

Guide to Proposal Writing

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Introduction

This guide to proposal writing was originally developed years ago to help my PhD students write their dissertation proposals and early career faculty write their grant proposals. It has seen many iterations since. The guide should be considered a work in progress, as I am continue to learn new proposal writing strategies. I appreciate the comments I've received from folks along the way, including Vivian Go, Brad Gaynes, and my wife, Clara Lee.

The guide is intended for use with both NIH-style grants and doctoral dissertation proposals. For their dissertation proposals, I encourage my students to use an NIH-style format. Students may be required to include expanded sections, such as a longer background. Adapt as needed. Also, note that this guide can be used for other types of grants—labels might change but the content doesn't.

This guide is directed to people doing public health, clinical, health services, and similar research. The tips will be helpful for basic scientists, but some details will differ—particularly about specific structure.

Proposal writing is an acquired skill. It gets easier with practice. Here is one critical piece of advice that I will attribute to Gene Orringer: **“I've never heard of an NIH grant getting funded when it wasn't submitted.”** The corollary is that an unsubmitted grant proposal is always not discussed...every time. So, clearly, one key to proposal writing is to do it... and keep doing it.

Keep in mind that NIH grant proposals are rarely critiqued for being too focused. The single biggest issue with many grant proposals is that they are overly ambitious.

If you're a trainee writing your first proposal or a graduate student writing your dissertation proposal, use the writing process as an opportunity to get feedback from experienced researchers. Your goal is to learn. Feedback from experienced investigators is helpful—at least most of the time. Try to worry less about what people will think of you and focus instead on what you can learn from this process.

You may share the guide with anyone you wish. I only ask that you attribute the original source.

Good luck.

GENERAL TIPS

1. Assume that the reader is a) tired; b) generally disinterested; c) grumpy and d) has difficulty concentrating.
2. Assume that the reader does not have any reason to be supportive of your grant/proposal over someone else's. Your goal is to get the reviewer to become your advocate.
3. Given 1 and 2, you have to SELL your idea in a CLEAR, CONCISE, and COHERENT proposal. Keep

in mind that clear and concise go together.

4. Don't make the reader THINK. If they have to think to figure out what you are saying, you have not communicated effectively. Simplicity and clarity.
5. Simple words are a tool for clarity. Aim to write simply.
6. Tell a story...Tell the who (study population), what (what will be studied), where (where it will be done), why (why it needs to be done), and how (the methods you will use). Make a convincing argument for a) why your study is important and b) why your approach will address the important question appropriately. Everything in the story should flow logically.
7. The research question is everything. A strong question/good idea is the key to success. Spend a lot of time refining your question.
8. In planning your research, be sure to look for ongoing studies that are addressing your proposed research question. Good resources are NIH Reporter (<https://reporter.nih.gov/>) and ClinicalTrials.gov (<https://clinicaltrials.gov/>)
9. Remember that it is hard to answer even simple questions well. Don't overcomplicate your research questions or your design. I do that all the time, and then I scale back. Like your writing, simplify your questions.
10. Your proposal will be reviewed by three reviewers on an NIH study section (and 4-5 committee members for a dissertation proposal.) Write to those reviewers.
11. Your goal is to convince the reviewer to become your advocate. Your mission is to excite them. Try to grab them with your interesting idea—your research question and your approach. Excited reviewers will convince the other members of the study section that your great idea is great. If you don't create that spark, it will be hard to get the proposal funded. To get that spark, you must be excited first.
12. Make the long-term impact of your study clear. Identify how your study will affect human health in the future or move your field of science forward in a significant way. Spell it out for the reviewer. Don't make them read between the lines to figure out why it is important.
13. Assume the reviewer is intelligent but may not be an expert in your specific field.
14. The reviewers will assess your proposal first by reading the Specific Aims and possibly, the Project Summary. That initial impression has a huge impact on how they view the rest of the proposal. They will read the rest of the grant seeking justification from their initial impression of the Aims page. If you win them over on the Aims page, you have a great chance. If you lose them on the Aims page, you have lost them for the whole proposal and you won't win them back. The Aims page is critical.
15. For NIH, the 3 reviewers will read the whole grant. The rest of the study section will **ONLY** look at the Aims (and maybe, the Project Summary, and if you're really lucky, a quick flip through the rest of the proposal.) [Note: hopefully, a dissertation committee will read the whole thing, but not necessarily!!!]
16. In writing the proposal, a huge amount of time will be spent on getting the Aims page just right. It can take a lot of discussion and revision to get the Aims page right. Give the Aims the time that it needs. If you skimp on the Aims, the proposal will be weaker in the end. Once you have your Aims, the rest of the grant will follow relatively easily. That said, you may need to do some Aims revisions later when you discover a problem in the process of writing the Approach.
17. Make the impact and significance clear on the Aims page. Highlight the innovation if your project is

truly innovative. This page is your first and best chance to sell the reviewer on the idea.

