Institutional K Awards Tutorial

Planning and writing an institutional K grant to the GA CTSA KL2 Program and/or the BIRCWH K12 Program

Session #1 October 19, 2023

Presented by Janet Gross, Ph.D. *jsgros2@emory.edu*

1

Class #1 Objectives

- Role of Grants Tutorial Instructor
- Unique aspects of preparing a K and other Mentored CDA
- Getting Ready to Prepare a K application
- K Grant Writing Nuts and Bolts
  - ✓ Biosketch
  - ✓ Budget
  - ✓ Candidate Section

2

Class #2 Objectives

Letters of Support

- Plans and Statements of Mentor and Co-Mentor(s), Consultants, Collaborators
- Chair or Division Chief's statement of commitment to you for this award

Research Plan (Specific Aims & Research Strategy)

- Examples
- Organization
- Clarity
- Styles of writing

Using reviewers' comments to highlight:

- Qualifications issues
- Level of detail in writing
- Integration of Research Plan in other sections
- Integration of Training Plan

3

Ga CTSA Grant Writing Resources

- 2-session KL2 / K12 application prep tutorial (4 hrs total)
- Dropbox site
  - Examples of recently funded KL2 and K12 awards
  - Other grant writing resources focused on the NIH K
- I will work with you to develop and refine your proposal (~5 hrs/candidate) based on email agreement
- pdf and video of today's talk posted on Dropbox

4

Overview

	GA CTSA KL2	BIRCWH K12
2 years, 75% protected time - 50% for surgical specialties technical budget of $25,000/yr	✓	✓
Goal is for you to generate strong preliminary data for for the NIH K23, K08 (or similar)	✓	✓
Qualified MD or PhD (or similar) with a full time faculty appointment by Aug 1, 2024	Emory, Morehouse, GaTech, UGA – all GA CTSA partners	Emory
Commitment to a research and/or academic research career in:	Clinical investigation and/or translational research	Women's health and/or sex/gender life science
Application due date	February 1, 2024	February 1, 2024
Required mentor and career development plan	MSCR, CPTS (or menu option with approval)	Self-designed with guidance from BIRCWH leadership
Who funds this award?	National Center for Advancing Translational Science (NCATS) GA CTSA Institutional Career Development KL2 (Blumberg KL2 & Taylor UL1)	NIH Office of Research on Women's Health / NICHD Building Interdisciplinary Research Careers in Women's Health K12 (Ofotokun & Sterk)

5

NEW: K12 PREHS SEED application

Pediatric and Reproductive Environmental Health Scholars (PREHS) Southeastern Environmental Exposures and Disparities (SEED) Program -- K12

- Eligibility: Emory and Morehouse clinical faculty
- Goal: to receive comprehensive pediatric and reproductive environmental health research training
- Contact: Dr. Lisa Thompson, Emory SON
- https://www.nursing.emory.edu/pages/prehs-seed-program

6

MENTORED RESEARCH TRAINING is a requirement for a career development award

- In the CANDIDATE section, you will present a very strong and rational mentoring team
- Lead mentor (primary mentor) should be an established investigator with current federal funding (e.g., NIH, AHRQ, CDC, PCORI, etc. with R01 or equivalent funding) who has agreed to mentor/train/support you through this 2-year award
  - Typically, this primary mentor continues with you into the NIH K award (not required)
- Co-mentors, consultants, collaborators, advisors do not have to meet the same funding requirement, but this is always a competitive advantage

7

Didactic Training Options

- **MSCR** (Emory or MSM) – 30 credits https://georgiactsa.org/training/ms-clinical-research.html
  - Preferred training option
- **Certificate Program in Translational Science** (**CPTS**) –16 credits (previously Certificate Program in Translational Research (CPTR)) https://georgiactsa.org/training/certificate-program-translational-research.html
  - Flexible so that you can sub out for similar courses you've already taken
- **"Menu" Option** (***new – reflects the personalized training pathway for those who have already had MSCR/CPTS training***) – must include these 5 required courses from MSCR/CPTS curriculum
  - MSCR/CPTS 593 Research Ethics (required by NIH) [1 credit]
  - MSCR/CPS 594 Scientific and Grant Writing [2 credits]
  - MSCR/CPTS 761 Introduction to Clinical and Translational Science (CTS) [2 credits]
  - MSCR/CPTS 591 Community Engagement and Health Equity [1 credit]
  - MSCR 592 Clinical and Translational Science Colloquium [1 credit]
  - Electives (based on applicant's needs—can be at any of the Georgia CTSA institutions or workshops, etc.)

