February 18, 2020

'20 Biomarker, Imaging, & QOL Studies Funding Program (BIQSFP)

SYMPTOM SCIENCE/QOL Study Checklist

INSTRUCTIONS: Please submit a response to each of the criteria below and complete one Study Checklist for each Symptom Science/QOL endpoint. Refer to the 2020 BIQSFP Guidelines (*https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp*) for additional information.

1. The Symptom Science/QOL study application has been discussed with DCP staff and it has been determined that the collection of data requires resources beyond the usual DCP funding.
□ YES DCP staff member: _____ Date:_____

Please attach the DCP-provided letter to this document.

2. BIQSFP STUDY TITLE & CONCEPT NUMBER:

3. BIQSFP STUDY PI, LAB/SITE, EMAIL, PHONE:

4. LAB CO-INVESTIGATOR, LAB/SITE, EMAIL, PHONE:

5. TOOL OR INSTRUMENT SUMMARY INFORMATION**:** Complete the table below.

Tool/Instrument	Focus of Measurement	Standard of Care OR Investigational	Tool/Instrument Completion Timepoint(s)	Tool/Instrument Interpretation Timepoint(s)	Total # of Tests/Instruments Proposed

6. For each tool/instrument, identify whether it is INTEGRAL or INTEGRATED (Real Time or Non-Real Time). *See BIQSFP website for definitions.*

7. State the symptom science/QOL hypothesis(es) and its scientific foundation. Specify the study endpoint(s).

8. Identify the SYMPTOM SCIENCE/QOL instrument(s) to be used to test each hypothesis, the basis for choosing each instrument, and the timing of the assessments.

9. For each instrument, document its validity, reliability, and responsiveness in the selected patient population. Specify the minimum important difference (MID) or metric for clinically-significant change. Applicants are encouraged to submit Symptom Science/QOL scoring instructions as an appendix, to support validation of the test/tool/instrument(s) being proposed.

10. Describe any included *objective* correlates that enhance the patient-reported outcomes data (e.g. actigraphy, imaging, pulse ox, etc).

11. Explain how patient non-compliance, missing data and/or early death will be handled in the analysis.

12. How will visually-challenged patients be accommodated when completing the test/tool/instrument(s)?

13. Describe the procedures for data collection and data monitoring including the training of data collection personnel.

14. Provide turn-around-time for reporting instrument results to clinical PI (for INTEGRAL studies).

15. BUDGET

A. Include a budget that clearly details the direct and facilities and administrative costs requested using the PHS 398 budget form (***http://grants.nih.gov/grants/funding/phs398/phs398.html***) along with a narrative justifying each requested cost.
B. Include cost comparisons to justify the site(s) chosen to complete the assessment/test, where applicable.
C. Identify potential cost-sharing approaches for the assessment/test (e.g., billing to third-party payers, partial funding from commercial partners, etc.), as well as cost comparison and justification for academic vs. commercial settings, as applicable.

16. NIH BIOSKETCH: Include an NIH biosketch for each study Principal Investigator (PI). Form SF424 can be found at: ***https://grants.nih.gov/grants/forms/biosketch.htm***

Please complete and submit to the appropriate CTEP/DCP PIO and to the BIQSFP mailbox (ncibiqsfp@mail.nih.gov).