# Writing Winning Proposals

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# What is a grant?

"A grant is a *mechanism* by which an agency awards money to fund a research study or other activity, such as an educational program, service program, demonstration, or research project."

Gitlin, Laura N., Kevin J. Lyons. Successful Grant Writing: Strategies for Health and Human Service Professionals. 2nd ed, (2004).

# Why apply for a grant?

Grant writing is an important part of your professional activity and task. It should become a long-range plan for your professional growth and development:

- ❑ Develop professional career and build individual credentials and recognition
- ❑ Make a survival in your academic life (tenure and promotion)
- ❑ Build a track record of funding and contribute to the financial health of your department, school
- ❑ Advance scientific knowledge in your field
- ❑ Foster collaboration with researchers

(Gitlin & Lyons, 2004)

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# Where to apply for a grant?

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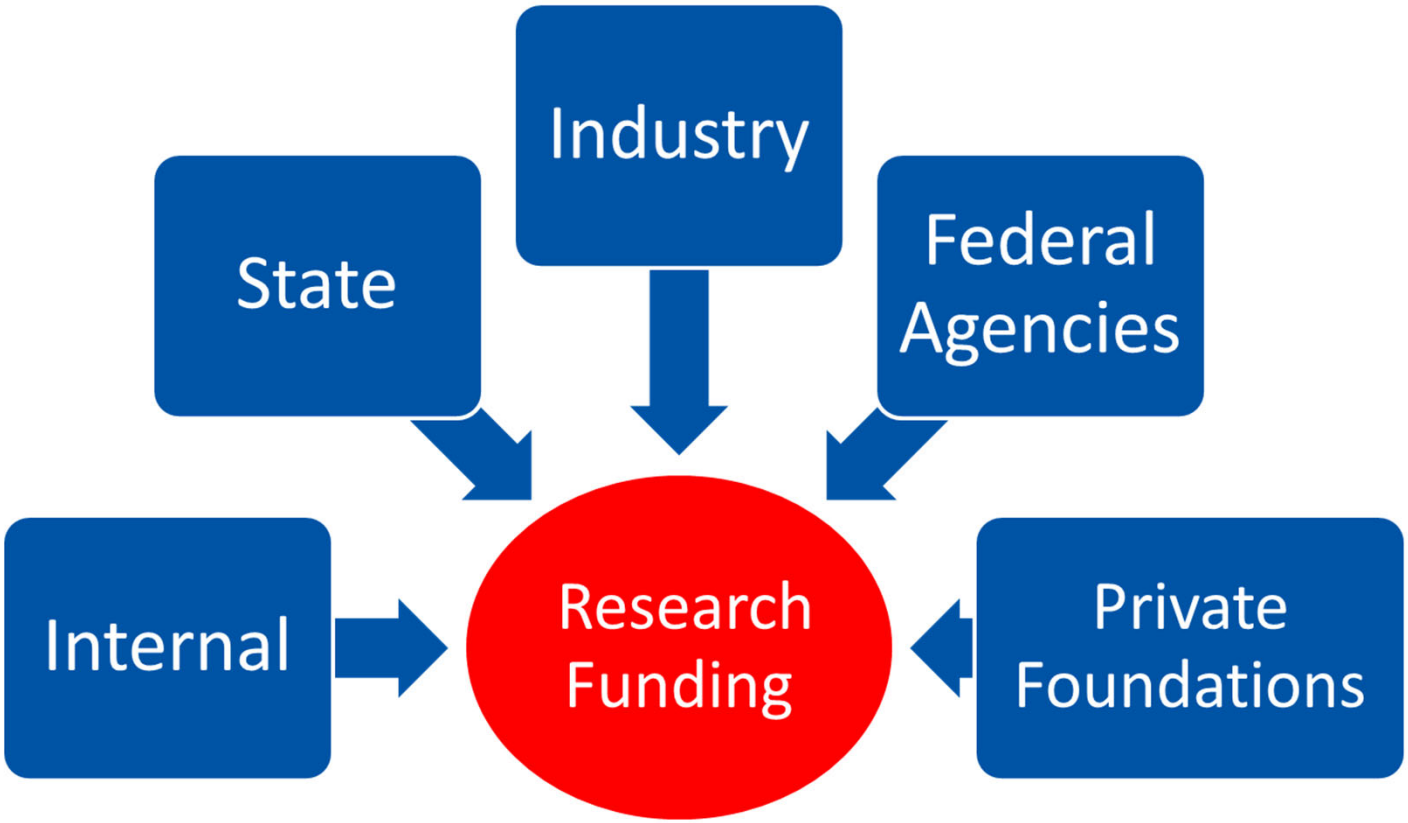
## Funding Sources



# Federal Government

- The majority of grants are received through the federal agencies.
- The Public Health Service within the Department of Health and Human Services has a variety of programs of potential interest to the health professionals.
- National Institutes of Health (NIH) is an agency of DHHS.