8

Goal of an Institutional K award

- To generate high quality NIH individual Research Career Development (K) award submissions
  - K23, K01, K22, other similar CDAs
- Advance academic research by developing the careers of the clinical scientists and academic researchers of the future
- This is the metric for success for the NIH grants that fund these pre-K awards

9

Create HIGH Overall Impact for your proposal

- Well written, follows the rules outlined in the Application Instructions
- Clear and focused objectives
- Doable and feasible given time and money
- Entire narrative is a cohesive whole with a focused theme (*i.e., advancing to an NIH K award*)
- Mentor section is VERY PERSONAL and VERY DETAILED
- Research plan and training plan are complementary

All this leads to →

10

Unique aspects of a K award

11

K Awards vs. other grant proposals

- You are an excellent candidate → Biosketch
- You have an excellent lead mentor who can commit to time, space and career development → Mentor's Letters of Support
- You have an excellent training plan for advancing in your area of research → Career Development Plan (Candidate section)
- You have a very good research idea (possibly a pilot study) with corresponding methods and plans for analysis → Research Plan
  - *good enough preliminary data*
- Required Institutional Support → Chair's (or division chief's) letter of support

12

What constitutes a Career Development Plan?

- Career Development Plan requires careful thought, consideration and strategy with Mentor input – thematically holds together the K award proposal
- Career Development Awards require a formal mentor/advisory team
- Reviewers will look for the answers to these questions:
  1. What new training will you receive and from whom?
  2. How will this training advance your career and the science you propose given this new skill set?
  3. Are you eligible? – citizenship, faculty position at time of award
  4. Are you competitive - biosketch, mentoring team, research plan
  5. What will be the next research step? Tell us that you will prepare an NIH K award or equivalent

13

Clearly justify and describe your choice of Didactic Training options

- **MSCR** may be appropriate for faculty who have had limited prior didactic research training
- **CPTS** would be an option for faculty depending on career interest
- If you select the **Personalized Pathway Menu** option, you need to be explicit in the didactic program you will follow and tell us why you've chosen this selection

14

Preview the NIH K to set the stage for your KL2 / K12

One Stop Shop for NIH Career Development Awards
https://researchtraining.nih.gov/programs/career-development

- Specific Program Announcement (PA) for each kind of K
- Each K has its own particular requirements
- Each K funder may have particular requirements/rules/restrictions
- Mentored (K23, K01) vs. Non-mentored (K22; R00 phase of K99/R00)
- Other resources for K awards and other Career Development Awards
  - AHRQ, CDC (e.g., NIOSH K01)
  - DoD, American Heart Assn, other foundations

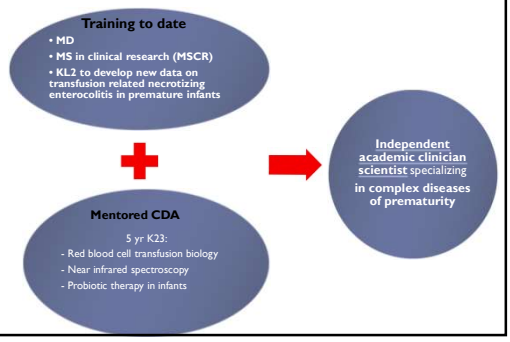
15

Study the NIH K procedures to gain a context for what reviewers are looking for

- K Funding Opportunity Announcement
  - https://researchtraining.nih.gov/programs/career-development
- NIH Career Development Application Instructions
  - https://grants.nih.gov/grants/how-to-apply-application-guide.html
    - See K Career Development Instructions (this gets revised regularly)

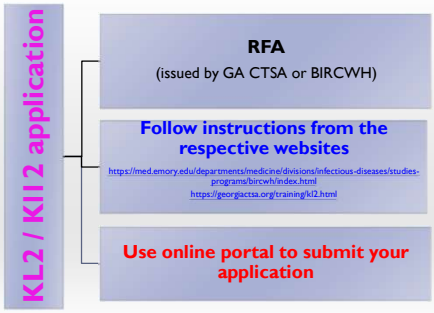
16

Career Path for a NIH K23 – Mentored Patient-oriented Research Career Development Award



17

All the moving parts for this grant application



18

NIH Review Criteria

F- Fellowship Grants	K - Career Development	Standard Grants
Fellowship Applicant	Candidate	Significance
Sponsors, Collaborators and Consultants	Career Development Plan / Career Goals	Investigator
Research Training Plan	Research Plan	Innovation
Training Potential	Mentors, etc.	Approach
Institutional Environment and Commitment to Training	Environment and Commitment to Candidate	Environment

19

NIH K Scoring System

- Follows NIH review criteria and process
- Component scores are rated 1 (best) to 9 (worst)
  - These 5 component scores are only given by main reviewers (you will not see these for the KL2 review – you will only see your Overall Impact Score)
- Generally, all component scores must be at least Excellent to be funded
- Your total score = Overall Impact Score (a fundable score is generally <30)
  - Everyone in the room votes based on their own reading and/or what they've learned from the main reviewers using a 10-90 point range
  - Your overall impact score is not the average of the main reviewers' component scores
- Any one of the 5 review criteria with a fatal flaw will result in NO SCORE (or Not Discussed)

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor
Other Designations for Final Outcome		
ND	Not Discussed	

Overall Impact range is 10 best - 90 worst

20

Center for Scientific Review

https://public.csr.nih.gov/

1. Scoring System and Procedures
2. Watch the Mock Review session video
3. See the review criteria

21

Getting ready to prepare the K application

22

Am I Competitive?

