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

Seed Grant Information Session
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Associate Director, UCLA AIDS Institute
Associate Director of Behavioral Science Prevention
Clinical Psychologist
Sex Therapist
4 Steps to a Successful Seed Grant Submission and Completion
Meet the Associate Directors

- Basic and Translational Sciences - Jerry Zack
- Clinical Therapeutics and Biomedical Prevention - Ron Mitsuyasu
- Prevention Implementation - Gail Wyatt
- International/Policy - Tom Coates / Greg Szekeres.

Learn which seed grants will be offered and the deadlines

Ask questions about the process
Letters of Intent include:

- 2 pages max (excluding biosketch)
- Your name, degrees, and full contact information (email, phone, mailing address)
- Brief summary of the proposed research project
- Brief summary of your experience conducting similar research
- Total amount of funding requested
- NIH biosketch
- Contact Dr. Wyatt (310.825.0193) for consultation.
Letters of Intent - outcomes

- LOI accepted
  - Applicants will be given complete instructions for online submission of their grant application.

- LOI accepted with modification
  - Reviewer may point out potential issues and suggest minor revisions, but still accept the LOI.

- LOI rejected
  - Typically because the work is not responsive to the RFA without major modification.
Step 3
Submitting a Seed Grant Application
Components of the application
(NIH forms downloaded from aidsinstitute.ucla.edu or NIH website)

- **NIH Form Page 2** (includes project summary, relevance, research location, list of personnel)
- **Research Strategy** (3 pages total; specific aims, significance, innovation, approach)
- **Detailed budget** (NIH Form Page 4)
- **Biosketches for key personnel** (new format required as of May 2015)
- **Resources available for the project**
- **Lay abstract** (may be sent to potential private donors).
Regulatory approvals (required before funds can be released).

- IRB approvals (human subjects)
- IACUC approval (vertebrate animals -ARC)
- IBC approvals (biohazard)
- International approval (requires foreign IRB and foreign site approval).
- Clinical approval (if the work is deemed “above minimal risk”)
- Note: NIH classifies research participants younger than 21 as children.
CFAR Core services available:

- Virology Core
- Cytometry Core
- Gene and Cellular Therapy Core
- Humanized Mouse Core
- Mucosal Immunology Core
- Biostatistics Core (inc. assistance with grant prep.)
- Clinical Research Facilitation Core (assistance with IRB submission and subject recruitment)

See hand-out, or www.aidsinstitute.ucla.edu for contact information
FAQs
How much detail is needed for the Specific Aims versus the Strategy 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 WITHIN THE FUNDING PERIOD. 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?

- Detailed statistical analysis is not needed.
- Contact the CFAR Biostatistics Core for free advice (see hand out).
- Remember to describe how you will draw conclusions from your data, especially with small sample sizes (a common pitfall).
How should we approach secondary analyses of human subjects?

- Data should be UCLA (and other university or organization) protected.
- Fill out and submit study proposal on webIRB explaining that you plan to conduct secondary analysis on XXX dataset. Describe:
  - how you plan to use the data,
  - whether it contains identifying information of human subjects,
  - if you plan to contact the human subjects,
  - security measures, and
  - if access to the data poses any risk to the subjects.
- If data contains identifying information, may need consent from human subjects or apply for authorization and/or consent waiver on webIRB.
- You will be asked a lot about the original data and how it was collected. Be prepared to have this information available.
What can be included in the Appendix?

- 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 two years
- Letters of Support
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.

The PI is responsible for ensuring any regulatory documents are in place before the work begins (ARC, IRB, international approvals etc).
Consortium/Contractual Arrangements

- Sub-contracts for other investigators from other universities and their indirect costs must be described and displayed in the budget. Please note that seed grants will not cover the indirect costs for subcontracts.
Do I need 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.
Who can assist me with:

- **Measures** – Dr. Wyatt (310.825.0193)
- **IRB Issues** – CFAR Clinical Research Facilitation Core. Alicia Wolfson awolfson@mednet.ucla.edu.
  See also https://webirb.research.ucla.edu and http://ora.research.ucla.edu (helpful templates)
- **Subject/Volunteer Recruitment**
  rsvp@mednet.ucla.edu
- **Statistical Analyses** – CFAR Biostatistics Core.
  Dr. Bill Cumberland, Ph.D wgc@ucla.edu
Review process

- Completed applications submitted *on time* will be sent to 2 reviewers who have related experience in your area of interest.

