

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

INTEGRATED BIOMARKER Study Checklist

INSTRUCTIONS: Please complete one Study Checklist for each INTEGRATED biomarker. Refer to the 2020 BIQSFP Guidelines (<https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp>) for additional information.

1. BIQSFP STUDY TITLE & CONCEPT NUMBER:

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

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

4. OBJECTIVE & HYPOTHESIS:

- A. Briefly describe the study objective, state the specific hypothesis(es), and indicate the role(s) in which the assay is expected to be useful (e.g., test for prognosis, test for response, test as a stratification factor, risk classifier or score, or some other use).
- B. For each assay, identify whether it is a Real Time or Non-Real Time INTEGRATED study. See *BIQSFP website for definitions*.
- C. Provide justification for the test or analysis to be completed in real time (if applicable).

5. ASSAY SUMMARY INFORMATION: Complete the table below.

Analyte/ Biomarker	Assay	Specimen(s) Tested	Collection Timepoint(s)	Timing of Specimen Testing (e.g. real time, batched, other)	Total # of Assays /Tests Proposed

6. BACKGROUND & SIGNIFICANCE: Provide data on the potential clinical utility of the integrated assay as it will be used in the trial.

- A. Provide background information that justifies the use of this assay result as a marker for this trial.
- B. Describe the expected distribution of the biomarker in the study population.
- C. If cut points will be used, specify the cut point(s) and describe how these will be used in the trial. Provide the rationale for the cut point(s) selected. What proportion of subjects is expected to have values above and below the proposed assay value cut points? What magnitude of effect (e.g., treatment benefit) or outcome (e.g., prognosis) is expected for patients with assay results above and below the proposed cut point(s)?
- D. Describe under what conditions treating physicians and/or patients will be able to access the assay test results.

7. DESCRIPTION OF ASSAY

- A. Specify the analyte(s), technical platform, and sources of assay components (e.g., reagents, chips, and calibrators).
- B. Describe the specimens and anticipated methods for specimen acquisition, fixation or stabilization and processing.
- C. Describe the scoring procedures and type of data to be acquired
 - quantitative/ continuously distributed
 - semi-quantitative/ordered categorical
 - qualitative/non-ordered categorical

8. ANALYTICAL PERFORMANCE OF ASSAY

- A. For *in vitro* tests, describe the status of studies defining the accuracy, precision, reportable range, reference ranges/intervals (normal values), and failure rate of the assay as it is to be performed in the trial (e.g., performance of test on specimens intended to be used in the clinical trial). Describe the use of positive and negative controls, calibrators, and reference standards for clinical assays. Describe any critical preanalytic variables.
- B. If the assay will be performed at more than one site, describe how inter-laboratory variability in the measurements listed in 6A above will be assessed. Describe how these sources of variation will be minimized to maintain performance at all sites within acceptable limits and to prevent drift or bias in assay.
- C. Applicants are encouraged to submit an assay Standard Operating Procedure (SOP) as an appendix, to support validation of the test(s) being proposed, if appropriate. If a laboratory validation study has been performed to meet the requirements of CLIA, please submit that data.

9. STATISTICAL PLAN

- A. Identify the clinical endpoints and the biomarker measurements involved in the analysis
- B. Specify the case selection method if only a subset of patients will be included.
- C. Justify the numbers of patients to be studied and biomarker assays/tests to be performed
- D. Describe the statistical analysis methodology and underlying assumptions.
- E. If the trial objectives include an evaluation of the association of the integrated marker with a new clinical endpoint or factor not previously studied, the statistical section of the concept should explain how the magnitude of the association or effect will be measured and provide power calculations for any statistical tests that are planned.

10. 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 laboratory site chosen to complete the assay.
- C. Provide plans for cost-sharing with entities that might eventually commercialize the test (when appropriate.)

- 11. 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 (ncibiqsf@mail.nih.gov).