- Publication record
  - >1 first author publication, preferably experimental research, in your current field, related to the aims of the K
  - Published with your mentor(s)
- Biosketch that shouts "I'm on the career path to becoming a (NIH) funded independent investigator"
  - *Personal Statement* states this explicitly
  - Track record is the evidence
- Other professional activities - awards, invited presentations, co-I, association memberships, etc.

23

Research Ideas → Research Plan

- A mentored CDA requires training in an area where you are currently **not** a recognized expert
  - NEW laboratory methods, analytical methods, modeling schemes, comparative systems, new animal models, etc.
  - Coursework, preferably the MSCR or CPTR
- Hypothesis-driven work is highly valued
- If you are already an expert in what you are proposing, you won't fulfill the criteria of a CDA.
  - Branch out in a new exciting direction
  - What new training would you need to complete the aims?
  - What is a reasonable amount / type of new training given the duration of the award and the timing of the aims

24

Vet your research idea with LOTS of smart people

- Is your Research Plan scientifically sound?
  - How do you know this?
  - Let others see your work – review and feedback from peers (not just your mentor)
  - Do you have preliminary data? How compelling is it?
- How will you write about research in an area where you are not an expert?
  - Get advice from your mentors
  - e.g., explaining new techniques for analyses in your proposed aims
  - You have to sound 'smart enough' but not a published expert (or why would you need the K?)

25

Examples of Reviewers' Comments:

Career Development Plan / Career Goals & Objectives

- *Training focused on reading textbooks and some hands-on training sessions by busy mentors is informal and weak.*
- *It is not clear if the whole of MSCR or only a part of it is included in the training plan*
- *Wet lab experience is lacking; plans to obtain this expertise are rather vague – terms like lab "rotations" not well defined in terms of location and duration*

Mentors, co-mentors, consultants, collaborators

- *There is concern about the lack of an individual with sufficient documented behavioral scientist or education expertise in the mentoring team, especially considering the major focus of the research activity.*

Research Plan

- *Rationale for duration of follow-up (6 months) is unclear*

26

Seek Career Advice and Guidance

- Mentoring is key in a KL2 and NIH K
  - Who is promoting you and your career?
  - Mentoring vs. pseudo-mentoring
  - Name names – this is an internally reviewed award
- Institutional Support
  - You must have a faculty position as of August 1, 2024, that is NOT CONTINGENT on you receiving the K12
  - Do you have Departmental support for resources as well as the balance of funds needed - salary, materials
  - The typical KL2 / K12 cannot be supported solely on the KL2 / K12 research budget – why? Research is expensive.
  - BE VERY CLEAR IN THE BUDGET JUSTIFICATION HOW YOU WILL COVER ALL EXPENSES including tangible support from mentor, co-mentors, etc.

27

CAREER DEVELOPMENT AWARDS want to know: WHAT ARE YOUR CAREER GOALS?

- What are your career goals, i.e., whose job would you like?
- Mentoring Plan - discuss your career goals (in detail) with your mentor and at least one other respected faculty member (division chief, etc.)
  - What is the NEW TRAINING you will seek?
  - Will you be supported - professionally, financially, etc.?
  - Are your career and research goals realistic?
  - This is where you make certain there is NOT SUBSTANTIAL OVERLAP in scientific aims with your mentor's R01
  - Can the award budget support your proposed research? (probably not)
  - Have you thought about a budget? Will you 'piggyback' on another project?
- All roads → NIH K submission
  - Your goal through the institutional K is to generate sufficient preliminary data / results to inform / support an NIH K application

28

Departmental/School Permission

- Who needs to know that you are submitting this grant?
- Get permission from your division chief
- Release from clinical time?
- Is your department ready to support you as an independent researcher?
- Promotion issues - postdoc vs. faculty
- Do you need to complete the MSCR? If you are not sure, please consult with Drs. Blumberg and/or Ofotokun
  - They are expecting to hear from you.

