2021 Biomarker, Imaging, & QOL Studies Funding Program (BIQSFP)
INTEGRAL BIOMARKER Study Checklist

INSTRUCTIONS: Please complete one Study Checklist for each INTEGRAL biomarker. Refer to the 2021 BIQSFP Guidelines **(https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp)** for additional information.

1. **GENERAL INFORMATION:** Please fill in the following information.

   BIQSFP STUDY TITLE & CONCEPT NUMBER: (Please give your study a unique BIQSFP TITLE distinct from the CONCEPT TITLE)

   BIQSFP STUDY PI:

   LAB/SITE:

   EMAIL:

   PHONE:

   LAB CO-INVESTIGATOR:

   LAB/SITE:

   EMAIL:

   PHONE:

2. **OBJECTIVE & HYPOTHESIS:** Briefly describe the study objective(s), specific hypothesis(es), and role(s) of the biomarker assay in the trial. (For example, is the biomarker an eligibility criterion, used for treatment assignment, a stratification factor, a risk classification, an outcome measure, or does it have some other use?)

3. ASSAY SUMMARY INFORMATION: Complete the table below. Please use a separate row for each different biomarker or assay.

Analyte/ Biomarker	Assay	Specimen(s) Tested	Collection Timepoint(s)	Timing of Specimen Testing (e.g. real time, batched, other)	Total # of Assays/Tests Requiring Funding:* Please consider the following example for estimating the maximum # of tests that would be performed: (Total # of assays requiring funding) = (Total # of patients whose specimens will be assayed) x (Total # of time points per patient)

* If identical processing procedure and assay will be run on different specimen types (e.g., blood and CSF), please provide total # of assays per specimen type. If different processing procedures and assay platforms will be used for different specimen types, the information should be listed in separate rows (e.g., one row for tumor and another row for blood).

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

A. Provide background information that justifies the use of this biomarker as proposed in this trial. For example, if the integral marker will be used as a stratification or treatment-determining variable, data supporting its prognostic or predictive association with a main trial endpoint should be described or referenced. Justification for use of a prognostic biomarker for stratification of randomization must be compelling, for example when the biomarker is strongly prognostic, and the trial is very small or biomarker prevalence is so low that there is a risk that the arms will become substantially unbalanced with respect to the biomarker.
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 biomarker assay results.

5. 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

6. ANALYTICAL PERFORMANCE

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 of the type 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. Applicants are encouraged to submit a laboratory Standard Operating Procedure (SOP) as an appendix if the SOP supports validation of the assay(s) being proposed. If a laboratory validation study has been performed prior to use of the assay and/or to meet the requirements for CLIA, please submit those data. For guidance on regulatory requirements for laboratory assays please visit: ***http://www.cms.gov/CLIA/05_CLIA_Brochures.asp***.

B. If the assay will be performed at more than one site, describe how inter-laboratory variability in the measurements will be assessed. Describe how variation will be minimized to maintain performance at all sites within acceptable limits and to prevent drift or bias in assay results.

C. Describe the process and targeted turn-around-time for reporting assay results.

7. STATISTICAL PLAN

A. Identify the clinical endpoints and the biomarker measurements involved in the analysis.
B. Justify the numbers of patients to be studied and biomarker assays/tests to be performed.
C. Describe the statistical analysis methodology and underlying assumptions.
D. If the trial objectives include an evaluation of the association of the integral 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.

8. CLIA CERTIFICATION: Provide the CLIA number for the lab that is performing the integral biomarker study(ies) and the expiration date of the certificate.

9. 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.
C. Include cost per assay/test.
D. Include cost comparisons to justify the laboratory site chosen to complete the assay.
E. Provide plans for cost-sharing with entities that might eventually commercialize the test (when appropriate.)

10. 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).