K Club, Week 2

Dr. Jenny Stewart, Ph.D.

Assistant Professor of Community Medicine, University of Tulsa

Associate Director for Training and Mentoring, Laureate Institute for Brain Research (LIBR)
Today's Topics

- Grant: People
- Research and Training Goals
- Specific Aims
- NIH Biosketch
- Email to Program Officer
- Action Items
Grant: People

- **Primary Mentor**
  - Has grant and mentoring success
  - Takes overall responsibility for your training

- **Co-Mentor(s)**
  - Has grant and mentoring success
  - Contributing to your training to help you gain future independence from Primary Mentor

- **Collaborators, Consultants, Other Significant Contributors**
  - Generally not directly involved in your career development to help you gain independence
  - **Collaborator**: Scientist whose distinct expertise complements your own, while a Co-Mentor shares your area of expertise and therefore contributes in guiding the scientific direction of the overall project. One provides unique expertise, the other umbrella expertise.
  - **Consultant**: People providing advice or services (often paid) and may participate significantly in the research, filling in smaller gaps (e.g., supplying software, providing technical assistance, setting up equipment)
  - **Contributor**: Add to scientific development or execution of your project but are not committing any specified measurable effort to your project (“as needed” or “effort of zero person months”)
We will discuss what other documents these people need to submit as we progress through this course.

- **Primary Mentor** and **Co-Mentor** statements
- Letters of Support from **Collaborators**, **Consultants**, and **Other Significant Contributors**
- **NIH Biosketches**
- Other Forms you will need to fill out (**Senior/Key Personnel**)
- Writing some of these people into the **Budget** and **Budget Justification**
- These people need eRA Commons and linked ORCID accounts!!
# K Application Sections

## Research
- **Specific Aims** (1 page)
- **Research Strategy** (6 pages: Significance, Innovation, Approach)
- **Training in Responsible Conduct of Research** (1 page)
- **Project Summary / Abstract** (30 lines of text)
- **Project Narrative** (3 sentences)
- **Protection of Human Subjects from Research Risk**
- **Inclusion of Women and Minorities**
- **Inclusion of Individuals Across the Lifespan**
- **Inclusion Enrollment Report**
- **Budget + Budget Justification**
- **Bibliography + References Cited**

## Career
- **Candidate Information and Goals for Career Development** (6 pages: Candidate Background, Career Goals/Objectives, Career Development/Training Plan)
- **Plans and Statements of Mentor and Co-Mentors** (6 pages)
- **NIH Biosketches for you, Mentor, Co-Mentors** (max 5 pages each)
- **Three Letters of Reference**
- **Letters of Support from Collaborators, Contributors and Consultants** (6 pages max)
- **Cover Letter**

## Setting
- **Facilities and Other Resources**
- **Equipment**
- **Environment and Institutional Commitment to Candidate**
- **Resource Sharing Plan**
Research and Training Goals

- At this point, you should have talked with your Primary Mentor to come up with at least one of these goals each for the:
  - K99 phase
  - R00 phase

- Next you are going to incorporate these goals into a Specific Aims document
  - The most important page of your application
  - Max one page long
  - Outlines the significance, innovation, and approach of your work in a concise format
  - Explains what the positive outcomes of your grant will be if it is funded
Specific Aims

- This page can be divided into four sections or paragraphs that we will go over in the next few slides.
- It is important to note that you will likely be revising this page multiple times over the next six months after feedback from:
  - Your Primary Mentor
  - At least one Program Officer
  - Your grant Co-Mentors and anyone else on your K99/R00 team (Collaborators)
  - Peers and colleagues
Specific Aims
(1 page)
A good **Specific Aims** page tells an exciting, compelling story… in four paragraphs.
Let’s say you’re interested in sex differences in major depressive disorder (MDD)

Your **Primary Mentor** suggested you focus on bodily inflammation = hot topic!