18. Make it clear why you and your team are the best team to conduct the study. Promote yourselves. If it fits, include a statement about your team in the Aims.
19. Don't be afraid to repeat critical aspects of your study. But repeat critical aspects only. Don't repeat less important elements of the study.
20. Use bold or italics to highlight critical points that you don't want the reader to miss. But do it sparingly. Too much use of bold or italics reduces its effect—and more importantly, may annoy the reviewer.
21. Minimize the use of underlining. Use bold or italics instead. Most professional typographers do not use underlining as it partially obscures letters that go below the line of text. I was once told “underlining should never be used. It was important on a typewriter when you had no other way to emphasize something. That’s not true anymore.” It’s not a hard and fast rule but some readers may be irritated by underlining.
22. When giving a proposal out for review, even internally, be sure that it has page numbers. It makes providing comments much, much easier.
23. Section numbers help. Typically, specific aims will be A, significance B, innovation C, and approach D. Within D, you may use subsections (D.1, D.2, etc.) I sometimes go even further D.1.a etc. but most of the time, I do not.
24. Leave white space. Do not make the text too dense.
25. Do not try to cheat. If the grant format specifies single spacing (usually Arial 11 pt font), use single spacing (not 0.9 spacing).
26. Use figures & tables to break up the text. Tables also allow you to convey a lot of information in a concise format – and smaller font.
27. Do not copy large chunks of text, plunk the text in a table, shrink the font, and call it a table. That’s not a table. You know what a table is...so do reviewers.
28. The NIH expectations for specific review criteria can be reviewed by looking at the parent program announcements. For example, the parent announcement for R01s is currently here: <https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html> Know the review criteria for your specific type of proposal. The criteria will be in a PA for your specific type of grant or in the RFA description.
29. NIH grant proposals are scored based on overall impact. For research grants, the core review criteria in determining overall impact include significance, investigators, innovation, approach, and environment. F-awards and K-awards have slightly different categories. Your job is to make sure the reviewer fully understands how your proposal will address each of these core areas in the most compelling way possible.
30. If you are responding to an RFA, examine the review criteria carefully. Copy them from the document describing the RFA and use that as a guide as you write. Make sure that your application explicitly addresses each criterion. Whenever possible, highlight each specific point in the application itself.
31. Overall impact: A reviewer’s impression of the potential impact of your proposed work is a function of two things: the importance (significance) of the work and the likelihood of success (whether the approach will work).

Impact = function(importance, likelihood of success)

32. The reviewers provide scores for each core criterion on a scale of 1 (excellent) to 9 (poor). They also provide an overall impact score on the same scale. After discussion, all study section members provide an overall impact score. Those scores are averaged and multiplied by 10 to give the final score that you will receive, which ranges from 10 (perfect) to 9 (poor). Since ~50% of proposals are typically not discussed, any score is a good score.
33. Most grants will also be given a percentile score. That score normalizes the raw score with the historical scores from a particular study section. The percentile score will determine funding. Proposals submitted through an RFA will not have percentile scores.
34. Although innovation is a core criterion for many types of grants, it is uncommon for lack of innovation to be a major concern if the idea and approach are otherwise strong. Strong innovation will often help your score but lack of innovation will usually not hurt it because the other sections tend to outweigh it.
35. Facilities and Other Resources: Use your Facilities and Other Resources section to your advantage. Make sure that the resources available to your team come through. Make unique aspects of your environment clear. But be careful about putting any critical information in this section. Some (most?) reviewers do not read it in depth.
36. A good way to become a better grant writer is to read grants...lots of them. Ask your mentors for examples; ask your friends for examples; check out the publicly available ones on the NIH website (although those are often basic science examples).
37. Write when you are fresh—during your most productive times. Use less productive times to do other tasks—make tables, create figures, look up references.
38. Beware of plagiarism. NIH uses iThenticate to check each proposal for plagiarized text, including text obtained from websites, other grants, and papers. Be sure to include appropriate citations, including of your own work.
39. This guide does not address many other elements of a complete proposal (human subjects, biosketch, training elements in F/K awards, etc.) Be sure to give these elements sufficient time.
40. Remember the story – make it clear, concise, coherent, and compelling.

TITLE

1. Use your title to convey meaning. When possible, it should provide some insight into the potential importance or impact of your work.
2. The title is limited to 200 characters.
3. Your title should emphasize the payoff – the product of your research.¹

PROJECT SUMMARY (aka Abstract)

1. Every full proposal (grant) has a Project Summary, which is limited to 30 lines of text.
2. The abstract is one of two things that the entire study section will likely read (the other is the Specific Aims), so it must be strong.
3. The abstract is the principal thing, along with a cover letter/assignment form, that is used for assignment to study section. Be sure to include the appropriate key words in the abstract to ensure

that the assignment is appropriate.