- http://www.nih.gov

# Federal Funding Agencies in US

- NIH
- DoD CDMRP
- NSF
- Dept of Agriculture
- Dept of Education
- Dept of Energy
- Dept of Homeland Security

# Private Foundations

- 700,000+ U.S. foundations offer grants to individuals, institutions, or other non-profit groups.
- Generally only independent foundations and community foundations provide grants to independent investigators.

# Corporations

- Large corporations are interested in the testing or evaluation of their own products. The private sector is a potential source of funding.
- Corporations provide grants for research projects that advance the interests of the company.

# Mission of NIH

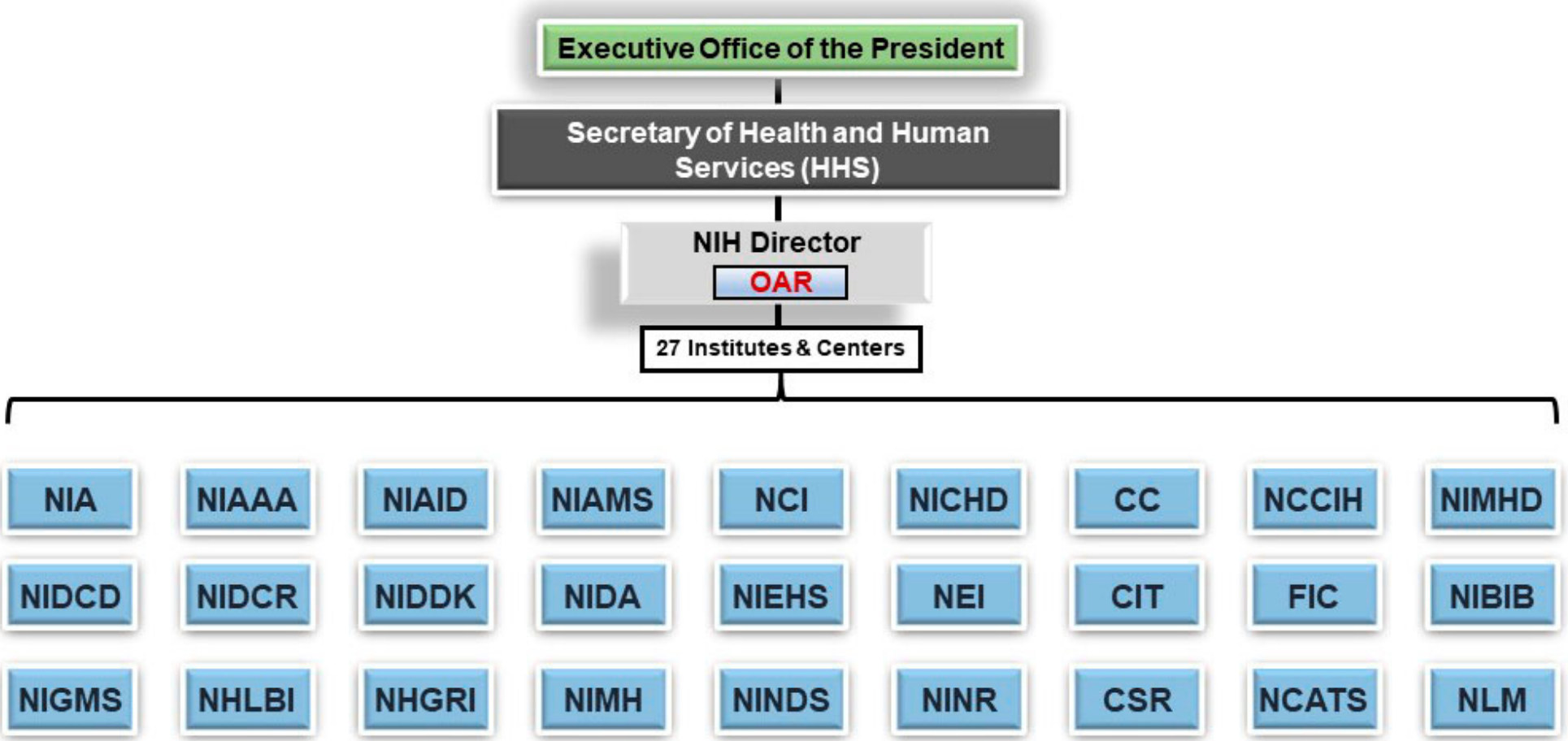
- Understanding what research NIH funds and why it does so can help you focus your application.

- NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

# National Institutes of Health (NIH)

- Budget (2021): $43 billion
- NIH is comprised of 27 separate components (Institutes and Centers)
- Your project should meet the mission of the institute or agency likely to fund it.
  - **NCI** leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.
  - **NIA** conducts and supports genetic, biological, behavioral, social, and economical research on aging and the challenges and needs of older adults
  - **NIGMS** supports basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention.
  - **NIBIB** is to improve health by leading the development and accelerating the application of biomedical technologies

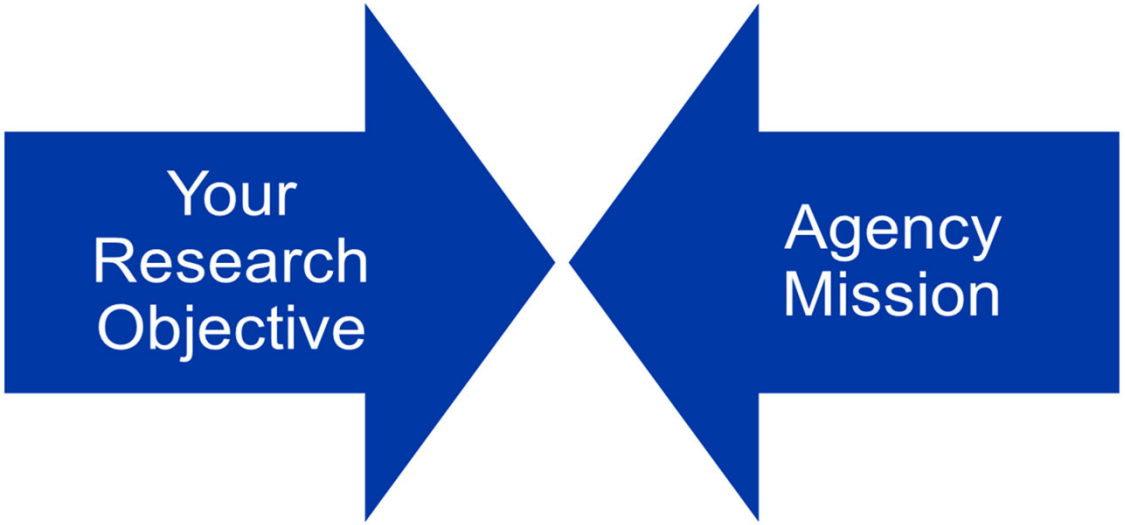
# NIH Office of AIDS Research (OAR)



# Funding =
# your interest + the interests of a funding agency

- "No matter how good your idea and how well-written your proposal, if the agency to which you are applying is not interested in your project, you will not be funded!"

Rief-Lehrer, Liane. Grant Application Writer's Handbook. 4th ed. (2005)



# Main Types of NIH Grants

- Research Grants (R01, R21)
- Career Development Awards (K99, K01, R35)
- Research Training and Fellowships (F31, T32)
- Program Project/Center Grants (P01)
- Resource Grants (R24, R25, S10)
- Small Business Grants (SBIR/STTR)

# What are Parent Announcements?

- Parent Announcements are requests for investigator-initiated, unsolicited research grant applications that do not fall within the scope of targeted announcements.
- The majority of NIH applications are submitted in response to parent announcements.
- Parent Announcements are also used for conference and scientific meetings grants

# Searching for Grants

- Determine what type of grant you will be using and which IC is most appropriate to fund this type of research
- Search for the proper FOA (funding opportunity announcement) through grants.gov
- Once you have identified the FOA, read the FOA in detail, read the instructions carefully and follow the instructions exactly

Finding and Applying for NIH Grants. SJM Family Foundation, Inc., 2008. p.21

# Still Have Questions?

- Contact the Program Officer – by email or phone.
- Be ready to answer:
  - What is your research objective?
  - How does this meet the agency's mission?

# If You Contact a Program Officer

- Be prepared with focused questions
- Listen (you don’t learn by talking)
- Remember that the Program Officer is NOT the panel (or reviewer)

# Select a Research Topic

Your research must be:

- Methodical, repeatable, and verifiable (preliminary data)
- Not done before (innovation)
- Significant (broad impact)
- Reasonable probability of success (feasibility)
- Lends itself to a viable research plan (grantsmanship)

You must have facilities to accomplish the research

# Know Your Field

- What is the current state-of-the-art?
- What are the top ten researchers in the field doing now?
- What are the sources for funding?
- What are the key research issues?
- Who would likely review your proposal?

# Build on Your Strengths

- Differentiate this proposal from your Ph.D. dissertation, and any other sponsored work
- Perform thorough up-to-date literature search and exploratory research before writing the proposal
- Establish and keep your contacts

# Proposal Writing Rules

# Strictly Follow the Funding Agency Guidelines

- Learn everything about  the sponsoring agency
- Find funded grant applications
- Examine them closely for the proposal format and structure

# Proposal Guidelines

- Page Limit
- Word Limit
- Budget Limit
- Abstract Format
- Reference Format
- PI and Co-PI Eligibility
- Submission Method (file types, size, etc.)
- Font Size
- Minimum Resolution
- Table of Contents
- Research Objectives
- Tables/Figures

# Basic Concepts

- Write to be readable
- Make the level of detail appropriate
- Find out how much money is available, and follow the budget guidelines
- Have clearly defined hypotheses, goals, and approaches

Now that you have an idea, how do you go about writing the proposal?