You analyzed data comparing blood biomarkers of inflammation between:

- MDD men
- MDD women
- Control (CTL) men
- Control (CTL) women

You got significant results (yay!) that you want to turn into a grant

- Biomarker #1: MDD women > CTL women (no diffs in males)
- Biomarker #2: MDD women > CTL women (no diffs in males)

You came up with a study design with your Mentor

- MDD women, MDD men, CTL women, CTL men
- Longitudinal: Biomarkers 1 and 2 and clinical symptoms measured at two timepoints
What is the specific problem?
Why would solving this problem make a difference?
What do you think should be the solution?
What is your specific, EXCITING approach to the problem?
Do a literature review to come up with “knowns” and “unknown(s)” (gap or critical need) regarding the problem
If this gap or critical need isn’t solved, what bad things will happen?
Do the Literature Review

► “Knowns”:
  ► MDD often chronic, relapsing illness, 50% do not respond to antidepressants or therapy so we need new innovative treatments that help this 50% get better
  ► Some researchers propose that MDD linked to inflammation (blood-based biomarkers)
  ► Two studies show Group effect (MDD > CTL) on Biomarker #1 (cross-sectional)
  ► One study shows Sex effect (Women > Men) on Biomarker #2 (cross-sectional)

► “Unknowns” or “Gaps” or “Critical Need”
  ► Is there a subset of MDD with blood-based inflammation that makes depression worse over time? If we know this, we can test whether anti-inflammatories help these people get well
  ► No studies examining Group*Sex interactions in Biomarkers #1 and #2 (maybe more MDD inflammation in women)
  ► No longitudinal studies identifying whether Biomarkers #1 and #2 predict future depression severity
Opening Sentence: Two Parts

- Hook reviewers’ attention, focusing on something that highlights the PROBLEM that will be addressed by your application.

- Highlight the NIH’s mission: apply research findings to enhance health, lengthen life, and reduce illness and disability.
Report the “Knowns”

- 3 - 5 sentences
- Stick close to the plot
- Try not to go off on tangents
Report the “Unknown(s)”

- The start of the CONFLICTS
- 1 sentence
Statement of Critical Need…or else!

- 1-2 sentences

- Frame the “Unknown(s)” as a problem that demands a solution NOW

- What explicitly is needed that will drive your grant proposal?

- What bad things will happen if this problem isn’t solved? [see picture to the right]
First paragraph draft = DONE!

Diagram:
- Gap/Critical need
- Objective
- Central hypothesis
- Specific aims
- Expected outcomes
Paragraph 2: What is your Study Objective and Central Hypothesis?

- What is your long-term goal of this research?
- What is your short-term goal of this study and how does it relate to the long-term goal?
- This study
  - What will you do? What kind of design will you use?
  - Who will be your participants?
  - Why is this the best design to answer the gap/unmet need?
- What is the central hypothesis of your study? How did you come up with it?
- What will be the next step if your central hypothesis from this project is supported?
Long-Term Goal

- 1 sentence
- What is the big picture of your research program that:
  - Is related to public health (aka NIH’s mission)
  - Goes beyond the current project (but is related to it)?
Overall Objective (Short-Term Goal)

1 sentence

Explain what this study seeks to accomplish and make sure to link it to the:
- Unmet need in Paragraph #1
- Your long term goal

Emphasize the PRODUCT you aspire to provide, NOT the process that will produce it
Explain Study Design

- Participants (characteristics relevant to study: age, body mass index, race/ethnicity, etc.)
- Groups (with sample sizes)
- Variables of interest
- How often data collected
- What kind of data collected
Central Hypothesis

1-2 sentences

Your best bet out of all possibilities as to how you can meet your overall objective

Explain how this was formulated – was it based on your own preliminary data or other published studies? If preliminary data, mention what you found
Rationale for Funding the Study

- One sentence

- Tell reviewers what will be possible after your research study is completed that is not possible now!
2nd paragraph draft = DONE!
Paragraph 3: Story CLIMAX
What are your Specific Aims?