4. Highlight your work's significance in the abstract. Add the innovation if your work is truly innovative.
5. Include your Aims statements.
6. Provide a brief overview of your approach.
7. Conclude with a statement of the impact.
8. Avoid using identical language in the abstract and Aims (except for the Aims statements, which must be word for word.) Think how annoying it would be if you had just read the Aims and start reading the abstract and the exact same wording is used.
9. The Project Summary often gets pushed toward the end of the writing process. Given its importance, try to draft it early. A good time is when the Specific Aims are finalized. Then you have the elements you need for a good Project Summary.

SPECIFIC AIMS

1. A note on terminology. For NIH grants, the Specific Aims page is 1 page long. It usually has introductory text and statements of the Aims. I use the term "Specific Aims" or "Aims" to refer to the Specific Aims page and the term "Aims statements" to refer to the short descriptions of the study objectives (e.g. "Assess the effectiveness of a brief alcohol intervention on PrEP uptake").
2. The question is everything. State your research question, hypotheses, and aims as clearly and concisely as possible. Spend an inordinate amount of time on the Aims (and Project Summary). The Project Summary and Aims are the first thing that a reader looks at. From them, the reader should have a very clear idea of what you're planning to do and why it is important in the "big picture." It is hugely important to sell your idea and its importance in the initial introductory portion of the Aims.
3. In drafting the Aims page, don't succumb to perfection paralysis. Feel free to draft long, then edit. Or "vomit on the page" and then edit. Editing is the process that will make your Aims page sing. Be patient with that process.
4. Every word on the Aims page is gold. Every word should serve a meaningful purpose, contributing to your description of your proposed work. If a sentence isn't relevant to your argument, delete it.
5. The structure of the Aims should be 3 - 4 introductory paragraphs of the most pertinent background, followed by a numbered list of aims. Under each Aims statement, you *may* include a subsection of the pertinent hypothesis and a very brief overview of how you will address the aim. When the reader is done with the Aims, they should have a pretty good idea of what you're planning to do, how you'll do it, and why it is important.
6. The paper test: If you cover the Aims statements at the bottom of the page with a piece of paper and read the introductory paragraphs, the reader should be able to state, reasonably precisely, what the Aims statements say because you led them so clearly to that point.
7. The Specific Aims should fit on 1 page.
8. Think of the introduction paragraphs as a funnel (Figure 1).



Figure 1: The introduction to the Specific Aims as a funnel. Start broadly, identify the gap, and move to your plan.

9. Generally, begin your Aims with a broad description of the significance of the problem you are addressing. Numbers are often used, such as the prevalence or incidence of a condition. But be sure that the numbers have enough context to be interpretable. Keep the statement of the importance/significance of the problem succinct.
10. Think of the second paragraph as the gap paragraph. This paragraph may require two or even three paragraphs. Less commonly, the gap may be incorporated into the first or third paragraph. Highlight the key gaps that must be addressed. Make it clear that the gap is big and meaningful, and that this research will have an important impact.
11. Your final introductory paragraph will be a brief description of what you will be doing...your plan.
12. Highlight the significance on the Aims page.
13. If your innovation is a strength, highlight it on the Aims page. But if it isn't a true strength, don't bother. You only want to bring the best to the Aims.
14. In getting started with writing the Aims page, draft an outline with the key points you want to make. What is the key problem you're trying to address? What are the gaps in our knowledge about that problem? How will your work plug that gap?
15. You should (almost) **always** state a hypothesis. The hypothesis may take one of two general forms. It may be a **central** or **overarching hypothesis** that underlies the entire project. This central hypothesis will be incorporated into the text preceding the Aims, usually in the final paragraph. Alternatively, you may choose to have **specific hypotheses** for each aim. If this is the case, then you will list each hypothesis after each aim.
16. If you state a central hypothesis, it should be set off in bold and/or italics. It should be easy to find. It should derive rationally from the preceding text. And it should address the entire study (broadly).
17. Limit the number of hypotheses. You should not have more than 2 hypotheses for each aim. One is preferable.
18. A hypothesis should be testable and falsifiable. It should also be clear and specific. For a single aim, the hypothesis should be directional, rather than just suggesting association. For example, the hypothesis "X will be associated with Y" is weak. The hypothesis should not be stated in statistical terms as a "null" or "alternative" hypothesis.
19. Beware of hypotheses that suggest no difference. If the hypothesis is that groups will be similar, you must plan an analysis that uses non-inferiority or equivalence testing.
20. In most cases, an aim that is purely descriptive does not need a hypothesis. But you can have one if it strengthens the aim. If you do, it should capture the descriptive nature of the aim.
21. Hypotheses for pilot studies (i.e. in K awards or R34) should fit the nature of the study and not be about effectiveness. Testing effectiveness should not be the goal in a pilot study. Instead, the goal is testing aspects like feasibility, acceptability, recruitment, retention, study procedures, etc. If you have a hypothesis for a pilot study, it should fit these outcomes.
22. The structure of the aims should meet your project's specific needs. No single, correct formula can guide you to a perfect Specific Aims. Tailor the Aims structure to your story and your approach. You can conceptualize the page with four general outlines, shown in the table. Modify as needed.

