

**CFAR R03 Mentored Research Award (CFAR-03)  
Clinical Trials Not Allowed**

**Funding Opportunity Announcement**

*expires 12/31/21*

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## CFAR R03 Mentored Research Award (CFAR-03) Clinical Trials: Not Allowed

- [NIH revised definition of Clinical Trials](#)
- [NIH Clinical Trials definition FAQ](#)
- [Determine if your proposed study is a Clinical Trial](#)
  
- [See also this document by the NIH CFAR re: requirements for Clinical Research Studies](#)

The Center for AIDS Research at Emory University (CFAR) R03 mechanism (CFAR-03) is designed to help move CFAR faculty toward independent investigator status in HIV/AIDS research at the National Institutes of Health (NIH). The goal is to fund mentored research projects and additionally to train the Early Stage Investigator (ESI) on how to write an NIH R01 grant. CFAR-03 funding is designed to help the faculty generate preliminary data that will strengthen the competitiveness of subsequent NIH applications in areas that align with NIH/OAR high-priority areas of HIV research (see <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html>).

CFAR-03 projects may be single or dual PI.

For this FOA cycle, projects should be planned to be completed in 12-months.

Direct costs for this mechanism are \$40K. Proposals requesting a larger budget may be considered with appropriate justification (such as proposals promoting team science, community engagement and through MPI leadership). Please contact the Developmental Core to discuss.

### NOTES

- Submission of a CFAR-03 application does not preclude concurrent submission of an NIH application containing substantially the same research proposal. Should both applications be funded, the CFAR award will be terminated and any unspent funds must be returned.
- CFAR-03 awards may not be used to supplement research currently being funded by NIH or to provide interim support of projects under review.
- CFAR-03 awards may not be used to supplement or extend research that is, or has been, funded by a CFAR-K or earlier CFAR-03 award. It is up to the applicant to demonstrate that a proposed CFAR-03 project meets this requirement.

### SCOPE

Examples of the types of projects that might be funded under this RFA include:

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

### ELIGIBILITY

#### INCLUSION CRITERIA:

- Faculty or faculty equivalent with eligibility to be PI on an NIH R-level grant, with an appointment at Emory University at the time of CFAR award start date
  
- Meets the definition of an NIH "[New Investigator](#)" in **HIV/AIDS**. Specifically, prior funding as an NIH independent investigator makes an applicant ineligible **ONLY IF** that funding has been in the field of HIV research.
  - Exception: Investigators with prior independent NIH funding in HIV are eligible if they have not been the PI on *any* NIH HIV grant within the last five years.

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## EXCLUSION CRITERIA:

- Individuals who are a PI on an active CFAR-series award (current awardees are not eligible to hold multiple active CFAR-series awards)

## APPLICATION DEVELOPMENT

### 1. Contact the Developmental Core

Applicants should contact Dr. Rama Amara for basic and preclinical science applications ([ramara@emory.edu](mailto:ramara@emory.edu)) and either Dr. Drenna Waldrop ([drenna.waldrop@emory.edu](mailto:drenna.waldrop@emory.edu)) or Dr. Kimbi Hagen ([kbs.hagen@emory.edu](mailto:kbs.hagen@emory.edu)) for social/behavioral or clinical science applications to discuss whether a proposed project matches the objectives of the CFAR-03 mechanism.

### 2. Identify a CFAR-03 Research Mentor, if applicable \*

Applicants without a history of R01-equivalent funding must have a research mentor on the study team.

### 3. Attend a CFAR Developmental Core Award grant writing seminar

Attendance at this seminar is recommended but is NOT a requirement of submission.

### 4. Consider presenting your specific aims and approach to the CFAR Core Directors for feedback

This optional meeting will take place by webinar and presentation slots are limited. Contact Dr. Galina Terbova ([galina.terbova@emory.edu](mailto:galina.terbova@emory.edu)) if you are interested in this opportunity.

