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

INTEGRAL BIOMARKER Study Checklist

INSTRUCTIONS: Please complete a Study Checklist for **each** INTEGRAL biomarker. Refer to the 2018 BIQSFP Guidelines *(https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp)* for additional information.

1. **STUDY TITLE & CONCEPT NUMBER:**

2. **OBJECTIVE & HYPOTHESIS:** Briefly describe the study objective, 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.

Analyte	Assay	Specimen source/ special requirement(s)	Time of specimen collection	Time of specimen analysis

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 assay result as a marker for 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.
   B. Describe the expected distribution of the biomarker in the study population.
   C. If cutpoints will be used, specify the cutpoint(s) and describe how these will be used in the trial. Provide the rationale for the cutpoint(s) selected. What proportion of subjects is expected to have values above and below the proposed assay value cutpoints? 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 cutpoint(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 <u>as it is to be performed in the trial</u> (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. For guidance on regulatory requirements for laboratory assays please visit: ***http://www.cms.gov/CLIA/05_CLIA_Brochures.asp.*** 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 to meet the requirements for CLIA, please submit that data.

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. Describe the process and note the 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. PERFORMANCE SITE: Identify the specific individual(s) and laboratory(ies) proposed to conduct the assay(s) for the trial. 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.
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.)

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).