Ga CTSA TL1 Application Writing Workshop

October 31, 2024

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

Objectives

- Understanding the TL1 proposal process (pre and postdoctoral tracks)
- Grant Writing Nuts and Bolts
  - ✓ NIH Fellowship Biosketch *(fellowship version – use FORMS H)*
  - ✓ TL1 Personal Statement
    - applicant's training
    - research background
    - career goals
  - ✓ Research and Training Plan: Clinical / Translational Research Proposal (6 pages total)
  - ✓ Resources

TL1 Overview

	Predoctoral Track - PhD students - Medical Students	Postdoctoral Track -PhD postdoctoral fellows -MD clinical fellows
US citizen or permanent resident	✓	✓
Enrolled at one of the GA CTSA partner institutions - Emory, Morehouse SOM, Ga Tech, UGA	✓	✓
- Award duration	1-2 years - Typically, 1 year for Medical Students	1-2 years -Typically, 1 year for most residents and MD fellows
Dedicated to a career that encompasses clinical and/or translational research	✓	✓
Application due date	**February 17, 2025**	**March 17, 2025**
Required mentor research training	✓	✓
Required didactic training	MD / MSCR or CPTR PhD / MSCR or CPTR	CPTR or MSCR (or equivalent with approval)
Budget	Tuition, NRSA stipend + $2,000 for travel + health insurance + child care expenses	Tuition, NRSA stipend + ~$11,000 for research supplies + $1,500 for travel + child care expenses

Goal of TL1 training

- **Research Education** is a critical component of the GA CTSA.
  - The GA CTSA is dedicated to providing predoctoral and postdoctoral trainees with state-of-the-art scientific knowledge, tools and methods to improve human health through rigorous clinical and translational research training.

- Through the TL1 Core, the GA CTSA will increase the translational research workforce and enhance career development of future leaders of the biomedical research workforce, a major mission of NIH.

Getting ready to prepare a TL1 fellowship application

Create HIGH **Overall Impact** for your proposal

- Well written, follows the rules outlined in the Application Instructions
  - https://georgiactsa.org/training/tl1.html
- Clear and focused objectives
- Doable and feasible given time and support available from your mentor's research environment
- Entire narrative is a cohesive whole with a focused theme (i.e., *the story of how you will advance in a career in Clinical and Translational Research*)
- Mentor section is VERY PERSONAL and VERY DETAILED
- Research plan and training plan are complementary

All this is integrated with

your near and long-term career goals

Articulate your Immediate and Long-term Career Goals

Reviewers will look for the answers to these questions:

1. What new training will you receive and from who?
2. Are you competitive - biosketch, mentoring team, research plan
3. How will this training you describe in the application advance your career and the science you propose given this new skill set?
4. What will be the next step?

→ Preview a research area that you are interested in pursuing.

Be very specific: What new research skills will you acquire?

-- Name the NEW laboratory methods, analytical methods, modeling schemes, comparative systems, new animal models, etc.

-- itemize the New specialized coursework / workshops / seminars

- Hypothesis-driven work is highly valued
- Human-oriented research is required

From the Application Guidelines - Support

In addition to didactic training (e.g., MSCR program), all TL1 trainees will have mentored research training and carry out a hypothesis driven research proposal (clinical or translational research) relevant to human health under the guidance of their lead mentor and mentoring team.

The proposed research project must include a well-articulated human component and an explanation of how the research translates to improving human health.

For example, studies including humanized animal model systems may be eligible.

However, studies that focus on basic science are not eligible for this particular TL1 funding mechanism. When in doubt, ask.

Do what successful grant writers do: 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 other mentors/advisors and peers (not just your mentor)
  - Do you have preliminary data?
    - Show data from your own work or from your lab (attribute appropriately)

- How will you write about research in an area where you are not an expert?
  - Get advice from your mentors
  - Especially for explaining new techniques

  or analyses in your proposed aims

Drobox Resources – you will receive a link after the workshop

- General Scientific Grant Writing materials
- Human Ss materials from NIH
- Information on the NIH NRSA F grants
- NIH Sites on Rigor and Reproducibility
- FindingFundingforResearch(7.2015).pdf
- JAMA ClinTrials(2016).pdf
- Preliminary Research- Don't Stop 'Til You Get Enough.docx

TL1 Application
Nuts and Bolts

TL1 Application Required Sections

1. **Cover sheet**
2. **Personal Statement** *(up to 2 pages – see directions)*
   - applicant's training, research background, and career goals
3. **Your NIH Biosketch** *(fellowship version)*
4. **Your lead mentor's NIH Biosketch** *(standard version)*
5. **Any co-mentors' or collaborators' biosketches** *(standard version)*
6. **Clinical / Translational Research Proposal**
   a) Title of proposal and list of mentors (its own page)
   b) Abstract/Summary (500 word maximum; separate page)
   c) **Specific Aims (1 page maximum, part of 6 pages)**
   d) **Research Plan and Training Plan (balance of 6 pages)**
   e) Bibliography
   f) Protection of Human Subjects (<2 pages)
   g) Inclusion of women, children and minorities (brief statement)
7. **Letters of support** – submitted directly to the administrator
   - Letter of commitment/support to serve as Lead Mentor and from any co-mentors and advisors
   - Letter of recommendation from Division Director or Chair or Dean of Students

Create PDFs

- Follow the online instructions
- Use our online portal to attach files and submit grant
- Questions:
  - GA CTSA Program Coordinator / administrator:

Rachel Hardison Rachel.Hardison@emory.edu

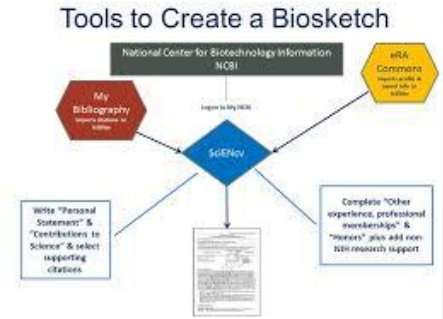
At each partner institution:

Emory: Dr. Vasiliki "Vas" Michopoulos -vmichop@emory.edu

MSM: Dr. Gianluca Tosini – gtosini@msm.edu

Georgia Tech: Dr. J. Brandon Dixon – dixon@gatech.edu

UGA: Dr. James Lauderdale – jdlauder@uga.edu



Preparing the NIH Biosketch for a TL1 award

Create your biosketch here!