Option 1	Option 2	Option 3	Option 4
Para 1: Broad overview setting the stage/describing the problem	Para 1: Broad overview setting the stage/describing the problem	Para 1: Broad overview setting the stage/describing the problem	Para 1: Broad overview setting the stage/describing the problem
Para 2: Specific issue(s) to be addressed with the gap identified. May need >1 paragraph	Para 2: Specific issue(s) to be addressed with the gap identified. May need >1 paragraph	Para 2: Specific issue(s) to be addressed with the gap identified. May need >1 paragraph	Para 2: Specific issue(s) to be addressed with the gap identified. May need >1 paragraph
Para 3: General objectives of/plan for of your study	Para 3: General objectives of/plan for of your study with central hypothesis	Para 3: General objectives of/plan for of your study with central hypothesis	Para 3: General objectives of/plan for of your study with central hypothesis
	Overview (Overall study)		
Aim 1 statement	Aim 1 statement	Aim 1 statement	Aim 1 statement
<i>Hypothesis:</i>			Overview: for Aim 1
Overview: for Aim 1			
Aim 2 statement	Aim 2 statement	Aim 2 statement	Aim 2 statement
<i>Hypothesis:</i>			Overview: for Aim 2
Overview: for Aim 2			
Aim 3 statement	Aim 3 statement	Aim 3 statement	Aim 3 statement
<i>Hypothesis:</i>			Overview: for Aim 3
Overview: for Aim 3			
		Overview (Overall study)	
Impact statement	Impact statement	Impact statement	Impact statement

23. Note that you can always extend these options further. For example, Options 2 and 3 could be used with hypotheses for each aim rather than a central hypothesis.
24. Whether you need the overview for each aim depends largely on the type of study you are proposing. If everything will be done in one study population, you can describe that in your final introductory paragraph or after the Aims statements, rather than a separate overview for each aim. Do NOT give lots of detail in the overview. The purpose is to give a brief description to show that you know what you're doing and the approach makes sense. For example, the analytical methods used will not usually be needed, unless the methods are a particular focus of the proposal.
25. Include your outcomes for each aim, or at least for the overall study. Identify the primary outcome and if space allows include the secondary outcomes.
26. Include the sample size in the overview.
27. Conclude the Aims page (or your introductory section) with a paragraph that highlights the innovation of your research and the expected impact of the research on the field.
28. Know the style of writing Aims for your research area. They may differ. Some disciplines have a first aim that is more procedural ("To recruit a cohort of patients..."). In basic science, the Aims often build on one another with the first and second aim building to the most important third aim. In interventions, the first aim is often the most important, with secondary analyses or exploratory analyses as second and third aims.
29. At the end of the final paragraph before the Aims statements, include a final sentence that says: "Our Specific Aims are:" or if you prefer, "Our Specific Aims are to:" In the first version, each Aims statement will be with an infinitive, such as "To examine...". In the second version, each Aims statement will begin with just the verb, such as "Examine..."

30. Use strong, meaningful verbs for your Aims statements. Common ones that I use include assess, compare, explore, and characterize. In pilot studies, you might have verbs such as adapt or develop; I don't use pilot as a verb, as that has a different meaning (i.e. to fly a plane or steer a boat).
31. Most proposals include 3 aims. That's not a rule though. You can have 2 or 4, or possibly even 1. I don't recommend having more than 4, though.
32. Beware of dependent aims. If Aim 3 requires Aim 1 or Aim 2 to be successful, the reviewers will be critical. It would mean that the project would be dead in the water in the middle of the grant period. Be sure that each aim can be completed, even if one of the earlier aims doesn't work.
33. I, personally, don't like sub-aims. They are more common in basic science. I think that you can get your point across with a well-written, single aims statement rather than needing sub-aims.
34. Some people do not use citations in the Specific Aims. I do. And I find it very helpful as a reviewer when the statements in the introduction of the Aims have citations.
35. You may see some guides recommending a concluding paragraph to the introduction (just before the Aims statements) that includes an "overall objective", "long-term goals" and a "central hypothesis." I am not a fan of that structure. The overall objective and long-term goals rarely add to most descriptions; 99% of the time those statements read as empty words. I find these sentences to be too formulaic and unhelpful.

