

Grant Writing

Part 1: General Elements for Research Project Grants

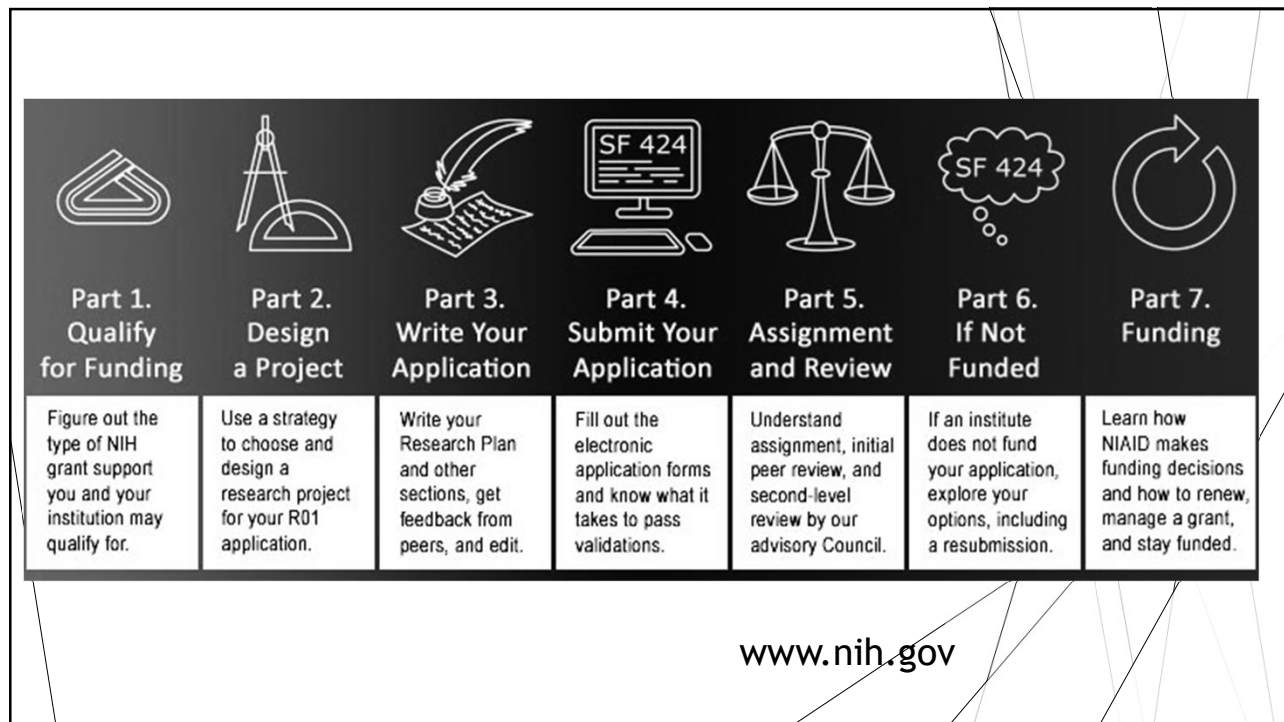
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How to get started?

- ▶ Come up with a project
- ▶ If responding to a specific Funding Opportunity Announcement (FOA), read the FOA carefully and make sure that your idea fits with the scope of the program
- ▶ Contact collaborators in the USA, UK and elsewhere
- ▶ Define specific aims for the project
- ▶ Start EARLY, at least 6 months before the grant deadline

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Development of Research Ideas

- ▶ Find your own niche area
 - Address a highly significant problem, a barrier to progress, or gap in knowledge - *significance*
 - Present an opportunity to move field forward - *innovation*
- ▶ Assess your skills
 - Strengths match the focus and scope of your proposal
 - Appropriate knowledge and skills to complete your proposal - *feasibility*
 - Track record of productivity
 - Find collaborators

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SCORING of NIH grant applications

- 1) Significance: RESEARCH PLAN
- 2) Investigators: BIOSKETCH & LETTERS OF SUPPORT
- 3) Innovation: RESEARCH PLAN
- 4) Approach: RESEARCH PLAN
- 5) Environment: FACILITIES & LETTERS OF SUPPORT

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Significance

- ▶ Does the project address an **important problem** or a critical barrier to progress in the field?
- ▶ Is there a **strong scientific premise** for the project?
- ▶ If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- ▶ How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

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Investigators

- ▶ **Source of information:** Biosketches and Letters of Support
- ▶ Are the PIs, collaborators, and other researchers well suited to the project?
- ▶ If Early-Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate **experience and training**?
- ▶ If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- ▶ If the project is collaborative or multi-PI (MPI), do the investigators have **complementary and integrated expertise**; are their leadership approach, governance and organizational structure appropriate for the project?

