

# Resubmission of the Grant Proposal

# 20

Given today's economic challenges and the corresponding low NIH paylines, it is important to anticipate that your first grant submission will be rejected and to factor this into your overall timeline. Indeed, even the most famous scientists have had their grant proposals rejected. Therefore, this chapter goes on to describe the resubmission process along with strategic tips for how to be highly responsive to reviewer concerns—the key criteria in a successful resubmission. Part I describes the pathway to resubmitting your grant proposal. Part II goes on to provide strategic tips for the Introduction to the resubmission, the most critical aspect of the resubmission. Finally, Part III describes issues in revising the remainder of the body of the application.

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## 20.1 PART I: PATHWAY TO RESUBMITTING

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Put the summary statement away for a few days. Then, sit down with a glass of wine or the beverage of your choice and read the reviewers' comments. When you first read them, you are likely to feel sad and angry—sad regarding the amount of work that you put into the submission and angry at the reviewers for not understanding what you meant.

However, it is important to remember that the reviewers were selected due to their substantial track record of NIH funding as well as expertise in peer review. If, as scientists, they misinterpreted your writing, then it is likely that many more people would make a similar misinterpretation. Therefore, any errors in their comprehension are ultimately due to the need for you to more clearly convey your points.

Do not call the funding agency at this point in time. Wait a week to calm down and then reread the reviews as well as your application. Ask your coinvestigators and mentors to read the reviews as well. A senior investigator/mentor skilled in reading NIH reviews will be invaluable. She or he can read between the lines to assess whether the flaws should be considered *fatal* and whether the reviewers showed any enthusiasm for your study. They can assess whether the comments are largely addressable.

Consider the reviewers' suggestions for change and their requests for more preliminary data, if applicable. Determine what parts of your application might have confused them. Then decide in conjunction with your mentor whether your application is fatally flawed or fixable. More often than not, the latter is the most likely decision.

## 20.1.1 Whether to Resubmit

There should almost never be a question as to whether to resubmit your grant proposal. Rejection on the first submission is so common, almost the norm, that it should be planned for. Specifically, your overall grantsmanship timeline should take into account the time to revise and resubmit even before you first submit the proposal.

This is not to say that you should submit a version that is not perfect but that instead you should anticipate that the reviewers will want to make their mark on your proposal. Always remember that in the grant proposal process, grit and persistence may be more predictive (or just as predictive) of ultimate success than scientific intelligence.

## 20.1.2 Contact Your Program Official

Now that the review has been completed, the **program official at the assigned institute(s) becomes your NIH contact**. After reading the summary statement and discussing with your colleagues, make an appointment to discuss the critiques and your options with the program official assigned to your application. The program official can help you in interpreting your summary statement as he or she may have listened to or attended the review meeting.

The program official may be able to provide guidance on what to address in your resubmission application, if this is your first submission.

## 20.1.3 Timing of a Resubmission

Resubmitting as soon as possible after you receive the summary statement is preferable to ensure that you maximize your chances of obtaining the same review panel. Remember that reviewers like to make their mark on your proposals, and if your resubmission is reviewed by a new reviewer, this will be their first chance to make comments.

The primary reason for delaying a resubmission would be in response to a reviewer request that you provide additional pilot data. However, while your original submission was under review, you ideally already started a pilot study. If so, you will be well positioned to submit this new data as part of your resubmission.

eg  
example

Imagine a reviewer comment that you should conduct a small feasibility study prior to the proposed study. In the Introduction to the resubmission, you could state

Since the time of the original submission, we have been in the field with a pilot feasibility study, “Healthy Heart Pilot” (Faculty Research Grant; PI: yourself). The goal of this pilot is to evaluate the feasibility and acceptability of the proposed intervention. The pilot has randomized 47 men to date and is on track for its goal of 66 men. Participants endorsed the interest and utility of the study materials (86%), ability to access a telephone for telephone interviews (100%), and the amount of time spent on the study (appropriate 86%, sometimes too much time 14%). Recruitment and retention rates were used to inform the revised power calculations.

## 20.1.4 Not All Reviewer Comments Are Equal

Remember the criteria for Research (R series) awards as presented in Chapter 19, *Review Process* (Table 20.1).