29

K Grant Writing Nuts and Bolts

30

KL2 / K12 Required Sections

a) Cover page (see respective cover sections)
b) Cover Letter from Applicant
c) Abstract (30 lines)
d) Research Training Plan (13 pages total; upload in order specified in jotform)
   - Introduction to Application (1 page; resubmissions only)
   - Specific Aims (1 page)
   - Candidate Section + Research Strategy (12 pages)
   - Human Subjects Protection / DSMP (if needed; no page limit)
e) Facilities and Other Resources (2 pages)
f) Human Subjects / Data Safety and Monitoring Plan (no limit)
g) Literature Citations (no page limit)
h) Budget and Budget Justification (2 pages)
i) NIH Biosketch and Other Support page (NIH instructions)
   - Applicant and all mentors' and advisory committee members
j) Letters of Support
   - Department Chair's Letter (or division chief)
   - Lead Mentor (followed by any other co-mentors, advisors, collaborators; 5 slots)

31

Each PDF gets uploaded into its 'slot'

- Use online portal to submit grant
- Questions:
  - PREHS SEED: **lisa.thompson@emory.edu**
  - GA CTSA: Cheryl Sroka csroka@emory.edu
  - BIRCWH: Shannon.walker@emory.edu

32

Preparing the Biosketch for a K award

New Tools to build and store your biosketch
- Use the Forms G version for applications due >2022
https://grants.nih.gov/grants/forms/biosketch.htm

Create your biosketch here!
SciENcv
Science Experts Network Curriculum Vitae

http://www.sph.emory.edu/research/grand-rounds/index.html
http://www.sph.emory.edu/research/documents/NewNIHBiosketch.pdf

33

NIH Review Criteria

F- Fellowship Grants	K - Career Development	Standard Grants
Fellowship Applicant	**Candidate**	Significance
Sponsors, Collaborators and Consultants	Career Dev Plan/Career Goals	**Investigator**
Research Training Plan	Research Plan	Innovation
Training Potential	Mentors, etc.	Approach
Institutional Environment and Commitment to Training	Environment Commitment to Candidate	Environment

You are not your research, but you are your biosketch

34

Which Biosketch should I use?

- All K applicants→ use Standard Biosketch
- If you are updating from a NRSA F Award biosketch, you will need to use a new form page
- Instructions for Foundations and non-NIH funders might be different

35

Sections of the NIH Biosketch

Name, eRA commons, Position, Education & Training

A. **Personal Statement**
B. **Positions and Honors**
C. **Contributions to Science**

Form Name	Biographical Sketch Format Page (non-fellowship) - Due Dates on/after January 25, 2022
Description	Prepare biographical sketches for applications and progress reports for all applications and awards, except fellowships.
How to Access	Non-fellowship Biosketch (blank format page, Word)

36

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Hunt, Morgan Casey

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

POSITION TITLE: Associate Professor of Psychology

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.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/1990	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

eRA commons user name – obtain this through Office of Sponsored Programs

37

A. Personal Statement

Briefly describe why you are well-suited to receive the award for which you are applying. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (**you may mention specific contributions to science that are not included in Section C**). Also, you may identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project.

If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

38

Suggestions for Writing Personal Statements

1. Customize the personal statement for each grant proposal
2. Mention the name of the grant proposal (e.g., KL2) and speak directly to the purpose of this funding mechanism

- *I envision using the training, experience and research findings from this KL2 award to establish a career in cardiovascular research focusing on the role of shear stress affecting the interface of endothelial cells and leukocytes in maintaining the balance of immune activation and immune tolerance, on cardiovascular diseases.*

39

Funded KL2 → K01 → R21→ R01

Once we have thoroughly characterized both the behavioral and neurophysiological effects of stimulation at the amygdala in biasing, I will be poised to make the next step to a K01 project wherein I hope to establish an independent lab to systematically examine the contributions of limbic regions (also frequently implanted in epilepsy patients) to emotional perceptual bias, and to broaden our focus to include other measures of affective system function. Emory is the ideal environment for the implementation of the proposed brain stimulation research: in addition to the availability of rare DBS patients, we have a world-renowned epilepsy surgical team, which provides access to approximately 1 patient per week with implanted electrodes in the limbic system making this KL2 and a future a K01 project highly feasible.

40

Writing Suggestions

3. Lots of overlap with Candidate Section in K grant
4. Be succinct, revise this several times after you have developed the Candidate section essays
5. All these sections need to be great – Reviewers really care about these sections
6. Could be a place to remind the reviewers which didactic training plan you've chosen and why (in brief)

41

More Suggestions for Writing Personal Statements

- Length – generally no need to exceed Page 1
- Convey excitement and passion to do the proposed work
- Depending on the type of grant, emphasize your role for:
  - Leadership (PI of a R grant)
  - Training potential for you to advance in your field (need for training for KL2)
  - Are you a mentor? (you need to review your mentors' biosketches)
  - Track record and experience to support the proposed aims
  - Tone should be confident but not arrogant
  - Don't just walk us through your accomplishments but speak to the science in this proposal

42

If you are the PI of the grant….