SciENcv

Science Experts Network Curriculum Vitae

Preparing the Biosketch for a TL1 award

New Tools to build and store your biosketch

- https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

- https://grants.nih.gov/faqs#/biosketches.htm

TL1 Review Criteria
(≈ NIH F31, F32, T31, T32)

F- Fellowship Grants Review Criteria Categories
Fellowship Applicant
Sponsors, Collaborators and Consultants
Research Training Plan
Training Potential
Institutional Environment and Commitment to Training

You are not your research, but you are your biosketch

Which Biosketch should I use?

- Predocs and Postdocs use the Fellowship version of the NIH Biosketch
- All Faculty → use Standard Biosketch

Fellowship Biosketch (blank format page)

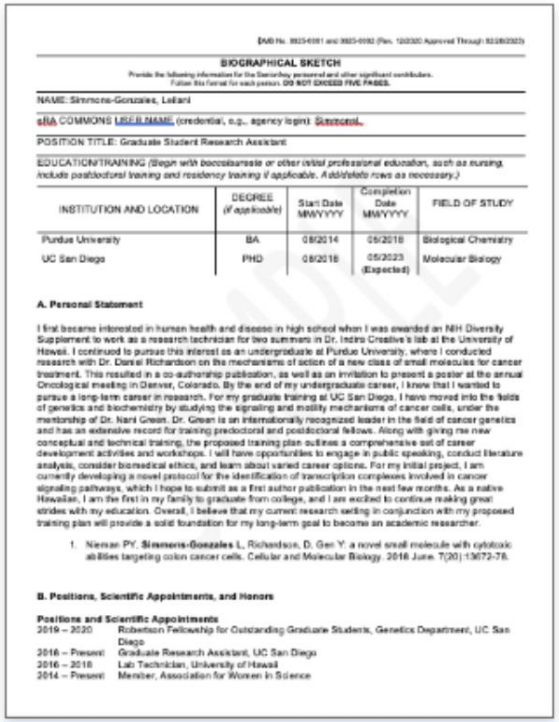
The format page should be submitted as an attachment in grant applications progress reports.

Instructions

Instructions for Biographical Sketch

Additional Information

Sample: Fellowship Biosketches



BIOGRAPHICAL SKETCH

NAME: Simmons-Gonzales, Leilani

POSITION TITLE: Graduate Student Research Assistant

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Purdue University	BA	08/2014	05/2018	Biological Chemistry
UC San Diego	PHD	08/2018	05/2023 (Expected)	Molecular Biology

A. Personal Statement

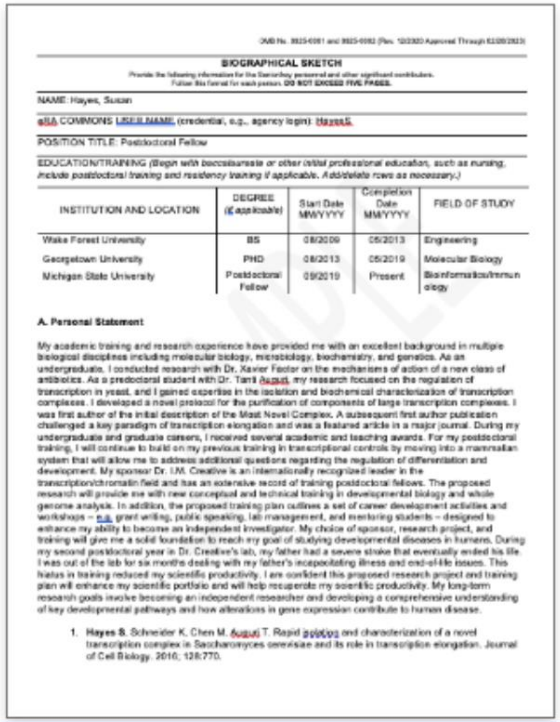
I first became interested in human health and disease in high school when I was awarded an NIH Diversity Supplement to work as a research technician for two summers in Dr. Indira Creative's lab at the University of Hawaii. I continued to pursue this interest as an undergraduate at Purdue University, where I conducted research with Dr. Daniel Richardson on the mechanisms of action of a new class of small molecules for cancer treatment. This resulted in a co-authorship publication, as well as an invitation to present a poster at the annual Oncological meeting in Denver, Colorado. By the end of my undergraduate career, I knew that I wanted to pursue a long-term career in research. For my graduate training at UC San Diego, I have moved into the fields of genetics and biochemistry by studying the signaling and motility mechanisms of cancer cells, under the mentorship of Dr. Nani Green. Dr. Green is an internationally recognized leader in the field of cancer genetics and has an extensive record for training predoctoral and postdoctoral fellows. Along with giving me new conceptual and technical training, the proposed training plan outlines a comprehensive set of career development activities and workshops. I will have opportunities to engage in public speaking, conduct literature analysis, consider biomedical ethics, and learn about varied career options. For my initial project, I am currently developing a novel protocol for the identification of transcription complexes involved in cancer signaling pathways, which I hope to submit as a first author publication in the next few months. As a native Hawaiian, I am the first in my family to graduate from college, and I am excited to continue making great strides with my education. Overall, I believe that my current research setting in conjunction with my proposed training plan will provide a solid foundation for my long-term goal to become an academic researcher.

1. Nieman PY, **Simmons-Gonzales** L, Richardson, D, Gee Y. a novel small molecule with cytotoxic abilities targeting colon cancer cells. Cellular and Molecular Biology. 2018 June. 7(20):13672-78.