- They will score your application based on significance, innovation, approach, investigators, environment and overall impact (follows NIH scoring system).

- The impact scores from both reviewers are averaged to generate a final score.
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.
Review criteria: 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?
Review criteria: 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?
Review criteria: 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?
Review criteria: Environment (Resources)

- 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?
Review criteria: Protection of Human Subjects

- Research that poses very little risk to human subjects may be exempt under 45 CFR part 46. Generally involves anonymous or publicly accessible data, or low risk research experiments. UCLA IRB will evaluate:
  - 1) if study falls within one of 6 federally-defined exempt categories,
  - 2) the degree of risk to human subjects (very low risk), and
  - 3) human subjects involvement and characteristics (use personal identifiers?).

- Proposed research that involves minimal or greater than minimal risk to human subjects will be evaluated on:
  - 1) justification of risks (reasonable risk, adequacy in minimizing risk)
  - 3) enrollment of participants (informed consent, equity of selection)
  - 3) potential benefits to participants and others,
  - 4) importance of knowledge to be gained from study, 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.
Review criteria: Letters of Support

- Letters from mentors
- PIs
- Co-Investigators
Review criteria: 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.
Review criteria: 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.
Review criteria: Multiple Project Director/PI Leadership Plan

- How will the PI roles be shared and how will both PIs communicate to resolve differences?
Resource Sharing Plan(s)

How will you share resources that will minimize costs and increase the quality of the research?
When it is reviewed, what does my score mean?
# Average final impact scores

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<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>The very best, absolutely must be funded</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Excellent application, fund if there’s sufficient resources</td>
</tr>
<tr>
<td>Medium</td>
<td>3, 4</td>
<td>Good grant but needs some work</td>
</tr>
<tr>
<td>Low</td>
<td>5-9</td>
<td>Needs major revision, should not be funded</td>
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<tr>
<td></td>
<td>NRFC</td>
<td>Not recommended for further consideration. Not meeting the criteria of the RFA.</td>
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“Borderline” grants

- Borderline grants (impact scores that flank 3) move forward to the Grant Review Committee— a multi-disciplinary group of UCLA faculty.

- They will discuss the strengths and weaknesses of each grant and generate a revised impact score, based on their discussion.

- Grants are funded, starting with the best (lowest score) until funds are exhausted.
If you are Funded

Step 4

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
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) for an appointment. Bring your application and the redacted reviews. We will schedule another group session.
Step 5

Next Steps
When your Seed Grant is Complete

- The AI/CFAR is required to keep a comprehensive spreadsheet of all seed grantees and any follow-up funding and publications from the seed grant project. Please keep in touch! aidsinst@ucla.edu

- Attend the next **How to be Mentored and How to Mentor** workshop. This is offered two times a year by Dr. 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 (1 or 2) you should seek consultation when you receive your redacted reviews.

- Keep in touch with the AI/CFAR office (aidsinst@ucla.edu) as you progress in your research so that when you receive other federal or privately funded awards, we will know!
Acknowledging the funders

- Funders, including the NIH, need to be recognized! Public and private funders may not continue to support us if they are not acknowledged.

- Your Notice of Award will tell you which funding sources have been used in your award.
  - Typically, UCLA CFAR, AIDS Institute, CTSI, private donors or a combination.

- These funding sources should be listed in any publications, presentations describing the work.
  - CFAR and AIDS Institute logos are available by emailing aidsinst@ucla.edu
Where can I find more grant writing information?

- You are welcome to attend any Institutes of the HIV, Substance Abuse Trauma Training Program (Wyatt and Milburn, PI).
- Go online to grants.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 opportunities.
Good Luck!!
You can do this!!