Weaknesses that fall under *Overall Impact* and *Significance* should be considered the most serious. However, before deciding to shift the grant’s focus, consider whether these comments reflect a failure on your part to clearly convey the (1) research gap, (2) clinical significance, and (3) public health implications of your study findings.

In contrast, concerns about *approach* are typically more addressable as they may reflect logistic concerns about your ability to pull off the actual study.

Parts II and III of this chapter provide examples of responding to concerns pertaining to each of the review criteria.

**TABLE 20.1** Review criteria for research awards

Overall impact
1. Significance
2. Investigators
3. Innovation
4. Approach
5. Environment

## 20.1.5 How Much Revision Is Necessary

A general rule of thumb is that the amount of revision should be **proportional** to the score of the application. In other words, significant revisions are required if your application was triaged. If the application was scored, the number of revisions should decrease as the score decreases. In fact, if you have a low score, be careful not to make dramatic revisions—just a few tweaks may be sufficient to respond to the reviewer comments.

This advice, however, assumes that the score is congruent with the content of the reviews. This is not always the case. While all reviewers are instructed to justify their numerical scores with appropriate text, variability exists among reviewers in the extent to which they describe the strengths and weaknesses of the scored criteria. If one of the critiques provided little justification for a low criterion score, try checking the corresponding comments on the other critiques. These can provide you with multiple viewpoints on that criterion.

In addition, check the *Resume and Summary of Discussion* section of the summary statement (included on all discussed applications). This resume may have additional information on the content and emphasis of the verbal discussion held by the reviewers about your proposal. Your NIH program official also can help you to interpret this summary, and he or she may have listened to or attended the review meeting.

## 20.1.6 Study Section Review of Resubmissions

For resubmissions, the study section will evaluate the application as now presented, taking into consideration the responses to comments from the previous study section and changes made to the project. The committee will consider whether the responses to comments from the previous study section are adequate and whether substantial changes are clearly evident.

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# 20.2 PART II: INTRODUCTION TO THE RESUBMISSION

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Just as the Specific Aims page was the most important page of your original application, the Introduction is the **most vital part** of the resubmission. Approximately half of your time revising your application should be spent on this **one-page** Introduction. Early drafts of the Introduction should be sent to your coinvestigators/mentors well in advance of the resubmission date.

In general, the scientific review officers will assign your revised application to the same reviewers who reviewed the first submission, given that they are still available. These reviewers will be reading your application for the second time and will **focus primarily on your responsiveness to their critique** as summarized in the Introduction. Specifically, they will cross-check each of their prior comments against your response in the Introduction as well as your marked changes in the body of the proposal.

Even new reviewers who are assigned to your resubmission will often defer to the expertise of the prior reviewers and therefore focus primarily on how responsive you are to these prior reviewers' comments.

Below are **strategic tips** for writing the Introduction. You will see that the **overall theme** is "If at all possible, try to take the advice of the reviewers."

## 20.2.1 General Format of the Introduction Page

Table 20.2 is a typical format for the Introduction page:

**eg**  
example

**Example Paragraph #1:**

This is a resubmission of DKxxxxx-01 "An Exercise Intervention to Prevent Diabetes" to test the hypothesis that an exercise intervention is an effective tool for preventing diabetes. The comments of the review panel were very helpful in revising this proposal. As the reviewers noted, "The application addresses a highly significant area in women's health that may have a lasting impact in a high-risk population for development of obesity and diabetes." "Using moderate intensity exercise to diabetes is innovative and could easily be translated into clinical practice." Changes made to the proposal are highlighted in italics throughout the text.

The majority of the remainder of the Introduction page will be made up by a point-by-point response to the major reviewer concerns.

How to determine which concerns are major?

