Candidate Sections, Significance, & Innovation

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ICTS K Grant Writing Series Workshop
Wednesday, April 21, 2021
Objectives

• Candidate sections
  ➢ Candidate background
  ➢ Career goals & objectives
  ➢ Career development & training activities

• Research strategy
  ➢ Significance
  ➢ Innovation

• NIH Loan Repayment Program

• Pointers & pitfalls + Q&A
CANDIDATE SECTIONS
Candidate section:
General grantsmanship tips

- Should be clearly written & well- formatted.
  - Reviewer may be outside of your specific field.
  - No typos, misspellings, incorrect punctuation, nonadherence to margins.
  - Figures should be crisp/clear (caution with color).
  - Caution with use of appendix.
- 12-page limit for candidate section + research strategy.
  - Candidate section: 4 pages
    - Candidate background: 1 page
    - Career goals & objectives: 1 page
    - Career development & training activities: 2 pages
  - Research strategy: 8 pages
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<thead>
<tr>
<th>SECTION</th>
<th>DESCRIPTION</th>
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<tr>
<td><strong>CANDIDATE BACKGROUND</strong></td>
<td><strong>“Telling a story”</strong> Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. Any additional information not described in the Biographical Sketch Format Page, such as research and/or clinical training experience, may be included in this section.</td>
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<tr>
<td><strong>CAREER GOALS &amp; OBJECTIVES</strong></td>
<td><strong>“Short &amp; long term goals”</strong> Describe your short-term and long-term career goals and objectives are, and how the career development award is envisioned to enable you to develop and/or expand your research career. It is important to justify the need for the award. You are encouraged to include a timeline, including plans to apply for subsequent grant support.</td>
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**BE SURE TO READ THE ENTIRE SF424 REQUIREMENTS!**

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<tr>
<td>CAREER DEVELOPMENT &amp; TRAINING ACTIVITIES</td>
<td>Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award. <strong>If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career.</strong> For mentored awards, describe any structured activities that are part of the developmental plan, such as coursework, or workshops that will help you learn new techniques or develop needed professional skills. If coursework is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, other than research, in which you expect to participate. Include a percentage of time involvement for each activity by year, expressed in person months, and explain how the activity is related to the proposed research and the career development plan.</td>
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<tr>
<td>“Nuts &amp; bolts of your self-designed curriculum”</td>
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Candidate background section

• A personal narrative of your professional career.
• Can use NIH biosketch as your guide.
• OK to use first-person.
• Do not hold back! (But don’t over-exaggerate)
  ➢ Need to convince reviewers that you are worth the investment!
  ➢ Toot your own horn
    • “I conducted the seminal study looking at...”
    • “I presented my findings at the foremost/#1 Cardiology meeting...”

Candidate background section

- Key elements to include:
  - Examples of opportunities you have had to engage in research as evidence of your long-standing commitment to research.
    - Basic, clinical, & translational research.
  - Evidence of your early productivity.
    - Scientific presentations, publications.
  - Formal research training.
    - MPH, PhD, Certificate
  - Try to relate the above to your proposed research.
Example #1

CANDIDATE’S BACKGROUND: My goal in seeking a Mentored Research Career Development Award is to acquire the necessary training, practical experience, and knowledge to become a leading independent clinical investigator in implementing public health interventions to reduce the burden of obesity and diabetes in low-income communities. I propose to investigate the association between food insecurity and the incidence and management of obesity and diabetes using two longitudinal studies. I will then undertake a pilot project to determine whether reducing financial barriers to fruit and vegetable consumption improves dietary intake and diabetes self-management in a clinical population at high risk of food insecurity.

I received my Bachelor of Arts in Biology from Williams College (Magna Cum Laude, 1996) and my Doctor of Medicine from Baylor College of Medicine (Alpha Omega Alpha Honor Society, 2000). I then completed Internal Medicine internship and residency at the University of California San Francisco (2000-2003). I entered UCSF’s Fellowship in General Internal Medicine and received a Master’s of Advanced Studies in Clinical Research, and then joined UCSF’s faculty in 2006. I received a CTSI KL2 award in 2009. This KL2 award has funded additional preliminary research supporting the association between food insecurity and poor chronic disease self-management. However, I must still generate data supporting food insecurity as a causal factor in the development of obesity/diabetes (Aim 1) and poor self-management (Aim 2), and generate pilot data in preparation for submission of an R01-level intervention to shift dietary intake among food insecure patients with diabetes (Aim 3). This application will build on my KL2-funded activities to better position me to obtain R01-level funding.

