NIH BUILD PODER Pilot Projects and Meetings

California State University, Northridge

Friday, September 8: 11:00 am - 12:15 pm, Sierra Hall 320
Tuesday, September 12: 2:00 - 3:15 pm, Sierra Hall 320

**Purpose:** BUILD PODER Pilot projects are intended to encourage developing faculty (newer faculty members and those established scholars who are “retooling”) interested in biomedical sciences to conduct small empirical projects that strengthen their applications for subsequent funding with the NIH. Please use NIH guidelines to complete your application: NIH guidelines will be used to evaluate your proposal.

Check out “Healthy People 2020” to get ideas about how to fit your project into the mission of the NIH.


**Fundamentals:**

- There will be two pilot projects for the 2018-2019 academic year. Projects MUST be approved by the NIH, so we need to decide early and negotiate their approval. CSUN’s IRB or IACUC approval will help!
- Maximum 2 Principal Investigators per pilot
- Pilots can be funded for up to $50,000 for the year and must be completed in a year
- Period for funding: July 1, 2018-June 30, 2019
- Your department chair and dean MUST approve your project before you can go forward with the full application.
- **Full applications will be due November 1, 2017** – application sheet signed by chair and dean, NIH biosketch, NIH budget and justification, mentor statement, other support, 6-page narrative, references, evidence of IRB or IACUC progress or approval if relevant.

Three resources: there is a great series of books from the Grant Writer's Seminars and Workshops (GWSW) called “The Grant Application Writer's Workbook.” In addition, please ask about the PowerPoint on writing NIH grants from our Faculty Scholar Academy. The NIH website (nih.gov) is a remarkable resource, and the NIAID institute’s website has a GREAT DEAL of instructional material on writing grants.

**You will need to complete three NIH forms, they can be found here:**


- NIH Biosketch
- FP4: Detailed Budget
- FP5: Budget for Entire Proposed Project Period (ONLY budget justification)
Here are some budget pointers:

- 3 units = Base salary x 0.125 + fringe ("real" benefits level, 38-60%)
- Fringe: you must call the benefits office to find out your "real" level of benefits as this is what is charged to the grant.
- Each month of summer salary = Base salary x 0.125 + fringe (9.1% in summer)
- Check the University Corporation website for current fringe rates for staff, students, etc. http://www.csun.edu/sponsoredprograms/spactivities2008-2009.htm

TIPS:
- Undergraduates typically earn around $12/hour, graduates $15-18 depending on their skill level
- Consultants: you can include others on your grant as consultants; consider their expertise and level of experience
- You can pay participants or sites where you need to collect data
- You MUST include a justification for each budget item (so if you request salary, what will you do with your time, what will your mentor do, what will your consultants do, why are you paying participants, etc.).

Narrative

Specific Aims (1 page)

Your specific aims are the objectives of your research project, what you want to accomplish. The project aims should be driven by the hypothesis you set out to test. Make sure they are highly focused.

Research Plan (6 pages total for significance, innovation, and approach)

Significance

- Keep the statement of significance brief. State how your research is innovative, how your proposal looks at a topic from a fresh point of view or develops or improves technology.
- Show how the hypothesis and research will increase knowledge in the field. Relate them to the longer-term, big picture scientific objectives and to the betterment of public health.
- Justify your proposal with background information about the research field that led to the research you are proposing. The literature section is very important because it shows reviewers you understand the field and have a balanced and adequate knowledge of it.
- Use this opportunity to reveal that you are aware of gaps or discrepancies in the field. Show familiarity with unpublished work, gained through personal contacts, as well.
- Identify the next logical stage of research beyond your current application.

Innovation

- Since innovation is a review criterion, you want to think outside of the box—but not too far.
- It's enough to show how the work you propose is new and unique and will push the frontiers of knowledge ahead starting from what's known.
- A reviewer may take a challenge to the status quo as a challenge to his or her world view or research.

Approach (the majority of your narrative)

- This is the main section that you should focus on; it is where you can easily “fall down” in review.
- State why you chose your approach(es) as opposed to others.
- If you are choosing a nonstandard approach, explain why it is more advantageous than a conventional one. Ask yourself whether the innovative procedures are feasible and within your competence.
• Spell out your methods in detail. While you may assume reviewers are experts in the field and familiar with current methodology, they will not make the same assumption about you. It is not sufficient to state, "We will grow a variety of viruses in cells using standard in vitro tissue culture techniques." Reviewers want to know which viruses, cells, and techniques; the rationale for using the particular system; and exactly how the techniques will be used. Details show you understand and can handle the research.