# Keep in Mind While Writing

- **Carefully** follow all instructions provided by the funding agency

- Don't run the risk of having your science "down-graded" or your proposal rejected, because you didn't follow instructions

# State Your Research Objective

- Make clear in the first paragraph exactly what your proposal is about
- The statement of your research objective should lead you directly to your methodology

# Clear Presentation

- State the problem or hypothesis
- State why the issue is significant
- State what you are going to do
- Explain how you will carry out the proposed work

# Competitive Proposals

- Keep the narrative focused on the project
- Use tables, charts, and figures effectively
- Present preliminary results if you have them

# Common Errors in Proposals

- Does not fit agency's mission
- Violates one or more agency guidelines
- Beyond capabilities of PI, students, or institution (don't propose too much)
- Lack of proofing: Grammar, spelling, formulas, numbering, math errors

# More Common Errors

- Missing pages, figures, tables, or signatures
- Unfocused, poorly organized
- Low personnel budget – Not enough people
- Low impact – no publishable results even if funding is obtained

# Proposal component (NIH R01)

- Abstract/Summary (ca. 30 lines)
- Specific Aims (1 page)
- Research Design and Methods (12 pages)
  - Significance
  - Innovation
  - Approaches
  - Timetable
  - Future Directions (optional)

# Abstract and Specific Aims

- Very important (many reviewers will evaluate your application mainly by reading Abstract and Specific Aims)
- It should summarize the whole application
- Use concise and clear sentences
- Emphasize the specific aims

# Abstract/Summary

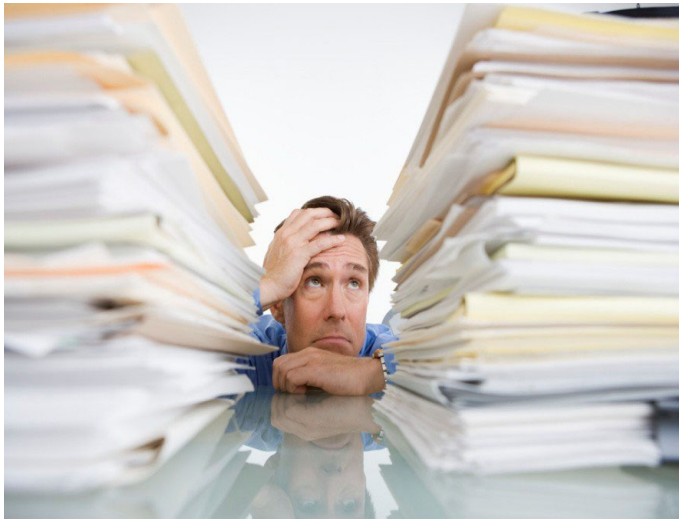
- Clearly state your long-term goal
- Review the background of this area and unsolved problems
- Clearly state your objective(s) of this project and why you select this objective
- Summarize your specific aims and anticipated results
- State the significance of this project

# Specific Aims

- The most important component
- Grabs the reviewer immediately
- Is roadmap for your application
- Begin with an overall section
  - State general purpose
  - Include some key supporting data
  - State the hypothesis
  - State long-term objectives and expected impact
- Organize the aims in a sequential, numeric format
- *Tell reviewers what the results will mean!*

NIH Reviewers:

- 10 – 15 proposals as primary reviewers
- Up to 100 proposals for reading



# Specific Aims – Do's and Don'ts

- Specific Aims are the central focus of an NIH research grant application
- Develop your Specific Aims carefully
- Do's and don'ts of Specific Aims
- Aims combined with good ideas, good grantsmanship, good timing, good reviewers, and good luck make for funding success

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# Specific Aims

- **Most important part of the proposal**
- **Should teach the reviewers about**
  - Research objectives
  - Significance and innovation of the proposed studies
  - Central hypothesis
  - Experimental approach to test the hypothesis

# Specific Aims: How To Do It?

# Develop Your Specific Aims

## Get Help

- Discuss your Specific Aims with colleagues
- Obtain collaborators and plan with them
- Learn about approaches different from yours
- Secure a mentor who can help you succeed
- Develop a network of your supporters and colleagues whom you support in their work

# How many aims?

- Between 2 and 4 (generally 3)
- The aims should NOT be inter-dependent on one another

# Specific Aims – Do's and Don'ts

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# Develop Your Specific Aims

## Communicate with the NIH

- Contact NIH staff at your planning stage
- Give yourself enough time to revise your Specific Aims appropriately
- Speak to a Scientific Review Officer about how your Specific Aims fit with a study section
- Get to know one or more Program Officers in relevant Institutes and Centers

# Develop Your Specific Aims

**Know Your Audience**

- Write the Specific Aims for the entire review committee, not for the “specialist” in your field
- Write for the Institute’s programs
- Learn about PA’s & RFA’s from multiple sources in the NIH and other funding agencies