SIGNIFICANCE

1. Distinguish between Significance and Innovation:
Significance = positive effect of your project on science, medicine, and/or public health
Innovation = a new or different – and better – approach
2. Know the literature: A good knowledge of the literature is the foundation of a good significance section. Your question will only be relevant if you know what's been done before. You can't make a compelling argument for your study, unless you know what others have done. Actually, you have to know the literature before you really decide on your question in its final form.
3. Significance sections are written in many different ways. Pay attention to what works—what conveys information effectively. I have found one that works well for me, and I think, works well for successful grant writing.
4. Tell a story: Telling the story means making a compelling, logical argument for the importance of what you're doing. To do that, you need to *briefly* include the background, i.e. the status of the literature in the area you're dealing with, and relate that to the significance of what you are proposing to do. Make it flow easily, so that you start with general information and work to more specific areas directly related to your topic.
5. Synthesis is key: In writing this section, you cannot provide an exhaustive review of the literature. You must synthesize the key points and include only those that highlight the significance of your work.
6. Use the NIH review criteria as a guide for this section. Make sure that you're hitting the points that NIH expects for significance.
7. Don't go too broad in the Significance. Remember space is limited. Keep it to the major points related

to your project.

8. Write this section for an intelligent, interested audience. On the one hand, assume that at least one reviewer will know the literature and recognize when you leave out some key reference. On the other hand, also assume that at least one reviewer is not an expert in your area.
9. Try to find out who is likely to be on the study section that would review your proposal. Know their research areas and any biases they may have. Use that information to help guide your significance section. (But be careful: I once had a grant do miserably because I knowingly sent it to a study section with a famous spatial statistician...but my grant was geostatistics and I didn't really understand the difference.)
10. Keep it short. The Significance should be less than two pages for a 12-page proposal; often 1-1.5 pages is sufficient.
11. Make it easy for the reader to know what that story is.

Remember the reader is tired, grumpy, and doesn't really want to be reading this document...

Use these three tools to make the Significance easy to read:

Tool 1: Use declarative *subheadings* in bold or italics that are statements rather than traditional subheadings. Think of these subheadings as *headlines*. These subheadings should be one line or less whenever possible. If the subheading is set off and contains useful information, then the reader (especially a tired one with too much to do) can pretty much skim the subheadings and have the gist of the significance and the reason for doing the study. Here are the headings from a recent successful grant (2022).

Unhealthy alcohol use is common among Asian men who have sex with men.
Unhealthy alcohol use causes substantial morbidity and mortality.
Unhealthy alcohol use increases HIV and STI risk.
PrEP prevents HIV infection among MSM but unhealthy alcohol use may interfere.
Vietnam has adopted PrEP but poor persistence hampers its effectiveness among MSM.
Vietnam is an ideal setting to test a brief alcohol intervention (BAI) among MSM.
Interventions to reduce alcohol use among MSM are uncommon.
The BAI is grounded in theory, feasible, and effective.
Summary

Reading through these short statements gives you a good overview of the significance of this project.

- One great way to begin working on the Significance is to write just these subheadings. If you can tell the story with these subheadings and make them flow logically, then you've done the hard work of the Significance. After that, it's just filling. I usually write these subheadings, rearrange them until they flow, then set it aside and fill them in later.
- Use your Specific Aims to guide the Significance. Your Significance should map onto your Specific Aims introduction.

Tool 2: Topic sentences (the first sentence of the paragraph or the first sentence after the short, declarative subheading) should be strong and contain most of the important message of any given paragraph. Between the subheadings and the topic sentence, the reader should be able to know what is being said. The rest of the paragraph provides the detail and supportive arguments for the topic sentence, which the reader can choose to read if they require or desire that information.

- Note: Some people choose to highlight (bold) the topic sentence rather than having a separate short statement as a subheading. This bolded topic sentence approach is reasonable, but personally,

when I review grants, I find the short statement approach is easier to read and follow. The short statements are easy to grasp quickly, whereas the topic sentences often require more thought to digest.

Tool 3: If you put an important statement in the middle or end of a paragraph, it will usually be lost to the reader. Avoid putting important things in the middle or end, if possible. If for some reason, you must put a key sentence somewhere other than as the topic sentence, use bold or italics to draw the reader's attention to it.