### 5. Consult with Biostatistics Core faculty to review your data collection and analysis plan \*\*

Please contact Dr. Robert Lyles ([rlyles@emory.edu](mailto:rlyles@emory.edu)) to request the consultation. After the meeting, the Bios Core will provide a required letter of verification for inclusion in the application packet

### 6. Meet with other CFAR Science Cores, as applicable, to get Letter(s) of Support (LOS) documenting Core services provided to your project.

Support may include consultation, services, materials, training, and/or shared research space / equipment. Limited subsidized support may be available through CFAR Cores. Any additional support must be proposed on a fee for service basis and should be included in the budget. The letter should indicate the cost, and the project budget should account for the anticipated expense. As appropriate to the support proposed, the Emory CFAR Core will provide you with information addressing rigor and reproducibility to include in your Significance/Approach section.

### 7. Get pre-review comments on the application draft from your CFAR-03 research mentor \*

A copy of the application review form is available on the Developmental Core page of the CFAR website

\* Steps 2 & 7 are mandatory for any applicant with no prior history of NIH independent investigator funding

\*\* Step 5 is mandatory for all applicants

## SCHEDULE / DEADLINES

### CYCLE A:

LOI due	<b>October 1</b>
Application due	<b>November 1</b>
Study Section held	Normally held the first week in December
Funding announcement	Normally announced mid-December

## LETTER OF INTENT INSTRUCTIONS

The letter of intent (LOI) should include:

- Funding mechanism being applied to (CFAR-03)
- A preliminary title for the project
- Contact information, including:
  - PI: name, phone, and email
  - CFAR-03 Research Mentor (if applicable): name, phone, and email
  - Co-investigators, and proposed collaborators, if any: name and email
- A list of people who are well qualified to review the application
- A list of individuals, if applicable, who would be considered to be in conflict with reviewing the application

- A **one page** research pre-proposal that includes:
  - One to three sentence background of the research problem
  - Proposed research question(s) or hypotheses
  - Proposed specific aims
  - A brief description of the proposed approach

Applicants should email a pdf of the letter of intent and one-page research pre-proposal to the CFAR-series Program Officer, Galina Terbova (galina.terbova@emory.edu), cc'ing Jenny Anderson (jenny.anderson@emory.edu).

## APPLICATION INSTRUCTIONS

Applicants should work with their department's RAS unit to develop, assemble and submit the application. Applications should be prepared using the Cayuse 424 system and then emailed as a single pdf packet to the CFAR. Do **NOT** deliver or route the application through Emory's OSP office.

**Applicants without prior experience writing NIH-style applications may want to review the NIH "[How to Apply – Application Guide](#)" website.**

## COVER LETTER

The PI and, when applicable, the PI's Research Mentor should both sign a cover letter including the following:

- PI name(s), department(s), and contact information
- Application title
- Application type (New or Resubmission)
- Direct Costs requested
- Post Award administrator name and contact information
- A statement, if applicable, confirming that the PI's Research Mentor provided pre-review comments on a final draft of the new or resubmission application

## FORM PAGES

- Applications should be prepared using updated [FORMS-F](#) forms and NIH FOA [PA-20-200](#) (the current Funding Opportunity Announcement for investigator-initiated applications for the NIH Small Research Grant Program (R03) mechanism upon which the CFAR-03 is based).
- Except when CFAR-specific instructions are provided below, applicants should follow NIH instructions for completing an SF424 form set.

## PHS 398 RESEARCH PLAN

- Format all documents per NIH rules
  - 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 pdf upload to the application packet should follow this heuristic: "PI Last Name.SectionName.pdf."
 

For example:

  - "Doe.SpecificAims.pdf" (**Limit=1 page**)
  - "Doe.ResearchStrategy.pdf" (**Limit=6 pages**)
- Rigor and Reproducibility: The research plan should fully address rigor and reproducibility.
  - See [NIH FAQs](#) for [NOT-16-011](#)
- Inclusion Across the Lifespan: For projects including human subjects, the research plan **must** fully address inclusion across the lifespan.
  - Read NIH [NOT-OD-18-116](#)

- Sex as a Biological Variable: All research projects conducted with human subjects, vertebrate animals, or materials (e.g. blood, tissue, cell lines) from human or vertebrate animal subjects must fully address sex as a biological variable in the research plan
  - Read [NOT-OD-15-102-Guidance](#)
  - Read (<https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>)
- The Approach section should include a project activities timeline.