# Specific Aims- Do's and Don'ts

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# Do's and Don'ts of Specific Aims

- **Well-designed Aims**
  - More than one possible outcome is acceptable
  - Success is not dependent on any single outcome
- **Unacceptable Aims**
  - Only one possible outcome is interesting
  - Success of a subsequent aim is dependent on this outcome
- **Fatally flawed Aims**
  - Descriptive, unfocused, obvious, naïve, or uninterpretable

# Specific Aims: How To Do It?

## Paragraph 1. Introduction

- Opening statement including the “big picture” goal of the project
- What are known
- What are unknowns (gaps)

Briefly how the proposed studies address an important scientific question and/or fill an important gap in our understanding of the “big picture”

- Frame the problem which is most important

# Specific Aims: Introduction

Idiopathic pulmonary arterial hypertension (PAH) is a fatal and progressive disease with a very poor prognosis. The estimated median survival is only 2.8 years with a 5-year survival rate of 34%. (Big picture) Although significant progress has been made, many patients do not benefit sufficiently from current treatments. (What known) The development of safe new therapies that target specific drivers of disease pathogenesis is essential to improve outcomes for PAH patients. (What unknown) Autophagy is an evolutionarily conserved lysosomal-mediated degradation process that facilitates the turnover of organelles and selected long-lived proteins. Aberrant autophagy has been reported to contribute to the development and progression of PAH by generating alternative sources of metabolic fuel to maintain cell survival under stress conditions and promote increased proliferation of pulmonary vascular endothelial cells (EC), PA smooth muscle cells (PASMC) and fibroblasts (FB). The critical role of autophagy in PAH pathogenesis suggests that disrupting autophagic degradation may be a promising approach to treat the disease.

# Specific Aims: How To Do It?

Paragraph 2. Goal, objective and hypothesis paragraph

- Long-term goal
- Objective of this project
- Hypothesis (sometimes how developed)

# Specific Aims: Goal, objective and hypothesis

We and others initially repurposed the FDA approved anti-malarial drug chloroquine (CQ) as a potential therapy for PAH due to its off-target autophagy inhibitory effects (our findings). *In vivo* studies established proof of concept that disrupting autophagy at the lysosomal stage of the pathway with CQ had significant benefit in preventing the development of experimental pulmonary hypertension (PH) and antagonizing the progression of active disease. However, clinical evidence indicates that CQ and its related analog hydroxychloroquine (HCQ) do not impair the pathway completely at tolerated doses and their continued use for this purpose is driven by the lack of better alternatives (Bring problems). This underscores both the challenge and opportunity to pursue novel chemical entities with druglike properties to clinically target the autophagy pathway. We recently generated a series of novel orally available autophagy inhibitors that are significantly superior to CQ/HCQ. Our first hit, ROC-325, is 10X more potent than HCQ, orally active, well tolerated, and demonstrated significant therapeutic benefit in its ability to prevent and treat PH in preliminary *in vivo* studies (our contributions). We **hypothesize** that disrupting autophagy at the lysosomal stage is a novel therapeutic strategy for treatment of PAH. Our **major goal** is to use state-of-the-art drug discovery tools and techniques to optimize the biological and pharmacological properties of the ROC-325 scaffold yielding a novel autophagy inhibitor that can be tested in a clinical trial for patients with PAH and other disorders where autophagy contributes to disease pathogenesis.

# Specific Aims: How To Do It?

Paragraph 3. Individual aims

- Concise and clear words
- Cover the experimental designs and methods
- Don’t overstate them
- Should not contain comments
- State the outcomes of the Aim

# Specific Aims: Individual aims

**Specific Aim 1: Design and synthesize novel lysosomal autophagy inhibitors with optimized pharmacological properties.** Our structure activity relationship (SAR) studies with ROC-325 have revealed that basicity was a critical factor contributing to efficient autophagy inhibition through lysosomal deacidification. We propose to develop 4 distinct approaches to design and synthesize ROC-325 derivatives (total 50-60 compounds) guided by our prior SAR studies and the principles of structure-based rational drug design. ***We expect that the proven design strategy will yield novel structures with superior potency and drug-like properties.***

# Specific Aims: Individual aims

**Specific Aim 2: Characterize the *in vitro* pharmacological properties and therapeutic effects of ROC-325 derivatives on PH.** We will conduct rigorous studies to establish the pharmacological profiles of our novel compounds. The selectivity of each new derivative will be determined using lung EC and PASMC from normal subjects and patients with PAH as well as lung tissues, lung EC and PASMC isolated from rats/mice with experimental PH. ***Through our pipeline refinement strategy, we expect to identify at least 12 compounds that are superior to ROC-325.***

