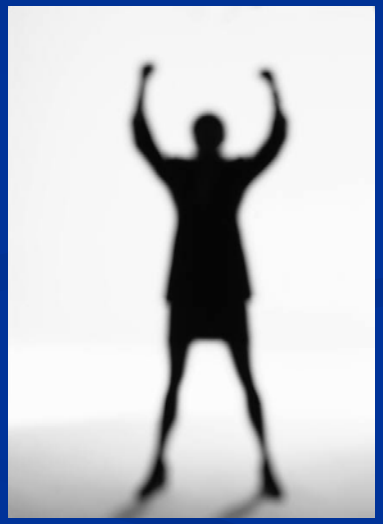
How to Write a Successful CFAR/AIDS Institute Seed Grant Application



Sponsored by the Developmental Core

March 28, 2012 12:00 – 2:00 P.M.

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CFAR CENTERS FOR AIDS RESEARCH

UCLA AIDS INSTITUTE

4 Steps to a Successful Seed Grant Submission and Completion

Letters of Intent to Submit a Seed Grant Application

- Your LOI is read and suggestions are offered as you proceed through the process
- You can receive consultation about preparing your application. Contact Dr. Wyatt (310.825.0193, gwyatt@mednet.ucla.edu) for individual meetings about your research.

Step 2

Submitting a Seed Grant Application

2A. Application Cover Letter should include:

- The title of your research
- The area to which you are applying (fellowship, basic, clinical or behavioral research)
- The mentor(s) of your work (if applicable)
- The amount that you are requesting
- Any key personnel or consultants that are included in the research.

This information will help us to assign your application to experts familiar with your area of interest.

2B

- The application will be sent to 3 reviewers who have related experience in your area of interest

2C

- Decisions about funding will be made by the Seed Grant Review Committee, a multi disciplinary group of UCLA faculty

2D. You will receive a score

Impact	Score	Description
High	1	The very best, absolutely must be funded
	2 and 3	Excellent application, fund if there's sufficient resources
Medium	4 and 5	Good grant but needs some work
Low	6,7,8,9	Needs major revision, should not be funded
	NRFC	Not recommended for further consideration. Not meeting the criteria of the RFA

2E

- If you are funded, you will prepare your IRB application and receive consultation from the Clinical Core, specifically Robert La Ferte, (310.557.1892, rlaferte@mednet.ucla.edu).
- Funding will be withheld until you send the AI office (Jina Lee, 310.794.5335, jinalee@mednet.ucla.edu) your approved IRB notification.

2F

- As a CFAR/AI seed grant awardee, you are allowed up to 5 hours of consultation on your statistical design and analyses before submitting your IRB application and beginning your research. Contact Dr. Bill Cumberland (310.206.9621, wgc@ucla.edu)

FAQs

How much detail is needed for the Specific Aims versus the Methods section?

- The 'Specific Aims' and 'Research Strategy' sections should be limited to 3 pages.
- If the Specific Aims section is about one page or less, you have two remaining pages for:
  - No more than a half page of literature review
  - Ample space to describe your preliminary work that qualifies you (or your mentor) to conduct this work
  - A description of the measures and their psychometrics properties
  - Data analyses
- REMEMBER TO DESCRIBE HOW YOU WILL COMPLETE YOUR WORK IN TWO YEARS. This is a major shortcoming of many projects. They are overly ambitious, or have extensive IRB procedures to tackle (especially outside of the U.S.).

Do I need to go into detail about the statistical analyses?

- If you do not have any assistance available to help you to craft plans for your analyses, contact Dr. Cumberland (310.206.9621, wgc@ucla.edu). He will help you decide about how much you need to say about how you will analyze your data. Consultation will be no longer than 5 hours. If you need additional assistance, you will be charged for statistical services.

Am I able to include additional information in the Appendix?