12. When the reader is done reading the Significance, they should feel that a) you know what you're talking about, and b) that the research question to be addressed is significant.
13. Focus on synthesis rather than regurgitation. The Significance should synthesize the pertinent literature, rather than re-state it. Your objective is to tell the reader why what you propose is important, why it fills a gap in knowledge. Simply restating what others have done with their ORs and CIs, etc. does not do that. Your objective is to pull the literature together – and make sense of it.
14. Avoid statements like “Previous research has shown...” or “Jones, et al found that...” Nearly always, if you delete these portions of sentences and include the citation at the end of the sentence, the remaining text will stand alone. And in standing alone, the sentence will be more concise, direct, and powerful. (“Previous research has shown that the world is round” becomes “The world is round.^{cit}”).
15. When the literature shows mixed results or uncertainty, use words that reflect that our current understanding is less clear: “may”, “probably”, “uncertain”, “unknown”.
16. Use a table or figure to present critical and summary information. One advantage of tables and figures is that you aren't limited for font size (although 8 pt is probably the limit) and can therefore squeeze more information into them. But pick and choose what's important. Remember the reviewer wants to know the story – the “why this is important” – and does not want to have to work to get that information. Tables and figures can help provide that information, if carefully done.
17. Convince the reviewers of the importance of your research in the Significance by explicitly stating:
 - a) How your research will advance your field.
 - b) How it will fill knowledge gaps -- show you are aware of opportunities, gaps, roadblocks, and *research underway*.
 - c) How the work is new and unique.
 - d) How it meets the NIH mission to improve health through science -- can lead to cures, treatments, or preventions for human disease.²
 - e) The contribution of your work to the field. Consider using those exact words – “This project will contribute” or “This project will lead to...”
18. When drafting the Significance (and elsewhere!), don't stop to look up references. Just put (REF) and keep writing. Writing is hard—don't interrupt the flow.
19. Conclude this section with a summary statement of significance. In this summary, make the significance clear and obvious. Develop a paragraph or more that addresses very clearly how your study will advance your field. You want to leave the reviewer with an understanding that your study is important and will have an impact. A clear statement also provides the reviewer with something they can directly state in their review.

NOTE to Graduate Students: Most dissertation committee members will expect more background than the NIH-style significance section will allow. You have two viable options: 1) ignore the NIH format for your proposal and give a more complete background in the main text, or 2) use the NIH format, but

include an appendix with a complete background section. I personally favor option 2. Writing the more complete background section is important because it will be plunked almost verbatim into your dissertation with some updating. Be sure to confer with your committee about expectations of the background section (Option 2 may not always be allowed.)

INNOVATION

1. The innovation section is usually short, often about ½ page.
2. Consider documenting what the standard has been to date, so that you can convince them that your approach is different and innovative.
3. Tell the reader why your study is innovative. In telling the story, be sure that you convey the novelty and importance of your work. Note that reviewers have to state in their review how it is innovative. Give them the text to use! In stating the innovation, sell your idea, but don't oversell it. Reviewers can see through too much hyperbole.
4. If you have developed a new framework or significantly modified an existing framework, consider highlighting it in the innovation section. You might include it fully here or a brief description and a fuller description in the approach.
5. Be careful about claiming to be the first study to do something. At the least, soften it with "To our knowledge" and even then, be sure you've done a thorough review of the literature and ongoing studies.
6. To be innovative for NIH's purposes, it's enough to show how the work you propose is new and unique and will add significantly to existing knowledge.²
7. Your work can be innovative if you take either path described below, but the first choice will raise fewer reviewer eyebrows:
 - a) Refine, improve, or propose a new application of an existing concept, method, instrumentation, or clinical intervention.
 - b) Shift a current paradigm.¹
8. Note that in the first option, simply refining or improving an existing intervention is considered innovative. For intervention-oriented research, that is likely the biggest innovation in your work. Highlight it. Reviewers may look for more but from NIH's perspective, you've done your job.
9. If you decide to forge ahead and challenge an existing paradigm, build a strong case for your ability and your reason for doing so.
 - If you're a new investigator going this route, expect reviewers to be skeptical. If reviewers feel they could not get the work done, they are unlikely to have confidence that you could either.²

APPROACH

The approach section is used to describe the research design. This section is your opportunity to describe how you will do your proposed research.

1. Writing a strong approach section is challenging. It is a balance of giving sufficient detail without giving so much detail that the reader cannot see the forest for the trees. The forest must be clear. And you need to see enough of the trees to know what type of a forest it is.
2. How you lay out the overall research design section depends on the Aims. You can think of the two

extremes as **sequential** or **integrated**. The **sequential** approach is used if each aim has different study populations or different data; then you will need to repeat most or all of the sections for each aim. The **integrated** approach is used if the Aims have significant overlap, sharing the study population, study setting, data collection, etc.; you'll develop all the sections only once, covering all the Aims. A hybrid approach is common, where the shared sections are described once (e.g. study population, study setting) and other elements are developed aim by aim.