• Make sure any proposed model systems or theories are appropriate to address the research questions and are highly relevant to the problem being modeled.

**Human or animal participants:** You absolutely MUST be through the Human Subjects or IACUC process by July 1, 2018 if relevant. That does not mean turning in materials at that point, it means having been approved. We may choose a back-up project in the event that the project is not approved before submission for funding.

**Selection:**

• The extent to which your project represents a topic related to STEM and biomedical fields will be crucial – this should be clearly stated in your significance section

• Standard NIH criteria will be considered the primary vehicle for evaluation; we will also evaluate your budget for feasibility, completeness, rationale

____ Relevance to biomedical STEM fields.

____ Significance. Does the project address an important problem or a critical barrier to progress in biomedical fields? 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?

____ Investigator(s). Are the PD/PIs, collaborators, and other researchers 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 established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Do the investigators suggest mentors that will provide support such that they will advance in their field of interest?

____ 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 of theoretical concepts, approaches or 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? 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 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 strategy 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 to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact/priority score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores, and multiplying the average by 10; the final overall impact/priority score is reported on the summary statement. Thus, the final overall impact/priority scores range from 10 (high impact) through 90 (low impact).

**Submission CHECKLIST:**

- PHS 398 face page(s)
- NIH Biosketch
- NIH “Detailed Budget for Initial Budget Period” Form (FP4)
- NIH Budget Justification (on form entitled “Budget for Entire Proposed Project Period”) (FP5, bottom)
- Mentoring approach/strategy, experiences (1-3 paragraphs)
- PI Other Support
- Narrative/Research Plan (6 pages)
  - Significance
  - Innovation
  - Approach
- References
- Evidence of IRB or IACUC approval or progress if relevant

Submit all materials as one PDF file to: buildpoder@csun.edu

Questions? Please contact Carrie Saetermoe at carrie.saetermoe@csun.edu or for administrative questions, please contact Mirranda Salas at mirranda.salas@csun.edu

**NIH Guidance and details:**

**For faculty-led research, follow the Pilot Project Approval guidance detailed in the Notice of Award:**

- Below is an excerpt from the GY2 NoA:

  The recipient institution will provide NIGMS with written study protocols that address risks and protections for human subjects in accordance with [NIH’s Instructions for Preparing the Human Subjects Section of the Research Plan](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html), and [NOT-OD-12-130](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-130.html).


  The recipient institution will provide NIGMS with specific plans for data and safety monitoring, and will notify the IRB and NIGMS of serious adverse events and unanticipated problems, consistent with [NIH DSMP policies](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html).

  If live vertebrate animals are to be involved, include the five required elements of the VAS: [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html); and OHRP and/or OLAW-approved Institutional Assurance(s), if any.
Reminders:
- Include PHS 398 face page(s) and budget forms, research plan section(s) (limited to 6 pages) for each project. If mentored student experiences are involved, provide the mentoring approach/strategy and PIs experience with mentoring students from diverse backgrounds and/or in the relevant area of science (1-3 paragraphs).
- The lead investigator’s (i.e., PI noted on the mini-grant PHS form) other support with percentage of effort (see PHS 2590/RPPR Other Support Format Page). If you have problems downloading the form, submit it as a Word document.
- If the proposed project involves human subjects research, please submit certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects.
- Note: Relevant IRB and IACUC approvals are needed before projects can commence. For human subjects research, the appropriate inclusion enrollment information must be entered into the Inclusion Management System (IMS) through the eRA Commons (by the BUILD PODER grant PI or designee).

Deadline: December 1, 2017 to
buildpoder@csun.edu

Byline: BUILD PODER PILOT PROJECT
BUILD PODER

Pilot Project Application

Building Infrastructure Leading to Diversity
Promoting Opportunities for Diversity in Education and Research
National Institutes of Health

Funding for Pilot Projects – $50,000 for one year

Due November 1, 2017

Name: ____________________________________________

Department: _______________________________________

Title of Proposal: __________________________________

NIH RFPs of interest: _________________________________

Phone extension: ___________ Mail drop: _______________

I understand that ____________________________ is requesting ___ units of reassigned time for the 2017-18 academic year to participate in BUILD PODER’s pilot project funding at the internal buyout rate of $5149 per 3 unit block.

__________________________________  _______________________
Signature of Chair, date              Signature of Dean, date