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2019 – 2020 Robertson Fellowship for Outstanding Graduate Students, Genetics Department, UC San Diego
2018 – Present Graduate Research Assistant, UC San Diego
2016 – 2018 Lab Technician, University of Hawaii
2014 – Present Member, Association for Women in Science



BIOGRAPHICAL SKETCH

NAME: Hayes, Susan

POSITION TITLE: Postdoctoral Fellow

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Wake Forest University	BS	08/2009	05/2013	Engineering
Georgetown University	PHD	08/2013	05/2019	Molecular Biology
Michigan State University	Postdoctoral Fellow	09/2019	Present	Bioinformatics/Immunology

A. Personal Statement

My academic training and research experience have provided me with an excellent background in multiple biological disciplines including molecular biology, microbiology, biochemistry, and genetics. As an undergraduate, I conducted research with Dr. Xavier Factor on the mechanisms of action of a new class of antibiotics. As a predoctoral student with Dr. Tami August, my research focused on the regulation of transcription in yeast, and I gained expertise in the isolation and biochemical characterization of transcription complexes. I developed a novel protocol for the purification of components of large transcription complexes. I was first author of the initial description of the Mast Novel Complex. A subsequent first author publication challenged a key paradigm of transcription elongation and was a featured article in a major journal. During my undergraduate and graduate careers, I received several academic and teaching awards. For my postdoctoral training, I will continue to build on my previous training in transcriptional controls by moving into a mammalian system that will allow me to address additional questions regarding the regulation of differentiation and development. My sponsor Dr. I.M. Creative is an internationally recognized leader in the transcription/chromatin field and has an extensive record of training postdoctoral fellows. The proposed research will provide me with new conceptual and technical training in developmental biology and whole genome analysis. In addition, the proposed training plan outlines a set of career development activities and workshops – e.g. grant writing, public speaking, lab management, and mentoring students – designed to enhance my ability to become an independent investigator. My choice of sponsor, research project, and training will give me a solid foundation to reach my goal of studying developmental diseases in humans. During my second postdoctoral year in Dr. Creative's lab, my father had a severe stroke that eventually ended his life. I was out of the lab for six months dealing with my father's incapacitating illness and end-of-life issues. This hiatus in training reduced my scientific productivity. I am confident this proposed research project and training plan will enhance my scientific portfolio and will help recuperate my scientific productivity. My long-term research goals involve becoming an independent researcher and developing a comprehensive understanding of key developmental pathways and how alterations in gene expression contribute to human disease.

1. **Hayes S**, Schneider K, Chen M, August T. Rapid isolation and characterization of a novel transcription complex in Saccharomyces cerevisiae and its role in transcription elongation. Journal of Cell Biology. 2016; 128:770.

Sections of the NIH Biosketch

Name, eRA commons, Position

Education & Training

A. **Personal Statement**
B. **Positions, Scientific Appointments and Honors**
C. **Contributions to Science**
D. **Scholastic Performance**

OMB No. 0925-0001 and 0925-0002 (Rev. 11/16 Approved Through 10/31/2018)

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: Robertson-Chang, Leilani
eRA COMMONS USER NAME (credential, e.g., agency login): RobertsonL
POSITION TITLE: Graduate Student Research Assistant

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	START DATE MM/YYYY	END DATE MM/YYYY	FIELD OF STUDY
Swarthmore College	BA	08/2008	05/2012	Biology
UC San Diego	PHD	08/2012	05/2018	Molecular Biology

A. Personal Statement

eRA commons user name – obtain this through your department

Emulate this NIH Biosketch example – predoctoral versus postdoctoral
- Pay attention to tone, layout, style, subheaders

A. Personal Statement

- Briefly describe why you are well-suited for your role(s) in this project. 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/or
  - your past performance in this or related fields.

- You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

Research Support follows Personal Statement (updated biosketch instructions)

1. If you are currently on ANY kind of grant as a pre- or post-doc, show this support using the standard presentation style used in the Standard Biosketch
   - Examples might include:
     - F30, 31, T32 trainee
     - named fellowship grant
     - Funding as a pre-doc or Postdoc on a PI's R01 grant

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

R01 DA942367

Hunt (PI); Role: Postdoctoral Fellow

09/01/16-08/31/21

Health trajectories and behavioral interventions among older people with substance use disorders

Personal Statement section recap:

1. Personal Statement paragraph
2. Up to 4 highly impressive literature citations (otherwise save your literature citations for the Contributions to Science section)
3. Research Support (now and recent)

- Most medical students and pre-doctoral fellows will not have much to put after the Personal Statement paragraph. This is not a problem.
- If you have forthcoming abstracts or manuscripts, you can include these for the fellowship version of the biosketch.
- Preprints are allowed (follow citation instructions)
- You can also include papers on which you have received an Acknowledgement

NOTE:

- There are 2 items labeled “Personal Statement” in this application
  - #1: As part of the main application, there is a 2-page required essay describing your training, research background and career goals called Personal Statement
  - #2: The **Personal Statement is an important** section of the NIH Biosketch (here 1 para is sufficient)

These are different but very similar; include both

Suggestions for Writing the NIH Biosketch Personal Statement

1. Customize the personal statement for each grant proposal

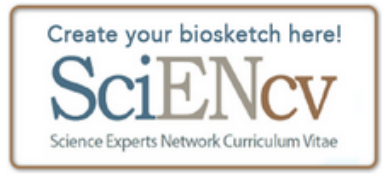
2. Mention the name of the grant proposal (e.g., TL1) and speak directly to the purpose of this funding mechanism

   - *I envision using the training, experience and research findings from this TL1 award to launch my 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.*

Writing Suggestions

3. Lots of overlap with the required TL1 Personal Statement about your training and career goals
4. Be succinct, revise this several times after you have developed the other essay sections
5. Convey passion and excitement about your work
6. All these sections need to be great – Reviewers really care about these essays
7. TIPS
   - read essays aloud to yourself
   - - ask someone else to read over your essays for flow, clarity, grammar

B. Positions, Scientific Appointments and Honors



Positions and Employment

Other Experiences and Professional Memberships

Honors

- Clarify what specific awards/honors were for

→ You can load this info into My NCBI

- online tool (via SciENcv) to support building/storing your personal data including linking to all your publications

Examples of additional creative subheaders

Patents

Board Certifications

Consultant/Reviewer

Course Instructor/Director

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

External Advisor

Section C. Contributions to Science

- Summarize your research contributions using this organization:
  1. Early Career
  2. Graduate Career
  3. Postdoctoral Career

- List up to 4 four peer-reviewed publications or other non-publication research products (*this includes abstracts, posters, etc.*)

- "Descriptions of contributions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication. These contributions do not have to be related to the project proposed in this application."