# Specific Aims: Individual aims

**Specific Aim 3: Investigate the tolerability, efficacy, PK and PD of optimized oral autophagy inhibitors in experimental PH models.** Robust *in vivo* studies will be conducted to establish the safety, efficacy, and pharmacokinetic/pharmacodynamic profiles of our best compounds selected from *in vitro* analyses. Our rigorous approach includes multiple animal (rat and mouse) models with experimental PH including chronic hypoxiainduced PH (HPH) in rats and mice (mild PH model), monocrotaline (MCT)-induced PH (MCT-PH) in rats (severe PH model), and hypoxia/sugen-induced PH (Hyp/Sug-PH) in rats and mice (severe PH models). The ability of our autophagy inhibitors to prevent and treat PH will be determined. ***We believe that our synergistic efforts and complementary expertise will lead to the identification of promising clinical candidates.***

# Specific Aims: How To Do It?

Paragraph 4. Significance and impact

- How innovative
- Expected results
- Impact

# Specific Aims: Innovation and Impact

No truly novel autophagy inhibitors have been clinically tested to date. ***Our chemistry-driven study is a high priority as it directly addresses 2 major unmet medical needs: better approaches for PH therapy and the generation of new clinically relevant autophagy inhibitors.*** (Innovation) The successful execution of this program will produce first-in-class lead compounds for preclinical development. Given the importance of autophagy to the pathogenesis of many diseases, it is expected that the new autophagy inhibitors will have broad therapeutic implications that extend far beyond our primary focus on PAH. (Impact)

# Background and Significance

Purpose:

1) To frame the problem needs to be resolved
2) To demonstrate the significance of the  project
3) To justify how you developed your hypothesis

# Background and Significance

Problems:

- Too broad and not focused,
  - Solution: only review the related materials
- Never frame the problem.
  - Solution: clearly state what the problem is
- Too many references
  - Solution: cite only critical papers
- Ignore the critical or new reports
  - Solution: cite newest and influential references

# Preliminary Studies

To prove

- your hypothesis is correct, feasible, and the work has potential impact
- you have the ability, methodology and facilities to do it

# Preliminary Studies

Problem 1: Not enough data

Solution: 1) Wait for next cycle

2) Apply for smaller grants, R21 or R03

Problem 2: Data are not solid

Solution: Don't use them

Problem 3: Showing too much data

Solution: Select best data to show.

Focus on the goals;

1 or 2 figures or tables for each aim

# Preliminary Studies

Problem 4: Data are poorly presented

Consequences:

1) Difficult to follow you;

2) Unable to analyze and present your data

Solutions:

1) Organize data in the same order as specific aims

2) Right style and size (easy to understand)

3) Clearly explain the experiments and the labels in legends

# Preliminary Studies

Further Suggestions:

- Always use clear figure legends
- Use original pictures for all copies of application if color pictures are used

# Research approach

- Does your plan flow logically from the literature review and prior studies?
- How will each hypothesis be tested?
- Do your measures capture the variables needed to test hypotheses?
- Why did you choose those measures?
- Methods and analyses must match.
- Consider organizing each aim the same way, including:
  - Rationale
  - Experimental approach
  - Anticipated results
  - Alternative approaches/pitfalls

# Outline for your experimental approach as follows

- Restate each specific aim at the beginning of each section
- Restate the hypothesis for the specific aim
- Provide a rationale for the specific aim
- Provide a detailed “plan” for the experiments
- What are the expected outcomes?
- Be sure to include alternate plans if the selected approach fails.

# Research Design and Methods

Common Mistakes:

- Too ambitious
- Descriptive
- No anticipated results
- No alternative plan
- Inappropriate methods

# Research Design and Methods

Problem 1: Too ambitious

Solutions:

1) Calculate the work amount

2) Focus on one critical issue

# Research Design and Methods

Problem 2: Descriptive  Solutions:

1) Select one important issue

2) Study the underlying mechanism

3) Delineate the issue completely

# Research Design and Methods

Problem 3: No anticipated results

Solutions:

- Describe what results you expect to get
- State the weakness of the design and methods
- List potential problems and anticipated difficulties
- Predict the impact on the whole project

# Research Design and Methods

Problem 4: No alternative plan

Solutions: Design solid backup plan

How to do it:

- Only for critical issues
- Clearly explain your alternative studies
- Use reliable and predictable design
- Don’t use risky procedures

# Research Design and Methods

- Problem 5: Inappropriate methods
- Solutions:
  - Always use cutting-edge technology
  - Clearly describe methods
  - Discuss strength and weakness of the methods
  - Plan backup methods if risky procedures are used
  - Use more than one methods for critical studies
  - Develop collaborations if you don’t have a strong background for some methods

# Research Design and Methods

## Common Mistakes in Choosing Methods

- Not using cutting-edge technology
- Misusing methods
- No details for methods
- Too much details for auxiliary methods

# Research Design and Methods

Not using cutting-edge technology

Solutions:

- ❑ Learn and use new technology as much as possible
- ❑ Never reset your goal to a lower level because of the lack of expertise and experience
- ❑ If you need some new methodologies, establish a collaboration teem, such as, invite co-investigators or consultants, or develop a sub-project

# Research Design and Methods

Misusing technology

Solutions:

- Fully understand all the methods you use
- Don’t use a method you don’t really need
- Don’t use a method solely because it is fancy
- Don’t use a method which is in controversial

# Research Design and Methods

Problem 3: No details Solutions:

For a new method

- Provide technological details, i.e., procedures
- Discuss strength and weakness of the method
- Show your experience in using this method (cite your publications)

# Research Design and Methods

Problem 4: Too much details for auxiliary methods

Solutions:

f it is a frequently used common methods, don't need details; e.g., "protein content will be determined as described by Lowry et al (1951)."