- Even if you are a postdoctoral fellow, you need to read/review / edit the Personal Statement of all other contributors to this proposal
- WHY?
  - Because this is the PI's job
  - Each Personal Statement must reflect that writer's role on the project
- If someone is sponsoring / mentoring / collaborating with you, that should be mentioned in that person's Personal Statement

43

Research Support now follows the Personal Statement

- Research Support (section D.) formerly came at the end of the biosketch
- Now, you are instructed to include the projects that are most relevant to the research proposed in the application.
- Do not include number of person months or direct costs.
- For junior-level investigators, I recommend that you include ***all current and previous funding***
- For the most current NIH guidance, look at the file: **non-fellowship-biosketch-sample-2021.docx**
- Exact instructions for the New Biosketch are found in the NIH K application guide

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.240-r&r-seniorkey-person-profile-(expanded)-form.htm#Instructions

44

Research Support

……..Your personal statement here……

Ongoing and recently completed projects that I would like to highlight include:

R01 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older people with substance use disorders

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression, and substance use among older adults

Citations:
1. Gross, J, xxxx
2. Gross, J, xxxxx

45

B. Positions and Honors

- You can load info into My NCBI
  - online tool (via SciENcv) to support building/storing your personal data including linking to all your publications
- Be thorough
- Clarify what specific awards/honors were for
- Sometimes you might want to add an alternative (unique) subheader if the grant supports it
  - Patents
  - Board Certifications

46

Example of creative subheader

Consultant/Reviewer

Course Instructor/Director

Program Developer (could be an international program, or software)

External Advisor

47

Section C. Contributions to Science

- List up to 4 peer-reviewed publications or other non-publication research products (*my interpretation: this could include abstracts but not papers in preparation or under review*)
- Each of the 5 'contributions' can be no more than ½ page each including citations
- Provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine*

  Complete List of Published Work in My Bibliography:
  http://www.ncbi.nlm.nih.gov/myncbi/……

  * must be a .gov link (not google scholar or research gate)

48

C. Contributions to Science

1. Topic #1….(use an explanatory subheader)
   - Brief narrative (written in 1st person)
   - Published manuscripts (underline or bold your name)
2. Topic #2….(use an explanatory subheader)
   - Brief narrative
   - Published manuscripts

49

C. Contribution to Science

3. **Early caffeine therapy is associated with a lower risk of bronchopulmonary dysplasia**

Caffeine therapy is widely used to treat apnea related to prematurity. A landmark international, multicenter trial demonstrated that caffeine reduces the risk of bronchopulmonary dysplasia, a serious and chronic respiratory complication of prematurity. My research has focused on examining the comparative effectiveness of various approaches to initiation of caffeine therapy. Initial studies at our center, which we later validated in a large US cohort of over 60,000 very low birth weight infants, showed earlier initiation of caffeine therapy, compared to later initiation, was associated with a lower risk of bronchopulmonary dysplasia. Our initial novel findings have recently been replicated by several other research groups in the US and internationally.

- **Patel RM**, Leong T, Carlton DP, Vyas-Read S. Early caffeine therapy and clinical outcomes in extremely preterm infants. *J Perinatol*. 2013;33(2):134-40. PMID: 22538326
- Dobson N*, **Patel RM***, Smith PB, Kuehn DR, Clark J, Vyas-Read S, Herring A, Laughon MM, Carlton DP, Hunt CE. Trends in caffeine use and association between clinical outcomes and timing of therapy in very low birth weight infants. *J Pediatr*. 2014 May;164(5):992-998.e3 PMCID: 3992195 **Contributed equally*

50

Thinking about my "Contributions to Science"

- What goes here?
- How do I organize this?
- How much do I report (i.e., how many items)?
- Some ideas
  - In your previous research experiences, what did the team do and what exactly did you do?
  - What did you learn from what you did?
  - Can you reflect on what you found and how it may have led to the current proposal?
  - Be aspirational – express your professional hopes and desires

51

Recommendations

- Follow the directions – use the example as a model
- Do not misrepresent any facts
  - List all publications as they would appear in PubMed or in any other searchable database
- *Advice from a sage academician:*
  - *Extraordinary evidence for extraordinary claims*
  - *The magnitude of your supposed accomplishment must align with your tangible contributions*
  - *Self-aggrandizing will certainly backfire. Probably better to lean towards humility to increase likability factor*

