September 18, 2018

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

Checklist for Clinical Trials with QOL/PRO Endpoints

INSTRUCTIONS: Please submit a response to each of the criteria below and complete one Study Checklist for each QOL/PRO endpoint. Refer to the 2018 BIQSFP Guidelines (***https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp***) for additional information.

INTEGRAL QOL/PRO studies must be included in the concept as a primary objective and submitted along with the parent concept. **INTEGRATED** QOL/PRO studies should be noted on the parent concept and included as a secondary objective. If real time data points/assessments are required for the study the BIQSFP application should be submitted after the Principal Investigator has been notified of the approval of the parent concept. If real time data points/assessments are NOT required, the BIQSFP application should be submitted after the parent trial has reached 75% of target accrual and no later than six months following the publication date of the trial's primary outcome.

1. The QOL/PRO study application has been discussed with DCP staff and it has been determined that the collection of data requires resources beyond the usual DCP Cancer Control credits.

   ☐ YES DCP staff member _____

   Please attach the DCP-provided letter to this document.

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

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

4. 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/PRO scoring instructions as an appendix, to support validation of the test/tool/instrument(s) being proposed.

5. For each instrument, identify whether it is INTEGRAL or INTEGRATED.

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

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

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

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

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

11. 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.

12. 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).