- Concerns shared by more than one reviewer
- Concerns that were highlighted in the *Overall Impact* section
- Concerns that were highlighted in the *Resume and Summary of the Discussion* section

**TABLE 20.2** Outline for the introduction page of a grant resubmission

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1. Paragraph #1
    - Specify the title and NIH assigned number of the grant proposal
    - Thank the reviewers
    - Quote several positive remarks from the reviews
    - Clarify how revisions are highlighted in the body of the proposal
  2. Point-by-point response to most important reviewer comments (bulk of the page)
  3. Brief summary of response to more minor comments (one to two sentences)
  4. Final positive summary (one to two sentences)
-

eg  
example

### Example Final Positive Remark:

In summary, since the original submission, we have been in the field with three pilot studies. We have utilized information gleaned from these studies to make cultural modifications to our intervention materials, ensuring that the materials will be efficacious in Hispanics, the ethnic group with the highest rates of diabetes, as well as the other ethnic groups represented in the study population, while being sure to retain the integrity of our evidence-based intervention approach.

Examples of Introduction pages in their entirety are included at the end of this chapter.

## 20.2.2 Tip #1: Clearly Connect Your Responses to Specific Reviewer Concerns

While it is important to be brief in summarizing reviewer concerns to save space in the Introduction, be sure that the reviewer(s) can clearly find their concerns and your corresponding response in the Introduction.

How to Summarize Reviewer Concerns in the Introduction:

- List which reviewers share this concern according to reviewer number (i.e., R1, R2, R3).
- Repeat some of the identical phrasing used by the reviewers in your response.

Citing the reviewer number when listing the reviewer concern is a way of being kind to your reviewers. This will not only reassure the reviewers that you have covered their points but also help you to be sure that you have not missed any reviewer comments.

## 20.2.3 Tip #2: Resist the Urge to Defend Yourself

If you are a new investigator, your first instinct may be to try to *prove* yourself to the reviewers. The natural tendency is to defend yourself against their concerns by spending time justifying your original decisions.

In contrast, the reviewers' priority is to see that you have been **responsive** to their concerns. They don't want you to spend time showing that you are smart, well-educated, and/or never make errors. Instead, they will be going through each item in your Introduction and *checking off* in their notes whether or not you have made the changes they suggested.

Therefore, the most tactical approach is to set aside any need to prove yourself. Instead, if the suggested revision is feasible and does not seriously detract from your goals, then simply make the change. In the Introduction, simply state that you

have made this change—there is no need to waste space by providing a rationale for why you originally did it another way.

## 20.2.4 Tip #3: Avoid Disagreeing with a Reviewer

It is almost never effective to not be responsive to a reviewer comment. Even a small revision is better than no revision. That is, you need to show that you are doing something in response to a reviewer concern.

If you are unable to be fully responsive to reviewer concerns,

1. Acknowledge the reviewer concern.
2. Describe the revision you made in response (even if it is a slight alternative to the reviewer's suggestion).
3. Describe what you are unable to address and why.

This approach avoids the common pitfall of starting your response by sounding non-responsive or, at worst, argumentative. Instead, start out by saying that you recognize the reviewers' concern, followed by the positive change that you have made to the application in response to the reviewer comments (even if this is an alternative way to satisfy their concern), followed by any caveats regarding what you are unable to address.

eg  
example

### Original Version

**R1. Recommend the addition of a 6-month follow-up study to ascertain if the effect persists after the structured intervention.**

We chose not to conduct a follow-up study as our primary focus in this application was to determine whether the intervention could be effective in real time.

### Improved Version

**R1. Recommend the addition of a 6-month follow-up study to ascertain if the effect persists after the structured intervention.**

The reviewer raises an important point. Therefore, we have added a 3-month postintervention focus group that will assess whether the family continues to dance together, how often, and in what format. We are unable to follow the participants for 6 months due to the fact that recruitment is rolling over the first 2 years of the grant, leaving insufficient time to follow the last recruited family. However, we will also perform a 6-month focus group in a subgroup of the first 50 recruited families.

## 20.2.5 Tip #4: If You Must Disagree with a Reviewer, Focus on the Science

It is okay to disagree with reviewer concerns if you explain your decision in a way that will engage the reviewer scientifically. Do not write to the reviewers; write to the science. However, even in this situation, it is important to still try to be somewhat responsive to at least a part of their concern if at all possible.

eg  
example

**R2: The investigators should consider defining physical activity using three cut points instead of two cut points.**

In response to the reviewer's suggestion, we have added an additional analysis utilizing three cut points. However, because prior validation studies support the use of two cut points,<sup>1,2</sup> we also propose to retain our analysis using two cut points. This will facilitate comparisons with the prior literature that has, in general, utilized this approach. We will present findings from both approaches.

## 20.2.6 Tip #5: Avoid Using Cost or Logistics as a Rationale for Not Being Responsive to a Reviewer Comment

eg  
example

**Original Version**

**R1. Concern that dropout rates may be high—monetary incentives should be considered.**

The reviewer's valid point about possible attrition without monetary incentives concerns me also. However, our budget cannot afford such incentives.

**Improved Version**

**R1. Concern that dropout rates may be high—monetary incentives should be considered.**

We agree with the reviewer. We have added a modest monetary incentive and will also partner with the school/community to incorporate nonmonetary ways to incentivize the participants.





### Original Version

**R1: It is unclear why the proposed data analysis plan will only adjust for family history of diabetes and not history of pre-term birth.** The dataset that we will be using does not include information on history of preterm birth.

### Improved Version

**R1: It is unclear why the proposed data analysis plan will only adjust for family history of diabetes and not history of pre-term birth.** While our dataset does not include information on history of preterm birth, we will address the threat of confounding by history of preterm birth by repeating the analysis among nulliparous women. We will compare the findings from this sensitivity analysis to the primary analysis to evaluate the degree of potential confounding by this variable.

## 20.2.7 Tip #6: Multiple-Bullet-Point Response to Major Concerns Is Highly Responsive

The space dedicated to each response should be in proportion to the importance of the reviewer concern. As mentioned earlier, concerns that fall under *Overall Impact* and *Significance* are often the most serious. In these situations, a bulleted list of multiple responses to this concern is recommended.



### R1, R3 Need for data to demonstrate the efficacy of the physical activity intervention among pregnant Hispanic women.

In response to this important concern, our investigative team has been in the field with three pilot studies since the time of the original submission:

- Pilot #1 is our focus group work among Latinas led by Dr. Smith (new coinvestigator). We have revised the intervention to address the themes from these six focus groups (Sections C.1 and D.3).
- Pilot #2 is our ongoing exercise intervention among eight pregnant women that provides strong support for the efficacy of our exercise intervention (Section C.2).

- Pilot #3 is our completed pilot of acceptability/feasibility among 40 prenatal care patients that showed that the stage-matched manuals were feasible and acceptable in our population of multiethnic pregnant women (Section C.3).

Finally, since the time of original submission, a small vanguard pilot study has been published<sup>1</sup> supporting the efficacy of an exercise intervention in pregnant women at risk for GDM.

## 20.2.8 Tip #7: Acknowledge Your Mistakes or Lack of Clarity

At times, reviewers will make **basic errors of understanding** in their interpretation of your proposal. This may simply be due to the fact that they are facing a heavy load of proposals to review with a tight deadline, in combination with your proposal's failure to present something clearly.

In this case, it is important to be humble and apologize for your lack of clarity—even if you feel that the proposal was already clear and the reviewer was mistaken. Resist the temptation to point out that the first submission already described this point. Remember, you are not trying to prove to the reviewer that you are *smart*; instead, you are trying to prove to the reviewer that you are responsive to their comments.

eg  
example

Imagine that you proposed to conduct a matched case-control study with age, race, and gender being your matching criteria. The reviewer missed the fact that you already included age as a matching criteria and asks you to do so in their comments.

While it will be tempting, **avoid saying** the following:

### Original Version

We already included age as a matching criteria as noted on page 18 of the original application.

### Improved Version

We apologize for our lack of clarity in describing the study design. We will include age as a matching criteria. Specifically, cases and controls will be matched on age <18, age ≥ 18 (see Section C.4. Study Design).

## 20.2.9 Tip #8: Don't Skip Any Reviewer Comments

Address each reviewer comment, if not individually, then at least in a summary paragraph near the end of the Introduction. The reviewers have each spent a lot of time reviewing your original application and will therefore carefully check whether you have addressed all their comments.

## 20.2.10 Tip #9: Avoid Collapsing Too Many Reviewer Concerns into One Bullet Point

This tip falls under the concept of being kind to your reviewer. In the example below, you can see how collapsing multiple concerns can lead to reviewer confusion.

eg  
example

Imagine a proposal to conduct focus groups among girls.

### Original Version

**R1, Aim 1 unclear; measurement of fun; control group.** The aim of the focus group is to determine whether the girls will find the activities fun and will want to participate; and to obtain advice from the mothers and daughters regarding potential barriers to the proposed intervention. Girls' enjoyment (fun) will be measured using the Facial Affective Scale. We have revised the methods to ensure that the control group will be seen as frequently as the other two groups.

### Improved Version

**R1, R2: Aim 1 is unclear.** We apologize for our lack of clarity. Aim #1 is to conduct focus groups to (1) determine whether the girls will find the activities fun and will want to participate and (2) to obtain advice from the mothers and daughters regarding potential barriers to the proposed intervention.

**R2, R3: Clarify how “fun” will be measured.** Girls' enjoyment (fun) will be measured using the Facial Affective Scale.

**R1, R3: Concern that the control group has less contact time.** We have revised the methods to ensure that the control group will be seen as frequently as the other two groups.

## 20.2.11 Tip #10: Be Sure to Make Changes to the Body of the Proposal

In general, all responses to reviewer comments should refer to a section in the body of the proposal—so that the reviewer will be assured that you made the change to the protocol itself. The only exception would be items that reviewers suggested that you delete (however, sometimes even these are worth mentioning in the *Alternatives and Limitations* section).

Avoid the mistake of simply stating that you made a change in the Introduction and then leaving the body of the proposal unchanged. Reviewers will check this.

## 20.2.12 Stylistic Tip #1: Use Active (Not Passive) Voice

The use of the active voice in writing the Introduction to a resubmission further highlights your responsiveness to reviewer comments.

eg  
example

### Original Version

**R2. The intervention should incorporate a social support component based on recent findings supporting the efficacy of this approach.**

Changes were made to the proposal to incorporate a social support component.

### Improved Version

**R2. The intervention should incorporate a social support component based on recent findings supporting the efficacy of this approach.**

We agree with the reviewer and have now revised the intervention to incorporate a social support component.

## 20.2.13 Stylistic Tip #2: Avoid Use of the First Person

As with the body of the proposal, it is best to avoid use of the first person. You will almost always be submitting an application with a team of coinvestigators, collaborators, consultants, or mentors. The use of the term *we* always sounds more impressive than *I*, which can inadvertently come off as sounding like your own personal opinion.

eg  
example

### Original Version

**R1, R3: Lack of rationale for choosing the Facial Affective Scale.**

I have selected the Facial Affective Scale in light of the lower validity which I believe the other scales face.

### Improved Version

**R1, R3: Lack of rationale for choosing the Facial Affective Scale.**

We selected the Facial Affective Scale based on published findings that show higher overall validity for this scale ( $r = 0.75\text{--}0.88$ ) as compared to alternative scales ( $r = 0.33\text{--}0.66$ ).

## 20.2.14 Stylistic Tip #3: Don't Waste Too Much Space Apologizing

Space in the Introduction is at a premium as you are limited to one page. Your primary emphasis will be on highlighting the changes you have made in response to reviewer concerns, as opposed to apologizing.

eg  
example

### Original Version

**R1. Application fails to address alternatives if aim #1 is not successful.**

We apologize for not explaining what will happen if we do not successfully establish the methodology. Since the time of the application, the methodology has been developed and validated as now described in Section C.3.

### Improved Version

**R1. Application fails to address alternatives if aim #1 is not successful.**

We apologize for this omission. Since the time of the application, the methodology has been developed and validated as now described in Section C.3.

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## 20.3 PART III: BODY OF THE RESUBMISSION

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### 20.3.1 How to Identify Revisions to a Grant Proposal

As noted in the current NIH guidelines for resubmissions, you should mark revisions in the body of the proposal by bracketing, indenting, or italicizing or changing the font (to one of the other acceptable fonts). The guidelines do not allow you to underline or shade the changes. Typically, *italics* are the easiest and clearest approach to take.

Be sure to cross-check the body of your revised proposal with your Introduction. Check that all revisions that you mentioned in the Introduction are not only made but also indicated by italics in the body of the proposal. Similarly, be sure that any changes to the body of the proposal are also summarized, even briefly, in the Introduction.

In the situation where the revisions are substantial, it is best not to mark them, as this would be distracting for the reviewer and make it difficult to read. Instead, the Introduction can state the following:

eg  
example

Over the past x months since the initial proposal submission, we have continued to develop the research outlined in the original proposal and hence can be more specific about the next steps that need to be undertaken. This has resulted in extensive changes in the proposal, including a change in the proposal's title to more appropriately reflect the central theme of the research. Every section of the proposal has been rewritten; new sections are not highlighted.

### **20.3.2 Rereview the Published Literature to Check for Recent Relevant Publications**

This is a critical task in the resubmission process as there will be a time lag between your first submission and your resubmission during which new relevant findings may have been published. Assess whether the new data answer or inform your specific aims. If they do, refine your goals and specific aims and inform the reviewers about these new findings. At a minimum, add relevant citations to your Background and Significance section.

### **20.3.3 Obtain Revised Letters of Collaboration**

Given the time lag between the original submission and the resubmission, it is important to obtain new letters of collaboration with a recent date for the purposes of the resubmission. The use of original letters will raise reviewer concerns that these collaborators may no longer be available to your proposed study.

### **20.3.4 Update Biosketches: Both Your Own and Those of Your Coinvestigators**

Again, due to the time lag, be sure that all biosketches are revised to include any recent relevant publications as well as newly funded, or completed, grants.

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## 20.4 EXAMPLES

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### 20.4.1 Proposal to Conduct a Randomized Trial of a Postpartum Diabetes Prevention Program

#### Introduction to Revision

This is a resubmission of R03 DK12345 “*Randomized Trial of a Postpartum Diabetes Prevention Program for Hispanic Women*” (16th percentile score) to test the efficacy of a culturally and linguistically modified, individually tailored lifestyle intervention to reduce risk factors for type 2 diabetes and CVD among postpartum Hispanic women with a history of abnormal glucose tolerance during pregnancy. We thank the reviewers for noting, “Innovative proposal from an experienced team of investigators targeting a high risk population.” “Finding effective, culturally relevant ways to reduce risk of developing T2D among Hispanic women with GDM or glucose intolerance has substantial public health significance.” The comments of the review panel were very helpful in revising the proposal. Changes are highlighted in *italics* throughout the text.

**R1: Weight loss not included as an intervention target.** As recommended by the reviewer, we have revised the protocol to focus on weight loss as a key intervention target in addition to the exercise and dietary targets. Consistent with this revision, we now utilize dietary intervention materials found to be efficacious in our recent WIC Postpartum Pilot Study<sup>102</sup> that focused on *reduction in total caloric intake* (C.2. and Appendix II). We also provide our prior weight loss findings to support our ability to achieve these goals (C.2. Preliminary Studies).

**R1. No expert in dietary assessment is included.** We have added Dr. Taylor, professor of Nutritional Epidemiology and an expert in Hispanic dietary assessment, to lead the dietary assessment. Dr. Taylor and the PI have a track record of collaboration (C.1. *Progress Report* and Biosketches). We now describe the training and certification of the diet assessors in the Methods section (C.3. *Measure of Adherence with Diet*).

**R1. Dietary intervention is not sufficiently developed nor described.** We have revised the Methods section to carefully describe the dietary intervention in detail (C.3. and Appendix II). We now clarify how quality control procedures ensure that stage of change and social cognitive constructs are consistently represented in all intervention materials. Our systems-based pilot study

ensures that all mailings of physical activity and dietary intervention materials are synchronized such that participants receive them at the same time (C.3. *Lifestyle Intervention*; Table 20.2). We provide revised power calculations for the expected reduction in total daily caloric intake based on prior postpartum interventions.<sup>1</sup>

**R2. Conduct a small feasibility study prior to the evaluation study.** Since the time of the original submission, we have been in the field with a pilot feasibility study, “Healthy Pilot” (Faculty Research Grant; PI: yourself). The goal of this pilot is to evaluate the feasibility and acceptability of the proposed intervention. The pilot has randomized 47 women to date and is on track for its goal of 66 women. Participants endorsed the interest and utility of the study materials (86%), ability to access a telephone for telephone interviews (100%), and the amount of time spent on the study (appropriate 86%, sometimes too much time 14%). Recruitment and retention rates were used to inform the proposed power calculations (C.3. *Power Calculations*).

**R1: Initiate intervention during pregnancy after GDM diagnosis.** We have revised the proposal to now initiate the intervention in pregnancy immediately after GDM diagnosis and the baseline assessment (randomization at ~29 weeks gestation) to capitalize on the fact that pregnant women with abnormal glucose tolerance receive counseling during that time period (C.3. *Usual Care*) and are motivated to make behavioral changes.

**R1: Assessment of breastfeeding status is not well described.** We have revised the protocol to now utilize a validated Infant Feeding Questionnaire<sup>2</sup> to assess history of breastfeeding and frequency and duration of current breastfeeding (i.e., exclusive breastfeeding, percentage of mixed breast and formula feeding, exclusive formula feeding), timing of introduction of solids, and other breastfeeding behaviors and beliefs.

**R1: Comments on Budget/Appendix.** We have revised the Methods section and budget to identify the participant incentive value. We have removed photos from the stage-matched manuals that depicted parents swinging toddlers and now use more appropriate photos (Appendix II).

**R3: No concerns.**



## 20.4.2 K Award Proposal to Conduct a Web-Based Intervention Study to Prevent Weight Gain in Men

### Introduction to Resubmission

We are pleased that the reviewers noted several strengths of our original application including “a candidate with a good publication record and positive letters of support; an outstanding team of mentors with specific and varied expertise that is ideally suited to the proposed training and research plan; and an excellent research and training environment.” We are also pleased that the reviewers recognized the importance of the research topic. We have carefully considered the reviewers’ comments and have made significant revisions to the application. Specifically, we have refocused the research plan to develop and test the feasibility and acceptability of a theory-driven web-based intervention to prevent excessive weight gain that uses evidence-based strategies to help men achieve recommendations for weight gain, nutrition, and physical activity. We believe the application is significantly improved by our efforts to address the reviewers’ comments. Major additions are *in italics* throughout the application and are summarized below.

**R1, R2. Concern that characterization of weight gain patterns will not add to known determinants of excessive weight gain nor be a fruitful approach to intervening to prevent excessive weight gain.** In response to these concerns, we have refocused the research and training plans on intervention development and testing feasibility and acceptability (Section APPROACH). We feel these changes have considerably strengthened the application and better reflect training and mentored research experiences needed to accelerate the candidate’s research program in the area of weight gain and long-term cardiometabolic health.

**R3. Suggest eliminating unwieldy stratification of focus groups.** We have revised the application to conduct four focus groups of “all comers” as suggested by the reviewer (Section FGs).

**R1, R3. Need for a more detailed description of proposed intervention including specific behavioral strategies.** We now provide a more detailed description of our theory-driven web-based intervention to prevent excessive weight gain that uses evidence-based strategies to help men achieve the recommendations for weight gain, nutrition, and physical activity (Section INTERVENTION).

**R2. Add a pilot randomized controlled trial (RCT) to evaluate intervention feasibility and acceptability.** We have added a pilot trial to evaluate intervention feasibility and acceptability (Section RCT), which will provide critical data to support an R01 application to conduct a large RCT to evaluate efficacy (Section FUTURE).

**R1, R2. The candidate does not list publications directly related to proposed research topic.** Since the time of the original submission, the candidate now has two papers in the area of weight gain published or accepted for publication and an additional three under review (Sections CAND and PRELIM).

**R1, 2, 3. Need for additional preliminary data.** We now highlight the work we have done in direct support of this application since the time of the original submission (Section PRELIM).

**R1. Replace the semester-long statistical courses with didactic training in obesity biology.** We have added didactic training obesity biology and clinical shadowing; the revised training plan now better aligns with the revised research plan (Section TRAIN).

**R2. Clarify how mentors will monitor progress, including yearly team meetings.** See Section MENTORS.

**R3. Clarify manuscripts and grant applications to be submitted during award period.** See Section DISSEM.