Grantsmanship for the Young Investigator—The lab you Never took…

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Disclosures/Conflicts of Interest

I have no conflicts of interest to disclose…

Outline of Presentation

We Will Cover the Following Topics:
• General Concepts & Guidelines
• Picking the Right Mechanism for You
• How Long Will it Take?
• Writing Tips
• The Scoring System
When to start thinking about Grant Writing

- **Now!**
  - Regardless of your status, this is the time to get started.
  - The time will FLY by.
  - You need to begin to plan for the next phase of your research career while in the middle of your current position.

When to start thinking about Grant Writing

- The process takes 9-10 months from submission to funding (at the minimum).
- Most applications are not funded on the first round.
- Plan for a resubmission in your career development timeline.
General Concepts & Guidelines

The Four Points of the Compass

Significance

Scope

Impact

Feasibility

General Concepts & Guidelines

Significance

• Make sure that you have identified an important issue that either is novel, addresses a gap in the literature or is likely to lead to a new direction in prevention or treatment
• The literature review should lead the reviewer to the same conclusion—that there is a need for this research and that you are the person to lead the project.

Feasibility

• Convince the reviewers that you can do the proposed work.
• Work this into the Approach (Pilot Data) as well as the Institutional Environment & Resources.
• Budget must match the scope of the work proposed.
General Concepts & Guidelines

Scope

- **Less** is more.
- Overestimate time and underestimate work.
- Keep research focus narrow, avoid overly ambitious applications.
- Research generally takes longer than expected.

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IMPACT

**Impact** (noun)

1. the striking of one thing against another; forceful contact; collision: The impact of the colliding cars broke the windshield.
2. an impinging: the impact of light on the eye.
3. influence; effect: the impact of Einstein on modern physics.
4. an impacting; forcible impinging: the tremendous impact of the shot.
5. the force exerted by a new idea, concept, technology, or ideology: the impact of the Industrial Revolution.

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General Concepts & Guidelines

Percent Effort (calendar months)

- There is no limit on R01 (K’s and F’s require a minimum level of effort by the PI)
- For new R21/R01 investigators, recommend that you calculate the scope of the work and adjust accordingly.
- Be careful not to spread yourself too thin---consider your other responsibilities!
General Concepts & Guidelines

Multiple PI/PD

• Most important factor is if the science dictates the need for two Pis.
• Typically for collaborative, multidisciplinary research where both contribute critical expertise to conduct at least one of the Specific Aims.
• Can include a junior plus more senior PI.

General Concepts & Guidelines

Multiple PI/PD--some cautions!

• Once you apply for and are awarded a Multiple PI/PD grant, you are no longer an Early-Stage Investigator (ESI).
• ESI gain some advantages such as higher pay lines, more lenient reviews, less expectations of preliminary data, no reviewed along side more experienced PI, more opportunities for bridge funding.

NIDA Training Sites

http://www.drugabuse.gov/funding/research-training/extramural-research-training-career-development/research-training-sites-2
Picking the Right Grant Mechanism for You

Picking the Right Application for You

Training (K Awards) vs Research (R)-Type

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<td>Are you ready to compete for independent grants?</td>
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<td>No</td>
</tr>
<tr>
<td>Do you have pilot data?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Considered &quot;high risk&quot;, but high impact?</td>
<td>Yes</td>
<td>No</td>
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- Yes: Apply for R01 Grant
- No: Apply for K Award
- No: Apply for R21 Grant
- Yes: Apply for R03 Type Grant

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Picking the Right Application for You

Requests for Applications (RFA) and Funding Opportunity Announcements (FOA)
- Do not forget to check these out to see if there is a special call for proposals in your field.
- And the NIH RePORTER to see what is being funded now…

Choosing Between R21 and R03

**R03**
- Pilot/feasibility studies
- Secondary analyses
- Small, self-contained studies
- Develop methods
- No preliminary data

**R21**
- New exploratory or development in early stages
- May be high risk, but may lead to key breakthrough
- Supports development of novel techniques, agents, methods, model or applications
- Breaks new ground
- No preliminary data*

* in your dreams!