- Maximum number = 3 aims!
- Explain how you will test SPECIFIC PARTS or COMPONENTS of your CENTRAL HYPOTHESIS from Paragraph #2
- Brief, informative and open-ended, followed by at least one specific DIRECTIONAL hypothesis
- The first aim should flow logically into the second aim, which should flow logically into the third aim
- No aims should be dependent on an outcome of a previous aim
Specific Aim #1: Cross-Sectional

- Identify whether sex moderates the relationship between MDD and biomarker inflammation at baseline.

- Hypothesis: Based on our pilot data, we predict a group*sex interaction, such that within women but not men, MDD will show significantly higher levels of Biomarker #1 and Biomarker #2 than CTL at baseline.
Specific Aim #2: Longitudinal

- Identify the degree to which baseline biomarker inflammation predicts follow-up depression symptoms within MDD (accounting for sex and baseline depression symptoms).

- Hypothesis: We predict that above and beyond baseline depression symptoms and sex, greater baseline Biomarker #1 and #2 inflammation will significantly predict higher depression symptoms at follow-up.
3rd paragraph draft = DONE!
Paragraph 4: The Payoff, RESOLUTION

- **Expected Outcomes:** 1-2 sentences total explaining the payoff reviewers can expect to get if they vote to recommend funding for your project; there should be at least one expected outcome for each Aim and they should collectively relate to your overall objective from Paragraph #2.

- **Generality Regarding Positive Impact:** Explain in 1 sentence how your expected results will positively advance your field of research.
Important Note

- Somewhere in your **Specific Aims** you want to mention how this project will give you the skills to transition into an Independent Investigator position!

- This sentence may fit best in Paragraph 4, The Payoff
NIH Biosketch (max 5 pages)

- Allows applicants to:
  - Describe the magnitude and significance of their scientific contributions (including publications)
  - Provide detailed info about their research experience/skills within the context of the proposed project

- Who fills this out?
  - You
  - Anyone on your K Mentorship Team
  - Typically, Collaborators, Consultants and most “Other Significant Contributors”

- Forms, instructions, and samples available at: https://grants.nih.gov/grants/forms/biosketch.htm
**NAME:** Stewart, Jennifer Lorraine

**eRA COMMONS USER NAME** (credential, e.g., agency login): jlstewar

**POSITION TITLE:** Assistant Professor, Associate Director for Training and Mentoring/Principal Investigator

**EDUCATION/TRAINING** (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, San Diego</td>
<td>B.S.</td>
<td>06/1998</td>
<td>Psychology</td>
</tr>
<tr>
<td>University of Illinois, Urbana-Champaign</td>
<td>M.A.</td>
<td>05/2005</td>
<td>Clinical Psychology</td>
</tr>
<tr>
<td>University of Illinois, Urbana-Champaign</td>
<td>Ph.D.</td>
<td>05/2008</td>
<td>Clinical Psychology</td>
</tr>
<tr>
<td>University of Arizona</td>
<td>Postdoctoral</td>
<td>01/2010</td>
<td>Depression</td>
</tr>
<tr>
<td>University of California, San Diego (UCSD)</td>
<td>Postdoctoral</td>
<td>07/2014</td>
<td>Addiction</td>
</tr>
</tbody>
</table>
A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

What to Include:

- Key aspects of your training, past experience, technical expertise, significant collaborations, and past performance important for success of this project

- Here you can explain anything else you’d like the Reviewers to know about your career and research directions (e.g., proposing work in a new direction, or any personal/family situations impacting your work)

- You can provide up to 4 publications or “research products”

