

NCMRR/NICHD Planning Grants
Additional Guidelines For Applicants

In parallel with the Request for Application (RFA) announcement that describes the background and goals of this funding mechanism, we hope that these additional comments will serve to further clarify the expectations and goals of this RFA, and guide you in preparing applications.

- The purpose of this grant application is to plan the details of the proposed study and set up the infrastructure for a study. This is not a mechanism to collect pilot data or do a study.
- The emphasis of application should be on program development, rather than on the measurement problem.
- Provide an overview of the issues for which the study is needed. What are the methodological, biological, and technical or other gaps that need to be addressed by any study that ultimately would be proposed in a subsequent R01?
- Describe the work that is necessary to develop a study to answer the issues that have been identified. What is the rationale for this R21 application as opposed to an R01 application?
- Address why time and money is needed (R21) as a first step to prepare for a subsequent R01 application.
- Describe plans for the funding period that address a detailed and specific formulation of the research question. For example, what is proposed to address the process of settling on the primary research question?
- What methods are best to study the issues? Appropriate outcome measures, including measures of function, disability, and participation may need to be considered. The applicants may explore design options and decide which is most appropriate and feasible for their question(s).
- What are the inclusion and exclusion criteria for the subjects? This is often a complicated issue and one that bears careful pre-R01 application thought and discussion.
- Provide information regarding subject availability, recruitment and retention issues if appropriate.
- Provide information regarding the means by which subject confidentiality will be protected.
- Describe data analytic challenges, and how these will be addressed. This may require discussion with biostatistician-methodologist, and allocating funds to do that may be an important issue. For example, if there are any innovative techniques required (e.g., Structural Equation Modeling or Hierarchical Linear Modeling) there is a good deal of work needed to find people who can do these important but less familiar analyses.
- Demonstrate how the team of investigators and sites for multi-site studies will be assembled, to ensure a strong case is made for feasibility. Delineate the strengths and unique resources of the responsive sites.
- Describe how protocols and other measures will be standardized and consistent across all sites to ensure inter-site reliability.

- Focus on addressing and resolving the methodological and feasibility aspects of the proposed study, so that the section of the R01 that asks about the applicants' previous work can speak to all these issues.