Picking the Right Path for You

Paths to that first R01…

[Diagram showing various paths to R01 from different awards and positions]

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Pathways to a Research Career

Training mechanisms—Quick Summary

**F31** Pre-doctoral—Provides salary support and limited research funds during the various phases of graduate school, leading to a doctorate degree.

**F30** Pre-doctoral—Similar to F31 except that clinical training is incorporated as candidate works toward an M.D./Ph.D. degree.

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Pathways to a Research Career

Training mechanisms—Quick Summary

**F32** Postdoctoral—Provides stipend and limited research funds during training in a relatively new direction for the candidate.

**T32** Institutional Training Programs—Provides stipends to an institution to train pre and postdoctoral fellows.

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Pathways to a Research Career

Training mechanisms—Quick Summary

**K01**—For all research scientists in biomedical, behavioral or clinical fields. Mostly a mechanism used by Ph.D.

**K08**—For clinical (physician) research scientists in non patient-related research (i.e., basic science).

**K23**—For clinical (physician or clinical psychologists) research scientists in patient-related research.

**K25**—To foster interdisciplinary collaboration for scientists with engineering, mathematical or statistical backgrounds.
Training mechanisms – Quick Summary

K22—Facilitates transition from the mentored stage to independent stage; often used by postdoctoral fellows to move to assistant professor.

K99/R00—Pathway to Independence to provide Ph.D. or M.D. up to 5 years of support in 2 phases (mentoring and then independent grant support).

START

Science Track Award for Research Transition

• I/START for Imaging ($150K/year for 1 year)
• B/START for Behavior ($50K/year for 1 year)
• A/START for AIDS ($100K/year for up to 2 years)

These are Small Grants (R03) and are non-renewable. Preliminary Data are not required. You can have one of these while also having a K award (just cannot take salary until last two years of the K)

Review Criteria—K Applications

• Candidate
• Career Development Plan/Career Goals and Objectives/Plan to Provide Mentoring
• Research Plan
• Mentor[s], Consultant[s], Collaborator[s]
• Environment and Institutional Commitment to the Candidate
Review Criteria—K Applications

Hot “TIP”: Reviewers are asked to identify the major STRENGTHS and WEAKNESSES of your proposal—USE those words in your application to help guide the reviewer!

How Long Will It Take?

New Investigators prepare for first R01
• Plan on 2-3 months (human subjects and any contract with other institution will take longer).
• Can then take 7-18 months after receipt at NIH before an award is made!
• If need to resubmit, can take 28 months for a notice of grant award (NGA).
How Long Will It Take? About 8-10 weeks

All Sections are not created equal

- Brainstorm an Idea
- Review the Literature
- Organize Preliminary Studies
- Write the Preliminary Studies

1-2 weeks 2-3 weeks

- Rough out 5-7 Specific Aims
- Pare down to 3 Specific Aims
- Reflect on proposed approach

- Write
- Approach
- Review the FLOW of Aims -> Preliminary Studies -> Approach

- Write the Background/Significance
- Write the Abstract
- Write the Title

3 weeks 3-4 days 1 week 1-2 days

- Review
- Pare down to 3 Specific Aims

- Reflect
- on proposed approach

- Budget
- Get some major help from your mentor on this

- Need to have accurate estimates of personnel time and cost of items

- Modular Budgets are $25K blocks

- Plan to spend 2-3 weeks developing a budget

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How Long Will It Take?

How to Craft Realistic Budgets—K Awards
- Primary funds are for Candidate’s salary.
- Research-related funds of $50K allowed.
- Review your power analysis and identify the costs associated with running the study (subject costs are usually highest):
  - payments and lab studies for clinical
  - animal purchase/housing for preclinical

How Long Will It Take?