- Starts out with summary statement of long-term research and career goals.
- Shows the need for acquiring K23 (currently has KL2).
Example #1

I have published two first-author publications addressing health literacy as a barrier to behavior change among patients with diabetes, both under the mentorship of Dr. Dean Schillinger (my primary mentor). The first publication, a randomized, controlled trial of screening for limited health literacy in the clinical setting,\(^1\) won the Best Poster Award at California’s Society of General Internal Medicine meeting. The second publication relates to the development of written health education material for patients with limited health literacy.\(^2\)

I am part of a national multidisciplinary team of experts funded by the American College of Physicians Foundation (ACPF) to develop self-managements guide targeted toward adults with limited health literacy (diabetes and COPD, in press; coronary artery disease, in progress). As project site director, I supervise activities related to content development at UCSF, including focus groups, cognitive interviews, photography production, and Spanish translation. I also acted as site director for a feasibility evaluation of the effectiveness of the diabetes self-management guide in association with brief counseling. We enrolled 80 Latino patients with diabetes receiving care in the General Medicine Clinic at San Francisco General Hospital and achieved a 96% retention rate over three months of follow-up. Two manuscripts resulted from this work.\(^3,4\) I have spoken about behavior change counseling and health literacy at a number of national meetings, including the Joint Commission on Accreditation of Health Care Organization’s National Symposium on Health Literacy and Patient Safety (plenary session, 2006), the American College of Physicians National Meeting (workshop, 2007), and the Institute for Healthcare Advancement (plenary, 2007 and workshop, 2008).

- Highlights productivity -> “first-author publications”; “Two manuscripts resulted from this work”; spoken at national meetings.
- Highlights award won at California SGIM meeting.
- Shows leadership roles -> “project site director”; “site director for a feasibility evaluation...”
- Shows track record in patient oriented research methods.
Example #2

I graduated *Summa Cum Laude* from Northwestern University, where I studied medical engineering. It was at Northwestern where I first became interested in medicine and research, studying the biomechanics of an intra-thoracic artificial lung. I went on to attend medical school at Northwestern University Feinberg School of Medicine. During this time, I took on leadership and mentorship positions in both university and community organizations. During internship and residency training at the McGaw Medical Center of Northwestern University, I developed a passion for interstitial lung disease. While I was at Northwestern, I sought out the mentorship of Dr. J. Tasha Sznajder, the Chief of the Division of Pulmonary and Critical Care Medicine. With his mentorship, I studied the molecular mechanisms of insulin on the alveolar type II cell and the physiologic effects of insulin in a mouse model. This experience allowed me to gain important laboratory skills and a solid foundation in basic science research. This work resulted in achievement of the top award for basic science research at the Northwestern University Resident Research Symposium.

When I completed residency training, I had a year off before starting my fellowship in Pulmonary and Critical Care Medicine at UCSF. I decided to use this time to further my training in basic science research and the molecular mechanisms of lung injury. I approached Dr. Michael Matthay about potential research opportunities (Dr. Matthay is the principal investigator of the NHLBI-sponsored SCCOR grant in translational research in acute lung injury). In his lab, I worked on an endotoxin model of acute lung injury; specifically, investigating the role of priming. During this time, I acquired skills in complex mouse model work, biochemical assays, and cellular analysis. In addition to learning the technical aspects of basic science work, I also learned practical aspects of research in general, including hypothesis generation, execution of study design, problem solving, critical analysis of my findings, and perseverance. My work in Dr. Matthay's lab resulted in a poster discussion session at the American Thoracic Society (ATS) meeting in 2008 and the manuscript is currently submitted to Anatomical Record for review.

