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

INSTRUCTIONS: Please complete a Study Checklist for **each** imaging test or analysis tool. 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, state the specific hypothesis(es), and indicate the role(s) of the imaging test/analysis tool in the trial. (For example, is it an eligibility criterion, used for treatment assignment, for stratification, risk group classification, a prognostic marker, a response assessment, or does it have some other use?)

3. IMAGING TEST, SCAN, OR TOOL SUMMARY INFORMATION: Complete the table below.

Imaging Modality, Agent, Tool, and/or Technique	Imaging Measurement	Standard of Care OR Investigational?	Test/Tool Completion Timepoint(s)	Test/Tool Interpretation Timepoint(s)	Total # of Scans/Tests Requiring Funding: Please consider the following example for estimating the maximum # of scans/tests: (Total # of scans requiring funding) = (Total # of scans used) x (Total # of patients) x (Total # of time points)

4. BACKGROUND & SIGNIFICANCE: Provide data on the potential clinical utility of the integral imaging test or tool as it will be used in the trial.

A. Provide background information that justifies the use of this imaging test or analysis tool as a part of this trial. For example, if the integral imaging test or analysis result 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 imaging test results 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 the subjects is expected to have values above and below the proposed imaging cut-points? What magnitude of effect (e.g., treatment benefit) or outcome (e.g., prognosis) is expected for patients with imaging results above and below the proposed cut-point(s)?
D. Describe under what conditions patients will be able to access the imaging test or tool results.

5. DESCRIPTION OF THE TEST OR TOOL

A. Specify the imaging devices, imaging agents, and/or image analysis tool.
B. Describe any patient preparation procedures, as well as the procedures for imaging, analysis, and interpretation of the results.
C. Describe the scoring procedures and type of data to be acquired:
    - quantitative/ continuously distributed
    - semi-quantitative/ordered categorical
    - qualitative/non-ordered categorical

D. Where applicable, indicate if the test is standard of care (SOC) or investigational and the number: e.g., 300 MRIs (SOC): 100 patients x 3 per patient; 200 FDG PET/CTs (investigational for the proposed indication/time point): 100 patients x 2 per patient; 100 FMISO-PET/CTs (investigational): 100 patients x 1 per patient
E. Describe the process and note the turn-around-time for reporting imaging test or analysis results, including whether the read is local or central.

6. ANALYTICAL PERFORMANCE OF THE TEST OR ANALYSIS TOOL

A. Describe the known performance characteristics of the imaging test or tool. State and justify the limits of acceptable performance. Describe the published performance characteristics of the diagnostic test – for sensitivity, specificity and repeatability (if semi quantitative or quantitative) or how they are factored in the analysis using the imaging tool.
B. Describe how inter-facility variability in the measurements will be assessed and/or how the analysis tool manages inter-site variability. 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 imaging test results or analysis. Describe the site credentialing process.
C. Applicants are encouraged to submit a Standard Operating Procedure (SOP) for the imaging test or tool as an appendix, to support validation of the test or tool being proposed, if appropriate.

7. SITE OF TEST PERFORMANCE: Identify the specific individual(s) and site(s) that are proposed to perform the imaging test and/or analyze the results.

8. STATISTICAL PLAN

A. Specify the clinical endpoints and the imaging measurements involved in the analysis
B. Describe the statistical analysis methodology and underlying assumptions.
C. State the target accrual and include justifications based on expected effect sizes and magnitudes of association and power and sample size calculations.

9. BUDGET

A. Include a budget that clearly details the direct and facilities and administrative costs requested using the PHS 398 budget form **(https://grants.nih.gov/grants/funding/phs398/phs398.html)** along with a narrative justifying each requested cost.
    1. Site/scanner qualification costs (usually done prior to patient enrollment in multi-center trials)
    2. Technical costs for each type of scan (including facility use, scanner time costs, etc.)
    3. Professional costs for each type of scan (*e.g., local radiologists / nuclear medicine physicians to interpret the images*)
    4. Image transfer (*e.g. network costs, shipping/mailing costs for physical media*)
    5. Central imaging review costs (*if central review is performed*) for each type of scan
    6. Real time image review costs (*if applicable*) for each type of scan
    7. Image quality assurance costs (*in addition to basic interpretation or central review costs*)
    8. Imaging agent and contrast material costs, for each type of scan (*including categories such as agent manufacturing, transport, or storage costs*)
    9. Image storage (*e.g., long term storage of imaging data, archiving, back-up systems, etc.*)
    10. Statistical support (*e.g., a contracted statistical center)*
    11. Salary support (*e.g., investigators, imaging technologists, research coordinators, study nurses, research assistants, etc.*)

B. Include potential cost-sharing approaches for the test (e.g., billing to third-party payers, partial funding from commercial partners, IROC support, etc.), as well as a cost comparison and justification for academic vs commercial imaging sites.

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).