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

## <u>'13 Study Checklist for Randomized Phase 3 Trials</u> with Quality of Life (QOL) Components

INSTRUCTIONS: Please submit a response to each of the criteria below and complete one Study Checklist and the standard PHS 398 budget form (http://grants.nih.gov/grants/funding/phs398/phs398.html) along with appropriate budget justifications for each QOL endpoint.

- 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.

3/09,3/10,3/11,3/12,4/13