QOL/PRO STUDY EVALUATION TEMPLATE
Quality of Life/Patient-Reported Outcomes

Evaluator's Name:

Date of Evaluation:

Concept/BIQSFP ID Number and Title:

Instructions for BIQSFP Evaluators: You have been asked to provide an evaluation of the quality of life (QOL) /patient-reported outcome (PRO) study associated with the phase 2 or phase 3 concept listed above. Your responsibilities as an evaluator consist of evaluating the proposed study and completing this form with your written comments by filling out the fields that follow each review criterion.

Please use the applicant's responses within the *BIQSFP Study Packet, including the Checklist and Budget documents,* in completing your evaluation.

After completing this form, please save it to a new file, attach the form to an e-mail message referencing the concept/BIQSFP number, and forward the email to the NCI/EMMES Program Staff responsible for sending this evaluation. Submit your response at least 3 business days preceding the study evaluation conference call, so that all perspectives may be shared, and your written comments viewed by other evaluators of this study. You will likewise be provided access to the written comments of the other evaluators.

Criteria for Review and Prioritization of *QOL Studies*

1. **The potential to impact patient morbidity or QOL with clinically meaningful benefit**

   Strengths:

   Weaknesses:

2. **The potential to move science forward in cancer-related QOL/PRO by adding critical knowledge**

   Strengths:

   Weaknesses:

3. **The strength of the preliminary data supporting the hypothesis(es) to be tested and methods proposed**

   Strengths:

   Weaknesses:

4. **A clearly defined process for data collection and specimen collection**

   Strengths:

   Weaknesses:

5. **A statistical plan with adequate power for the primary symptom management and/or QOL/PRO correlative study hypothesis(es)**

   Strengths:

   Weaknesses:

6. **Measures that are reliable, valid and appropriate to the population of interest**

   Strengths:

   Weaknesses:

7. **Feasibility of proposal addressed such that completion can be accomplished efficiently in a reasonable time frame**

   Strengths:

   Weaknesses:

8. **Based on the definitions provided and on your evaluation of the study do you consider this test(s) to be **INTEGRAL* or *INTEGRATED (see * below) to the associated treatment/ prevention concept and why?**

- ***Integral studies** - Defined as assays/tests/assessments that must be performed in order for the trial to proceed. Integral studies are inherent to the design of the trial from the outset and must be performed in real time for the conduct of the trial. Integral biomarkers associated with QOL/PRO studies require a CLIA-certified lab. QOL/PRO studies that can be conducted in the future on archived assessments will not be eligible for BIQSFP funding, except if the results are critical to the stated primary or secondary objectives of the trial.

- ***Integrated Studies** – Defined as assays/tests/assessments that are clearly identified as part of the clinical trial from the beginning and are intended to identify or validate assessments, tests, or tools that are planned for use in future trials. Integrated studies in general should be designed to test a hypothesis, not simply to generate a hypothesis. Integrated studies include complete plans for administration of the assessment/test/tool, persons administering the assessment/test/tool, and statistical analysis. One example would be an assessment/test/tool where the result is not used for eligibility, treatment assignment, or treatment management in the current trial; a second example would be the use of an assessment/test/tool where the results are not used as a primary study endpoint.

    - **REAL TIME** INTEGRATED ASSAY? Some integrated studies may require that assays or tests be performed during the trial, for example, biomarker assays that require a fresh tumor biopsy or real time processing of a blood or tissue sample, or imaging tests to measure treatment response.

    - **NON-REAL TIME** INTEGRATED ASSAY? Other integrated studies do not require real time assays/tests or sample collection or processing. Examples of NRT integrated assays/tests include tools to analyze scans collected as part of standard treatment, gene expression studies that correlate with outcome, and PD-L1 assays performed on diagnostic tumor samples where the results are not used for eligibility, treatment assignment, or treatment management.

9. **It is not intended that any priority or particular level of merit be assigned to one of the previous criteria over another. Based on the totality of the information, the strength of the data presented, and your scientific judgment, is your level of enthusiasm for the study:**

High				**Mild**
1	2	3	4	5

10. Please comment on the attached Budget and justification. Provide recommendations if needed.

It is understood that by agreeing to assist in this evaluation, you have no conflicts of interest with this concept. In addition, all unpublished information, reports, and discussions are strictly confidential.