#### REQUIRED ATTACHMENTS.

**Applications that fail to include the following four required attachments will be returned without review.**

- Attachment #1: Applicability to NIH/OAR Research Priorities:** (Limit = 1 paragraph)  
See [NOT-OD-20-018](#). This attachment should identify *which* High Priority topic the proposed project addresses and describe *how* the proposed project will address that topic.
- Attachment #2: Future Plans for NIH Applications:** (Limit = 1 page)  
This attachment should 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.
  - **Given that almost half (40%) of an application's overall impact score will be based on the proposed project's potential to contribute to a future NIH application, the importance of this attachment cannot be overstated**
- Attachment #3: Emory CFAR Scientific Core Statement:** (Limit = 1 page)  
This attachment should include one of the three options below:
  1. A description of the Emory CFAR Science Core support to be used during implementation of the project, referencing the appended Core letter(s) of support (limit: 1 paragraph per Core).  
*Note: to avoid being marked down on review, the narrative text should recapitulate and be consistent with the description of support provided in each attached Core LOS.*
  2. A statement that no Emory CFAR core can provide access to consultation, services, training, materials, and/or shared equipment / research space 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*
  3. A statement explaining any other reason why the applicant is not planning to use any of the Emory CFAR cores.
- Attachment #4: Letters of verification / support:**
  - A letter signed by the Director or Associate Director of the CFAR Biostatistics and Biomedical Informatics Core, verifying that Core faculty reviewed and approved the proposed data collection and analysis plans;
  - If applicable, a letter signed by the Director of each CFAR Science Core that will provide services for the proposed project. Letters should clearly describe specific assistance to be provided and the amount / limits of that assistance. (Provide a separate letter from each Core to be used);
  - If applicable, a letter signed by the PI's CFAR-03 Research Mentor, verifying participation in the development of the CFAR-03 application and, if funded, in the implementation of the CFAR-03 project and the production of publications based on project findings;
  - If applicable, letters of support 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, approving the application's submission.

#### APPENDICES

Follow the guidelines contained in NIH [NOT-OD-17-098](#) (released 8/02/17).  
This CFAR-03 FOA contains one FOA-specific appendix:

**CFAR-03 mentoring plan (if applicable):** (Limit = 1 page). Include:

- Brief description of each member of the mentoring team
- Goals of the mentoring plan
- Brief description of each mentoring activity included in the plan
- How, and how often, the mentoring team will meet
- How success at meeting the identified goals will be assessed.

**BUDGET** (Use the R&R, NOT modular, budget)

Stipulations:

- It is not required that the PI(s) request salary. If PI salary costs are requested, they may not exceed \$8,000 (including fringe benefits) without prior permission from the CFAR-series program officer, Galina Terbova.
- Funds may be requested for travel and activities 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. Supported travel must be completed within the award's project period.
- Do not request:
  - Salary or travel for senior faculty
  - Equipment purchases of > \$5,000 (**NOTE:** items like computers or tablets fall under "supplies" category, unless they are a part of a larger equipment system).
  - Indirect Costs (although these may be awarded later, depending on the source(s) of funding used to support the award)
  - Funds for services that a CFAR Core has agreed to subsidize  
See Appendix A. Each CFAR Core provides a limited amount of subsidized support for CFAR-03 awardees. Any additional support proposed on a fee for service basis should be included in the budget and well justified

\*Applicants may request funds for CFAR Core 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 the study section judges that a requested budget item should reasonably be subsidized by the CFAR Core, the budgeted item will be denied. **Cores are not required to subsidize the cost of services beyond what is negotiated and documented in the letter of support provided with the application.** Investigators may be required to cover the cost of services with a non-CFAR Speed Type if services requested exceed those described in the letter of support included in the application. For this reason, **it is extremely important that applicants fully understand the full range of subsidized research support available to CFAR-03 grantees** and that they discuss the full range of required research support with applicable CFAR Cores during application development.