3. It can sometimes be helpful to repeat the Aims statements in the Approach, especially when using a sequential approach.
4. Do NOT repeat yourself in the Approach unless it is a crucial point that you want to be sure the reader remembers. Refer to other sections if necessary.
5. Make sure all elements are provided for all the Aims in one way or another.
6. Typical sections in the Research Design section (for whole human being research) include:
 - a. Preliminary studies
 - b. Overview
 - c. (Rationale for Proposed Design)
 - d. (Intervention)
 - e. (Staff Training)
 - f. Study Design
 - g. Study Setting or Site
 - h. Study Population (Selection Criteria; feasibility of recruiting necessary sample)
 - i. Recruitment and retention
 - j. Data Collection (Questionnaire, Exam, Laboratory Data, etc.) or Data Sources
 - k. Measurements (Outcome, Factor of Interest, Confounding variables)
 - l. Data Management and Data Analysis (Bivariable, Multivariable, Approach to Missing Data)
 - m. Sample Size and Power
 - n. Limitations and Potential Problems (Challenges)
 - o. Timeline
 - p. Impact Statement/Future Directions
7. The specific order of sections may vary. The goal is to make it flow logically for your particular study design.
8. In the current NIH format, the preliminary studies section does not have a designated place. You may put it at the beginning, middle or end, but wherever it is, it should flow logically. Personally, I think putting it at the beginning of the approach section makes the most sense.
9. Preliminary studies provide the reader with the evidence that you and your team can do what you say you're going to do. Preliminary studies include your team's published and unpublished work.
10. Depending on the type of grant, the preliminary results can be very important. For R01s and similar grants, they are critical. In an R21, they are officially not required but in practice, having preliminary studies will help. In K awards, they may be a little less important, but most K's still need some. Often in K awards, you can describe your previous research that speaks to your potential—even if it isn't directly needed for your proposed work.
11. In grants that are not for career development (career development awards include F and K awards) preliminary studies may include work from any team member, including your consultants.
12. In career development awards (F, K), preliminary studies should reflect work that you have been

involved in. That said, as long as you're clear that it was a mentor or other team member and not you, you can include it with a disclaimer or highlight it somewhere else in the grant.

13. The preliminary studies can include work that shows you can do the type of study you're proposing to do, that you can recruit and retain the study population, and any pilot study data.
14. Try to tell a story with the preliminary studies. Show how they lead *logically* to the work that you are proposing. Use headings and/or summaries of each study to assist in this.
15. Preliminary studies may also provide a brief description of your research team and their skills. If you don't include the research team in the preliminary studies, then include it as a separate section elsewhere in the approach.
16. Some investigators use a section called "Justification and Feasibility." This section includes specific background material under justification (usually with a much shorter significance section) and preliminary studies included within the feasibility part of this section. Alternatively, it might be called Justification and Rationale, with the preliminary studies as a separate section. Generally, I'm less in favor of this structure, as I find that typically, the significance and often the preliminary studies are underdeveloped when this structure is used.
17. Proposals that use a theoretical model or conceptual framework are usually viewed as stronger. Use the model/framework to ground your research questions and your analysis. Include an appropriate figure of your theoretical model or conceptual framework to provide a visual overview.

NOTE: Thinking through a theoretical model or conceptual framework is more than just an exercise. It can provide you with the framework for your research questions and actually guide your analysis. How else do you decide what factors are important in your analyses? You must consider the various pathways to your outcome of interest. If you're doing a behavioral intervention, or measuring behavior, your work should be based on accepted behavioral theories or frameworks.

18. In describing the overall study design, be sure that it is clear how you will address your aims. That includes brief descriptions of the study population, key instruments/measurements, and outcomes.
19. Occasionally, I have used a rationale section before or after the overview that explains why I chose to do certain things in specific ways. For example, if you could be doing a cohort study, but you chose to do a case control, explain why here. In fact, I sometimes use questions for the subheadings in this section and then answer them. "Why choose a case control design, rather than a cohort design?" Essentially, I am trying to anticipate the specific questions of the reviewer and telling them—upfront—the answers. That way, they do not read the rest of the proposal with questions in their mind. Smaller issues can be explained within specific subsections rather than upfront.
20. The overview provides a summary of the activities near the start of the Approach section. It gives the reader a map for the rest of the grant. I encourage you to include a figure of the overall study design to provide a visual representation of the study activities.
21. Keep in mind that it is very helpful to justify the rationale for decisions regarding the design, and not just present the design itself. Stating your thinking behind the decisions is very helpful to the reader/reviewer.
22. In shorter grants, you can provide less detail about how you will do something. The goal is to be clear enough about the overall approach. If you are using novel methods, then they would need to be described in more detail. If you're adding to existing methods, you would need to describe how it will be different and justify that approach. If you are using standard methods, then the method can be described with less detail.

