Specific Aims Page (maximum 1 page)

Your specific aims page should be structured as follows:

- What is the health care/biomedical research problem (topic) and how important is it?
 What is the unmet need (ie. Gaps in knowledge, ways this will bring the field forward)?
- What is already known and accepted in this area?
- What is the problem, roadblock, the unknown?
 - Limitations of prior studies
 - Unaddressed questions
- Long-term goal: What final "big result" will the research help achieve down the road?
- What is the specific narrow goal of this research?
- Statement of the research question of your study
- How will your study address:
 - Limitations of prior studies and what is not known
 - The research question
- How is your study innovative?
- Statement of specific aims and hypotheses
 - o If the aims/hypotheses are met, what are the implications for the unmet need?
 - o If the aims/hypotheses are not met, what the implications?
- Study design (for clinical/population-based research: population to be studied, sample size, source of subjects, measures etc.; for basic science: animal model, cells, protein, experimental procedure etc.)
 - Alternatively, this can go above aims/hypotheses.
- Public health implications (summary)

Although the focus of this workshop is on writing Specific Aims, we have included information on the suggested structure and format for the Research Strategy sections.

Research Strategy (i.e. Significance, Innovation, Approach sections) (the page limit is dictated by the type of application you are submitting – please review NIH application instructions carefully to find out what the page limit is).

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 are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

• Suggest format: Provide background of scientific area. What is already known. What is not known (i.e. scientific gaps in knowledge). Why do these gaps matter for human health. Describe overall research question. How will your study address these gaps.

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?

Approach:

- Overview of study design and methods to be used, and how they are appropriate for assessing your hypotheses.
- Study design: Include strengths and advantages of your chosen design, discussion of possible alternatives and the reasons for not choosing them. Tie your choice of design to your specific aims, and why it works.
- Subjects
 - Population being targeted
 - o Entry criteria & recruitment information
 - Any issues related to eligibility/attrition
 - Randomization procedures (if applicable)
- Variables
 - Exposure(s)
 - Outcome(s)
 - Adjustment variables (covariates)
- Statistical plan
 - For each aim, describe the statistical procedures and techniques you will apply to address your main hypotheses; tie explicitly to your specific aims.
 - o Plans for data management (where/how will data be collected and stored)
 - Sample size justification: Give a justification (power or precision) for the sample size you will employ.
- Potential problems, pitfalls, and alternative strategies
 - o Describe problems that you foresee and strategies for overcoming them.
- Timeline and benchmarks
 - Give a timeline and possible benchmarks that you can use to monitor your progress.

References (no limit)