

1. The primary review will be a peer review conducted by the SEP. A committee of reviewers with appropriate expertise will review all applications for scientific merit using current National Institutes of Health (NIH) criteria (a scoring system of 100–500 points) to evaluate the methods and scientific quality of the application. All categories are of equal importance, however, the application does not need to be strong in all categories to be judged likely to have a major scientific impact.

Factors to be considered will include:

a. Significance—Does this study address an important problem? Does the applicant justify the present proposal using existing scientific knowledge? 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 describe the specific questions this research is intended to address? Does the applicant describe how relevant behavioral theories will be applied to encourage the proposed activities? Does the applicant describe the hypotheses to be tested, the specific study goals, measurable objectives, and outcomes? 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? Does the applicant provide a detailed time-line for the first year of the study as well as a projected time-line for the subsequent years?

Does the applicant describe methods for selecting the study population and study sample, timing of assessments post-injury, and identifying participants (case definition for MTBI) measure(s) or validating existing measure(s) of outcomes of MTBI, and for assessing the reliability and validity of those measures?

Are there adequate plans for data collection and data management including security of data, assurance of participant confidentiality, data entry, editing, and quality assurance procedures? Is there a statistical analysis plan appropriate for the study design?

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 TBI-related research? Does the applicant document capacity to accomplish the proposed study as demonstrated by relevant past or current experience conducting research on TBI outcomes and/or developing and validating outcome measures?

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? Does the applicant describe the personnel and study collaborators needed to accomplish the proposed activities? Does the applicant provide evidence that the study personnel have the expertise and capacity to accomplish the proposed activities and to provide appropriate scientific oversight necessary to fulfill study goals and objectives?

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? Is there evidence of the experience and capacity for all key staff members including CVs and position descriptions?

f. Study Samples—Are the samples 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?

g. 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 part 46 for the protection of human subjects? Not scored; however, 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.

Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? 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.

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?

j. Budget—The SEP 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. 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