# References

Problem 1: Too many references

Solutions:

Select related, new, and influential papers to cited

Reference number should not over 100 for R01 application

Problem 2: Incorrect references

Solutions: Search the whole area and select critical papers

# References

Problem 3: Unclear format

Solutions:

List references numerical or alphabetical and clearly cite them in the text

Problem 4: Incorrect citing

Solutions: Check the list and citing carefully

# Collaboration

For collaborations, attach a letter of consent to the PI:

- From each co-PI or consultant, not from their organizations
- Letters should clearly state the willingness of participation, the collaborative work, and the expertise or methodologies or equipment provided

# Budget

Mistakes: Too large or too small

Solution:

- Understand that budget size will not influence your score
- Calculate your cost correctly
- Request in modules

# Hallmarks of an outstanding grant application

- Strong significance, important problem in public health: IMPACT is high
- High degree of novelty and innovation
- Strong track record of a well-qualified applicant; compelling publications
- Clear rationale
- Relevant, supportive preliminary data
- Clear and focused approach that provides unambiguous results
- Careful attention to details
  - Spelling, punctuation, grammar, fonts, clarity of data, error bars, spelling, etc.

# Understanding the NIH Review Process

- Evaluative Criteria:
  - Significance
  - Approach
  - Innovation
  - Investigator
  - Environment

# Grant reviewing is a subjective process

Reviewers are never wrong;
Reviewers are never right

They simply provide an assessment of material that you provide in your application

# What do the 1-9 scores mean (Priority scores)?

## The lowest scores indicate the highest level of merit

| Impact | Score | Descriptor | Additional Guidance |
|---|---|---|---|
| High | 1 | Exceptional | Exceptionally strong with essentially no weaknesses |
| | 2 | Outstanding | Extremely strong with negligible weaknesses |
| | 3 | Excellent | Very strong with only some minor weaknesses |
| Medium | 4 | Very Good | Strong but with numerous minor weaknesses |
| | 5 | Good | Strong but with at least one moderate weakness |
| | 6 | Satisfactory | Some strengths but also some moderate weaknesses |
| Low | 7 | Fair | Some strengths but with at least one major weakness |
| | 8 | Marginal | A few strengths and a few major weaknesses |
| | 9 | Poor | Very few strengths and numerous major weaknesses |

# Competition

- The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible.

Photo by Marc Soller

# Reviewers want to know

1) What is it about (research objective)?
2) How will you do it (technical approach and methodology)?
3) Can you do it (you and your facilities), and is it worth doing?
4) Are there any secondary objectives that are relevant to the agency (*e.g.,* education of students, broader impacts of research)?

# Proposal Review Criteria

1) Significance:
   - Does this study address an important problem?
   - If aims of application are achieved, how will scientific knowledge be advanced?
   - What will be the effect of these studies on concepts or methods that drive this field?

# Proposal Review Criteria

2) Approach:
   - Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
   - Does the applicant acknowledge potential problem areas and consider alternative tactics?

# Proposal Review Criteria

3) Innovation:
   - Does the project employ novel concepts, approaches, or methods?
   - Are the aims original and innovative?
   - Does the project challenge existing paradigms, develop new methodologies, or technologies?

