images must be included in the Research Plan. However, images embedded in publications are allowed.
- Publicly accessible publications. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section and/or the Biographical Sketch section.

BUDGET (NIH Instructions section 4.7):

Stipulations:

- It is not required that the PI(s) request salary. If PI salary costs are requested, they may not exceed 20% of the budget
- Do not request:
  - Salary or travel for senior faculty
  - Equipment purchases of > $5,000
  - Indirect Costs
  - Funds for services available through a CFAR Core*

* Core services in facilitation of a CFAR03-supported project are subsidized by the CFAR Administrative Core so requests for research support that can be provided by one or more CFAR cores should not be included in the budget. Subsidized research support is not unlimited in scope or time however and the *description* and *limits* of all CFAR-provided services, equipment, consultation, training, or materials ("research support") to be provided to a project should be agreed upon in advance and that agreement documented in a letter of support from the Director of the applicable Core(s). Applicants may request funds for research support in excess of what a Core has agreed in advance to subsidize, but the request must be well justified in the Budget Justification.

If a study section reviewing a CFAR03 application judges that a requested budget item can be reasonably provided by the CFAR they will deny that budget item request. **Cores are not required to subsidize research support that was not negotiated and documented prior to application submission** and Cores may request that a non-CFAR03 Smartkey number be provided to pay for any research support not included in a letter of support included in the application. For this reason **it is extremely important that applicants be conversant with the full range of research support available to CFAR03 grantees** and that they discuss any and all needed research support needs with the CFAR Cores during application development.

Applicants may request funds for research support provided by non-CFAR cores and entities and, as described above, for research support in excess of what a Core has agreed in advance to subsidize, but the request for those funds must be well justified in the Budget Justification.

- Funds may be requested for travel associated with writing an NIH research grant proposal based on project findings and/or attending meetings to establish collaborations or to present project-related data. Unless permission of the Core has been granted to extend the travel deadline, supported travel must be completed within one year of the end of the project period.

COVER LETTER (NIH Instructions section 5.2)

The PI(s) and – in the case of CRCMP participants – members of the Application Committee must sign the cover letter. It should include the following information:

- PI name(s)
- Application title
- RFA title and Month/Year (e.g. CFAR03 Supplement, May 2013)
- Application type (New or Resubmission)
- List of individuals considered capable of reviewing (and not in conflict with) the application
- List of individuals who should not review the application and why
- Disciplines involved, if multidisciplinary
- For Mentorship Program Participants only:
  - A statement that all required reviews were held (see Application Development Process, p. 3-4)
  - A statement from the Application Committee signing off on the submitted/re-submitted application.

APPLICATION SUBMISSION PROCEDURE

1. CFAR03 applications should be submitted via CFAR DropBox. Sign up for a (free) account at www.DropBox.com. Installing the desktop client is not required as access to DropBox is available via the Internet. A DropBox account needs to be in place before LOI submission.
2. When an LOI is received, a CFAR DropBox folder will be created for the applicant PI(s) and an invitation to share it will be sent to the PI(s). **Accept the invitation and save the email** –it will be required for future access to that DropBox folder.
3. Submit CFAR03 applications by saving the completed packet to the assigned CFAR DropBox folder.

APPLICATION REVIEW

- Members of the Emory CFAR Scientific Review Group review proposals in an NIH study section format, with two reviewers assigned to each proposal. Outside reviews will be requested as needed.
- In assigning an Impact* score, CFAR reviews are not limited to the five NIH review criteria (approach, significance, innovation, investigators, environment). Half (50%) of a reviewed application's overall Impact* score will take into consideration two additional, CFAR-specific criteria (potential to contribute to a future NIH application and quality of writing) and one additional Children's-specific criteria (significance to child health).
- A written critique will be prepared for each proposal. These critiques, known at NIH formally as a "Summary Statement" and informally as "pink sheets," will be forwarded to the applicant approximately three weeks following completion of the study section.