Yes, but consider the essential information that you really want to include. Remember that the reviewers will be grateful for concise information such as:

- Specifics about your conceptual or theoretical model
- The measures and their description (reliability and validity)
- Any articles that you or your team have published on your seed grant topic
- Your specific timeline for data collection over 2 years
- Additional letters of support from mentors or community partners who will join you in this project. There is also an opportunity to include letters as part of your text.

When it is reviewed, what does my score mean?

Overall Impact

- Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field involved, in consideration of the following review criteria:
- Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Significance

- Does the project address an important problem or a critical barrier to progress in the field? How will scientific knowledge, technical capability, and/or clinical practice be improved? How will the aims change the concepts, methods, technologies, treatments, services or preventative interventions that drive the field?
- How will data be used in other research?
- Investigator(s)
- Are the PD/PIs, collaborators and other research well suited to the project? If early Stage Investigators or New Investigators or in the early stages of independent careers, do they have appropriate experience and training? If the project is collaborative, or multi PH/PI, do the investigators have complimentary and integrated expertise? Is the leadership approach, governance and organizational structure appropriate for the project?

Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation or interventions?
- Are the concepts, approaches or methodologies, instrumentation or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement or new application, the theories or approaches, methodologies, instrumentation or interventions proposed?

Approach

- Are the overall strategy, methodology and analyses well reasoned and appropriate to accomplish the specific aims of the project? If the project is new, will the strategy establish feasibility and will particularly risky aspects be managed?
- If the project involves clinical research, are the plans for
  - 1) protection of human subjects from research risks, and
  - 2) inclusion of minorities and members of both sexes/genders as well as the inclusion of children justified in terms of the scientific goals and research stratify proposed?

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 adequate for the proposed project?
- Will the project benefit from collaborative agreements or subcontracts?

Protections for Human Subjects

- Research that does not involve human subjects may be exempt under 45 CFR part 46. The proposed study will be evaluated on the
  - 1) justification for the exemption,
  - 2) human subjects involvement and characteristics (For example, do you have personal identifiers?) and
  - 3) sources of materials (are you using patient files?).
- However, research that involves human subjects will be evaluated for the justification if
  - 1) risk to subjects,
  - 2) adequacy of protection against risks,
  - 3) potential benefits to the participants and others;
  - 4) importance of the knowledge to be gained, and
  - 5) data and safety monitoring for clinical trials.
- Another important consideration is if IRB approval can be attained in a timely fashion for a two year award.

Inclusion of women, minorities and children

- For clinical research, the proposal will be evaluated for its inclusion of minorities and members of both genders as well as the inclusion for children.

Vertebrate Animals

- The proposed study involving vertebrate animals will be evaluated on the following:
  - 1)use of animals and species, strains, ages, sex and numbers to be used;
  - 2) justification for the use of animals and the appropriateness of the species and numbers proposed;
  - 3) adequacy of veterinary care;
  - 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic and tranquilizing drugs and/or comfortable restraining devices; and
  - 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. (See Worksheet for review of the Vertebrate Animal Section for HHS grants)

Biohazards or Select Agent Research

- Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel or the environments and how they were disposed of

Multiple Project Director/PI Leadership Plan

- Describe how the PI role will be shared and how both PIs will communicate to resolve differences

Consortium/Contractual Arrangements

- Sub-contracts for other investigators from other universities and their indirect costs must be described and displayed in the budget.

Letters of Support (e.g. Consultants)

- Letters from mentors
- Co-Investigators

Resource Sharing Plan(s)

- How will you share resources that will minimize costs and increase the quality of the research?

Who can help me revise my application?

- Your mentor and/or consultation from Dr. Wyatt (310.825.0193, gwyatt@mednet.ucla.edu)

Can I revise my application and apply again?

- Yes, use a one page cover letter explaining your revisions and re-submit your application during the next round, beginning with a revised letter of support.