Applicants may request funds for support provided by non-CFAR cores and entities and as described above, for research support that exceeds subsidized support through the Cores. Requests for funds to cover additional Core provided services should be well described in the Budget Justification.

**SUBMISSION PROCEDURE**

All documents must be submitted as NIH-compliant pdf files.

CFAR-03 applications do NOT have to be routed for approval through the PI's Department / School. They must, however, include a letter signed by the PI's department/division chair indicating approval for the application's submission

Do NOT submit the completed application package to OSP. Instead, email a pdf of the application to the CFAR-series Program Officer, Galina Terbova (galina.terbova@emory.edu), cc'ing Jenny Anderson (jenny.anderson@emory.edu).

## **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 NIH-style Impact score (1-9), CFAR reviews are not limited to the five NIH review criteria (approach, significance, innovation, investigators, and environment). Over half (60%) 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.' See Review Criteria table (Appendix B) for additional details.
- A written critique will be prepared for each proposal. These critiques, formally known as a "Summary Statement" and informally known as "pink sheets," will be forwarded to the applicant approximately three weeks following completion of the study section.

## **RELEASE OF FUNDS**

A response to the pink sheets and proof of all necessary institutional approvals must be provided to the Center for AIDS Research prior to release of funds. Additional stipulations may also be included in the Notice of Award.

## **CONTACTS**

### **CFAR-series Program Officer**

Galina Terbova

E-mail: [galina.terbova@emory.edu](mailto:galina.terbova@emory.edu)

### **Scientific Questions**

Rama Amara, PhD

Email: [ramara@emory.edu](mailto:ramara@emory.edu)

