

K Club, Week 8

Dr. Jenny Stewart, Ph.D.

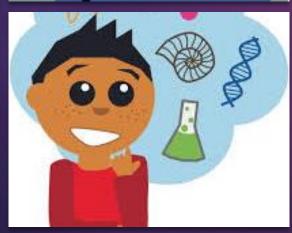
Assistant Professor of Community Medicine, University of Tulsa

Associate Director for Training and Mentoring, Laureate Institute for Brain Research (LIBR)

Today's Topics









- Grant Title
- Inclusion Enrollment Report
- Letters of Support from Collaborators, Contributors and Consultants
- ► Three Letters of Reference
- Action Items

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



Grant Title for your K Application

- It can be up to 200 characters long
- Include research keywords (e.g., cognitive control, depression, autism spectrum)
- Place the most important words first
- Keep it short
- Point to the outcome of your grant
- Avoid unnecessary words
- Avoid punctuation
- Brainstorm with peers/colleagues/Mentors
- Example: "Plasticity of aversive salience in opioid use disorder"
 - ► This grant evaluates whether early abstinence from drugs is linked to changes in negative emotional processing over time in people meeting criteria for opioid use disorder



Study Enrollment

- You need to specify how many subjects you plan to enroll in your study
- By now you should have a decent idea of your ballpark sample size you need to detect effects (based on your Approach section's power analysis)
- However, you may have needed to modify this number based on your **Budget** limitations (reminder that you only get \$20K for Research funds for the K99 – how much are you paying subjects per hour and for how many hours?)
- Now you need to start thinking about how you will recruit and enroll subjects as a function of biological sex and race/ethnicity considerations
 - Will you base estimates on local population?
 - Are these considerations relevant to testing any of your hypotheses?





Inclusion Enrollment Report: Heads Up!

inclusion Enrollment Report		Remove Inclusion Enrollment Report		
1. * Inclusion Enrollment Report Title				
2. * Using an Existing Dataset or Resource				
3. * Enrollment Location Type Domestic Foreign 4. Enrollment Country(ies)				
Add New Country	•			
5. Enrollment Location(s)				
6. Comments				

Inclusion Enrollment Report

Planned

Racial Categories	Ethnic Categories					
	Not Hispanic or Latino		Hispanic or Latino		Total	
	Female	Male	Female	Male		
American Indian/ Alaska Native	0	0	0	0	0	
Asian	0	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	
Black or African American	0	0	0	0	0	
White	0	0	0	0	0	
More than One Race	0	0	0	0	0	
Total	0	0	0	0	0	

- You will need to fill this out next week
- You will be justifying these numbers in your Inclusion of Women and Minorities section next week
- For now, make sure that your total # of subjects matches what you say you will recruit in other places in your application, including your:
 - Specific Aims
 - Approach
 - Budget do you have enough money allocated for subject payment?

Letters of Support from Collaborators, Contributors, and Consultants (6 pages max)

Other Significant Contributors

Other Significant Contributors (OSCs) are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards. A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. However, if an award is to be made, Other Support information will not be required or accepted since considerations of overlap do not apply to these individuals. Should the level of involvement change for an individual listed as an OSC, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

Consultant

A consultant is an individual/firm retained to provide professional advice or services for a fee but usually not as an employee of the requiring organization. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under "professional services costs." In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. For example, consulting fees that are paid by an educational institution to a salaried faculty member as extra compensation above that individual's base salary are allowable, provided the consultation is across departmental lines or involves a separate or remote operation and the work performed by the consultant is in addition to his or her regular departmental workload. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services.)