- Tells a story of how applicant developed interest in pulmonary disease.
- Shows track record in basic science research in lung disease.
- Also shows achievements -> “summa cum laude”; “leadership and mentorship positions”; “top award.”
- Also shows productivity -> “ATS poster”; “manuscript submitted.”
Example #2

While working with Dr. Harold Collard, the director of the UCSF Interstitial Lung Disease Program, I began to learn about acute exacerbations of idiopathic pulmonary fibrosis (IPF). I found this area to be interesting and challenging and felt this area of research integrated my interests in interstitial lung disease and acute lung injury. After learning more about this area, I became interested in the role of gastroesophageal reflux (GER) and secondary microaspiration in patients with IPF. With careful consideration and discussion with several mentors, I decided to pursue further training in clinical research to address this issue. During my last year of dedicated research time, I have accomplished the following goals: 1) Awarded a Ruth L. Kirschstein National Research Service Award investigating the role of microaspiration in patients with IPF; 2) Completed a comprehensive review of the literature resulting in a manuscript that has been accepted to the American Journal of Medicine; 3) Designed and implemented a retrospective cohort study investigating the significance of hiatal hernia in patients with IPF that has resulted in a manuscript that has been submitted to Thorax; 4) Designed and implemented a retrospective cohort study investigating bronchoalveolar lavage pepsin levels in patients with acute exacerbations of IPF that has resulted in a manuscript that has been submitted to the American Journal of Respiratory and Critical Care Medicine; 5) Formed research collaborations both locally (Gastrointestinal Motility group and Lung Transplant group at UCSF) and abroad (acute exacerbation study with Korea); 6) Enrolled in the Master’s degree program in clinical research at UCSF where I am obtaining essential skills in epidemiology and biostatistics.

• Uses an efficient method of outlining achievements:
  • F32 award
  • Manuscript accepted to Am J Medicine
  • Manuscript submittd to Thorax
  • Manuscript submitted to Am Jl of Respiratory and Critical Care Medicine
  • Research collaborations with credible research groups
  • Masters program in clinical research at UCSF
Career goals & objectives

• A good approach to developing this section is thinking about your “deficiencies” in your training background/experience.
• These will then become the focus of your career goals & objectives.
• Specific areas where there may be deficiencies:
  ➢ Analytic methods
  ➢ Patient oriented research methods
  ➢ Recruitment, primary data collection, biobanking
  ➢ Biostatistics
  ➢ Qualitative research methods
  ➢ Content-specific areas
• Would be sure to include plans to apply for independent funding.
Example #3

My goal is to become an independent clinical investigator and leader in the study of diffuse lung disease. To continue my progress towards this goal, I am proposing an observational prospective study addressing specific hypothesis surrounding the role of gastroesophageal reflux in IPF, a timely and important topic. Specifically, I am interested in studying 3 primary topics: (1) the clinical characteristics of reflux in patients with IPF, (2) the biomarkers of reflux and microaspiration in patients with IPF, and (3) the impact of reflux and microaspiration on outcomes in patients with IPF. The knowledge and experience gained from this proposal will allow me to successfully compete for R01 funding and lead directly to a study validating these findings in a multicenter fashion utilizing the resources of the NIH-funded IPFNet.

I have made progress in developing my clinical research skills, but there are four important areas where I require additional training, mentoring, and experience: (1) multi-disciplinary collaboration with clinical and basic scientists, (2) the design and implementation of prospective study design with involvement in the IPFnet, (3) advanced study design and biostatistical methodology, and (4) focused mentorship and career development through the UCSF Clinical and Translational K Scholars (CTSK) program. In the following section, I present a detailed career development plan designed to enable me to acquire the additional training and mentored research experience I need to address these deficiencies and compete successfully for R01 funding, thereby achieving independence as a clinical investigator.

- Describes long-term goal of becoming an independent clinical investigator & leader in diffuse lung disease.
- Highlights plans to pursue an R01 award & the specific study that may be the subject of the R01.
- Discusses 4 short-term goals over the K award.
  - Highlights the need for the investigator to have a K23 in developing into an independent investigator.
Career development & training activities

• Should describe the training areas you will pursue to acquire new set of skills needed.
  ➢ Would provide explanation why these training and mentored research experience are critical to achieving short- & long-term career development goals, including path to independence.