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A. Personal Statement

I possess the expertise, leadership, training, and motivation necessary to successfully complete longitudinal projects using functional magnetic resonance imaging (fMRI) during decision-making to predict relapse versus abstinence in substance use disorders. I was trained as a scientist-practitioner in clinical psychology and possess 10 years of experience with fMRI data collection, analysis, and interpretation. As a post-doctoral researcher and project scientist at UCSD, I supervised research assistants on successful participant recruitment and one- and three-year follow-up retention, as well as fMRI, self-report, and behavioral assessments, on Co-Investigator Dr. Martin Paulus’s NIDA-funded longitudinal studies of stimulant use disorder (R01DA027797, R01DA018307, R01DA016663). Within the past 6 years, I have co-authored 27 publications on addiction, interoception and/or decision-making that together demonstrate four important findings: (1) recent-onset/early stimulant addiction is characterized by heightened insular cortex sensitivity to pleasant touch, in contrast to chronic addiction, which is linked to blunted responsiveness; (2) both recent-onset and chronic stimulant addiction are marked by attenuated insular cortex responsivity to interoceptive/behavioral punishment, whereas early-onset non-stimulant (alcohol/marijuana) addiction shows heightened sensitivity; (3) future relapse to drug use is predicted by disruptions in decision-making, including attenuated reward learning and blunted evaluation of risk; and (4) individual differences in comorbid psychopathology and recency/chronicity of drug use moderate neural responses during decision-making. Brain biomarkers of stimulant addiction across studies implicate dysfunction in insular cortex, anterior cingulate cortex, and prefrontal cortex (inferior frontal gyrus). My current research focuses on delineating brain markers of recovery from opioid use disorder. My work was highlighted by NIDA in 2015 (http://www.drugabuse.gov/news-events/nida-notes/2015/09/brain-imaging-predicts-relapse-to-cocaine) and relevant articles are listed below:


Section B
Positions and Honors

Positions and Employment

- 2014-2018: Assistant Professor, Department of Psychology, Queens College, CUNY, Flushing, NY
- 2014-2018: Assistant Professor, Department of Psychology, The Graduate Center, CUNY, Manhattan, NY
- 2018-Present: Assistant Professor of Community Medicine, University of Tulsa, Tulsa OK
- 2018-Present: Associate Director for Training and Mentoring/Principal Investigator, Laureate Institute for Brain
  Research, Tulsa, OK

Other Experience and Professional Memberships

- 2000-Present: Member, Society for Psychophysiological Research (SPR)
- 2009-Present: Ad-hoc Reviewer: Biological Psychology
- 2013-Present: Member, Society for Biological Psychiatry (SOBP)
- 2013-Present: Ad-hoc Reviewer: Addiction, Addiction Biology, Addictive Behaviors, American Journal of
  Psychiatry, Biological Psychiatry, Brain and Cognition, Cerebral Cortex, Clinical Neurophysiology, Cognitive Affective
  and Behavioral Neuroscience, Current Directions in Psychological Science, Drug and Alcohol Dependence, Emotion,
  Neuroscience, Neuroimage, Neuroscience Letters, Personality and Individual Differences, PLoS ONE, Psychopharmacology,
  Psychophysiology, Social Cognitive and Affective Neuroscience, and Translational Psychiatry
- 2016-Present: Member, College on Problems of Drug Dependence (CPDD)
- 2017-Present: Consulting Editor: Psychophysiology

Honors

- 2000: Massachusetts General Hospital fMRI Visiting Fellowship Program
- 2004: Excellence in Teaching, University of Illinois, Urbana-Champaign, IL
- 2005: University of Wisconsin Madison Emotion Symposium Travel Award
- 2007: University of Michigan Training Course in fMRI Travel Award
- 2008: Ed Scheiderer Dissertation Award, University of Illinois, Urbana-Champaign, IL
- 2010: Biological Psychology Reviewer Award (10+ reviews in one year)
- 2011-2013: National Institute on Drug Abuse (NIDA) Loan Repayment Award

If you have any clinical licensure info, you would put it here

If you have been asked to review articles for journals, you can list that here

Teaching experience could also go here if the topic is relevant to your project

Travel and poster awards should definitely be included
C. Contributions to Science

1. My early work demonstrated that two individual styles of anger expression, anger-out (linked to aggression and approach motivation) and anger-in (linked to suppression of angry feelings and withdrawal motivation) presented with divergent patterns of EEG/ERP activation and differential links to depression and anxiety. Anger-in was linked to heightened worry and anhedonic depression, with reduced attentional bias to negative stimuli, whereas anger-out was associated with exaggerated attentional bias to negative stimuli. Trait anger regardless of expression style was linked to greater relative left frontal lobe asymmetry, which typically characterizes approach motivation and pleasant emotions. Results suggest that facets of anger are more complex than most models of emotional processing allow. Relevant articles are listed below:


Complete List of Published Work in MyBibliography:
IV. Contributions to Science

1. What advice do you have for new scientists filling out their scientific contributions?

In general, reviewers base their expectations for contributions based on the seniority of the person filling out the biosketch. A scientist with one publication may want to summarize the key finding of the paper and its importance in a short contribution. Scientists with no publications may wish to provide a contribution describing their efforts on other peoples' papers and projects (e.g., I used this method, I conducted the literature review for this paper, I care for all the animals in this lab, etc.). If a new scientist has no actual research or thesis experience, they might just want to list one contribution about their training to date. You might want to consult with your colleagues who serve as reviewers in your area of science.

3. Does the PD/PI need to be an author on a publication used to reference a contribution to science in a NIH biosketch?

No, the publication does not need to be their own. It is up to the applicant to describe their contributions. Listing a key publication that builds on their work is one way of doing so.

4. Can manuscripts still in the review process be included in the Personal Statement or Contributions to Science section of the biosketch?

Yes. The NIH encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work. See the Interim Research Product FAQs for more information on how to cite this information.
**Section D**

**Additional Information: Research Support**

- **Active Research Support**
  - P20 GM121312 (Paulus)  
    07/01/2018 – 06/30/2022  
    NIH/NIGMS  
  - The Center for Neuroscience-based Mental Health Assessment and Prediction (NEUROMAP)  
  - Administrative Core  
  - Major Goals were to provide state of the art neuroimaging and laboratory infrastructure to conduct biological experiments with multi-level assessments, to create a career development infrastructure to accelerate the investigator’s transition from young investigator to established investigator, and to build an operational infrastructure that provides the tools necessary to conduct the research projects, standardize assessments and provide a data repository for future pilot project.  
  - Role: Associate Director of Training and Education

- **Completed Research Support**
  - P20 GM121312 (Paulus)  
    12/01/2018 – 12/01/2019  
    NIH/NIGMS  
  - Refining frontal brain asymmetry as a biomarker for major depressive disorder  
  - The goal of this secondary data analysis project is to determine whether frontal brain asymmetry computed using fMRI regions of interest (obtained during four cognitive-emotional tasks and a resting state from the Tulsa 1000 study) are biomarkers of pure and comorbid major depressive disorder. Sex differences and two types of anxiety, anxious apprehension and anxious arousal, are included in analysis.  
  - Role: PI, Pilot Project
Biosketch Summary

- Make it personal: tell the Reviewers about you, your career, and your expertise
- This is where you tell the Reviewers that you are the most qualified investigator to do the work
- Reviewers are instructed that publication track records for Junior Investigators will not match more Senior Investigators
- Try not to speak in too many technical terms – write it so that your family members could (maybe) understand what you are trying to say
- Be clear and to the point!
Drafting an Email to the Program Officer

- Briefly introduce yourself, your degree/training/area of research, and your current position
- Explain that you plan to submit a K (e.g., K99/R00, K23) application for a specific deadline, listing the FOA you plan to apply under
- Explain the research project and training goals for the grant in 3-4 sentences max
- Be specific in your request for feedback on whether the project in your **Specific Aims** would be of interest to this Branch/Division of the Institute
- Attach your **Specific Aims** and **NIH Biosketch**
Action Items

- Write drafts of your **Specific Aims** and **NIH Biosketch** and get feedback from your **Primary Mentor**
- Search for a **Program Officer** fitting your research and send an email to this person, attaching your **Specific Aims** and **NIH Biosketch**
- Email Investigators to ask if they will be part of your **K Mentorship Team**
  - Also attach **Specific Aims** and **NIH Biosketch**
  - If they are interested in joining the Team, request feedback on both documents
- Treat yourself to a break after all this hard work! 😊