LIBR
Laureate Institute for Brain Research

THE UNIVERSITY of TULSA

K Club, Week 13

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Today's Topics




- Forms
- Getting the Grant Ready to Submit
- Action Items

FORMS

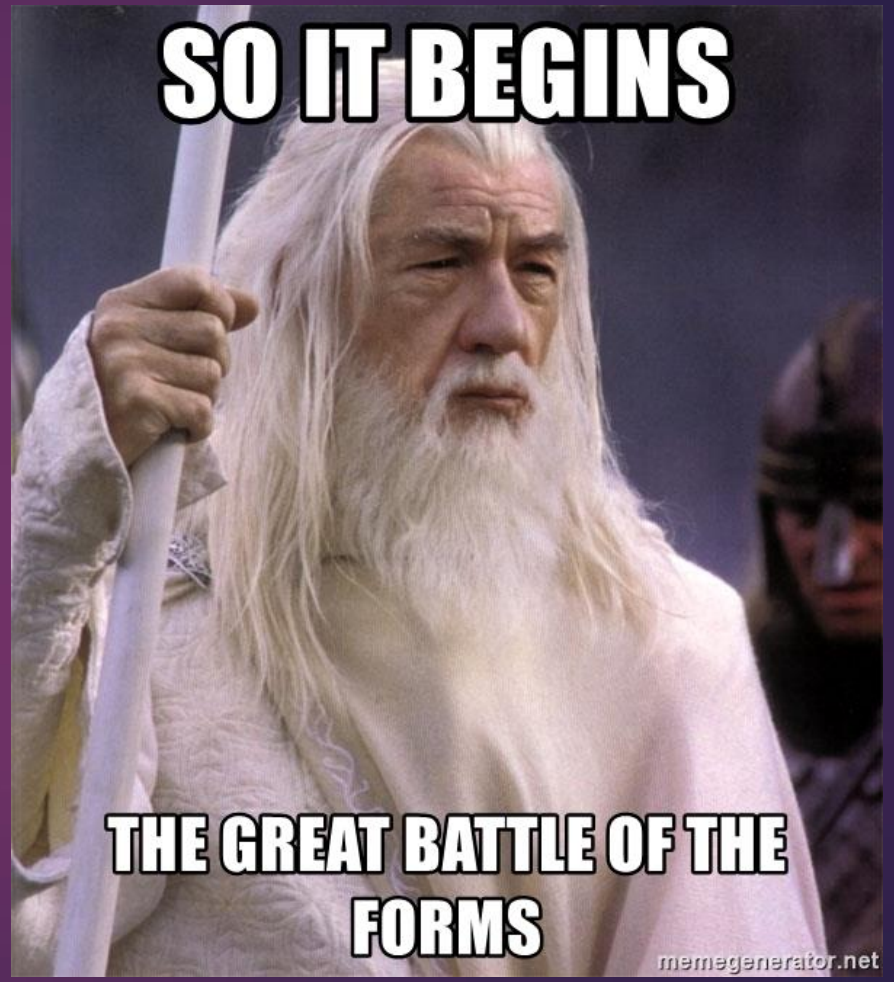
Typically you are following K instructions in SF424 (R&R) Application Guide (Forms version F) except where instructed by your FOA

Your grant is submitted using the NIH Assist platform

Find out who in your Institution actually submits your grant and fills out online forms – you or a designated Grants Administrator

At LIBR we have a **K Proposal Starter and PI Checklist** giving our Grants Director all of the info she needs to fill in online forms for your K application

Let's go through this Proposal Starter now to see what additional info you need to include in your K application via online forms!



K99/R00 Proposal Information *(Forms Version F)*

Follow Career Development (K) Instructions in SF424 (R&R) Application Guide except where instructed by FOA

ASSIST ID	
General Information	
Submission Type (New, Resubmission, Renewal, Continuation, Revision - specify reason)	
Name of Federal Agency	
Does this application involve a change of investigator or institution? If yes, specify.	
Is application being submitted to other agencies? If yes, specify agencies.	
Title:	
Funding Announcement:	
Funding Announcement Link:	
Start Date:	
End Date:	
Submission Deadline:	
Citizenship - *these questions are required on the grant application*	
US Citizen or Non-Citizen National?	
If no, select most appropriate Non-US Citizen option:	
With a Permanent US Resident Visa	
With a Temporary US Visa	
Not Residing in the US	

If you are a non-US citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here:

Cover Page Supplement	Yes/No
Does this study involve Human Subjects?	
1.4.b. Are participants assisgned to an intervention?	
1.4.c. Is this study designed to evaluate the effect of the intervention on the participants?	
1.4.d. Is the effect to be evaluated a health-related biomedical or behavioral outcome?	
Human embryonic stem cells? (If yes, list registration number of specific cell lines OR indicate cell line cannot be referenced at this time.)	
Will study be registered as a clinical trial on clinicaltrials.gov?	
Vertebrate Animals? If yes, will animals be euthanized?	
Proprietary/privileged info included?	
Actual or potential impact on environment?	
Partnerships outside US or international collaborators?	
Is program income anticipated during periods when the grant support is requested? If yes, specify anticipated amount, sources for each budget period.	
Renewal Apps only : Inventions and Patents? (If yes, previously reported?)	

Senior/Key Persons on your grant:

- You = PI
- Primary Mentor
- Co-Mentors
- Consultants
- {Sometimes but less often Collaborators and Other Significant Contributors}

Sr/Key Person Profile (if two PIs indicate which is contact PI and should be listed 1st on application) *Roles: PD/PI, Co-PD/PI, Co-Investigator, Other: Mentor (specify primary if more than one), Consultant, Faculty, Post Doctoral, Post Doctoral Associate, Post Doctoral Scholar, Other Professional, Graduate Student, Undergraduate Student, Technician, Other (specify)*				
Name	**Institution**	**Role**	**Effort (in calendar months)**	**Note: PI is required to commit minimum of 75% effort during K99 mentored phase.**
	LIBR	PD/PI		
Project/Performance Site Location(s) other than LIBR - sub institutions or places where research will be conducted (for example 12&12)				
Organization Name	**Organization Address**	**Contact**		

Project/Performance Site Locations:

- Typically this will just be your main Institution, but if you are doing work at another location, talk to your Grants person about what other paperwork might need to be completed to list another site

1	**PI Documents Checklist**		
2			
3	**X or N/A**	*If space is filled in black, no document needed. Enter text or provide Word docs for items where text entry is required.*	
4	**Budget**	*(contact Penny Olaya to assist with budget and justification)*	
5	X	Budget	
6	X	Budget Justification	
7	**R&R Cover**		
8		Letter of Intent (if applicable)	
9		Pre-application (if required)	
10		Cover Letter (if applicable)	
11	N/A	signed PHS 398 Grant Application Face Page	
12		PHS Assignment Request form (if preferred - if you would like your application to be assigned somewhere specific)	
13	**Other Project Information**		
14	X	Project Summary/Abstract	30 lines of text
15	X	Project Narrative	3 sentences
16	X	Bibliography & References Cited	
17	X	Facilities and Other Resources	
18	X	Equipment	
19		Other Attachments (if applicable)	

	PHS 398 Career Development Award Supplemental Form and Research Plan	Limits
N/A	1. Introduction (resubmission or revision only)*	1 page
X	2. Candidate Information and Goals for Career Development Candidate Background Career Goals and Objectives Candidate's Plan for Career Devlopment/Training Activities During Award Period	12 pages total for this section combined w/ research strategy
X	3. Specific Aims	1 page
X	4. Research Strategy	see #2 above
N/A	5. Progress Report Publication List (renewal applications only)*	
X	6. Training in the Responsible Conduct of Research	1 page
N/A	7. Candidate's Plan to Provide Mentoring (include only when required by specific FOA)*	6 pages
X	8. Plans and Statements of Mentor and Co-Mentor(s)	6 pages
X	9. Letters of Support from Collaborators, Contributors and Consultants	6 pages
X	10. Description of Institutional Environment	1 page
X	11. Institutional Commitment to Candidate's Research Career Development	1 page
N/A	12. Description of Candidate's Contribution to Program Goals	
N/A	13. Vertebrate Animals (if applicable)	
N/A	14. Select Agent Research (if applicable)	
	15. Consortium/Contractual Arrangements (PHS 398 Grant Application Face Page and SOW - only if app has subcontracts)*	
	16. Resource Sharing	
N/A	17. Authentication of Key Biological and/or Chemical Resources (if applicable)	
	18. Appendix (if needed)	

Reference Letters - REQUIRED - READ CAREFULLY
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. This is a separate process from submitting an application electronically. Reference letters are submitted directly through the eRA Commons Submit Referee Information link and not through Grants.gov.