- In other words, show us EVERY paper or presentation where you are an author

At the end of Section C.

- Provide a URL to a full list of your published work
- Use the myncbi instructions
- This link will be part of your 'research identity' going forward. It is worth it to start curating this now.
- At your level, this is not required but highly recommended
- If you have no publications, you may omit this
- *Do not use Google Scholar or any other non-governmental link, such as ResearchGate*

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

C. Contributions to Science *(see directions and examples)*

1. Early Career
   - Brief narrative (written in 1st person)
   - Published manuscripts, abstracts, etc. (underline or bold your name)

2. Graduate Career

3. Postdoctoral Career

C. Contribution to Science

1. Dietary composition has long been identified as a modifiable risk factor in the development of a variety of health outcomes. My undergraduate research, under the mentorship of Dr. Krzystof Czaja and supported by the CURO research assistantship at the University of Georgia, was focused on the impact of macronutrient composition on gut-vagal-brain physiology. We found statistically significant differences in vagal and hindbrain composition between rats maintained on diets of varying macronutrient composition, with those fed a high sugar, high fat diet showing the highest level of inflammatory markers in the vagus nerve and most significant neuronal restructuring in cerebral feeding centers. I was *acknowledged* in Czaja, K., et al (2017) for my contribution to body fat composition measurement using MRI, macroscopic and microscopic anatomical dissection, cryosectioning, immunohistochemistry, data organization and management, statistical analysis, and preparing text for publication. The results of this work provided a mechanistic framework for the impact of diet on host physiology. The significance of the results gave me an opportunity to present at a university wide research conference and provided scientific background for my honors thesis exploring the connection between broad spectrum antibiotic use and obesity, which was later published under first authorship.

a) Gawey, B., Czaja, K. (2017). “Broad-Spectrum Antibiotic Abuse and its Connection to Obesity”. Journal of Nutritional Health & Food Science. 5. 2-21.

b) Acknowledgements, Sen, T., Cawthon, C., Ihde, B., Hajnal, A., DiLorenzo, P., de La Serre, C. and Czaja, K. (2017). Diet-driven microbiota dysbiosis is associated with vagal remodeling and obesity. Physiology & Behavior. 173. 305-317.

Abstract: Gawey, B. “High Dietary Sugar and Fat Content Leads to a Change in Intestinal Innervation and Gut-Brain Communication”. CURO Research Symposium. UGA Honors College. Athens, GA. 8 April. 2016. Poster presentation.

Honors Thesis: Gawey, B. Broad-spectrum antibiotic use and the connection to obesity. 2016. University of Georgia

Contributions to Science

1. Medical School Research Experience:

The microbiome is emerging as an important target for influencing health outcomes. During medical school, I have been involved in research in the Clinical Microbiome Program at Emory Clinic under the mentorship of Dr. Smith. I completed an elective focused on exploration of current models of clinical research focused on the investigation of the microbiome. Forthcoming results of our metabolomic analysis of microbial derived small molecules will have important implications for human health, disease biomarker tracking, and preventative medicine, providing additional insight and therapeutic perspective to microbiome and metabolome-based interventions, such as probiotics and fecal transplants as a means of preventing, controlling, and reversing disease.

(this Contribution to Science had no publications - this is ok)

Contributions to Science

3. Postdoctoral Career:

I worked with the team that created a novel shared decision aid, called iChoose Kidney, for providers (nurses, social workers, or physicians) to use with ESRD patients to help them make treatment decisions about kidney transplantation vs. dialysis. I worked with the PI to calculate the risk prediction models, and convert these to a widely accessible, free mobile tool (on iTunes and on a website). This tool is currently being used in practice by more than 400 providers across the US, and our preliminary scientific studies suggest the tool improves knowledge and decision-making ability among patients. A multi-center, randomized study at 3 of the largest transplant centers across the nation (Emory, Columbia, and Northwestern) is testing the clinical effectiveness of the tool.

a. iTunes iPad and iPhone app of iChoose Kidney: https://itunes.apple.com/us/app/ichoose-kidney-patient-education/id685381934?mt=8
b. Website: www.ichoosekidney.emory.edu

C. Contribution to Science *(e.g. is from Standard Biosketch, not TL1 level)*

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*

D. Scholastic Performance

- Scholastic Performance
  - Follow directions, use grid

Recommendations

- Follow the directions – look at the NIH sample and compare your biosketch to it (layout, etc.)
- Reviewers are looking for specific information in particular places – make it easy for the reviewer by following the rules and the formatting
- Do not misrepresent any facts
  - List all publications as they would appear in PubMed or in any other searchable database
- Advice from reviewers:
  - “Self-aggrandizing will certainly backfire. Probably better to lean towards humility to increase likability factor.”

Personal Statement for the TL1 Application

TL1 Personal Statement (2 pages max.)

- formatting: **use Arial 11 font and .5-inch margins throughout**

a) Applicant's Training
b) Research background
c) Career Goals

Theme - how this TL1 training program and training afforded by the mentoring team will specifically enhance your career development in CTR

This essay will be somewhat redundant with your Personal Statement from biosketch. However, don't cut/paste. Make these unique. Reviewers will read these very carefully.