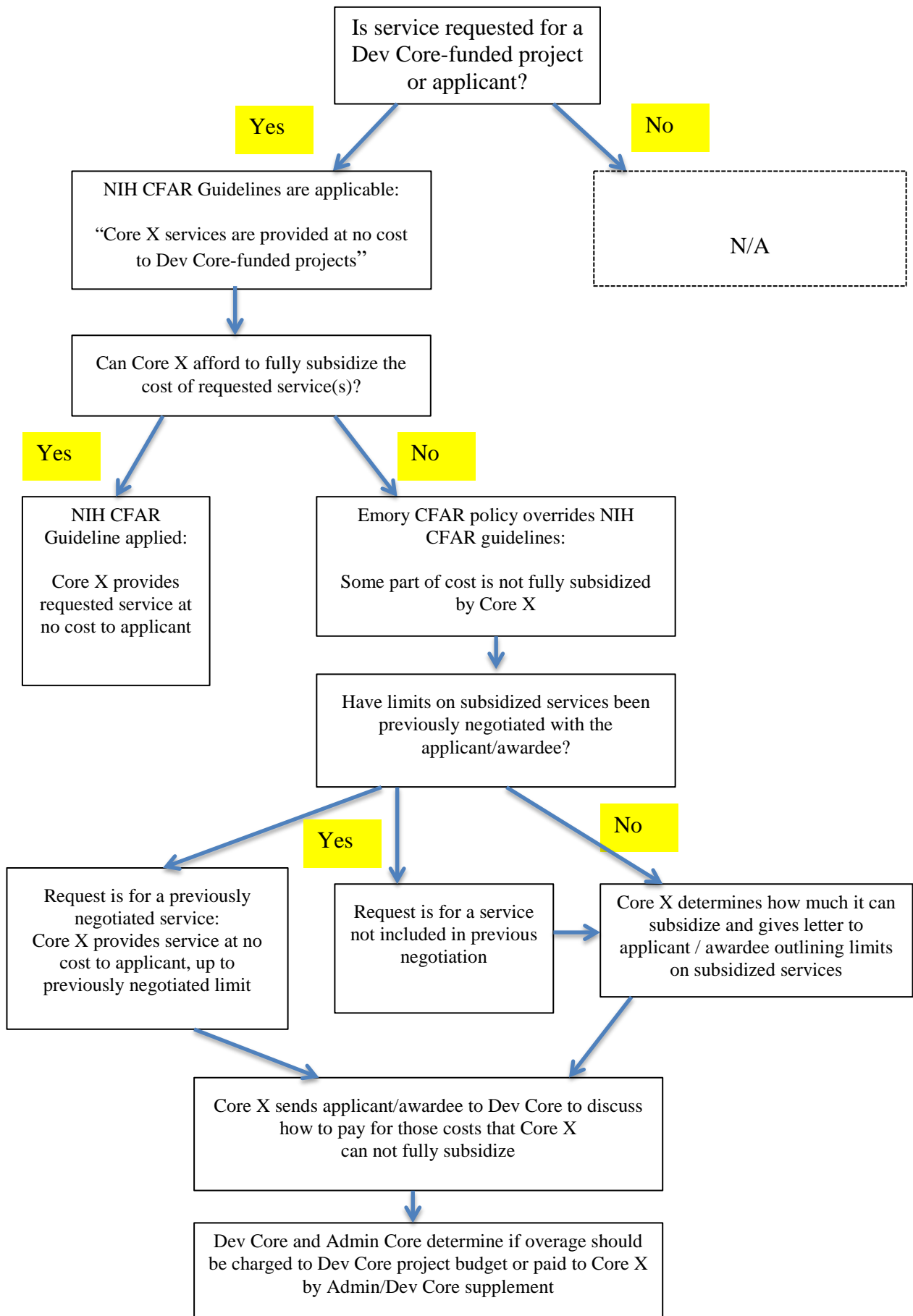
Drenna Waldrop, PhD

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Kimbi Hagen, EdD

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**APPENDIX A: SUBSIDIZED CORE SUPPORT DECISION TREE**





**APPENDIX B: CFAR-03 REVIEW CRITERIA**

Weight	Item	Section of application scored
40%	<p><b>Future:</b> Does the proposed project have a high potential of contributing to a future NIH application?</p>	<ul style="list-style-type: none"> <li>* Entire narrative</li> <li>• “Future Plans for NIH Applications” statement</li> <li>• “Applicability to NIH/OAR Research Priorities” statement</li> </ul>
20%	<p><b>Writing:</b> Does quality of writing in the application (including grammar and spelling) meet the standard found in successful NIH applications?</p>	<ul style="list-style-type: none"> <li>• Entire narrative</li> </ul>
25%	<p><b>Approach:</b> Does the application describe how the experimental design and methods will achieve robust and unbiased results? Does the proposal explain how biological variables, including sex, are factored into research designs and analyses? For example, is strong justification provided for applications proposing to study only one sex?</p> <p>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?</p> <p>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?</p>	<ul style="list-style-type: none"> <li>• Specific Aims</li> <li>• Research Strategy: (c) “Approach”</li> <li>• CFAR scientific core statement</li> <li>• Letters of support</li> <li>• Inclusion of Individuals Across the Lifespan</li> <li>• Inclusion of Women and Minorities</li> <li>• Vertebrate Animals</li> </ul>
15%	<p><b>Significance*:</b> Does the proposal describe a research problem considered to be High Priority by NIH/OAR? Does the proposal describe the scientific premise for the proposed project? Will successful completion of the aims lead to larger research studies that can change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?</p>	<ul style="list-style-type: none"> <li>• Research Strategy: (a) “Significance”</li> <li>• “Applicability to NIH/OAR Research Priorities” statement</li> </ul>
	<p><b>Innovation:</b> 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?</p>	<ul style="list-style-type: none"> <li>• Research Strategy: (b) “Innovation”</li> </ul>
	<p><b>Investigators:</b> Is the research team well suited to the project? Do the PI(s) have appropriate experience and training? If dual PI, do the PIs have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?</p>	<ul style="list-style-type: none"> <li>• Biosketches</li> <li>• Dual PI Leadership Plan</li> <li>• Mentoring Plan</li> </ul>
	<p><b>Environment:</b> 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 CFAR scientific environment, subject populations, or collaborative arrangements?</p>	<ul style="list-style-type: none"> <li>• Resources page</li> <li>• Letters of support</li> <li>• CFAR scientific core statement</li> </ul>