23. If you are recruiting participants, be clear about how you will recruit them, especially if they may be a difficult to reach population.
24. Sample size: Sample size really is considered in two ways. 1) You must show your sample size is sufficient to identify a meaningful effect with reasonable power (at least 80%). But you must also show that you can accrue a sample of that size. Reviewers are skeptical about enrolling participants, because it is hard to do. The paragraph about how you will reach your proposed sample size is critical to show that you can do what you say you're going to do. Be conservative in your estimates. This second paragraph is often included under Study Population.
25. Power: Consider presenting a power curve or a table showing power over a range of different circumstances. Provide power for your primary outcome and for major secondary outcomes.
26. Intervention: For intervention studies, include a clear description of the intervention, its rationale, underlying theoretical basis, and any planned adaptations prior to implementation. Adaptation is common and a thoughtful description of how that will take place will be expected by the reviewer.
27. Training: If staff must be trained for study implementation, include a brief description of how that will happen and who will do the training.
28. Secondary data: If your study uses secondary data, describe the data sources clearly. Describe the population included and if possible, the underlying target population that those data represent. Include an indication that the data will support the necessary sample size. And include a clear assessment of potential biases arising from the way the data were collected, including the potential for missing variables that might be important (e.g. as confounders) and missing data more broadly.
29. Outcomes: You must clearly describe the outcomes for each aim—primary and secondary outcomes. Give clear definitions. You may choose to have alternative outcomes for secondary analyses or sensitivity analyses.
30. Outcomes: Consider putting the outcomes in a table. It makes it very easy for the reviewer to find and assess them quickly. In the table, give the outcome, the definition, and ideally, how it will be measured.
31. Measures: Clearly describe the measures you plan to use. If using existing scales and indices, give supporting references. In a large study, I typically include a table of the measures.
32. Include a schedule of events—what will be measured when.
33. Quantitative data analyses: The data analysis section MUST be clearly thought through. What variables are you likely to be looking at? How are you planning to code major variables (outcome and factor of interest)? Why are you coding that way? Be sure to explain why you are approaching an analysis with a particular method. Justify your selections.
34. Missing data: Always describe how missing data will be handled.
35. Qualitative data collection and analyses: Be sure to provide sufficient detail about who will be interviewed, the method (e.g., in-depth interviews, focus groups, observations), any strata/subgroups you want to purposively sample, and a justification for sample size. Include how the data will be collected, transcribed, coded, and analyzed. Make sure that you have qualitative expertise on your team. Consider describing who will be doing the interviews, transcription, and coding, and if appropriate, how they will be trained. Ideally, don't just use boiler plate language from other grants—reviewers with qual expertise will pick up on that. Try to use a content-relevant example to show how

the process will be used (e.g., an example question that might be asked or a table with example domains for the interviews).

36. In some situations, you may not be able to anticipate exact details for certain types of data collection. For example, with qualitative interviews or stakeholder interviews, the initial interviews or focus groups may help guide the questions asked in subsequent data collection. The same can be true with adaptation of interventions or survey development. In these cases, use examples and then note that the specific elements may change after the developmental work.
37. For all types of interviews and other primary data collection, address quality assurance.
38. The Approach should include a section on weaknesses, limitations, and potential problems (challenges). What are you going to do if this or that doesn't actually happen the way you expect it to? Include possible solutions to the problems. Be thorough here.
39. The limitations can follow the analysis section for each aim or can be a single section after the entire design section. If carefully thought through, this section can be the foundation for the discussion sections of your manuscripts.
40. Being forthright in discussing the limitations will often head off concerns of the reviewers. Assume that reviewers will find the problems with your grant. The strengths should be made evident throughout the rest of the proposal and should not be listed in a separate section. If there is a specific design decision that was difficult and relates to a limitation, discuss the basis for that decision. This can be done in the research design section, rather than the limitations.
41. Most proposals should include a timeline at the end of the approach section describing when work will be completed. Be realistic. If you are too overambitious, it will come through and the reviewer will consider you to be inexperienced and naive. Note that if you are proposing a study that meets the NIH definition of clinical trial, you will have a timeline within the special clinical trials section and do not need to duplicate it in the approach.
42. Often, it is helpful to have a future directions section. This provides the evidence that you've thought through what comes next. This section is particularly true for career development awards
43. Conclude the Approach with a paragraph highlighting the impact of your work. This paragraph is your last chance to leave an impression and a way to ensure that the reviewer leaves with a clear idea of what will be accomplished. Think of this section as "what will the scientific community receive if this work is funded?"

Three final thoughts: 1) Writing proposals is hard work. But it is also the essence of what we are trying to do in science: We identify problems, develop a research question to address that problem, and try to figure out how best to answer that question. The more that you can enjoy this process, the more you'll enjoy your career as a researcher. 2) Take pride in each step of the process: successfully submitting your grant (or dissertation proposal), getting your first score, and receiving your first notice of award. Both of those first two steps are wins, even if the grant isn't funded. 3) Give yourself the time needed to succeed. Write clearly. Try. If you don't submit, you won't be funded.

Good luck!

¹Russell SW & Morrison DC. The grant application writer's workbook. Grant Writers' Seminars and Workshops.

² <http://funding.niaid.nih.gov/researchfunding/newsletter/2010/pages/1013.aspx#f01>