

GRANT WRITING WORKSHOP

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Purpose

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- To help demystify the grant writing process
- Provide insights into what reviewers are looking for in a grant proposal
- Hands on experience with specific aims

Road Map

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- Early steps in grant writing
- Grant sections – what belongs where?
- NIH review criteria
- What about the budget?
- Common pitfalls
- Grant worth considering – NIH K43

- Specific Aims small group workshop

Where should I start?

Early Steps

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- Identify a mentor(s) and discuss if s/he is willing to take on this role
- Develop a detailed timeline. Stick to it!
- Carefully review the grant instructions
- Review several successful grant applications

What makes a good mentor?

Ideally. . .

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- NIH-funded or funded by other well-recognized research body (Wellcome Trust, MRC, etc)
- Has mentored other investigators through grant writing
- Can highlight prior research trainees who have successfully transitioned to independent research (track record)
- Co-mentor(s) option
- If your mentor can't review your grant for feedback, is s/he the right person?

Who needs to be involved?

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- Mentor and co-mentor
 - Provide drafts early in the process and according to agreed upon timeline
 - May need to provide a letter of support
- Biostatistician
- Institutional Research Administration
 - Must be signed by person authorized to commit the institution to agreements
 - Department grants manager (if applicable)
- An external reader

Obtaining Biostatistical Support

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- What types of support might I need?
 - Sample sizes and power calculations
 - Anticipated statistical analysis (clinical or basic research)
- When do I need to request support?
 - Before you start writing the grant
- Where can I obtain support?
 - Center for AIDS Research (CFAR)
 - University Biostatistics Department
 - Discuss with your mentor


NIH Research RePORTER


<http://projectreporter.nih.gov/reporter.cfm>


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Home > RePORTER > Query Form Font Size: - +




 ABOUT RePORTER DATA

 VIEW PROJECT BY NIH SPENDING CATEGORY

 FREQUENTLY ASKED QUESTIONS

 ExPORTER ^{BETA}



SUBMIT QUERY

NIH Recovery Act Projects: **SELECT** ▶

Term Search:

Logic: And Or

Hint: Multiple terms are accepted. Separate each term with a space. You may also use terms in "" (double quotes) for exact terms match.

Project Title:

Fiscal Year (FY): **SELECT** ▶
Current FY is 2010

NIH Spending Category: **SELECT** ▶

State: **SELECT** ▶

Congressional District: **SELECT** ▶

Principal Investigator: ,
(Last Name, First Name)
Use '%' for wildcard

SUBMIT QUERY

CLEAR QUERY

Agency/Institute/Center: **SELECT** ▶
 Admin Funding

Funding Mechanism: **SELECT** ▶

Award Type: **SELECT** ▶

Activity Code: **SELECT** ▶

Project Number:
Format: 5R01CA121298-04
Use '%' for wildcard

Study Section: **SELECT** ▶

RFA/PA:
Format: RFA-IC-09-003 or PA-09-003
Use '%' for wildcard
[Funding Opportunities and Notices](#)

Public Health Relevance:

Organization:

CLEAR QUERY

Scientific components of research grant

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- **Specific Aims**
- **Research Strategy**
 - Significance
 - Innovation
 - Approach (includes preliminary studies)
- Page limit usually does NOT include references

Specific Aims

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- Most important part of the application
- Provides an overview of the entire project
- Persuades reviewers that
 - This is an important project
 - You (and your team) are the right people to do it
 - Your project will advance the state of the science
- Is often 1 page (or shorter if grant is short)