	NIH Biosketches - REQUIRED - READ INFO REGARDING PRIMARY MENTOR BIOSKETCH	Limits
X	NIH Biosketch for all Sr/Key Personnel	5 pages
	Primary Mentor Biosketch must address the following in the biosketch personal statement:	
	Maintaining a record of, and training in rigorous and unbiased experimental design, methodology, analysis, interpretation and reporting of results;	
	Efforts taken to enhance diversity in the biomedical research workforce, and to ensure the research environment is inclusive, safe, and supportive for trainees from all backgrounds.	
	Commitment to fulfilling the need of the trainees to complete their training in a timely fashion with the skills, credentials and experiences to transition into independent careers in the biomedical research workforce.	

IF PROJECT INVOLVES HUMAN SUBJECTS YOU MUST COMPLETE THE FOLLOWING INFORMATION/DOCUMENTS	
Section 1 - Basic Information	
	1.1. Study Title
	1.2. Exempt from IRB review?
	1.3. If exempt, exemption #
	1.4. Clinical Trial Questionnaire
	1.4.a. Does this study involve human participants?
	1.4.b. Are participants assigned to intervention?
	1.4.c. Is this study designed to evaluate the effect of the intervention on the participants?
	1.4.d. Is the effect to be evaluated a health-related biomedical or behavioral outcome?
	1.5. Provide ClinicalTrials.gov identifier (e.g. NCT87654321) if applicable
Section 2 - Study Population Characteristics	
	2.1. Conditions or Focus of Study
	2.2. Eligibility Criteria (text entry)
	2.3. Age Limits (Min to Max age range)
X	2.3.a. Inclusion of Individuals Across the Lifespan
X	2.4. Inclusion of Women and Minorities
X	2.5. Recruitment and Retention Plan
	2.6. Recruitment Status (not yet recruiting, recruiting, enrolling by invite, active-not recruiting, completed, suspended, terminated, withdrawn)
X	2.7. Study Timeline
	2.8. Enrollment of First Participant (date and anticipated or actual)
X	Inclusion Enrollment Report(s)
Section 3 - Protection and Monitoring Plans	
X	3.1. Protection of Human Subjects
	3.2. Is this multi-site that will use same protocol at more than one site? If yes, describe single IRB plan.
X	3.3. Data and Safety Monitoring Plan
	3.4. Will Data and Safety Monitoring Board be appointed for this study?
X	3.5. Overall Structure of the Study Team

IF PROJECT IS A CLINICAL TRIAL YOU MUST COMPLETE THE FOLLOWING INFORMATION/DOCUMENTS

Please do NOT complete template form. Contact Amber for instructions to complete this section.

Section 4 - Protocol Synopsis		
	4.1. Study Design	
	4.1.a. Detailed Description (text entry)	32000 character limit
	4.1.b. Primary Purpose (treatment, prevention, diagnostics, supportive care, screening, health services, basic science, device feasibility, other - specify)	
	4.1.c. Interventions (Type, Name, Description)	
	4.1.d. Study Phase (I, II, etc; if other - specify)	
	4.1.e. Intervention Model (single group, parallel, cross-over, factorial, sequential, other - specify)	
	4.1.f. Masking (if yes - participant, care provider, investigator, outcomes assessor)	
	4.1.g. Allocation (randomized, non-randomized, N/A)	
	4.2. Outcome Measures (Name, Type, Time Frame, Description)	
	4.3. Statistical Design and Power	
	4.4. Subject Participation Duration (text entry)	
	4.5. Will the study use FDA-regulated intervention	Yes/No
	4.5.a. If yes, describe availability of IP and IND status.	
	4.6. Is this an applicable clinical trial under FDAAA?	Yes/No
	4.7. Dissemination Plan	

Formatting

- Use black 11pt Arial font
- ½ inch margins for side of all pages
- No headers/footers (automatically generated by system)
- Type density (including characters and spaces) can be no more than 15 characters per inch and no more than six lines per inch

Getting your Grant Ready to Submit!

- Go through this Proposal Starter and make sure that you have all of the documents done, including NIH Biosketches for all Senior/Key Personnel
- Talk to your Grants Administrator to determine:
  - Their deadline for you submitting the final documents to them for review and submission (if applicable)
  - How to best organize and get them your documents and info for online forms

Action Items

- Treat Yourself! ☺
- Navigating this process and just the process of writing and submitting a K is a gigantic accomplishment!
- Add this grant application info to your CV and take a well-deserved break!
- You have ~3 months before you hear anything about your grant!