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Innovation

- ▶ Does the application **challenge** and seek to shift current research or clinical practice **paradigms** by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- ▶ Are the concepts, approaches or methodologies, instrumentation, or interventions **novel** to one field of research or novel in a broad sense?
- ▶ Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

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Approach

- ▶ Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- ▶ Have the investigators presented strategies to ensure a **robust and unbiased approach**, as appropriate for the work proposed?
- ▶ Are **potential problems, alternative strategies**, and benchmarks for success presented?
- ▶ If the project is in the early stages of development, will the strategy establish **feasibility** and will particularly risky aspects be managed?

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Approach (continued)

- ▶ Have the investigators presented adequate plans to address relevant **biological variables**, such as sex, for studies in vertebrate animals or human subjects?
- ▶ If the project involves human subjects or clinical research, are the plans to address these justified?
 - 1) protection of human subjects from research risks
 - 2) inclusion (or exclusion) of individuals on the basis of sex, race, and ethnicity
 - 3) inclusion or exclusion of children

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Environment

- ▶ **Sources of information: Facilities & Letters of Support**
- ▶ Will the **scientific environment** contribute to the probability of success?
- ▶ Are the **institutional support, equipment** and other **physical resources** available to the investigators adequate for the project?
- ▶ Will the project benefit from unique features of the scientific environment, **subject populations**, or **collaborative arrangements**?

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Different Sections of Research Plan

- ▶ **Specific Aims**
- ▶ **Research Strategy**
 - A. Significance
 - B. Innovation
 - C. Approach

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Structure of Specific Aims

- ▶ Short, one paragraph background noting the significance and innovation of your research
- ▶ State the goal or the hypothesis of the project
- ▶ List of specific aims and how they will be accomplished
 - use “strong” verbs *identify, define, quantify, determine*
- ▶ Best if aims are not dependent on each other
- ▶ Sometimes including expected results is a good idea
- ▶ Final paragraph: bring up the importance and innovation of the project to human health, and future direction of research

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Research strategy: Very IMPORTANT!!!!

- ▶ Significance
- ▶ Innovation
- ▶ Approach: organize around your specific aims
 - Rationale
 - Preliminary data
 - How will the work be done?
 - Statistical and bioinformatics approaches
 - Timetable
 - Pitfalls and alternative approaches
- ▶ Investigators: short summary of strengths and interactions
- ▶ Environment: highlight unique resources that will guarantee success of the project

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Research strategy: Significance (1)

Put your project into context

- ▶ Gravity of the problem
- ▶ Current state of the field
 - Consider order of presentation
 - Highlight critical knowledge gaps, but tie-in each gap with an aim
- ▶ Your long-term research plans
- ▶ Your key preliminary data (including relevant publications)

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Research strategy: Significance (2)

- ▶ Make a case for your specific research proposal
- ▶ Avoid making this a literature review!
- ▶ Try to include one figure/table per page
- ▶ Remember: significance is one of the review criteria

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Research strategy: Innovation

- ▶ Can be innovative in either:
 - Hypothesis
 - Methodology
 - Study population
- ▶ Be innovative, but not too innovative
 - Do not propose to shift the paradigm (unless you have very strong preliminary data and track record)
 - Showing that you would move the field forward with positive or negative results is sufficient

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Research strategy: Preliminary Studies (1)

- ▶ Show that:
 - You have the expertise and resources
 - Can interpret results appropriately
- ▶ Give alternative interpretations of your results
 - Demonstrates your insight into the problems
 - Shows preparedness for future stumbling blocks

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Research strategy: Preliminary Studies (2)

- ▶ Show preliminary results that support your hypothesis
 - Present *your* previous work that led to your current proposal
 - Connect preliminary findings to current aims
- ▶ Highlight your available resources
 - You have or can get the data
 - You have the study population
 - Prior successful collaborations with co-investigators
 - Measurement methods are feasible, accurate, and reliable

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Tips for writing a successful grant application

- ▶ “Keep it all in sync”: Writing is an iterative process: as you develop and finalize the experiments, you will go back to other sections and make sure that they are consistent with your plans (including your budget!)
- ▶ Make sure you say “*who, what, when, and how*” the project will be carried out
- ▶ Be organized
- ▶ Use sub-headings to bring up most important points and help the reviewer find the most important information
- ▶ Be consistent in numbering sections

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Tips (continued)

- ▶ Have zero tolerance for typographical errors, misspellings, grammatical mistakes or sloppy formatting. A sloppy or disorganized application may lead the reviewers to conclude that your research may be conducted in the same manner.
- ▶ Use the active, rather than passive, voice. For example, write "We will develop an experiment," not "An experiment will be developed."
- ▶ Write simple and clear sentences, about ≤ 20 words in each

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Tips (continued)

- ▶ Be consistent: terms, references and writing style
- ▶ Make your points as direct as possible. Avoid jargon or excessive language
- ▶ Use diagrams, figures and tables, with appropriate legends, to assist the reviewers to understand complex information
 - ▶ These should complement text and be appropriately inserted
 - ▶ Make sure figures and labels are readable in the size they will appear in the application at 100%, not 400%!