Suggestions for Personal Essay Writing in the TL1 application:

- Follow all directions
- Dot your PERSONAL ESSAYS with scientific facts, findings, interests, goals, etc.
- “Speak” to the reviewer; “Sell” your idea; Be compelling!!
- Write in the 1st person but don’t be “folksy” or overly casual
- Reflect on your personal experiences in science and where this TL1 award will lead you professionally
- Make a case for your personal career path - describe what you hope will be your contribution to the field
- Don’t simply walk us through your biosketch (we just read that)
- Pay attention to aesthetics/layout – NO TYPOS, NO GRAMMATICAL ERRORS

TL1 Personal Statement instructions

a) Describe your training to date

- Draw attention to any special technical or clinical skills
- Does not have to be related to the proposed project

b) Describe any research background

- In any discipline; share what you've done research-wise
- Highlight exciting findings / skills
- If you don't have any research background to speak of, be brief (and don't worry).

c) Describe your career goals

- in clear, concrete terms

c) Describe your Career Goals

- How has 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
- Justify the TL1 award - How will it help you develop and advance your career - where will you go with this award and 5 years hence scientifically speaking.
- Identify exactly what your training goals are, for example:

    1. Epidemiology of TB/HIV coinfection
    2. Advanced cohort study methodology
    3. Molecular epidemiology
    4. Bioinformatics
    5. Spatial transcriptomics

c) Describe your Career Goals (continued)

- Tell us about your Training Plan
- What will be the elements of your Training Plan
  - MSCR – Master of Science in Clinical Research (30 credits, thesis, grant proposal)
    - highly recommended for medical students, residents, fellows, those who have had limited didactic research training
  - CPTS – Certificate Program in Translational Science (16 credits, grant proposal) – common option for PhD students
  - Menu Option – 5 required courses plus electives based on personalized training pathway (no required credit minimum outside the 5 required courses)
    - 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 [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.)
    - If you select this option, describe in detail your plan and why you've chosen this option

What are the Reviewers Looking for?

- What new scientific skills / techniques / areas will you learn?
- Who is spearheading your training and looking out for your career development (i.e., name the mentor / lab)?
- How will the new training support your ability to carry out the proposed research aims?
- All this can be very concrete and specific; write in the 1st person to make this flow nicely

Selecting a Primary Mentor for Mentored Research Training

- Lead mentor should be an established investigator with current federal funding
  - NIH, AHRQ, CDC, PCORI, etc. or R01 equivalent)
  - Co-mentors do not have to meet similar requirements

- If you are uncertain about the suitability of your lead mentor, it is advised that you run this by the TL1 leadership
  - **VASILIKI "VAS" MICHOPOULOS, PHD, MSCR; VMICHOP@EMORY.EDU**
  - **HENRY BLUMBERG, MD; HBLUMBE@EMORY.EDU**
  - **JAMES D LAUDERDALE, PHD; JDLAUDER@UGA.EDU**
  - **GIANLUCA TOSINI, PHD; GTOSINI@MSM.EDU**

- Review the Mentor tab at the GA CTSA TL1 website

Research and Training Plan for the TL1 Application

Writing up the Research section (6 pages total)

This consists of two parts:

1. **Specific Aims** (~1 page, traditional style / presentation for your discipline; study other examples and your mentor's work)

2. **Research Plan** (~5 pages, see instructions)
   - Significance
   - Innovation
   - Approach

NIH Specific Aims page

→ Master Plan for your application

- See examples of Specific Aims pages on Dropbox (I will share with you)
- One page maximum
- ***Encapsulation of the entire proposal – sets the stage for how compelling, exciting and feasible is your work***
- Presentation style for this 1 page reflects the style used in your field of work – standard, stereotyped presentation style

  i. Introductory section establishing public health relevance and scientific rationale
  ii. How this project exemplifies clinical and/or translational research
  iii. Followed by listing of the research objectives/tasks/overarching scientific questions
  iv. Sometimes followed by a summary of 'what is the value of this work to the field'

An excellent Specific Aims page:

- Favorably disposes the reader for the rest of the application
- Augers well for your qualifications, your grant writing and your research skills
- Conveys excitement and importance while using a very logical, compelling and articulate presentation
- Becomes the "master plan' for the rest of your research plan
- This section of a grant is the **#1 most important section** to the reviewers and to your research

Specific Aims instructions from the NIH grant proposal guidelines

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

- List succinctly the specific objectives of the research proposed, e.g.,
  - –to test a stated hypothesis,
  - –create a novel design,
  - –solve a specific problem,
  - –challenge an existing paradigm or clinical practice,
  - –address a critical barrier to progress in the field, or
  - –develop new technology.

Words in **RED** are all good words to use in a Specific Aims section

- Specific Aims page cannot exceed one page.

RESOURCES for writing the SPECIFIC AIMS page

- Look at others' Specific Aims pages
- See my Dropbox site
- Google "how do I write an NIH F31" (or F32)
- NIH Specific Aims writing support
  - https://www.niaid.nih.gov/grants-contracts/draft-specific-aims
- Writing an NIH F31 proposal
  - https://www.niaid.nih.gov/grants-contracts/three-new-f31-sample-applications
- Northwestern University CLIMB writing program
  - https://www.northwestern.edu/climb/resources/written-communication/nih-grant-and-dissertation-proposals.html

Structure:
According to Russell and Morrison (2018)
(see my Dropbox folder)

1. Introductory paragraph will contain a high impact opening sentence that "immediately establishes the relevance of the proposal to human health"
2. Current knowledge
3. Gap in the knowledge base and/or unmet need, i.e., what is the clinical problem
4. What/Why/Who – long-term goal, objective of this application, and central hypothesis and how it is formulated
5. Listing of the Specific Aims

Each Aim should yield interesting findings

- You should be able to test hypotheses (or conduct the research) for each aim regardless of the outcome of the other aims

- Being able to conduct Aims 2 and 3 cannot be dependent on an anticipated outcome from Aim 1
  - Unless, you have strong preliminary data for what you anticipate you will find in Aim 1 (i.e., Aim 1 is a replication of previous work)

- The work proposed can be achieved in the 1-2 year time allotted (depends on how long you will be a TL1)
  - How will you substantiate this?
  - Preliminary data, past experience, timeline?

Example of Specific Aims using the term "Objectives"

Objectives

Objectives of the proposed study include:

Objective 1. To estimate prevalence of latent tuberculosis infection among HIV positive individuals in Georgia, using two IFN-g assays (T.SPOT-TB and QuantiFERON Gold in Tube) and tuberculin skin test.