52

Recommendations

- Each new grant proposal should prompt you to revise your biosketch, especially the Personal Statement (and possibly Contributions to Science), so that it speaks *directly* to this particular grant proposal
- Pay attention to aesthetics and layout – spacing, font, page break
  - Does your printed out biosketch look like the example?
  - Do you need to customize any subheaders to make a point – e.g., teaching or curriculum development
- Reviewers are looking for specific information in particular places – make it easy for the reviewer by following the rules and the formatting

53

54

K Budget

- This is a non-modular budget
- There are only 2-line items in a K budget –
  1. Salary support for PI
  2. Technical Budget
- Plan in advance to be sure you can do the work for the money
- Reviewers will ask: *Can this work be carried out with this budget?*

55

Technical Budget ($25,000/yr)

a) tuition and fees related to career development (allot $10,000 for MSCR for Year 1; if you are not taking the MSCR, you have more discretion)
b) research expenses, such as supplies, equipment and technical personnel
c) travel to research meetings or training
d) statistical services including personnel and computer time
e) Maximum $2,500/yr for travel (airfare, lodging, per diem)

56

Required Expenses you should itemize in your Budget Justification

From within the technical budget, you need to allocate

1. $10,000 tuition for MSCR in Year 1 (if applicable)
2. Annual Ga CTSA scientific meeting at Callaway Gardens (expected)
   - Hotel, travel by car, registration (this is cheap or free)
3. Annual NCATS Association for Clinical and Translational Science meeting in Washington, DC (required)
   - Airfare and hotel
   - Discounted registration (Alexey will register you)
   - Poster / talk preparation

57

Budget Justification (narrative; 2 pages)

A. Senior/Key Person – describe in narrative form why you are PI of this proposal (will be redundant with other sections)

(B – E indicate n/a)

F. Other Direct Costs

F.1. Materials and Supplies – in this section you detail the expenses to carry out your research. If you are getting money from the department or elsewhere to do the work, be clear what costs are coming from the grant and what are coming from elsewhere. Using standard budget categories will make this easier.

- travel expenses go here

58

RESEARCH COST

Supplies

Microdialysis (μD): A total of $10,190 is requested for μD supplies including the following: $2,895 for a CMA 107 μD pump. $6,475 for 28 CMA 60 μD probes ($231.25 per probe), $430 for 40 CMA syringe pumps, $285 for 250 μD microvials, and $105 for 5 CMA pump batteries.

AFB Culture and Drug Susceptibility Testing: A total of $2,100 is requested for supplies including the following: $800 for 100 MGIT tubes, $1,000 for DST reagents, and $300 for 100 tissue grinders.

Genome Sequencing: A total of $1,263 is requested for genetic sequencing supplies including the following: $633 for 250 DNA Qiagen Mini-Kits, and $630 for reagents necessary for freezing MTB isolates and DNA.

Lab supplies: A total of $319 is included for miscellaneous lab supplies including gloves and N95 respiratory masks.

Total = $13,872

Travel: All travel during year 1 will be supported by an ongoing NIH Fogarty TB research-training grant (#D43TW007124).

Coursework: Emory courtesy scholarship for faculty (5 credits/semester) will cover coursework in Year 1.

…

Patient enrollment costs: A total of $2,000 is requested to pay study staff in the Republic of Georgia to perform all the tasks required for patient enrollment including collecting informed consent, data collection, blood draw, DNA extraction, freezing MTB isolates, microdialysis, and shipping samples. (4 patients * $500 per patient).

Total = $10,128

59

Reviewer's Comments regarding the Budget for an NIH K23

Overall budget is reasonable, but it will be good to see a breakdown of the $25,000 Research Support. This seems to include a lot of travel. Patient costs itself will cover about $13,000 (160 women x 2 visits x $40/visit). This doesn't leave much for a Research Coordinator, Database manager and Biostatistics support.

60

Candidate Section

61

Candidate Information

(Candidate + Research Strategy = 12 pages)

a) Candidate's Background

b) Career Goals and Objectives

c) Career Development/Training Activities During the Award Period

- Refer to the NIH Career Development Application Guide for more detailed instructions:
  https://grants.nih.gov/grants/how-to-apply-application-guide.html

62

Suggestions for Candidate Information Writing Style:

- Organize according to guidelines – these are mostly PERSONAL ESSAYS that are dotted with scientific facts, findings, interests, goals, etc.
- "Speak" to the reviewer; "Sell" your idea; Be compelling!!
- Not written in manuscript or research plan style
- First person is ok but don't be "folksy"; name names and places
- Reflect on your personal experiences as a scientist and where this award will lead you
- Make a case for your personal career path - describe your contribution to the field
- Don't simply walk us through your biosketch
- Pay attention to aesthetics/layout

63

NIH Review Criteria

K - Career Development	Standard Grants
Candidate	Significance
Career Development Plan / Career Goals	Investigator
Research Plan	Innovation
Mentors, etc.	Approach
Environment Commitment to Candidate	Environment

64

Candidate Information
a) Candidate's Background

This must be brief and to the point.