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“
*Experience is what to get,
if you did not get what you
wanted*
”

If you did not succeed the first time, try
again: revise and re-submit!!!

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Part 2: NIH Research Program & Grant Mechanisms

Overview

Examples of NIH Funding Opportunities for LMIC Investigators

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National Institutes of Health (NIH), USA

- Leading supporter of biomedical research in the world
- Part of the US Department of Health & Human Services
- Primary Federal agency that conducts & supports *medical research*



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Foreign Researchers outside the USA

“Before applying, consider whether your application presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing U.S. resources. Also, in order to receive NIH funding, your research should benefit the health of the American population, as well as your local population.”

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NIH Institutes and Centers

- The *27 Institutes and Centers (ICs)* of NIH provide leadership and financial support to researchers both inside and outside the USA
- Each with a specific
 - mission & priorities
 - research agenda, focusing on particular diseases or body systems
 - budget & funding strategy

Very important to critically evaluate

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Funding Opportunity Announcement (FOA)

- A publicly available document
- A Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as **competition** for funds
- Types:
 1. Program Announcements (PAR)
 2. Requests For Applications (RFA)
 3. Parent Announcements (PA)

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Program Announcements (PA)

- ▶ *Investigator-initiated* applications
- ▶ May/ may not have allotted funds
- ▶ Multiple submission dates
- ▶ Usually *broad* in scope
- ▶ Reviewed by study section

Request for Applications (RFA)

- ▶ Narrow topics based on *institute's priorities*
- ▶ Specific, but limited funds allotted
- ▶ Usually single receipt date
- ▶ Applications compete only with each other
- ▶ Reviewed by special panel

Adapted from: Michelle M Estrella (2013)

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Parent Announcements

- ▶ Broad FOA for **unsolicited / investigator-initiated** applications for specific activity codes:
R-series
T-series
K-series
F-series
- ▶ E.g. foreign researcher has novel idea and **US collaborator**
- ▶ Certain NIH Institutes & Centers
- ▶ Open up to 3 years, use **standard due dates** (usually 3/year)

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Activity Codes (>200)

A 3-character code used to identify specific category of extramural research activity

F-series: Fellowships (e.g. F31, F32, F33)

P: Program Project Center Grant (e.g. P01, P20, P30, P41)

T: Training Grants (e.g. T32, T34)

K: Career-development Awards (e.g. K01, K05, K12): **K43**

D: International Research Training Grants (e.g. D71, D43)

R: Research Grants (e.g. R01, R03, R21, R24, R25, R34)

U: Cooperative Agreements (e.g. U01)

NOTE: Not all grant mechanisms are available to foreign institutions, e.g. most of K-series; exception: K43

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R: Research Projects

R01 - Research Project Grant Program: Most common NIH program; supports a *discrete, specified, circumscribed research project* for 3-5 years; budget <\$500,000 p.a. in direct costs.

R03 - Small Grant Program: *Limited funding for short period to support*, e.g. pilot / feasibility study, collection of preliminary data, secondary analysis of existing data, small-contained research projects, development of new research technology; not renewable; up to 2 years; budget <\$50,000 p.a. in direct costs.

R21 - Exploratory/Developmental Research Grant: Encourages *new, exploratory and developmental research projects* (could be used for pilot or feasibility studies); up to 2 years; budget <\$275,000 p.a. in direct costs.

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U01: Research Project Cooperative Agreements

- Supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies
- NIH staff have important role in coordinating the activities
- Many types of cooperative agreements, e.g., Clinical Trials Centers
- Usually no budget upper limit

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NIH Policy on “Next Generation Researchers”

- ▶ Goal: Increase the number of NIH-funded early-stage investigators (ESIs)
- ▶ ESI: Completed terminal research degree within the past 10 y
- ▶ Make sure you have **the year you received your degree** entered in eRA
- ▶ When making funding decisions, those ESI with meritorious scores will be prioritized for funding

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PAR-20-108: International Research in Infectious Diseases

► **Deadline:** 15 July 2022

► <https://grants.nih.gov/grants/guide/pa-files/par-20-108.html>

► **Goal:**

- Encourage applications from institutions in foreign countries that propose research related to infectious diseases that are of importance to that country
- Collaborations with investigators in the USA highly encouraged
- Grants will serve to build independent research capacity by providing direct funding to investigators who do not currently have NIH-funded grants
- Advance the development of local scientific expertise