How to Craft Realistic Budgets—K Awards
- Consider training related activities (travel to scientific meetings, course tuitions, books, etc.)
- Consider research related activities (supplies, instruments, small equipment, computer, etc.)
- Consider Support staff (research assistants, consultants, professional services).
How to Craft Realistic Budgets—K Awards
- Make sure that the budget items match the timeline highlighted in the Training Plan.
- Remember that startup costs may exceed maintenance costs.

While details of the budget justification are not necessary for the submission—you should do this so that you know if it can be done within the scope of the award!

How Long Will It Take?

How to Craft Realistic Budgets—R Types
- R21 and R03 are capped, so need to pay attention to the restrictions.
- R01s are capped at $500K.
- Regardless of the nature of the grant application—*your Personnel Costs will consume the largest percentage of your budget, so do those FIRST!*
How Long Will It Take?

How to Craft Realistic Budgets—R Types

- Identify costs that are necessary and reasonable.
- Are the costs justified based on the aims?
- If you are off, then the reviewers may think that you do not understand the scope of the work being proposed.

How Long Will It Take?

How to Craft Realistic Budgets—R Types

- Balancing the % effort of the PI and support staff is the most challenging task.
- Reviewers will look at the FTE and determine if that matches the budget.
- A new PI should have at least 35% effort budgeted, but probably no more than 50%.
- These are not written in concrete…

How Long Will It Take?

Detailed Budgets

- Must itemize and justify all items.
- Need detailed FTE for all staff.
- Separate other expenses by category.
- Used for all grants over $250K.
- Equipment is any one item that exceeds $5K.
- Include itemized details of all planned travel.
- Other costs listed by category (materials/supplies, animal costs, human subject costs, Consultants, etc.)
How Long Will It Take?

Modular Budgets
- Lump sums in $25K intervals.
- Details are not needed.
- Only for grants up to $250K.
- Streamlines the budget process.
- I recommend that you make up a detailed budget for your own use to make sure that the number of requested modules is sufficient.

Getting Prepared to Actually Write an NIH Grant Application

Preparing to Write NIH Grants
10 Steps to Writing Successful Applications
1. Review your interests and career objectives
2. Discover your inner niche
3. Write out 5-7 Specific Aims (pare to 3)
4. Identify the target Study Section for review
5. Access your Specific Aims considering a “reviewer’s perspective”
6. Outline the actual experiments
7. Identify your collaborators/support team
8. Identify and refine your resources
9. Craft your Budget to match the scope
10. Write with enthusiasm that will excite the reviewers to support your proposal

Preparation to Write NIH Grants
For Post F or K Awardees preparing for a R01
- Remember why you were awarded a F or K in the first place—to protect time so that you can gain valuable experience to prepare you for a career as an independent scientist.
- If you complete your training without publishing the results, then the reviewers’ enthusiasm for your R01 application will be significantly “dampened”.

- If it has not been published, then you did not do it!
- The new Biosketch format allows reviewers to access your entire research portfolio.
- If you have a lot of abstracts that have not resulted in papers then you may be perceived as being unfocused or cannot finish a project.
- Alternatively, if you convert abstracts to papers, then you show good promise.
• In the body of the applications avoid using the words “in preparation” -- *everything* is in preparation.
• Awards involving clinical or long-term studies need to be creative to ensure productivity along the way.
• Identify smaller components that make contributions to the field and warrant publication.

• One way to build a career is to collaborate on the grants of others — these publications count too!
• Use early awards to travel to other labs and meet with potential colleagues, both within and outside of your institution.

• Another good reason to publish is that you can (and should) use data collected during your K awards as pilot data/preliminary studies for your R-type application.
• Anticipate the need to resubmit, so do not wait until the 5th year of your K to submit your first application (*end of 3rd year or beginning of 4th year is a good time*).
Preparing to Write NIH Grants

What should you write about?