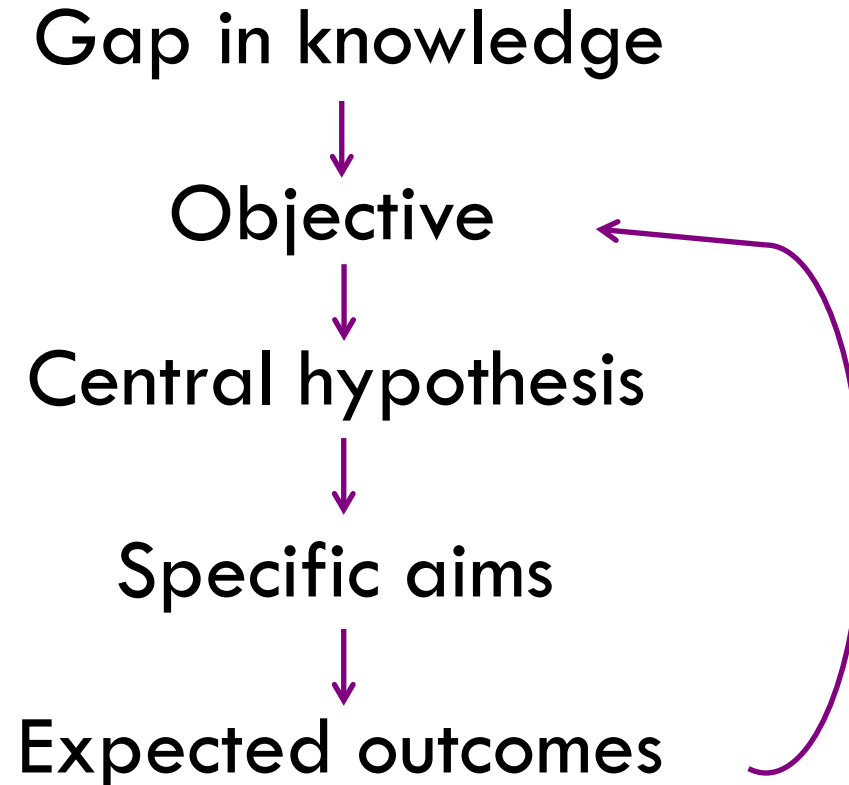
Specific Aims

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- Brief paragraph about the importance of the health problem and the scientific problem/gap in knowledge
- List of the specific aims themselves (2-3(4) aims)
 - Strong language (*identify, define, quantify, determine*)
 - Narrowly focused, concrete objective
- How this research meets the research priorities of the funder and impact the results will have on field
- How the candidate/mentor team are well-poised to complete the research and transition the mentee to independent funding

Specific aims section logic

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Importance of problem



What is known

Specific Aims

The dual epidemics of HIV and TB continue unabated in many urban areas in resource-limited settings, with TB the leading cause of death among patients enrolled in antiretroviral therapy programs in South Africa.^{1,2} Despite substantial investment in healthcare facility-based diagnosis and treatment of TB, only a quarter of HIV-infected South Africans have been screened for TB.³ Passive disease screening, in which people present to clinics with symptoms, has failed to control TB at the community level, with an annual risk of TB among school-age children in Cape Town of 4%.^{4,5} The rate of TB treatment completion for new cases in South Africa is 53%,⁶ with an estimated 20% failing to initiate treatment when diagnosed at stationary clinics using passive screening.⁷ Active, mobile, community-based TB case finding may add substantially to facility-based efforts and may improve both individual outcomes and TB control at the population level.⁸ However, community-based active case finding programs have been hampered by reliance on smear microscopy for TB diagnosis.

Gaps in knowledge

Critical need



Introduce solution

Extant TB case finding programs have not focused specifically on HIV-infected individuals, who are at highest risk for both incident TB and poor treatment outcomes.^{9,10} The difficulty in making an accurate and timely TB diagnosis in people with HIV stems from unreliability of symptom-based screening, low sensitivity of smear-based testing, lack of infrastructure, and long delays to TB culture diagnosis.¹¹⁻¹³ The Xpert MTB/RIF (Cepheid GeneXpert System, Sunnyvale, CA) is a novel, rapid, automated molecular diagnostic tool endorsed by the World Health Organization.¹⁴ It shows great promise in expediting TB diagnosis and has performed well in reference laboratories and district health facilities in resource-limited settings.^{15,16} South Africa, where over half of the world's Xpert MTB/RIF cartridges have been procured, deploys Xpert within highly centralized provincial hospitals.^{17,3,18} The greatest impact of this simple, user-friendly TB diagnostic tool in sub-Saharan Africa, however, may well be for intensified case finding at the community level, among people not accessing hospital-based services.

What do you want to do?

Why? How?

Long-term goal of your research

Objective of this application



Why you are well-poised

Building on the foundation of the Test and Treat approach for HIV,¹⁹⁻²¹ we propose to integrate mobile, community-based TB screening using Xpert MTB/RIF with rapid HIV testing to evaluate the effectiveness of a "Test and Treat TB" (T&T TB) strategy. This proposal builds upon a nurse-led mobile HIV screening unit operating at venues such as taxi stands and malls based in the townships of Durban, South Africa. We will leverage this unique program to evaluate the clinical impact and cost-effectiveness of integrating Xpert MTB/RIF screening with HIV testing, maximizing the impact of mobile units, which typically refer TB suspects to local clinics for evaluation and treatment.^{22,23} We will implement and evaluate a T&T TB intervention for promoting linkage to and retention in TB care. T&T TB includes: i) Xpert MTB/RIF screening on the mobile unit with rapid receipt of test results; ii) expedited TB treatment initiation at the mobile unit; and iii) monthly SMS appointment reminders. In a 3-arm design, we will compare: 1) T&T TB; 2) Expedited testing (Xpert screening on the mobile unit with clinic-based follow-up); and 3) Usual care (referral to clinic for TB screening). We propose a proof-of-concept randomized trial to accomplish the following specific aims:

Describe each aim & hypothesis

Link hypothesis to objective

Approach & expected outcome



Aim 1: To establish the feasibility, yield and clinical impact of a "Test & Treat TB" strategy on a mobile HIV screening unit in South Africa.