- Any additional research and/or clinical training experience
- Expand upon your biosketch (only if necessary)
- Will be somewhat redundant with your Personal Statement from biosketch

Just a paragraph or two (my recommendation)

65

Candidate Information
b) Career Goals and Objectives

- This is where you talk about your future goals that will include writing an NIH Career Development Award (or something else – depends), and your personal career goals in academic research / translational science / clinical investigation – BE SPECIFIC
- Justify the KI2 / K12 award - how will having this 2 year award help you develop and advance your career - where will you go with this award 5 years hence scientifically speaking.
- Past scientific history - how what you've studied to date has led you to where you are now
- Consistent themes or issues – challenges in the science that intrigue you, why, what will you do to solve these problems
- Change in path, discipline - explain
- Document a clear training and career path – timeline can go here (or later).

66

Short- and long-term career goals

- Identify a clear set of overarching career goals and corresponding training goals

1. Epidemiology of TB/HIV co-infection
2. Advanced cohort study methodology
3. Molecular epidemiology
4. Bioinformatics

67

Example of Table to convey K Career Goals

Table 3. Overview of K training objectives and future goals

Areas of Focus	Prior Training	KL2 Award Objectives	Future Goals
Epidemiology of obesity and diabetes	• Master's and doctoral training in ….	Gain in-depth knowledge of the ….. (Aim 1)	Establish an independently funded laboratory to …. Develop an K23 on the …. Join the NIDDK Network Initiative to examine ….
Cohort study methodology	• Limited experience with postdoctoral advisor in ….	Develop expertise in the design, implementation and analysis of large, multi-site cohort studies. (Aims 2 & 3)	
Mixed methods statistical approaches	• No prior training in …	Develop new skills in ….. (Aim 3b)	

68

Candidate Information

c) Career Development/Training Activities During Award Period

- "Stress the new, enhanced research skills and knowledge you will acquire…"
- Who comprises your Mentoring Team? Who will train you to do what for which aims? Mention people by name/role. This section will complement the *Letters of Support by Mentors*
- Be specific – what is the real new training you will receive
- Describe structured activities in DETAIL
  - formal supervision/mentoring – weekly time with mentors
  - coursework (course number and descriptive title – no elaborate discussion)
  - seminars, lab meetings
  - preparation for mentored NIH K award independent research, etc.
- You must propose Research and Training Activities for each of the 2 years
- Plan to submit your NIH K must occur by the end of your first 12 months as KL2 / K12 Scholar
  - State you will take my 6-hour NIH K grant writing tutorial and MSCR594 Grant and Scientific Writing (required) to prepare for your NIH K application

69

Important Considerations in Selecting a Mentor

1. ***Highly qualified, senior academic scientist*** who takes overall responsibility for overseeing your training activities and your original research
2. 'Apprentice model' of mentorship is highly valued
3. This person must be 100% committed and this must be crystal clear in this section
4. Mentor must have a 'stable financial environment' – R01 funding is excellent but not required (but there is a big bias for an NIH funded mentor for the NIH K award)
   - Answers the question "Where will the resources come from to support the research that is not supported by the grant?" Resources can come from lots of places – they must however be available (not anticipated through future grants).
5. All mentoring/consulting/collaborating must be coordinated and spearheaded by the mentor

70

Describe the Advisory / Mentoring Team

Everyone who is involved in 'helping you' with the K award has a job title.

- **Mentor**
- **Co-mentor**
- **Consultant**
- **Collaborator**
- **Advisory Committee**

71

Mentorship Team

I recognize the importance of mentoring throughout one's career, but particularly in making the transition from junior to independent investigator. I have established a team of mentors that are national and international experts in transplant immunology, immunotherapy, sickle cell disease, and HSCT. My primary mentorship team of Dr. Galipeau and Dr. Krishnamurti, who are both based at Emory, will provide the necessary expertise in scientific study design and implementation, clinical trial development, grantsmanship, and mentoring.

