SYMPTOM SCIENCE/QOL EVALUATION TEMPLATE

Evaluator's Name:

Date of Evaluation:

Concept/BIQSFP ID Number and Title:

Instructions for BIQSFP Symptom Science/QOL Evaluators: Please complete one (1) Evaluation Template for each symptom science/QOL study. There could be more than one BIQSFP application (e.g., multiple biomarkers, imaging, symptom science/QOL) associated with a single clinical trial, and each should be submitted on a separate BIQSFP form.

Your responsibilities consist of evaluating the symptom science/QOL tool/instrument performance and validation aspects of the proposed study by providing written comments on this form in response to the specific questions that follow the evaluation criteria below.

Please use the attached *BIQSFP Proposal Package* 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 CTEP, DCP, CCCT, or EMMES Program Staff who requested this evaluation from you. Submit your response at least 5 business days preceding the study evaluation conference call/meeting, 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.

Key evaluation criteria:

A. Whether the study is integral, real time integrated, non-real time integrated, or exploratory

Based on the definitions provided below, evaluators should assess whether the proposed study is *integral*, *real time integrated*, *non-real time integrated*, or *exploratory*. Integral studies have highest priority for BIQSFP funding. Exploratory studies are not eligible for BIQSFP funding.

Integral Studies are tools/instruments that must be performed in order for the trial to proceed or to support the primary analysis. Integral studies are inherent to the design of the trial and must be performed on all participants, usually in real-time.

Integrated Studies are intended to clinically validate symptom science/QOL instruments for possible use as an integral marker in future trials or in clinical practice. Integrated studies should test a specific hypothesis with a preplanned statistical design and are not hypothesis-generating or exploratory (please see the definition of "exploratory" below). The tools/instruments need to have already

been analytically validated. Integrated studies must be included in the protocol as secondary outcomes.

Real Time (RT) Integrated Studies need the tool/instrument to be performed and/or evaluated in real time during the trial. Real time studies may also involve special collection or processing of patient sample collection or processing and cannot be stored and batched for analysis later.

Non-Real Time (NRT) Integrated Studies do not require real time processing or analysis of tools/instruments results (e.g., NRT integrated tool/instrument assessments collected as part of the clinical trial wherein the results are not needed for trial eligibility, stratification, or treatment assignment).

Exploratory studies include novel tools/instruments that generate insights into new therapeutic or interventional approaches that might be worthy of further investigation. Studies are also considered exploratory when they aim to test preliminary hypotheses or to further refine such hypotheses in situations where background data in the specific disease type or therapeutic context are limited

B. Specification of tool/instrument procedure

For BOTH integral and integrated studies, evaluators should assess whether the tool/instrument has been specified in sufficient detail in the BIQSFP documents. For symptom science/QOL tools/instruments, the specification should include minimum important difference (MID) or metric for clinically significant change. The submission should include symptom science/QOL scoring instructions as an appendix, to support validation of the tool/instrument(s) being proposed.

C. Adequacy of information provided about the analytical (technical) performance of the tool/instrument procedure

Evaluators are requested to provide comments about whether sufficient documentation of acceptable analytical (technical) performance has been provided. The BIQSFP documents should provide information about accuracy, precision, reportable range, reference ranges/intervals (normal findings), limit of detection, limit of quantification, and failure rate of the tool/instrument, as applicable, and in the context of how the procedure is to be performed in the trial (e.g., performance of tool/instrument on the types of patients expected in the clinical trial and/or whether the tools/instruments will be batched for analysis or analyzed in real-time).

The evaluators should consider whether tool/instrument performance metrics have been clearly defined and sufficient information has been provided about the numbers and types of subjects involved in the analytical (technical) performance studies. Details should include the distribution of tool/instrument measurements in the subjects studied in the performance assessment (e.g., how many were positive versus negative for the tool/instrument) and descriptions of the replication schemes used for precision and reproducibility evaluations.

The above information is necessary for proper interpretation of the reported analytical (technical) performance results. The requirement for information on analytical

performance also applies to a commercially available tool/instrument. Regardless of whether a tool/instrument is laboratory developed assessment or is commercially available, the analytical performance study description should provide supporting data to establish that the tool/instrument performance has been evaluated at the site/laboratory that will be evaluating and analyzing results for the clinical trial, and according to the same technical protocol (including tool/instrument preanalytical factors).

Mechanisms for assessing inter-facility variability in the application of the tool/assessment along with the analysis tool to manage inter-site variability should be noted. How will these sources of variation will be minimized to maintain performance at all sites within acceptable limits and to prevent drift or bias in tool/instrument imaging test results or analysis?

D. Pre-specified hypotheses, intended role, and supporting data

Pre-specified hypotheses and aims and a clear intended role for the tool/instrument in disease management/evaluation, with supporting data from prior studies, should be provided in the BIQSFP documents. Evaluators should comment on the robustness of the preliminary or supporting data, considering factors such as the design and analysis of the studies that generated those data. The supporting data need to be of sufficient strength and quality to justify the proposed investigation of the tool/instrument in an integrated study or its proposed use in the execution of the parent concept (integral tool/instrument).

For integral tools/instruments that are an inherent part of the trial design (e.g., only patients whose have breast cancer are eligible for entry into the trial and for randomization to treatment), the symptom science/QOL hypothesis is intimately tied with the treatment or symptom science question and will have been reviewed already as part of the review of the treatment or symptom science/QOL objectives of the parent clinical trial. However, if the evaluators have any concerns about the adequacy of the background data supporting the use of the tool/instrument in the proposed manner, they are encouraged to comment.

If the BIQSFP study involves a comparison of tools/instruments, a data analysis plan should be provided which describes how tool/instrument superiority will be determined.

Evaluator Comments:

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

   Strengths:
   Weaknesses:

2. The potential to move science forward in the area of cancer-related symptom science/QOL 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 symptom science/QOL 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 strength of the information presented and your scientific judgment, please indicate your level of enthusiasm for the study:

High				**Low**
1	2	3	4	5

SCORE: _____

9. Please comment on the attached Budget and Justification. Provide recommendations if needed. Are there potential cost-sharing approaches that can be developed with entities that would eventually commercialize the tool/instrument?

10. Please list any KEY QUESTIONS that the study Principal Investigator could address, which might change your recommendation regarding the BIQSFP proposal.

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.