Letters of Support from Collaborators, Contributors and Consultants

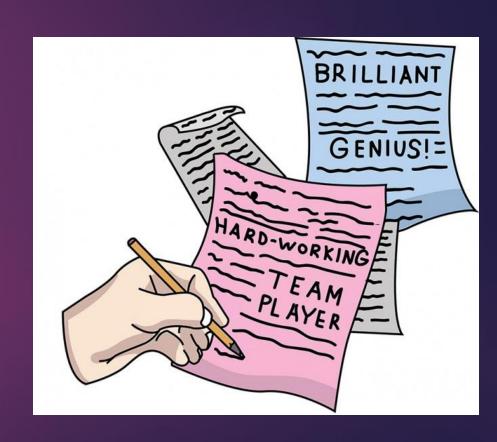
- Identify Collaborators, Contributors and Consultants involved with the proposed research and career development program, and not already included in the Plans and Statements of Mentor(s) and Co-Mentors section
- Letters should briefly describe their anticipated contributions and document their role and willingness to participate in the project
- The letters should also briefly describe research materials, data, guidance, or advice each person will provide
- Letters from Consultants should include rates/charges for consulting services
- Also ask these people for their NIH Biosketches in case you need them





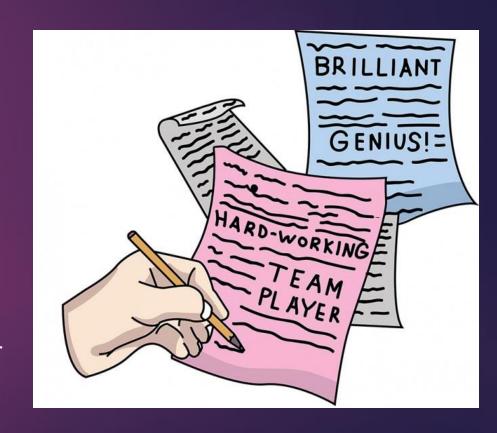
Three Letters of Reference

- These people should <u>not</u> be Mentors, Co-Mentors, Consultants, or Collaborators on your K
- They could be your: dissertation advisor, professor, Chair of PhD department, employer, etc.
- https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letters.htm
- These letters should address your:
 - Potential to become an independent research scientist
 - Evidence of originality
 - Adequacy of scientific background
 - Quality of research endeavors or publications to date, if any
 - Commitment to health-oriented research
 - Need for further research experience and training
 - Any additional related comments that the referee may wish to provide



Three Letters of Reference

- ► These people submit their letter about you through eRA Commons separately (these letters are NOT submitted by you as part of your K application)
- Candidates must carefully follow the SF424 (R&R) Application Guide, including the time period for when reference letters will be accepted
- Applications lacking the appropriate required reference letters will not be reviewed
- You do <u>not</u> automatically get to see this letter, unless the person wants to share with you what they wrote!
- You do <u>not</u> need to compile the letters along with the rest of your K application!
- Email these people your **Specific Aims** page, **Title**, **CV**, and **NIH Biosketch** when you ask them if they are willing to write a letter on your behalf for your K application
 - Send the link from the last slide about the letters and explain that they will be submitting the letter themselves
 - Give an estimated due date based on when your grant is due to NIH



Action Items

- ▶ Brainstorm and devise a title for your K, float it by your **Primary Mentor**
- Start thinking about your **Targeted/Planned Enrollment** numbers and make sure your total # lines up with what you reported in other documents
- Revise your (a) **Budget + Budget Justification** section and (b) **Plans and Statements from Mentor and Co-Mentors** section based on **Primary Mentor** feedback
- Assemble your (a) Research Strategy and (b) Candidate Information and Goals for Career Development, and send to Co-Mentors
- In addition, send **Co-Mentors** their respective **Plans and Statements** sections and request a copy of their NIH Biosketch that addresses their roles in your project
- Discuss with your **Primary Mentor** about the need for:
 - Any Collaborators or Contributors (these are typically unpaid)
 - Any Consultants (these are typically paid, so you need to allocate \$ for them in your budget in your Training Plan, you can add info as to what they are helping you with)
- Email these people asking if they are willing to be on your grant, and if this is for a Consultant, ask their going hourly rate for services to add to your Budget + Budget Justification
- If these people say yes, ask if you would like to provide them some language for their Letter of Support
 - Request a due date for their letter
 - Provide your Specific Aims and NIH Biosketch
- Email three people to ask if they will submit a letter of reference to NIH on your behalf
 - Include CV, NIH Biosketch, K title, and Specific Aims page along with the NIH link for letter writers
 - Provide letter due date