Primary Mentor: Jacques Galipeau, MD is a tenured Professor of Hematology and Oncology in the Departments of Pediatrics…… I will attend the weekly Gallipeau lab meetings where I will be expected to present …. (describe the components of the hands-on training you will receive by who, where and when)

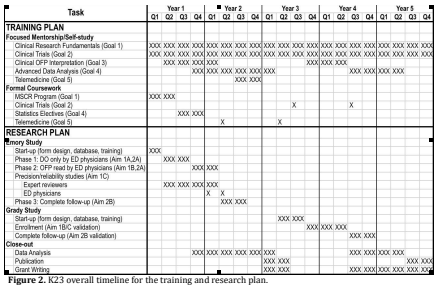
Co-Primary Mentor: Lakshmanan Krishnamurti, MD is a Professor of Hematology and Oncology in the Department of Pediatrics and Director of Pediatric Blood and Marrow Transplantation. ……

72

Table 1. Training and Research Plan by Year *Shows work x time for each semester*

Planned Activities by Year/Period		Year 1 (8/1/14-5/31/15)		Year 2 (6/1/15-5/31/16)		
Academic Semester		Fall	Spring	Summer	Fall	Spring
Training Plan						
MSCR Coursework	Analytic Methods for Clinical Research I	X				
	Biostatistics	X				
	Data Management	X				
	Community Engagement & Health Disparities	X				
	Fundamentals of Bioinformatics		X			
	Analysis of Clinical Research Data		X			
	Analytic Methods for Clinical Research II		X			
	Clinical Research Colloquium		X			
	Clinical Trial Design and Analysis		X			
Thesis	Preparation	X	X	X		
	Defense			X		
National Conferences	American Society of Hematology (ASH)	X			X	
	Tandem meeting (ASBMT/CIBMTR)		X			X
ASH CRTI	Submit application		X			
	CRTI program			X	X	X
Research Plan						
Specific Aim 1	Prospective sample collection	X	X	X		
	Ex-vivo expansion of MSCs		X	X	X	
	Phenotypic analysis of MSCs		X	X		
Specific Aim 2	Retrospective sample collection	X				
	Analysis of MSC function	X	X	X	X	X
Specific Aim 3	IFN-γ priming of MSCs	X	X	X	X	X
	Analysis of MSC function	X	X	X	X	X
Data analysis			X	X	X	X
Abstracts	ASH	X			X	
	Tandem meeting		X			X
Manuscript	Preparation	X	X		X	X
	Submission/publication		X	X		X
Haplo-BMT platform	Protocol development	X				
	Submit IND application		X			
	IRB submission for MSC clinical trial			X		
Funding	Preparation of K23 application		X	X		
	Submission of K23 application			X		
Clinical Plan (remaining 25% effort)						
Inpatient and outpatient BMT service (~12 weeks per year)		X	X	X	X	X

73



Task	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
TRAINING PLAN																				
Focused Mentorship/Self-study																				
Clinical Research Fundamentals (Goal 1)	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Clinical Trials (Goal 2)	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Clinical OFP Interpretation (Goal 3)		XXX	XXX	XXX	XXX					XXX	XXX	XXX								
Advanced Data Analysis (Goal 4)			XXX	XXX	XXX	XXX	XXX	XXX						XXX	XXX	XXX	XXX	XXX		
Telemedicine (Goal 5)						XXX	XXX													
Formal Coursework																				
MSCR Program (Goal 1)	XXX	XXX																		
Clinical Trials (Goal 2)											X				X					
Statistics Electives (Goal 4)			XXX	XXX																
Telemedicine (Goal 5)					X				X											
RESEARCH PLAN																				
Primary Study																				
Start-up (form design, database, training)	XXX																			
Phase 1: DO only by ED physicians (Aim 1A,2A)		XXX	XXX																	
Phase 2: OFP read by ED physicians (Aim 1B,3A)				XXX	XXX															
Precision/reliability studies (Aim 1C)																				
Expert reviewers		XXX	XXX	XXX	XXX															
ED physicians					X	X														
Phase 3: Complete follow-up (Aim 2B)						XXX	XXX													
Grady Study																				
Start-up (form design, database, training)									XXX	XXX										
Enrollment (Aim 1B/C validation)										XXX	XXX	XXX								
Complete follow-up (Aim 2B validation)											X			XXX	XXX					
Close-out																				
Data Analysis			XXX	XXX	XXX	XXX	XXX	XXX						XXX	XXX	XXX	XXX	XXX		
Publication									XXX	XXX									XXX	XXX
Grant Writing									XXX	XXX				XXX	XXX		XXX	XXX	XXX	XXX

Figure 2. K23 overall timeline for the training and research plan.

74

What are Reviewers Looking for?

- What scientific skills / techniques / areas don't you know?
- Who is spearheading your training and looking out for your career development?
- Where will the balance of research funding come from?
  - Lab tech, materials, cells, animals, datasets, staff support (research tech, clinical coordinator, recruiter, assessors, etc.)
- What new skills will you learn?
- How will the new training support your ability to carry out the proposed aims?
- All this can be very concrete and specific; write in the 1st person to make this flow nicely

75

Learn from funded proposals

- See KL2-BIRCWH folder on DROPBOX
- NIH RePORTER for K awards similar to yours

76