

judged likely to have a major scientific impact. Factors to be considered will include:

a. *Significance*. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. *Approach*. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

c. *Innovation*. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. *Investigator*. Is the principal investigator appropriately trained and well-suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior history of conducting injury-related research?

e. *Environment*. Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

f. *Ethical Issues*. What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, e.g., suspected child abuse? Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects? (An application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.) The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial

groups in the proposed research (See Attachment 1, AR-2).

This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

g. *Study Samples*. Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. *Dissemination*. What plans have been articulated for disseminating findings?

i. *Measures of Effectiveness*. The Peer Review Panel shall assure that measures set forth in the application are in accordance with CDC's performance plans. How adequately has the applicant addressed these measures?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of the ACIPC. The ACIPC Federal agency experts will be invited to attend the secondary review and will receive modified briefing books (i.e., abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). ACIPC Federal agency experts will be encouraged to participate in deliberations when applications address overlapping areas of research interest, so that unwarranted duplication in federally-funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the ACIPC Federal agency experts to assure that research priorities of the announcement are understood and to provide background regarding current

research activities. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered will be the same as those considered by the SPRS.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The secondary review committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010," the Institute of Medicine report, "Reducing the Burden of Injury," and the "CDC Injury Research Agenda."

d. Budgetary considerations.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. *Annual progress report*. The progress report will include a data requirement that demonstrates measures of effectiveness.

2. A financial status report, no more than 90 days after the end of the budget period.

3. Final financial report and performance report, no more than 90 days after the end of the project period.

4. At the completion of the project, the grant recipient will submit a brief (2,500 to 4,000 words written in nonscientific [laymen's] terms) summary highlighting the findings and their implications for injury prevention programs, policies, environmental changes, etc. The grant recipient will also include a description of the dissemination plan for research findings. This plan will include publications in peer-reviewed journals and ways in which research findings will be made available to stakeholders