

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

'16 Study Checklist for Clinical Trials with QOL/PRO Components

INSTRUCTIONS: Please submit a response to each of the criteria below and complete one Study Checklist for each QOL/PRO endpoint. The Proposal Package must also include a budget at the time of submission that clearly details the Direct and Indirect costs of the requested funding. The budget for the project should use the standard PHS 398 budget form (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) along with a narrative justifying each requested cost. The Budget packet must include a completed NIH biosketch form for each study PI. Form SF424 can be found at: <http://grants.nih.gov/grants/funding/424/index.htm#format>. Additional information on the new biosketch requirements can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html>.

NOTE: **Integrated** QOL/PRO study applications must be submitted after parent concept approval but prior to protocol activation. Subsequent NCI prioritization and approval for funding will be decided by CTROC after evaluation of the QOL/PRO study by DCP and the respective NCI Steering Committee (SC), if applicable.

1. State the symptom science/QOL/PRO hypothesis(es) and its scientific foundation. Specify the study endpoint(s).
2. 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.
3. 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 a symptom science/QOL/PRO Standard Operating Procedure (SOP) as an appendix, to support validation of the test/tool/instrument(s) being proposed.
4. For each instrument, identify whether it is INTEGRAL or INTEGRATED.
5. Describe any included *objective* correlates that enhance the patient-reported outcomes data (e.g. actigraphy, imaging, pulse ox, etc).
6. Identify any *biomarker or imaging* correlates of the patient-reported outcome measure(s) that will be collected (e.g., molecular, protein, other assays or tests).
7. Explain how patient non-compliance, missing data and/or early death may impact the analysis.
8. How will visually-challenged, non-English speaking patients be accommodated when completing the 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).

3/09,3/10,3/11,3/12,11/13,12/14,12/15

Please complete and return to the appropriate CTEP/DCP PIO and Dr. Raymond Petryshyn at CCCT (petryshr@mail.nih.gov). Thank you.