

### **1. Significance.**

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? 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?

### **2. Investigator(s).**

Are the PD/PIs, 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?

### **3. 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?

### **4. Approach.**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? 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? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

### **5. 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?

## Outlining Your Grant

**1. Significance.** – sub-section with one line heading of subject to address each subject below  
Clinical need – how many patients, outcomes, cost

What is the critical barrier to improved treatment

Scientific premise - evidence that your approach will address the critical barrier (preliminary data or literature findings)

Upon successful completion of this aims, we will ... MULTI-FACETED

- add scientific knowledge, technical capability, and/or improved clinical practice

Finish with impact on human health - How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field AND other fields

## 2. Innovation.

Link to critical barrier – what is missing = need for innovation

MULTI-FACETED innovation: what is new about your approach/how you are addressing critical barrier: methods, combination of things, new questions

- successful completion of aims, will generate new knowledge, new tools, new products, new clinical practice
- how will these new tools be applied to other clinical problems or technical hurdles

Bullet innovative aspects and highlight what is new knowledge, new tools, etc.

## 3. Approach.

Need overall approach figure to show aims and experimental design

Overview paragraph of aims that complements figure/schematic and highlights the capabilities of the team to complete these aims.

Each Aim:

- Rationale
- Preliminary data
- Experimental Design Overview
- Studies – experimental details
- Expected outcomes/success criteria/statistical analysis
- Potential Problems and Alternative Solutions