Objective 2. To examine factors associated with concordance and discordance between the three tests to be utilized.

a) To assess impact of degree of immunosuppression (by CD4 count) on performance of IFN-g assays and TST

b) To assess influence of co-infection with hepatitis C virus on the performance of IFN-g assays and TST.

Objective 3. To determine predictors of latent tuberculosis infection among HIV positive individuals

KL2 (funded) Specific Aims:

Aim 1: To develop an electronic decision support tool to communicate estimated risks of poor health outcomes for dialysis vs. kidney transplantation. There are three objectives for this aim:

1) To develop and validate predictive models for 3-year mortality for three treatment options: a) dialysis, b) deceased donor (DD) transplant, and c) living donor (LD) transplant.
2) To develop and validate predictive models for length of stay for 1) dialysis, b) DD transplant and c) LD transplant.
3) To translate these predictive models into a decision support tool (i.e. iPad App).

Aim 2: To determine the feasibility of implementing the decision support tool among a metro-Atlanta dialysis patient population. Our primary objective of this feasibility study is to gather preliminary data to inform a future, randomized study of the tool in a metro-Atlanta dialysis population to improve outcomes.

Example of Inter-dependent Aims

To test our hypotheses, we propose the following **3 Specific Aims:**

Aim 1. To determine if patients with chronic renal failure (CRF) have an exaggerated sympathetic response during exercise.

Aim 2. Test a pilot therapy of BH4 for patients with an exaggerated sympathetic response during exercise.

Aim 3. In patients with a good treatment response to therapy, determine if there is improvement in resting and exercise-induced sympathetic over-activity, endothelial dysfunction, and oxidative stress.

Consider:

- *Why are these aims inter-dependent?*
- *Is this a good strategy?*

…. Introductory para here …..

To investigate these associations, I propose to work with a multidisciplinary team with expertise in nutrition, endocrinology, metabolomics, and the gut microbiome to examine a dataset from the National Institute of Health's (NIH) Metabolomics Workbench, which contains metabolic profiling of >100 participants enrolled in the Prospective Registry (PRISM) in IBD study at Massachusetts General Hospital. We will test the following aims and hypotheses:

Aim 1: To investigate the associations of fecal level of 5-MIAA with Crohn's disease in humans.

Hypothesis: Higher fecal 5-MIAA will be associated with fewer diagnoses of Crohn's disease (CD).

We will conduct targeted analysis of the fecal metabolome database from a cross-sectional cohort of individuals enrolled in PRISM (N=102 selected individuals; CD (N=68), non-IBD (N=34) controls) by quantitating the levels of 5-MIAA in relation to CD. CD was diagnosed using standard endoscopic, radiographic, and histologic criteria.

K23 (funded)

AIM 1: To determine the pharmacokinetics of levofloxacin (LEV) and capreomycin (CAP) in patients with MDR-TB including the examination of drug levels in plasma, pulmonary tissue, and tuberculous cavitary lung among patients undergoing adjunctive surgical therapy.

Hypotheses: LEV and CM levels will be lower inside tuberculous cavitary lesions compared to plasma, and non-cavitary lung samples. Utilizing a cohort of MDR-TB patients undergoing adjunctive surgery and an innovative microdialysis method we will be the first group to assess SLD levels among various compartments including within pulmonary cavities, the site of the highest concentration of *Mycobacterium tuberculosis* (MTB). *Training will include coursework in pharmacology, learning the technique of microdialysis, and practical experience in pharmacology research.*

Specific Aims (1 page)

- Do you have too many aims?
- Are they logically interrelated?
- Are subsequent aims dependent on successful outcome of preceding aims? (bad idea)
- Do they belong in the same proposal?
- *Most proposals are overly ambitious.*

- ***You can weave in mentions of your Training Opportunity on the Specific Aims page for a training grant***

RESEARCH Plan (~5 pages)

a) *Significance*

- *Typically, a series of paragraphs, often organized by subheaders*

b) *Innovation*

- *Often this is a series of terse statements or small paragraphs that make a specific point that supports innovation, novelty, important groundbreaking techniques, first time to do something, etc.*
- *Can be a bulleted list*

c) *Approach*

- *A highly formatted 'recipe-like' presentation of methodology*

SIGNIFICANCE

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

THIS SHOULD NOT BE A LITERATURE REVIEW

Organization for Significance section:

(example #1)

SIGNIFICANCE

Critical Barriers to Eye Examination in the Emergency Department

Technical Improvements to the Funduscopic Exam

Telemedicine in Neuro-ophthalmology of the Future

RESEARCH STRATEGY *(example #2)*

A. Significance

A.1. Kidney Disease is a substantial public health problem in the Southeastern US. Kidney transplantation is the optimal treatment for ESRD patients

A.2. Racial disparities exist in access to optimal treatment for ESRD patients.

A.3. AA ESRD patients are less likely to be informed of kidney transplantation.

A.4. Patients who are most at risk for poor outcomes have the greatest difficulty in accessing health information.

A.5. Critically important treatment decisions are often made without evidence-based information about a patient's prognosis.

A.6. Shared decision making through decision support tools can increase patient involvement in the health care decision making process, leading to better health outcomes.

Important Preliminary Data might go HERE

Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

- *WORDS IN RED ARE GREAT GRANT WRITING WORDS*

INNOVATION

1) Research questions and hypotheses that have never been clinically tested:

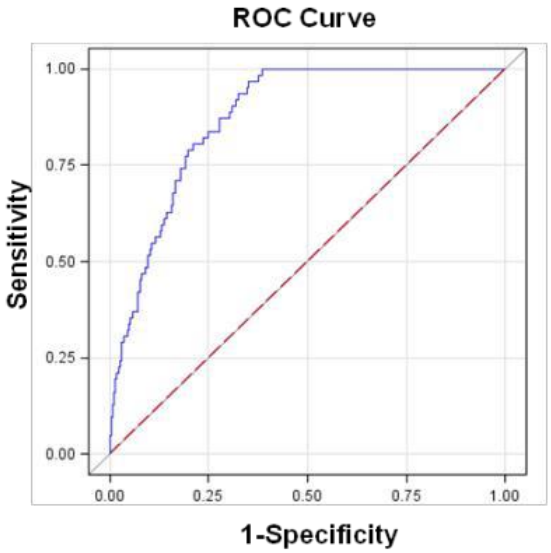
2) Studying a unique patient population:

3) Utilizing advanced technologies in an innovative fashion:

Innovation (KL2)

Figure 2. Clinical and Translational Framework for Research

Predictive Model Development



Aim 1

Refine Patient Education iPad Application

Aim 2

Translate to a Clinical Setting

K01

APPROACH

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
  - Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.
  - Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
  - Unless addressed separately in the **Resource Sharing Plan**, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
  - Resources and tools for rigorous experimental design can be found at the **Enhancing Reproducibility through Rigor and Transparency website**.