If you would like assistance with revisions, contact Dr. Gail Wyatt (310.825.0193, gwyatt@mednet.ucla.edu) for an appointment. Bring your application and the redacted reviews

Who can assist me with:

- **Measures?** – Dr. Wyatt (310.825.0193, gwyatt@mednet.ucla.edu)
- **IRB Issues?** – Robert La Ferte (310.557.1892, rlaferte@mednet.ucla.edu)
- **Statistical Analyses?** - Dr. Bill Cumberland, Ph.D. (310.206.9621, wgc@ucla.edu)

Who Needs a Mentor?

- If you are applying for a fellowship, you need a mentor who will write a letter of support and meet with you weekly.
- If you are conducting research in an area for the first time, as an emerging faculty member, you need experts who will work with you and letters of support from them as well. They may mentor you and also contribute to your research by serving as a non paid consultant, as well

How should we approach secondary analyses and the protection of human subjects?

- These data should be UCLA (and other university or organization) protected. The PI of that dataset would need to provide you an updated IRB approval notice.
- You should contact the Protection of Human Subjects Office and explain over the phone or by email that you plan to conduct secondary analyses on XX dataset. Attach the approval notice and permission to use the dataset (if needed).
- Depending on whether you need to access any participant identifiers or not, you would request permission to conduct secondary analyses. The request could be expedited given that you will not contact individuals or have limited information about them other than their ID numbers.
- With online or verbal instruction, download the IRB application and fill out the application. You will be asked a lot about the original data and how it was collected so be prepared to have this information available.

What is the role of the principal investigator?

- The role is to oversee, conceptualize and write up progress and end of study reports for the project. In order to be eligible to be PI, check the specifications of the seed grant description for which you are applying.
- For example, you can be in the research as well as in- residence series or higher to be a PI at UCLA or its affiliates on behavioral science seed grants.
- For seed grants in clinical research, you need to be faculty (clinical instructor or higher) at UCLA or UCLA affiliated institutions to be the PI
- For fellowships, you need to be a full time postdoctoral or fellow or a graduate or prospective graduate student to be the PI or to request funds ($5,000)
- You need to be a faculty member to be a PI on a basic research seed grant.

What are grant opportunities as they relate to African American Women and HIV/AIDS?

- If you are at the beginning stages of your career, the CFAR/AI seed grant is a great starting place!!

Where can I find grant writing information?

- You are welcome to attend any Institutes of the HIV/AIDS Translational Training Program (Wyatt, PI). One such Institute is coming up in May, 2012.
- Go online to nih.gov for information about summer institutes
- Contact NIMH, NIAID, NIDA, etc. directly or look on their websites
- Look for workshops at conferences usually presented by project officials from NIH divisions. Befriend these folks. They are an infinite resource of information about upcoming

If you are Funded

Step 3

Reporting Your Progress

Yearly Progress Reports

- Should include the progress made on each of your Specific Aims. Any delays or problems in achieving your goals should be discussed along with an adjusted timeline for completion of your project.

End of Project Reports

- Should include your findings and how they will be used in another proposal or to advance your current research or clinical care

Step 4

Next Steps

When your Seed Grant is Complete

- Attend the **HIV/AIDS Translational Research Training Institute** to obtain feedback from a multi disciplinary group of senior investigators in your area about how to integrate your data into a grant funded by NIH or private foundations.
- The CFAR/AI will track your progress in publishing your findings with the grant number included (MH) and in receiving grant funding to advance your work and your career.
- Attend **How to be Mentored and How to Mentor** workshop. This is offered two times a year by Drs. Hector Myers and Gail Wyatt . This workshop will inform Seed grant awardees or emerging faculty about what to expect in the mentoring process related to a career in HIV/AIDs research and how to successfully navigate through your departmental and university review process

Things to Remember:

- We recommend that you submit one grant per round. If you are included on someone else's application, the committee will have to decide which of your projects is stronger.
- If you do not receive a fundable score (3.5) you should see consultation when you receive your redacted pink sheets and resubmit your application
- Please keep in touch with the CFAR/AI office (Jina Lee – 310.794.5335, jinalee@mednet.ucla.edu) as you progress in your research so that when you receive other federal of privately funded awards, we will know!

Good Luck!!

You can do this!!