Hypothesis: Provision of convenient rapid TB test results with expedited treatment initiation, combined with SMS reminders, will significantly improve rates of TB treatment completion.

Aim 2: To assess the cost and cost-effectiveness of this mobile, integrated HIV/TB screening strategy for maximizing linkage to TB care and treatment completion.

Hypothesis: A T&T TB strategy will be very cost-effective compared to both expedited testing and usual care.

Summarize

Contribute to mission

Outcomes

Impact/payoff



This proposal is motivated by the 2013 Trans-NIH plan for HIV research to investigate new approaches to HIV/TB integration that promote early detection and effective engagement in care, and to assess the effects of these interventions on survival, quality of care, and cost-effectiveness. We hypothesize that this novel, mobile T&T TB intervention that brings Xpert TB diagnostics technology to the community level will improve retention in TB care for those with HIV. Our multi-disciplinary collaborative research group includes experts in the fields of HIV/TB care, clinical epidemiology, biostatistics, implementation science, and cost-effectiveness analysis, and builds on a long-standing and productive collaboration between US and South African investigators.^{4,8,13,24} This work will guide physicians and policy makers on how to maximize the benefits of community screening and expedited TB treatment initiation through a strategy of timely and integrated mobile HIV/TB diagnosis and linkage to care.

Shorter Specific Aims

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Importance of problem

What is known

Gaps in knowledge

Team's experience



Describe each aim & hypothesis

Include approach



Summarize

What is to be gained

Expected outcomes

Anticipated impact



SPECIFIC AIMS

Sub-Saharan Africa, home to 68% of all people living with HIV/AIDS worldwide, is the site of 3.5 million refugees and many long-standing refugee settlements.¹⁻³ Though HIV prevalence among refugees is largely unknown, they are a vulnerable, at-risk population, and face unique challenges accessing HIV testing and care.⁴ Efforts to meet daily survival needs while living in a refugee settlement can be all consuming. As such, barriers to HIV services that other people in resource-limited settings face are magnified.⁵ Research on refugees living in settlements is limited because of the remote location of the settlements, the multitude of languages spoken, the complex political and social dynamics, and the difficulty in obtaining permission to interact with individual refugees secondary to human protection concerns.⁶ Despite these challenges, refugee populations merit focused effort to ensure that interventions to scale up HIV testing and to motivate engagement in clinical care are successful. With the support of the Harvard University Center for AIDS Research (PI; 5P30AI060354-08), we developed a research site in Nakivale Refugee Settlement in rural southwestern Uganda with a dedicated and skilled refugee-centered research team to study HIV-related healthcare interventions. Having nearly completed a routine clinic-based HIV testing study in the outpatient department (OPD) in Nakivale, we now request a second year of funding for the following two aims:

Specific Aim 1: To develop, pilot and evaluate an enhanced communication intervention for HIV-infected clients diagnosed through routine clinic-based testing to improve linkage to care.

Hypothesis: The intervention will enhance linkage by an absolute increase of 25% at 8 weeks from diagnosis.

Specific Aim 2: To use qualitative methods to identify and describe impediments to linkage to care.

This study will help assess and likely improve linkage to HIV clinical care for HIV-infected clients in Nakivale. The current proposal will leverage the routine testing infrastructure we developed during the first year of HU CFAR funding, to assess linkage to care outcomes of HIV-infected participants identified in that study. This study will inform a future randomized linkage intervention study proposed in my K23 award (under review).

Thanks to: Dr. Kelli O'Laughlin

A hypothesis should be testable

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- “*Obese patients have worse cardiovascular outcomes*” is not testable
- “*Patients with BMI ≥ 30 have twice the risk of stroke by three year follow-up as compared with those with BMI < 30* ” is testable, quantifiable and can lead directly to sample size estimation

Research Strategy: Significance

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A. Significance

- Importance of problem or barrier to progress in field that project addresses
- Consideration of strengths and weaknesses of published literature or preliminary data
- How project will improve scientific knowledge, technical capability and/or clinical practice, and how results will fill knowledge gaps, advance the field
- One of 5 major review criteria

Research Strategy: Innovation

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B. Innovation

- How application challenges current research or clinical paradigms
- Describe novel approaches, methods, concepts, instrumentation or interventions
- Explain improvements or new applications of concepts, methods, approaches or interventions
- One of 5 major review criteria