• Focused sequence of studies that build on one another…
• Planned studies that:
  • have strong theoretical basis
  • are hypothesis-driven
  • provide useful info regardless of outcome
  • info from one study sets stage for others
  • have contingency plans if they do not work

What should you write about?

Questions:

• what is not known about a topic?
• what new information will be learned?
• why is it important?
• how will it be applied?
• will your project fill any gaps in the literature?

Review the Institute’s website for mission statements, look for specific FOAs and SPEAK TO NIH PROGRAM STAFF!

Focus:

• Your research focus should be narrow, not broad-based.
• Begin to think about a specific area of research within a field.
• Avoid making grandiose statements about the direction of the field and how your proposal will change it all…
Preparation to Write NIH Grants

Focus:
• Avoid the appearance of a “fishing expedition”.
• To do this, try to limit your proposal to 3 primary hypotheses.
• Avoid the temptation to get around this by adding multiple “secondary hypotheses”.

Grants Administration Processing

Prior to Submission
• Discussions with collaborators, mentors, program staff—they can help decide to which IRG the application should be submitted.
• Use era Commons to track your submission and ultimate assignment (it may not end up where you planned!)

Grants Administration Processing

After Submission but before review
• Check era Commons for updates and changes in assignment.
• You CAN request a reassignment, but needs to be done soon in the process (will need to contact the SRO of both committees).
Writing Tips

**Title:** The title is the FIRST thing that a reviewer will see so be creative and grab their interest.

**Summary:** This must give an overview of all key elements in the proposal. It is a miniature version of your application and should note the importance, background and goals of the research. It is archived in NIH databases separate from your proposal (RePORTER).

Writing Tips

**Summary:** Also consider highlighting the Significance and Impact of your research in this section as many reviewers will not be specialists and so will likely only read a few sections.
**Specific Aims:** Summary of proposal and goals. Try to keep to 1 page for this. State the hypotheses to be tested and how the various phases of the study fit together, especially if there are both short- and long-term goals. If you are responding to an RFA, then state the mechanism and how your application fits. Do not fill up with literature citations and avoid redundancy with the significance.

**Background & Significance:** A succinct, scholarly and persuasive dialogue that ends with why the work should be done and the impact that it will have. Point out the theoretical importance of your proposed research plan and end with how your research will move the field forward.

Review only most important literature; do not cite every paper written on the topic!

**Preliminary Studies:** Blend into the application within the Approach section!! Present real data (in graphic or tabular format) that describes the relevance to your application with the aim of showing that you have the required expertise to carry out the proposed studies. This is where PILOT DATA becomes very important as it demonstrates the feasibility of the study. When possible, try to use the same instrumentation that you propose to use in the application.
Writing Tips

Connect with your mentors, collaborators, consultants *early* in the process.

If you need letters of recommendation, make sure you give them plenty of time (at least 6 weeks).

If the sample size will affect your budget, make sure you consult with your statistician…

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Writing Tips

Statisticians are worth their weight in **GOLD**…

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Writing Tips

**Preliminary Studies:** Pilot data can be a few subjects, and if used properly, can convince the reviewers that the proposed studies are *feasible*. These should include your prior research findings, but other relevant experience or studies conducted by your co-investigators suffices as well.

Blend these within your Approach Section.
Pilot Data: If you cannot read the graph, then there is no reason to put it in your application.

Lack of Pilot Data [in an R01 application] is a fatal flaw, especially for young investigators.

IF you do not have any Pilot Data, then consider using a different mechanism such as a R03, R21, I/START, B/START (types of R03 applications).

Approach:
Introduction-why do the experiment in this particular way?
Hypotheses-be clear and concise
Subjects-describe in detail
Design-use diagrams when possible
Procedures-explain variations, cite standards
It is also important to explain why you chose a particular method or strategy if there are competing options.
Writing Tips

Approach:
- In my experience, this score is the one that most accurately reflects the reviewer’s overall sense of the impact.
- It is also the one score that tends to be the worse one in an otherwise innovative and significant project from a competent team.

