

## GUIDE FOR REVIEWER'S WRITTEN COMMENTS

### Evaluating Natural Experiments in Healthcare to Improve Diabetes Prevention and Treatment (R18)

See the full text of the FOA at: <http://grants.nih.gov/grants/guide/pa-files/PAR-13-365.html>

For the purposes of this FOA, health policies and/or programs are defined as laws, regulations, formal and informal rules, and systematic processes or care programs that are adopted or instituted to affect system functioning and collective behavior in the healthcare setting. Policies and/or programs may involve expanding, changing, or re-organizing services or increasing or redirecting resources in some way to change behavior at the individual, healthcare team or system level to improve care and clinical outcomes.

The goal of research supported by this FOA is to maximize what can be learned from healthcare policies and programs that are planned or recently implemented. This FOA is not intended to support the initiation and delivery of new policies or programs. Research support is for the evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of NIH grant funding. Further, the intent is to support evaluation of policies or programs that are large enough in scale to allow the results to have some generalizability outside of the specific setting of implementation.

Evaluation research that has the potential to inform healthcare policy or practice in other types of payment or clinical practice settings is encouraged. Research in response to this FOA may focus on programs or policies that target the patient, family, healthcare team, healthcare system, or some combination. Research can also focus on linkages between the healthcare delivery setting and community health efforts. Healthcare referral to community programs alone is not an adequate linkage. There should be 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.

This FOA is intended to fund natural experiments where comparable control data can be assembled and confounders and biases can be limited through study design, sample selection, and statistical analysis. This FOA is not intended to fund cross-sectional cohort studies.

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

Research examples include, but are not limited to, evaluation of healthcare policies and/or large scale healthcare programs designed to improve diabetes prevention or treatment through:

- Innovative models of health care delivery, including team approaches, Patient Centered Medical Homes, inclusion of care extenders (such as pharmacy support, patient navigators), models of care coordination/integration, group medical visits, pharmacy/pharmacist based initiatives, or use of eHealth, mHealth, or health information technology (such as EMR alerts decision tools).
- The use of patient and/or physician incentives, insurance or employer reimbursement or cost-sharing policies, or benefit designs to alter health outcomes.
- Changes in healthcare policy such as reimbursement for lifestyle intervention or obesity medications for patients at risk for diabetes.
- Healthcare or employer-based disease management and health promotion approaches.
- Programs designed to improve weight loss, patient self-management or adherence to efficacious treatments, such as medications, blood glucose monitoring, lifestyle change, or other aspect of diabetes prevention or care. Such programs and/or policies could target patient, provider, and/or healthcare system provider or some combination.
- Programs designed to improve physician, healthcare team/system adherence to established clinical care guidelines or evidence based screening and/or intervention.

Primary study endpoints should be diabetes-related health outcomes that are relevant to key stakeholders (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). Researchers are encouraged, where possible, to use electronic medical records or registries to ascertain study outcomes. Patient-centered outcomes are encouraged as additional primary or secondary outcomes (<http://www.pcori.org/research-we-support/pcor/>). If using more than one primary outcome, applicants should attend to appropriate analytical adjustments to accommodate for multiple primary end points.

## 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**: If recently implemented, a justification of the quality and relevance of the baseline data available should be included in the research strategy.

Grant applications should evaluate potential scalability, sustainability, and generalizability of the program and/or policy (e.g., consideration to cost, reimbursement, personnel and other resources), unintended consequences, fidelity of implementation, and an assessment of barriers and facilitators associated with implementation. This includes measures that will help identify why the healthcare policy or program succeeds or does not succeed. Investigators are also encouraged to include an evaluation of acceptability by relevant stakeholders in the program or policy implementation such as patients, clinical staff, caregivers, employers, healthcare systems or health policy makers.

This FOA encourages innovative scientific partnerships between researchers and public or private partners (e.g., healthcare delivery organizations and employers). Applicants must demonstrate that those who hold ownership or management of the program and/or policy will support access to the data required for the evaluation, including access to the data for the comparison group/s. Where appropriate, agreements must also be in place that allow for unrestricted publication of findings regardless of study outcomes.

## **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? Is the research proposed for the evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of NIH grant funding? Will the evaluation proposed meaningfully inform diabetes related healthcare practice or policy? If so, do the research findings have the potential to generalize to other settings and types of payment/ clinical practice situations?

### ***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? Are the study endpoints objective diabetes related health outcomes that are relevant to key stakeholders? Is the feasibility clear--e.g., are the measures practical and feasibly collected; are the appropriate partnerships in place, is the setting clearly committed to the research goals? Will the plan for baseline data collection and comparison group/s included provide sufficiently rigorous and relevant data to answer the primary research questions? Are patients and key stakeholders meaningfully and consistently involved?

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?

### ***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](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.