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Topics of interest

- TB and other infectious diseases
- Note! No clinical trials
- Development of capacity in:
 - ❖ Basic research
 - ❖ Immunological
 - ❖ Microbiological
 - ❖ Biostatistical
 - ❖ Epidemiological
 - ❖ Data management
 - ❖ Clinical research

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Research Objectives and Scope

- ▶ Any aspect of infectious disease research:
 - ❖ Epidemiology: e.g. define the incidence, clinical presentations, and outcomes of diseases
 - ❖ Natural history
 - ❖ Pathogenesis
 - ❖ Immunopathogenesis
 - ❖ Identification of resistance mechanisms and patterns
 - ❖ Characterization of susceptible cohorts for a particular pathogen
 - ❖ Pilot and feasibility studies in preparation for larger studies

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Intent to complement existing international research programs on infectious diseases supported by NIAID

- ▶ International Centers of Excellence in Research (ICERs)
- ▶ International Collaborations in Infectious Disease Research (ICIDRs)
- ▶ Tropical Medicine Research Centers (TMRCs)
- ▶ Centers of Excellence for Influenza Research and Surveillance (CEIRS)
- ▶ International Centers of Excellence for Malaria Research (ICEMRS)
- ▶ **Tuberculosis Research Unit**
- ▶ HIV Vaccine Trials Network (HVTN)
- ▶ HIV Prevention Trials Network (HPTN)
- ▶ International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)
- ▶ AIDS Clinical Trials Group (ACTG), Microbicide Trials Network (MTN)
- ▶ International Epidemiologic Database to Evaluate AIDS (IeDEA)
- ▶ Centers for AIDS Research (CFAR)

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Other expectations

- ▶ Establish multi-institutional collaborations
- ▶ Include activities that involve:
 - ❖ transfer of technologies and research methods
 - ❖ sharing of core resources including the administration of research grant programs
 - ❖ expansion of linkages to other sites via attendance at national and international meetings and other methods of communication

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Budget & time of support

- ▶ Annual direct costs: $\leq \$125,000$
- ▶ Total direct budget: $\leq \$625,000$
- ▶ Time: ≤ 5 years
- ▶ Subcontract to an institution in a high economy country: $\leq 20\%$ of the budget in any year

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NIH Scientific Contact for Infectious diseases other than HIV/AIDS

Glen C. McGugan, Jr., Ph.D.
Division of Microbiology and Infectious
Diseases
National Institute of Allergy and Infectious
Diseases (NIAID)
Telephone: 240-627-3314
Email: gm233g@nih.gov

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K43: Emerging Global Leader Award

- ▶ **Purpose:** provide research support and protected time (3-5 y) to an early career research scientist from a LMIC who holds a junior faculty position at an LMIC academic or research institution
- ▶ Intensive, mentored research career development experience
- ▶ Need LMIC and US mentor

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K43

- ▶ FOAs: PAR-21-252 & PAR-21-252
- ▶ Budget:
 - salary of upto \$75,000/year (with minimum of 75% effort)
 - \$30,000/year towards research development costs
- ▶ Max 5 years
- ▶ **NIH contact: Christine Jessup, PhD**
 Program Officer
 Fogarty International Center
 National Institutes of Health
 Phone: 301-496-1653
 Email: Christine.Jessup@nih.gov

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DOCUMENTS NEEDED FOR NIH R01 GRANT APPLICATION PAR-20-108 "International Research in Infectious Diseases (R01)":

<https://grants.nih.gov/grants/guide/pa-files/PA-20-108.html>

Item	Notes
Research strategy	Max 12 pages ¹
Bibliography	No page limit
Specific Aims page	Max 1 page
Project summary/abstract	Max 30 lines
Project narrative	Max 3 sentences
Equipment	
Facilities and resources	
Authentication of key biologicals	
Resource sharing plan	
Foreign justification	
Biosketches	Special NIH format
Multiple PI leadership plan	
Human subjects documentation	Special NIH form
Vertebrate Animals	
Select agent research	
Letters of Support (LoS)	
Budget: detailed for all 5 years	Special NIH form
Budget justification	
Appendix	Usually not allowed
Financial Conflict Of Interest form signed by all Key Personnel (University internal form)	Send signed forms to Grants Management Office

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Important Links

- National Institutes of Health <http://www.nih.gov/>
- Grants.gov <http://www.grants.gov/>
- Set up a weekly automated update with specific key words to your email address.

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Final take home messages

- ▶ Never give up!
- ▶ Science is team-work!
- ▶ Collaborate!

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