

## SF424 (R&R) Application Guide for NIH and Other PHS Agencies

### Preliminary Studies/Progress Report

#### *Preliminary Studies.*

For new applications, use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.

Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), and Phase I Small Business Research Grants (R41/R43), **peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.**

#### *Progress Report for Renewal and Revision Applications.*

A Progress Report must be provided for renewal and revision applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Discuss any changes in the specific aims as a result of budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials will be included in Section 7; do not include that information here. Six to eight pages are recommended for the narrative portion of this section.

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The instructions for preparation of the Preliminary Results provide very little detail regarding specific information to be included. However, the instructions emphasize the importance of Preliminary Results for a successful application. Construction of the Preliminary Results section is as much art, as it is science. The requirements are different for basic science and clinical projects. I asked several successful investigators for their thoughts on how to prepare the preliminary results section.

1. For many reviewers, the best predictor of future success is past success. A major goal of the Preliminary Results section is to convince the reviewers that you and your collaborators have the skills and experience necessary to carry out the work proposed. This may include experience assembling a study cohort, arranging the logistics of an RCT, conducting the kinds of exposure and outcome assessments that will be involved, applying the types of analytical methods (whether genetic, chemical, or statistical) involved in the proposed work, etc.
2. A secondary goal is to show the line of investigation that has culminated in the proposed work. This is secondary because it's not always one's previous work that has led to the application. In the latter case, all one can do is show that your other accomplishments which make it highly likely you will be able to complete the proposed work. You need to do is to convince the reviewers that you and your group are uniquely qualified to carry out the proposed work.
3. The Preliminary Results section is the main educational part of the grant proposal. The section allows the investigator to tell the reviewer what has been done, and why the proposed work is very important. It has to "wow" the reader and make the applicant look like he/she is an expert. The significance section will set up why the work is important, but the Preliminary Results section must support the notion. Otherwise the grant will sound mundane.
4. Recently, study sections have been asked to emphasize significance and innovation (is the research truly novel or is it just incremental?). The Preliminary Results section offers a place to present credible data in support of the significance and innovative nature of the ideas. It is usually a good idea to specifically point out why a result and the related aim are significant and innovative.
5. Reviewers will consider questions such as: Does the application convince me that the investigators know what they are getting into (i.e., is the amount or type of work proposed realistic for the project period? Too much or too little?), whether the expertise of the team covers all the areas that will be involved, and, if relevant, whether the proposed work follows logically from what the group has accomplished in previous studies (but again this is secondary, especially if the group is beginning a new line of inquiry).

6. Present data that has a purpose. The data should directly support the hypotheses that you are testing in the grant or your ability to perform experiments that you propose.
7. It is best to have preliminary data in support of all of the Aims. For a RO1 it is really necessary to have both a publication for each Aim and preliminary data. For a R21, even though the guidelines say preliminary data are not necessary, they are really needed to obtain funding. In general publications are not needed for each aim for a R21, but they definitely help.
8. For a clinical trial, the pilot data should allow the sample size to be calculated, demonstrate proof of feasibility of subject recruitment and performance of the protocol, such as pilot data for the therapies being tested.
9. For basic science projects, the data should be limited to feasibility studies for new techniques, or proof of concept results for new directions. It is important not to have data so extensive that reviewers will say that the project has already been completed.
10. The number of preliminary studies that will satisfy the reviewers is variable. A single experiment is not sufficient. In some cases 3 to 6 experiments will suffice, if they support the hypothesis. Evidence of careful analysis of each experiment showing that the investigator has identified initial problems and appropriately addressed them is important.
11. Small numbers without statistical significance are expected at this stage. But the initial data should support the hypothesis and the testability of the hypothesis. It is also important to specify at this point the specific type of statistical analysis that will be applied as more data is accumulated as well as indicate the number of subjects, procedures, tests, etc. that will be required to adequately test the hypothesis and show that such numbers can be feasibly reached. Evidence that the investigator has consulted a statistician to help design the study before it actually begins sheds a favorable light on the project.
12. The preliminary experiments should use the techniques listed and described in the Study Design section of the proposal. The work and techniques must be state of the art and appropriate for the work proposed. Rather than just saying what you are going to do, it is preferable that you actually describe previous work that employed these techniques, and hopefully was published.
13. Provide reviewers with a sense of how you interpret data and draw inferences, i.e., how cautious you are and that you understand any limitations and data gaps. Reviewers can get such information from reading previous publications, but given the work burden, most tend not to do this. The Preliminary Results section is a place to let them know how you think and, hopefully, convince them that your approach is thoughtful and nuanced
14. The Preliminary Results section needs to look good. Not just from a scientific perspective, but from a visual perspective. The illustrations and figures need to be pleasing to look at, well organized, as well as ordered and consistent in form. If the figures are all of different size and format, it looks bad and gives the impression that the grant proposal was thrown together at the last minute.
15. It is of importance to have interesting figures with each preliminary data entry, and these should always be figures that both look good in black and white copy well. Most reviewers will print out applications that they are reviewing, and the majority of the time will not use a color printer.
16. It is also important to keep the preliminary data and related figures localized in the Preliminary Results section of the grant. Many applications have preliminary results in the Significance section, and sometimes even in the Research Methods and Designs. This usually draws negative comments at the study section meeting that are not captured in the Summary Statement.
17. You do not want reviewers to struggle with incompletely labeled preliminary results or inadequate figure legends.
18. For revised applications, reviewers will look to see if preliminary results have been provided that address the prior criticisms. In reviewing, preliminary results that address prior criticisms are much more helpful for an application than arguments addressing the points of a critique.
19. For a competing renewal, this section is called the Progress Report. It is actually both a progress report and a place for preliminary data in support of the new aims for the competing renewal. In general in this setting, cite publications for progress and include only preliminary data in this section.