Research Strategy: Approach

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C. Approach

- Describe the overall strategy, methodology, and analyses
 - How will data be collected, analyzed and interpreted
 - Describe experimental design and methods and how they will achieve robust and unbiased results

Example structure - Approach

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- C.0 Preliminary studies
- C.1 Restate aim 1 & hypothesis
 - C.1.1 Study setting
 - C.1.2 Study population
 - C.1.3 Enrollment and data collection
 - C.1.4 Statistical considerations (outcomes, sample size, data analysis plan)
 - C.1.5 Deliverables

Research Strategy: Approach continued

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C. Approach

- What if you hit a roadblock? If the 1st aim fails?
If your enrollment fails? Discuss potential problems, alternative strategies and benchmarks for success
- Detailed list of deliverables: Proposed titles?
Meetings/dates for abstract submissions?
Manuscript submissions
- Timeline for when each aim/manuscript will be complete
- End with vision for future grant/next steps

NIH scoring system

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- 5 core review criteria:
 - Significance
 - Investigators
 - Innovation
 - Approach
 - Environment
- OVERALL IMPACT

Significance

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How do I know if my research is significant?

- Aligns with the objective of the organization
 - Example: Trans-NIH plan for HIV related research
- Identifies a gap in current knowledge or barrier to progress in the field
- The successful completion of the study will change the concepts, technologies, treatments or preventative interventions that drive the field
- How will this study lead to the next important study?

Investigators

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- Prior productivity
 - Abstracts, manuscripts, record of accomplishment
 - If a new investigator – appropriate training and experience
- The right expertise for the work proposed
- Right people at the right level

Facilities/Resource Page

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- Used to assess capability of the organizational resources to perform the work
- Identify facilities to be used (lab, animal, computer, office, clinical, other) and describe them
- How proposed study will benefit from features of the scientific environment
- Describe if resources for training, career development, administrative support
- Need a separate page for each performance site

Budget/Budget justification

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- What do you need to do the project?
 - If some resources/infrastructure needed are not included in your budget, where do they come from?
- Does the budget fit the science in the proposal?
- Under- and over-inflation equally detrimental
- Back and forth between science and budget – is the proposed project feasible within the budget?

Budget/Budget justification

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- The budget justification should be detailed
 - Personnel – qualifications, role on project
 - Supplies
 - Travel
 - Other (publication fees, IT)
 - Tuition if allowed

Common pitfalls/mistakes

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- Not following the instructions
- Not proofreading
- Project cannot be achieved within the budget of the award

Common pitfalls/mistakes

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- Significance
 - Not significant or exciting or new
 - Lack of compelling rationale or motivation
 - Doesn't align with priorities of funder

Common pitfalls/mistakes

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- Specific aims
 - Too ambitious, too much work proposed
 - Unfocused aims or goals
 - Uncertain future directions

Common pitfalls/mistakes

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- Experimental approach/research design
 - Inappropriate level of details
 - Feasibility of each aim not apparent
 - Little or no expertise with approach
 - Not directly testing a hypothesis

K43: Emerging Global Leader Award

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- NIH Mentored career development award
- Provides protected time to research scientist
 - citizen of low- or middle-income country
 - junior faculty or research scientist position at an academic or research institution for at least 1 year
- Expected to lead to an independently funded research career

K43: Emerging Global Leader Award

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- Includes BOTH career development and research
- Requires a primary mentor at your institution and a primary mentor at a collaborating US institution
 - Active researchers in area
 - Committed to the candidate
 - Can include additional co-mentors (expertise)
- Institutional environment – must have strong record of research and career development

What are the components?

Candidate & Research Plan (12 pgs!)

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- Candidate Information (~4 pages)
 - Candidate's Background
 - Career Goals and Objectives
 - Career Development/Training Activities
- Research Strategy (~8 pages)
 - Relevant to health priorities of their country
 - May be related but not duplicate mentors' research
- + 1 additional Specific Aims page

K43: Emerging Global Leader Award

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- Supports 75% of your salary and requires 75% of your commitment
- \$30K of additional funds for project, coursework or other training, statistical services, travel, etc
- Start writing at least 4 months before the deadline
- Deadline Dec 14, 2016 and 2017
- Only some NIH institutes are participating (Fogarty, Mental Health, Cancer, Women's Health, etc)
- Contact NIH Program officer
- Feel free to contact me for example K materials!

Take-home messages

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- Allow adequate time— especially for things that are out of your control (biostatistics, mentor letter)
- Pay attention to details and instructions
- Provide a strong rationale for your study and how it will advance knowledge
- Keep review criteria in mind and make it easier for reviewer to find all the important parts
- Find at least 1 external reader to review the grant
- If you are interested in research as a career – consider NIH K43 grant

Questions?