• Draw connection between your research project & career development plan.
  ➢ Training must directly relate to your career goals.

• Describe **in detail** how you will gain this training.
  ➢ Mentors
  ➢ Formal courses
  ➢ Hands-on laboratory/experimental training
  ➢ Conferences/seminars
  ➢ Scientific meetings
  ➢ Clinical duties
  ➢ Timeline with milestones
Mentors

• Description of mentors.
  ➢ Highlight their track record in mentoring & research.

• Rationale for being on mentoring team.
  ➢ What you will learn from mentor.
  ➢ Too many? Too few?

• Describe frequency & nature of meetings.
  ➢ Make sure this is consistent with the content of your letters.

• Mentoring committee.
  ➢ ICTS Mentoring Committee.
    • Highlight this in the section & request accompanying letter.
Formal courses & immersion training

• Formal courses.
  ➢ If limited experience/training in research methods used for K award.
    • List courses and numbers.
    • Timing of enrollment.
    • Describe course.

• Immersion training.
  ➢ Learning lab techniques/methods in a mentor or collaborator’s labs.
    • Timing and duration of training.

• Would mention training in responsible conduct of research.
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<tbody>
<tr>
<td>Mentorship</td>
<td>Kirsten Bibbins-Domingo, MD, PhD; Eric Vittinghoff, PhD</td>
<td>Barbara Laraia, PhD, MPH, RD</td>
<td>Dean Schillinger, MD (primary mentor)</td>
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<td><strong>Practical Experience</strong></td>
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<tr>
<td><em>Aim 1</em>: Food insecurity and obesity/diabetes incidence (CARDIA)</td>
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<tr>
<td><em>Aim 2</em>: Food insecurity and diabetes self-management in behavioral intv’n</td>
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<td><em>Aim 3</em>: Pilot intervention, F&amp;V voucher</td>
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Example #5

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<th>Sample Table Mentoring Team</th>
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<tr>
<th>Specific Aim #1</th>
<th>Training Goal #1</th>
<th>Training Goal #2</th>
<th>Training Goal #3</th>
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<tbody>
<tr>
<td></td>
<td>Primary Mentor’s Name</td>
<td>Co-Mentor’s Name</td>
<td>Co-Mentor’s Name</td>
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<tr>
<td>Specific Aim #1</td>
<td>X</td>
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<tr>
<td>Specific Aim #2</td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Specific Aim #3</td>
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Conferences, seminars, & scientific meetings

• Describe/justify how this will contribute to your training.
  ➢ Interactions with peers, mentors, collaborators.
  ➢ Presenting your research.
  ➢ Networking.
  ➢ Pedagogical/managerial experience.

• Describe frequency & nature of meetings.

• Seminars/scientific meetings should be accounted for in your budget justification.
Clinical duties, % time, timeline/milestones

• Need to highlight that you will have 75% protected time for research and training.
  ➢ Additional 25% accounts for clinical duties, administrative duties, teaching.
• Need to indicate what % of your time will be spent in training activities by year.
• Should also include a detailed timeline & milestones of training & research activities.
  ➢ Include manuscript writing/submission.
  ➢ Plans for subsequent grant support.
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<th>YR 1</th>
<th>YR2</th>
<th>YR3</th>
<th>YR4</th>
<th>YR5</th>
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<tr>
<td>Training</td>
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<td>Research</td>
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<tr>
<td>Clinical</td>
<td>100%</td>
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RESEARCH STRATEGY
Significance

• 1-2 pages
• Description of medical relevance.
  ➢ Expansion of the Aims page.
• Can serve as additional opportunity to highlight your prior research data.
  ➢ Abstracts, review papers, original research manuscripts.
• Utilize tables and figures.
Innovation

• ~0.5-0.75 pages
• Why is your research new/exciting?
  ➢ How does it advance the field?
  ➢ What knowledge gaps does it address?
• Areas that may be considered innovative:
  ➢ Concepts.
  ➢ Laboratory techniques.
  ➢ Tools/instruments.
  ➢ Epidemologic/biostatistical approaches.
NIH LOAN REPAYMENT PROGRAM
www.lrp.nih.gov
Objective

• Established by Congress to recruit and retain health professionals into research careers.