Writing Tips

Approach:
Data analysis—include statistical plan as well as a power analyses to justify the sample size.
Summary—restate the importance of experiment and future directions of the research should the experiments be successful.
Address potential problems and solutions (if you have any) AND offer contingency plans or alternatives.

Writing Tips

- **Power of suggestion:** highlight the strengths of your proposal wherever you can. Use the word “strength” in your text.
- **Humility:** it is far better to identify weaknesses and explain how you will deal with them than it is to “hope” that the reviewer will not find them—they usually do!
Writing Tips

• Start with an Outline! Remember these?
• Write a topic sentence for each main point 
  First one in paragraph & supported
• Make only one major point per paragraph!
  Makes it easier for reviewers to follow your logic and less likely to miss an important point (because it was hidden in the paragraph)
• KISS— Keep It Short & Simple
• Use transitions to identify key relationships 
  furthermore, in addition, in contrast, etc.

Writing Tips

• Use short sentences with a basic structure 
  subject • verb • object
  avoid introductory phrases that are > 6 words long
  keep sentences to 20 words or less
• Keep related ideas together
• Use strong active voice
  ”we developed a novel cell line to test the enzyme” not
  ”a novel cell line to test the enzyme was developed by us to”
• Use verbs instead of abstract nouns
  ”creating the assay leads to…” not ”the process of the creation of the assay leads to…”

Writing Tips

• Divide your application into clear sections.
  use headers when appropriate
  huge blocks of uninterrupted text are difficult to read!
• Use graphs and tables effectively.
  they help break it up but also serve to convey the idea
  make sure the legends match and explain the graph
• Edit and then prune red your application.
The Scoring System

The New Scoring System

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**Non-numeric Score Options:**
- AB = Not Recommended for Further Consideration
- DP = Deferred
- NR = Abstention
- CF = Conflict
- PF = Not Present
- ND = Not Discussed

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Major Weakness:** A weakness that severely limits impact

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research fields(s) involved.

Evaluate Overall Impact:
Consider the criteria: scientific significance, investigator(s) experience and training, environment of the research project, and other auxiliary factors.

Overall Impact Scores:
- 2: Strong
- 3: Medium
- 4: Low

Example:
- Application may be addressing a problem of major importance. Some weaknesses confined to specific aspects of the research project.
- Application does not have any major weaknesses and is likely to be a valuable addition to the field.

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A note about Unscored…

Study Section A

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Study Section B

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Parting [deep] Thoughts

If planning to submit a 3 year application…

Make a 5 year plan, but submit for 3 years of work

If planning to submit a 5 year application…

Make a 7 year plan, but submit for 5 years of work

If planning to submit a 5 year K Application…

Make sure that you have something left over for the R21 or R01 application that will be submitted in year 4!

Parting [deep] Thoughts

Highlight your Expertise throughout the application.

Make sure the reviewers know you can do the work

If there are alternative approaches, mention the others and then defend your choice.

It is okay to disagree, but justify your decisions

Always provide contingency plans.

If an experiment does not go as planned, the reviewers want to know that you have alternative approaches to solving the problem or studying the phenomenon.
Parting [deep] Thoughts

Make sure that all Table and Figure numbers line up, have the correct legends, and axes are labeled. *It is just plain sloppy if they do not.*

**Identify potential pitfalls or anticipated problems**

*It is better if you confess them up front instead of the Reviewer using them as “weaknesses” to your proposal.*

**Check all of your facts**

*Recheck them…*

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Do not simply propose something that you think has a good shot at getting funded because an RFA or FOA was released. There is nothing worse than working on a project (for 3-5 YEARS) that does not truly excite you. Above all, make sure that you will ENJOY conducting the research that you propose…

Getting to this point is more than half of the battle.