APPROACH (continued)

- For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery.
  - These methods can include a group- or cluster randomized trial or an individually randomized group-treatment trial.
  - Additional information is available at the **Research Methods Resources webpage**.

- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work

APPROACH (continued)

- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.
  - For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
  - Refer to the **NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research** for additional information.

- Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.
  - A full discussion on the use of select agents should appear in the **Select Agent Research** attachment below.

- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.

Rigor and Reproducibility including Sex as a Biological Variable (SABV)

- Required discussion of this issue in all NIH grants including the KL2/K12/TL1

APPROACH
(many options for organizing this)

- *Use subheaders to make this section very clear*
- *Be generous in using 'white space', indenting, stylized text*

A. Overview of research design
B. Methods (for each aim)
   - Analyses and Expected Results
   - Limitations/Anticipated Problems
   - Alternative Approaches
C. Timeline
D. Future Directions

Study good examples

- Read any kind of grant application from your mentor's lab
- Study my examples on Dropbox
- Review F31 and F32 examples
  - Examples from UAB: https://www.uab.edu/ccts/research-commons/grant-help/proposal-development/grant-library/nih-grant-f-series-samples
  - Examples posted by NIAID: https://www.niaid.nih.gov/grants-contracts/three-new-f31-sample-applications
  - Lots of interesting info on Google
- Look at F31 and F32 examples of abstracts on NIH RePORTER
  - https://projectreporter.nih.gov/reporter.cfm

Grant Writing

Terms/phrases to avoid

Expressions with no clear limits	Words of personal judgment	Causal colorful language	Use with caution as transitions but never as fillers
a lot	assuredly	agree to disagree	in effect
fairly	beautiful	bottom line	indeed
really	luckily	brute force	basically
slightly	obviously	few and far between	in terms of
sort of	sadly	okay	it goes without saying
	fortuitous	sketchy	
	intriguing	tip of the iceberg	

Can you deconstruct a paragraph?

Distracting	Useful
• Tangent – material that is not directly related	•Opening/introductory statement or lead statement
• Digression – going off in a different direction than the topic	•Factual support •Examples of the focal point
• Fluff/filler e.g., As part of this research, we plan to fulfill our mission of recruiting the maximum number of patients possible.	•Supporting data/findings e.g., We will enroll 10 patients per week which will be feasible based on the current census of more than 100 emergency room visits/week.
• Vague	•Implications of the facts presented
• Emotional/Jargon/Colloquial	•Transition
• Passive/indirect	•Summary statement
• Redundant	•Header/Subheader

Reviewers' Concerns and Criticisms of the Research Plan

Is the research design complete?

For example, if you are comparing 3 out of 4 cells of a 2x2 design, why are you omitting the 4th cell?

- Do not leave anything to the imagination.

Group 1: *Stroke Pts who are Smokers*

Group 2: *Stroke Pts who are non smokers*

Group 3: *MI Pts who are Smokers*

?? MI Pts who are non smokers

Research Plan

Level of Detail in Methods

1. Treatment of data
   - Raw data, transformed/scaled data
   - Collapsed by group
   - Confounds to the data

Research Plan

2. Well-specified, operationally defined variables and outcomes; what are they and how will they be obtained?
   - Demographics
   - Biomarkers
   - Correlates of depression
   - Immune functioning

Research Plan

3. Description of Experiments
   - Consistency of level of detail from one experiment to the next
   - General Methods section can save you space
   - Know your agents, your clinical interventions, your high tech procedures. Are there alternatives that you should mention? Have you thoroughly described them?

"It is clear that the applicant is not completely familiar with the drug interactions that follow the combined administration of substance x and substance y in patients with diabetic neuropathy."

Research Plan

4. Use of scientific terminology
   - Controversial terms vs. well-accepted terms
   - Are there philosophical “camps” in this scientific community? Are you considering all sides of the issue fairly?

5. Theoretical framework
   - Is this customary for your field?

6. Theoretical context
   - Is your idea supported by the research design and methodology proposed?
   - Are you using the best model/organism/ procedures for the research question proposed?
     - Substantiate all this

Sources of Data

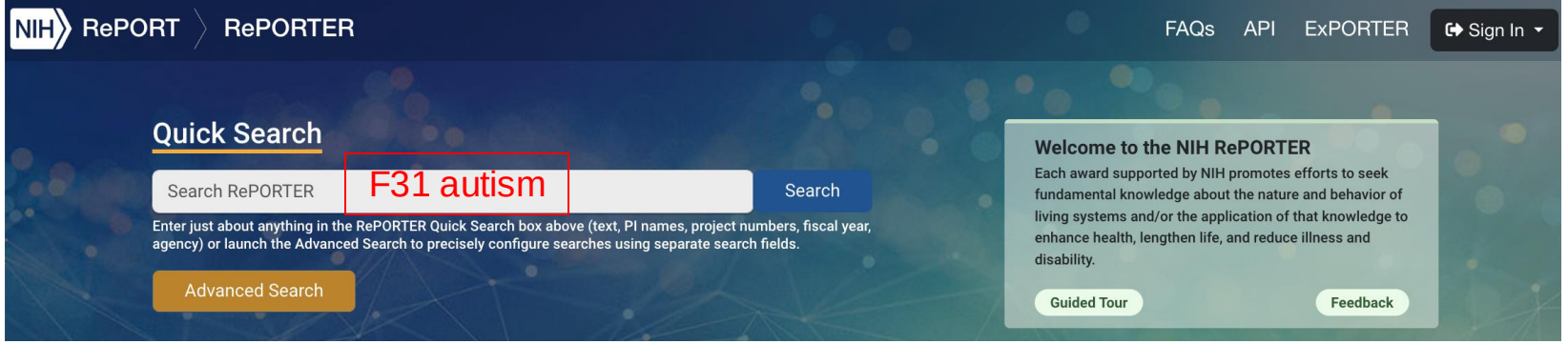
1. Most 1-2 year proposals will leverage existing data
   - Banked biospecimens
   - Access an available dataset or registry
   - Piggy-back on ongoing enrollment in a clinical trial