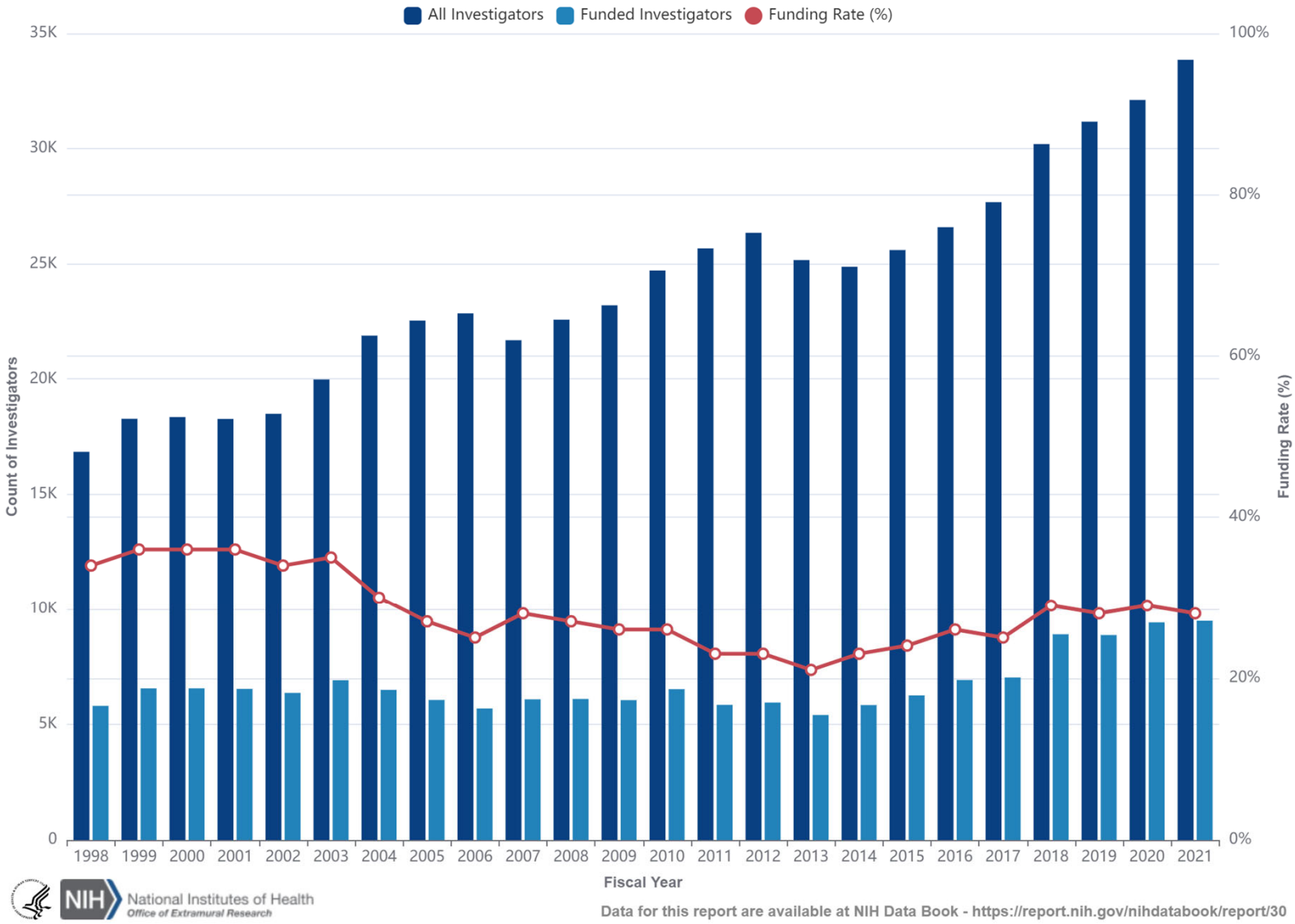
# Proposal Review Criteria

4) Investigator:
   - Is the investigator appropriately trained and well-suited to carry out this work?
   - Is the work proposed appropriate to the experience level of the PI (and other researchers, if any)?

# Proposal Review Criteria

5) Environment:
   - Does the scientific environment in which work will be done contribute to the probability of success?
   - Do proposed experiments take advantage of unique features of the environment, or employ useful collaborative arrangements?
   - Is there evidence of institutional support?

## R01-Equivalent Investigators: Number of Competing Investigators and Funding Rates




National Institutes of Health
Office of Extramural Research

Data for this report are available at NIH Data Book - https://report.nih.gov/nihdatabook/report/30

# If not funded, try again!

- You are in good company
- Know your options
- Get advice, regroup
- Contact your Program Officer

# Revising and resubmitting

- Opportunity to improve the application
- Acknowledge and accept the help of reviewers
- Write clear introduction section
- Address criticisms thoroughly
- Respond constructively and respectfully

# Resubmission
# (Chance enhanced by >50%)

| Fiscal Year | Competing Status (Type) and Submission Number[2] | R01-EQUIVALENT GRANTS[4] | | | |
|---|---|---|---|---|---|
| | | Number of Applications Reviewed | Number of Applications Awarded | Success Rate[5] | Total Funding[6] |
| 2020 | New First Submission (A0) | 24,948 | 3,789 | 15.2% | $2,571,229,221 |
| 2020 | New with Resubmissions (A1) | 8,222 | 2,636 | 32.1% | $1,556,646,621 |
| 2020 | Continuations (A0) | 1,906 | 788 | 41.3% | $465,791,723 |
| 2020 | Continuations with Resubmissions (A1) | 1,085 | 505 | 46.5% | $268,639,045 |
| 2020 | Supplements | 89 | 49 | 55.1% | $31,341,036 |
| **2020** | **FY Total** | **36,250** | **7,767** | **21.4%** | **$4,893,647,646** |

# Writing a Successful NIH Grant

## Elements of Grant Success

Good Ideas

Good Reviewers

Good Timing

Good Luck

Good Presentations

Good Grantsmanship

# Thank You for Your Attention!

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