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

'14 Study Checklist for Randomized Phase 3 Trials with Quality of Life (QOL) Components

INSTRUCTIONS: Please submit a response to each of the criteria below. Please complete one Study Checklist and the Form PHS 398 Grant Budget Worksheets for each QOL endpoint.

NOTE: One-time INTEGRATED QOL study applications must be submitted after parent concept approval and must be received within four months (16 weeks) of notification of parent concept approval. Subsequent NCI prioritization and approval for funding will be decided by CTROC after evaluation of the INTEGRATED study(s) by the respective SSC.

1. State the HRQOL (health-related quality of life) hypothesis(es) and its scientific foundation. Specify the study endpoint(s).

2. Identify the HRQOL 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.

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.

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