2. Be sure reviewers have all the information they need to evaluate the integrity of your sources of data
   - Data collection methods
   - Sampling techniques
   - Reproducibility and validity of assays
   - Representativeness of subjects
   - Previous publications with these data

Human Subjects Considerations

- If you are using an existing dataset
  - How much information should you provide?
- Why are you proposing the population you've chosen?
- What is the relevance of the selected population to state of the research - omitting children, omitting males or females
- What is the availability and likelihood of getting data from these subjects, tissue, animals, etc.
- Do you have enough subjects in your study?
  - Statistical implications - sample size calculation and power analysis – is this necessary for this kind of research?

For Grant Writing



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Researcher and Organization

Fiscal Year
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Current FY is 2025

Principal Investigator (PI)
PI Names or Profile IDs, semicolon ";" separated

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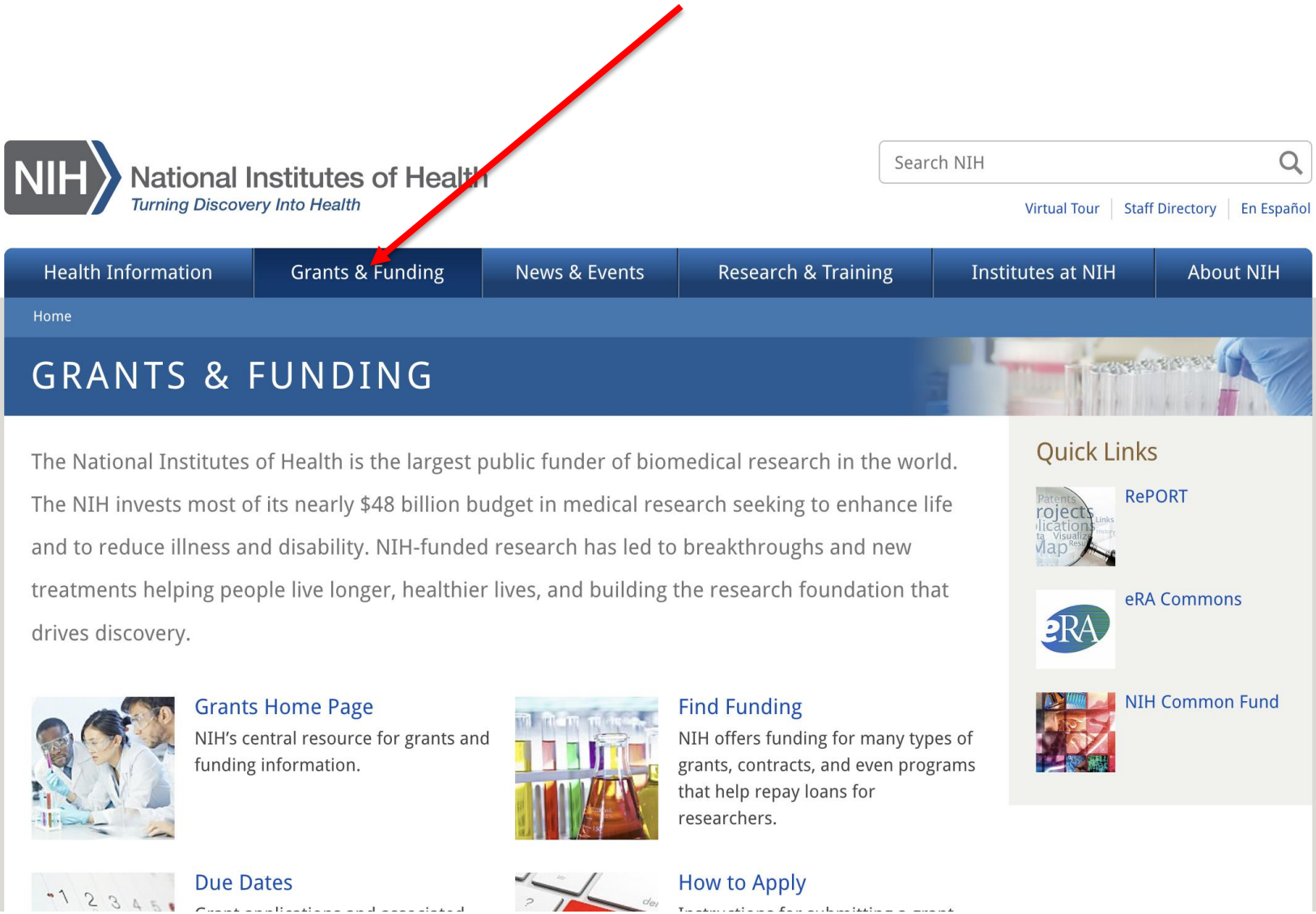
Excellent NIH Grant Writing Resource



Review: [Plain Language in the NIH Applications: Before and After Examples]

- ✓ Think critically
- ✓ Complete all sections carefully - avoid careless errors
- ✓ Have others read your work - ask for critical comments not just a cursory review
- ✓ Get feedback on the research plan from experts
- ✓ Build in time to reflect on your own product; read your own work “at an arm’s length” (preferably on paper)

Learn from funded proposals

- See DROPBOX for examples and grant writing resources
- See excellent examples of funded grants in RePORTER
- Find good grant applications from your peers / colleagues