• Provides direct repayment of up to $50,000 annually of a researcher’s educational debt in return for commitment to conducting NIH-mission relevant research.

  ➢ Annual amount may be lower than this.

• Duration:
  ➢ New award = 1-2 years
  ➢ Renewal award duration = 1-2 years.
Eligibility

- U.S. citizen, U.S national, or permanent resident of the U.S. by the LRP award start date.
- Must have total qualified educational debt equal to or in excess of 20 percent of institutional base salary at the time of award (i.e., 20% debt-to-income requirement).
- Must engage in qualified research for ≥20 hours/week over entire contract period. Of note, I have been advised that there is a high financial penalty for the awardee if this component is not fulfilled (i.e., higher than that of the payback requirements T32 awardees).
- Based on the above, postdoctoral research fellows in addition to early-career faculty are potentially eligible.
- Cannot be employed by a federal government agency, other than NIH, with a work schedule of more than 20 hours per week (5/8ths time or more).
- Cannot be a current recipient of an NIH Intramural Research Training Award or a Cancer Research Training Award.
Requirements

- Online application form
- 3-5 reference letters; 1 letter must be provided by the research mentor
- Certification of US citizenship by institution’s business official
- Research Activities (8-page limit)
- Training and Mentoring Plan (2-page limit)
- Research Environment (1-page limit)
- NIH Biosketch (5-page limit)
- Personal Statement (1-page limit)
- Research Accomplishments, for Renewal Applicants (2-page limit)
How to get started

Awards are now up to $100,000 over a two-year period. Use the repayment calculator to get an estimate on the amount of your award.
Supporting Scientific Discovery

The NIH Loan Repayment Programs (LRPs) are a set of programs established by Congress and designed to recruit and retain highly qualified health professionals into biomedical or biobehavioral research careers. The escalating costs of advanced education and training in medicine and clinical specialties are forcing some scientists to abandon their research careers for higher-paying private industry or private practice careers.

The LRPs counteract that financial pressure by repaying up to $50,000 annually of a researcher’s qualified educational debt in return for a commitment to engage in NIH mission-relevant research. Since tomorrow’s medical breakthroughs will be made by investigators starting in their research careers today, the LRPs represent an important investment by NIH in the future of health discovery and the wellbeing of the Nation.

Application Periods and Documentation Deadlines

Extramural New & Renewal Awards

- **Online Application Period**: Sep 1, 2020 - Nov 20, 2020
- **Supporting Documentation Period**: Sep 1, 2020 - Nov 20, 2020

Intramural New & Renewal Awards

- **Online Application Period**: Jan 4, 2021 - Mar 15, 2021
- **Supporting Documentation Period**: Jan 4, 2021 - Mar 15, 2021

Intramural ACGME New Awards

- **Online Application Period**: Jan 4, 2021 - Jun 1, 2021
- **Supporting Documentation Period**: Jan 4, 2021 - Jun 1, 2021
Navigating the LRP website

Essential First Steps

Registration
Before starting an application, prospective applicants must register for an LRP login account using one of the methods provided on the portal page. Registration must be completed during the open application period. Please review the Application Periods. Registration completed at other times will be invalidated.

Type of Award
The LRP has two broad types of awards: First Awards, called New Awards, and subsequent awards, called Renewal Awards.

New Award: If a prospective applicant has never received an LRP award, apply for a New Award.

Renewal Award: If a prospective applicant has received at least one prior LRP award, apply for a Renewal Award.
Other sources of information

NIH Loan Repayment

@NIH_LRP · 7h

Here's a look at the major sections within the #NIHLRP application. Reminder that we will begin accepting applications on September 1 - November 15. Now is the time to reach out to a program officer to discuss your research bit.ly/2otSl68 #ECR

The Application - Major Sections

Research Activities (‘meat and potatoes’)

- Personal Statement
  - Brag about yourself!
  - Highlight previous research training experience, how developed scientific interests/accomplishments; short and long-term career goals
- Training/Career Development Plan
  - Highlight skills you need to hone along your path to independent researcher (e.g., training and professional development opportunities; grantsmanship; teaching; mentoring; leadership skills; conference attendance, etc.)