

**Application # PI Last Name, First Name**

**RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**PUBLIC HEALTH RELEVANCE:**

**CRITIQUE 1**

Importance of the Research (Significance and Innovation): *(Factor score 1-9)*

Rigor and Feasibility (Approach): *(Factor score 1-9)*

Expertise and Resources (Investigators and Environment): *Appropriate or Additional Expertise and/or Resources Needed*

**Overall Impact:**

**1. Importance of the Research (Significance and Innovation):**

**Major Score-Drivers**

**Strengths**

- 

**Weaknesses**

- 

**2. Rigor and Feasibility (Approach):**

**Major Score-Drivers**

**Strengths**

- 

**Weaknesses**

- 

**Inclusion Plans:**

- Sex/Gender: Scientifically justified *or* Not scientifically justified *or* Not Applicable
- Race/Ethnicity: Scientifically justified *or* Not scientifically justified *or* Not Applicable
- For NIH-Defined Phase III trials, Plans for valid design and analysis (applicable to sex/gender and race/ethnicity): Adequate for work proposed *or* Not adequate for work proposed *or* Not Applicable
- Inclusion/Exclusion Based on Age: Scientifically justified *or* Not scientifically justified *or* Not Applicable

**3-FACTOR FRAMEWORK**

Main review criteria assessments organized around 3 Factors instead of 5 criteria. Factor scores only listed for Factors 1 and 2.

**INCLUSIONS AND PLANS FOR VALID DESIGN/ ANALYSIS**

Drop-down selections will remain the same for Inclusion plans, but will be listed under Factor 2 instead of Additional Review Criteria Section. Similarly, the drop-down assessment for plans for valid design and analysis for Phase III clinical trials will now be listed under Factor 2. Reviewers will only provide written comment if concerns are identified in the drop-down selection.

- *(Concerns not included in Factor 2 major score drivers)*

### **3. Expertise and Resources (Investigators and Environment):**

**Appropriate**

*or*

**Additional Expertise and/or Resources Needed**

- *(Comments if applicable)*

**Protections for Human Subjects:**

**Appropriate**

*or*

**Concerns**

- *(Comments if applicable)*

*or*

**Not Applicable**

**Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):**

**Appropriate**

*or*

**Concerns**

- *(Comments if applicable)*

*or*

**Not Applicable**

**Vertebrate Animals:**

**Appropriate**

*or*

**Concerns**

- *(Comments if applicable)*

*or*

**Not Applicable**

## **FACTOR 3 CHANGES**

Binary assessment for Factor 3: Expertise and Resources (“Appropriate” or “Additional expertise and/or resources needed”). If “Additional expertise and/or resources needed” is selected, reviewers will provide a written justification.

## **ADDITIONAL REVIEW CRITERIA**

The Additional Review Criteria section will contain Protections for Human Subjects, Vertebrate Animals, Biohazards and Resubmission/Renewal/Revision comments where applicable.

**Biohazards:**

**Appropriate**

*or*

**Concerns**

- *(Comments if applicable)*

*or*

**Not Applicable**

**Resubmission:**

- *(Comments if applicable)*

**Renewal:**

- *(Comments if applicable)*

**Revision:**

- *(Comments if applicable)*

**Authentication of Key Biological and/or Resources:**

**Appropriate**

*or*

**Concerns**

- *(Comments if applicable)*

*or*

**Not Applicable**

**Budget and Period of Support:**

**Appropriate to support the proposed research**

*or*

**Excessive to support the proposed research**

- *(Comments if applicable)*

**ADDITIONAL  
REVIEW  
CONSIDERATIONS**

Reviewers will continue to evaluate the following additional review considerations (non-score driving): Authentication of Key Biological and/or Chemical Resources, and Budget and Period of Support.

There are now three options for drop-down assessments of budget and period of support: (1) Appropriate to support proposed research, (2) Excessive to support proposed research, or (3) Inadequate to support the proposed research. There is a text box for reviewers to “Briefly address specific concerns regarding the proposed budget”.

or

**Inadequate to support the proposed research**

- *(Comments if applicable)*

**CRITIQUE 2**

**CRITIQUE 3**

**THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF THE DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS RESEARCH:**

**INCLUSION OF WOMEN PLAN:**

**INCLUSION OF MINORITIES PLAN:**

**INCLUSION ACROSS LIFESPAN PLAN:**

**VERTEBRATE ANIMAL RESEARCH:**

**BIOHAZARDS:**

**AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES:**

**COMMITTEE BUDGET RECOMMENDATIONS:**

**SCIENTIFIC REVIEW OFFICER'S NOTES:**

**COMMITTEE RECOMMENDATIONS**

Committee recommendations for Human Subjects Protections, Use of Vertebrate Animals, Budget will still appear on the Summary Statement (no change).