REVIEW CRITERIA

Weight	Item	Section of application scored
30%	**Future**: Does the proposed project have a high potential of contributing to a future NIH application in pediatric/adolescent HIV?	• "Future Plans for NIH Applications" statement
20%	**Writing**: Does quality of writing in the application (including grammar and spelling) meet the standard found in successful NIH applications?	• Entire narrative
25%	**Approach**: Are the overall strategy, methodology, and analyses well reasoned and appropriate for accomplishing the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves human subjects research, are the plans for 1) protection of subjects from research risks, and 2) decisions about the inclusion or not of minorities, women, children, and/or vulnerable peoples justified in terms of the scientific goals and research strategy proposed?	• Specific Aims • Research Strategy: (c) "Approach" • Letters of support • Protection of Human Subjects • Inclusion of Women and Minorities • Inclusion of Children • Vertebrate Animals
25%	**Significance***: Is the project significant to child health? Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?	• Research Strategy: (a) "Significance"
	Innovation: Does the application seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are they novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?	• Research Strategy: (b) "Innovation"
	Investigators: Are the PD/PIs, collaborators, and other researchers well suited to the project? Do they have appropriate experience and training? Do the PIs have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?	• Biosketches • Dual PI Leadership Plan
	Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?	• Resources page • Select agents research • Letters of support • CFAR scientific core statement

***** NIH makes the following distinction between “Significance” and “Impact:”

Significance: One of the five NIH review criteria. Measures perceived *theoretical* effect; i.e. the degree to which reviewers believe a project could theoretically change the way things are conceptualized or done in a research field ... assuming all goes perfectly, all specific aims are achieved, and all hypotheses are supported by research results.

Impact: The overall score given to an application. Measures perceived *actual* effect; i.e. the likelihood that – given reviewer- and PI-identified limitations of approach, environment, investigator training, etc. – a project will actually help lead to future NIH funding and exert a sustained, powerful influence on the research field(s) involved. This score is not necessarily an arithmetic mean of the scores from each separate criterion.

FUNDING DECISIONS

Recommendations given by the Study Section are presented to the leadership of the CFAR Administrative Core for a funding decision. Notices of Award are issued approximately three weeks after the completion of the study section.

RELEASE OF FUNDS

A response to the pink sheets and proof of all necessary institutional approvals (e.g. CITI, IRB/HIC, IACUC, biohazard, radiation safety) must be provided to the Center for AIDS Research prior to release of funds. Additional stipulations may be included in the Notice of Award as well.

CONTACTS

Scientific Questions
Dr. Dennis Liotta
phone: 404/727-8130
e-mail: dliotta@emory.edu

Dr. Ralph DiClemente
phone: 404/727-0237
e-mail: rdiclem@emory.edu

Application Questions
Dr. Kimberley Hagen
phone: 404/727-8855
e-mail: kbs.hagen@emory.edu

Budget or Administrative Questions
Ms. Shelle Bryant
phone: 404/727-9437
email: sbryant@emory.edu

APPENDIX A

The information below is provided by the NIH CFAR:

GUIDANCE for CFAR CLINICAL RESEARCH STUDIES
NIH Definition of a **Clinical Trial**- *A prospective study of human subjects designed to answer questions about biomedical and behavioral interventions, e.g., drugs, treatments, or devices or new ways of using known treatments to determine whether they are safe and effective*.
http://www.niaid.nih.gov/ncn/glossary/default2.htm#c

I. Studies that cannot be funded through the CFAR

- Studies involving new drugs, treatments, or devices, or off-label use of a licensed drug, are not allowed through the CFAR.

These studies must go through the NIH R34 process.

II. Studies that can be funded via CFAR but require additional NIH review

- Studies involving licensed drugs, treatments, or devices (allowed on a case-by-case basis)
- Studies that are deemed above minimal risk by the Institutional IRB
- Studies involving vulnerable populations

Studies involving behavioral interventions (above minimal risk)

For studies falling in the above two research areas, please send a completed CFAR Clinical Checklist.

III. Studies that do not require additional NIH review

Please include IRB approval letter in the annual progress report.

This guidance is based on the OHRP guidelines of research that would go through an expedited review procedure.

This may include research activities that present **no more than minimal risk t**o human subjects. Examples include but are not limited to the following:

- routine blood draws
- non-invasive procedures routinely employed in clinical practice (e.g. ultrasound, MRI)
- surveys, focus groups

For more information, please go to: http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm