

GUIDE FOR REVIEWER'S WRITTEN COMMENTS
Planning Grants for Pragmatic Research in Healthcare Settings to Improve
Diabetes Prevention and Care (R34)

See the full text of the FOA at: <http://grants.nih.gov/grants/guide/pa-files/PAR-13-367.html>

Large clinical trials have demonstrated that glycemic control and cardiovascular risk factor modification can reduce the risk of diabetes complications. Although there have been considerable improvements in diabetes treatment options and in risk-factor control over the past three decades, recent research demonstrates that most U.S. adults with diabetes do not meet the recommended goals for diabetes care. Further, it is well established that behavioral lifestyle interventions, with modest (5-7%) weight loss, can prevent or delay development of type 2 diabetes in individuals at high risk for the disorder and, in individuals who already have type 2 diabetes, can decrease sleep apnea, reduce the need for diabetes medications, help maintain physical mobility, and improve quality of life. Despite these findings, behavioral lifestyle interventions have yet to become part of routine care for most overweight or obese individuals at risk for diabetes. To address the growing problem of diabetes in the nation and improve the quantity and quality of life for Americans, we must find efficient ways to close the gap between outcomes achieved in clinical trials and the outcomes achieved in actual healthcare practice.

Most individuals are already seen in some type of healthcare setting but, as noted, achievement of appropriate preventive and diabetes care goals remains elusive for many. This FOA seeks research to test the effectiveness of practical and potentially sustainable strategies to modify healthcare delivery to prevent diabetes in at-risk individuals, improve diabetes care, and reduce long term complications. Pragmatic research designs in response to this funding announcement are strongly encouraged. Pragmatic trials evaluate the effectiveness of interventions or therapies in research designed to maximize applicability of the trial's results to routine healthcare conditions. As such, the research should leverage staff and facilities in routine and representative healthcare settings. This supports the practicality of the intervention and, if effective, approaches tested under routine conditions will have greater potential to be adopted by similar healthcare providers and systems.

Pilot and feasibility research/planning grants in response to this FOA may include approaches focused on the patient, provider, healthcare team, and/or healthcare system. Studies that focus on providers may target physicians as well as non-physician healthcare professionals or staff within the healthcare system being studied. Areas of research focus should have the potential to generalize to other settings and types of payment and clinical practice situations. Trials that include community resources to augment healthcare are permissible but the community resources must be well integrated into healthcare delivery. Referral to community programs by the healthcare system or staff is not, in itself, an adequate linkage. There should also be some evidence that the community program or policy is directly linked to healthcare delivery through a formal agreement, reimbursement, and regular communication about patient progress and outcomes.

Studies including low income/resource and diverse populations at disproportionate risk of diabetes and diabetes complications are encouraged.

Research examples include, but are not limited to:

- Studies of innovative models of healthcare delivery including Patient Centered Medical Homes, shared medical appointment/group visits, team care approaches, care coordination, integrated care, shared decision making, pharmacy/pharmacist based initiatives, or use of eHealth, mHealth, or health information technology.
- Studies of incentives to improve diabetes prevention, treatment, and/or outcomes. Examples include physician incentives to follow clinical care guidelines, provide weight loss therapy/intervention, and achieve target clinical outcomes in their enrolled patient panels or patient incentives to adhere to prescribed medications or follow prevention and treatment recommendations.
- Studies to improve patient adherence to efficacious self-management and treatments, such as medications, blood glucose monitoring, lifestyle change, or other aspect of diabetes care or prevention. Such interventions could target patient, provider, and/or healthcare system provider or some combination.

- Redesign of workflow in physician's office to improve screening, initial counseling, and follow-up of patients with diabetes or at risk for diabetes to enhance adherence to guidelines, weight loss or improve glycemic control

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

Please use the following guidelines when preparing written comments on R18 research project grant applications assigned to you for review.

Written Critiques

- The format of the critiques should follow the structured template provided for each mechanism, which can be downloaded from the Internet Assisted Review (IAR) site.
- Each core criterion and additional review criteria are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted form.
- The goal is to provide the maximum and most pertinent information in a concise manner. ***Please do not sacrifice clarity for brevity.***
- After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application in the Overall Impact section of the template.
- Assigned reviewers must upload critiques before entering an overall impact/priority score.
- Criterion scores should be entered in IAR before the review meeting.
- Assigned reviewers may submit criterion scores only after their critiques have been uploaded.
- The criterion scores may be changed following the review meeting during the EDIT phase.
- Please do not write your criterion scores on the critique template.

Preliminary Scores

- Each core review criterion should be given a score using the nine-point rating scale in accordance with the new Enhanced Peer Review Criteria.
- The criterion scores for the applications should be entered in the meeting Internet Assisted Review (IAR) site in NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and critique.
- The criterion scores may be changed following the review meeting during the EDITPhase.
- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them. Core criterion scores can be submitted only after your critique had been uploaded into IAR.
- The criterion scores will appear in the summary statement as part of your critique.

Overall Impact

NIH peer reviewers are asked to provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and the additional review criteria (as applicable for the project proposed).

Please note the additional requirements related to **Research Strategy**: The research strategy must include a discussion of how integration into the existing clinical setting will be accomplished, as well as the potential scalability, sustainability, and dissemination potential of the approach should it prove successful in an eventual full scale trial. This discussion should include, where applicable, issues related to appropriate partnerships, cost, potential for reimbursement, personnel, and other necessary resources for implementation and maintenance. While most research requires some infrastructure support and staffing, grant expenditures for these functions should be minimized. Research that evaluates effectiveness using existing healthcare staff or resources to deliver an intervention or make system changes is encouraged. If grant funding will be used to support intervention staff, the applicant must make a strong justification that, if the study achieves its aims, these personnel and their associated costs have the potential to be sustained in the healthcare setting beyond the research funding period. Some research funding can also go toward enhancement activities such as adapting or enhancing electronic resources or training personnel but, again, the sustainability of these investments beyond the research period should be justified. A full cost effectiveness analysis is not required but research funded implementation costs should be measured and considered in the study analyses.

Researchers are encouraged, where possible, to use registries and electronic medical records to identify potential participants and ascertain study outcomes. Study endpoints should be diabetes-related outcomes that are relevant to key stakeholders such as patients, clinicians, caregivers, health systems and health policy makers (e.g., HbA1c, weight/BMI change, diabetes risk factor control, screening and prescribing appropriate medication, patient adherence to effective therapies, hospitalizations, ER visits, healthcare utilization, healthcare cost). Patient-centered outcomes are encouraged as additional primary outcomes or secondary outcomes (<http://www.pcori.org/research-we-support/pcor/>). If using more than one primary outcome, applicants should apply appropriate analytical adjustments required for multiple comparisons. Investigators are also encouraged to include an evaluation of acceptability by clinical staff and patients.

Since this FOA is designed to support pilot and feasibility, an efficacy based power analysis is not necessary. However, applicants must detail their plan for determining feasibility and evaluating whether the approach is successful enough to warrant moving to a full scale trial. Also, the sample size needed to pilot the proposed approach, including the assumptions used when estimating the sample size, should be detailed in relation to the analysis plan.

Core Review Criteria

Reviewers are asked to consider each of the five scored review criteria below in the determination of scientific and technical merit, and give a separate score for each. These individual criterion scores are considered part of your critique and will not be discussed at the review meeting. They may be changed in the EDIT phase in Commons. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Will the research question and design meaningfully inform healthcare practice or policy? Does the research setting generalize to other healthcare settings?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Has the investigator demonstrated appropriate partnerships with the key decision makers and staff in the healthcare setting to justify that the proposed research is feasible? Have the researchers justified the sustainability and dissemination potential of the approach beyond the research period, including appropriate partnerships and consideration of cost and resources such as personnel and infrastructure? If so, was the plan for sustainability compelling--i.e. if successful would these research findings be likely to improve patient outcomes in routine care settings? Is

there a sufficient evaluation of the implementation costs and implementation process to meaningfully inform scalability and sustainability? This evaluation should include, where applicable, issues related to cost, reimbursement, personnel and other resources.

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers are asked to consider the following additional items in the determination of scientific and technical merit, but not to give separate scores for these items.

Protections for Human Subjects

See detailed guidelines.

Inclusion of Women, Minorities and Children

See detailed guidelines

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications

When reviewing a Resubmission application (formerly called an amended application), evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications

When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Budget and Period Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

1) Data Sharing Plan

(http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm) Applications requesting more than \$500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program Announcements may request a data sharing plan for all applications regardless of the amount of direct costs. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

2) Sharing Model Organisms

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). All NIH grant applications are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

3) Genome Wide Association Studies

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html>). Applications and proposals that include GWAS, regardless of the requested costs, are expected to include as part of the Research Plan either a plan for submission of GWAS data to the NIH designated data repository or an appropriate explanation for why submission to the repository will not be possible.

4/29/2014