Biomarker, Imaging, & Quality of Life Studies Funding Program (BIQSFP)

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH) http://www.nih.gov/

Components of Participating Organizations
National Cancer Institute (NCI) http://www.nci.nih.gov/

Website
http://www.cancer.gov/about-nci/organization/ccct/other-programs/biqsfp

Key Dates
Release Date: December 15, 2008; revised 4/1/10, 4/1/11, 4/1/12, 5/1/13, 12/23/13, 3/2/15, 12/31/15, 3/1/17.

Submission Date: A parent clinical trial concept with a BIQSFP study proposal can be submitted to the NCI Division of Cancer Treatment and Diagnosis' (DCTD) Cancer Therapy Evaluation Program (CTEP) or to the Division of Cancer Prevention (DCP) anytime during the calendar year.

I. BIQSFP Submission and Evaluation Process

A. **All** BIQSFP study applications **must** be evaluated by the respective NCI Steering Committee (SC) that reviewed the parent trial. If an appropriate NCI SC doesn't exist and the parent concept was not reviewed by a SC, the study will then be evaluated by an ad hoc evaluation committee convened by CTEP or DCP, respectively.

B. **INTEGRAL** Proposal Packages must be submitted at the time of parent concept submission and will be evaluated at the time the parent concept is reviewed.

C. **INTEGRATED** and **CEA** Proposal Packages should be annotated on the respective CTEP/NCORP *Trial Concept Submission Form* (see Appendix #1 and #2) at the time of parent concept submission and must be submitted **within three (3) months** of the principal investigator (PI) receiving notification by the respective CTEP/DCP Protocol Information Office (PIO), that the concept was approved.

D. Studies receiving a favorable evaluation for scientific merit from the NCI Steering Committee (or the ad hoc evaluation committee) are recommended to the NCI Clinical and Translational Research Operations Committee (CTROC) for funding.

E. CTROC approves, disapproves, and/or modifies BIQSFP study funding requests.

F. The respective NCI National Clinical Trials Network (NCTN) Group or the NCI Clinical Oncology Research Program (NCORP) Research Base is notified of the results of the CTROC review by the CTEP/DCP PIO.

Expiration Date: February 28, 2018
It is anticipated that the BIQSFP Guidelines will be reissued in subsequent years.

II. Key Changes for 2017:

A. **INTEGRATED** and CEA studies must be submitted **within three (3) months** of the PI receiving notification by the respective CTEP/DCP PIO, that the concept was approved (see Section I., page 1).

B. Anticipated/planned **INTEGRATED** studies should be annotated on the respective CTEP/NCORP *Trial Concept Submission Form* (see Appendix #1and #2) at the time of parent concept submission (see Section I., page 1).

C. QOL biomarker and imaging studies are eligible for BIQSFP funding. QOL/PRO studies, other than biomarker and imaging, should be submitted to DCP for Cancer Control credits. The routine

collection of QOL/PRO data is covered by DCP Cancer Control credit and is not eligible for BIQSFP funding (see Section VIII., page 5).

D. Exceptions to BIQSFP submission timelines are permitted in rare cases (see Section VI. E. page 3).

III. Overview and Summary

The NCI DCTD and DCP invite funded NCTN Groups and funded NCORP Research Bases to apply for funding to support biomarker, imaging, and QOL/PRO studies as well as CEA proposals. All study applications must be associated with NCI clinical trial concepts.

IV. Purpose

As part of its Prioritization and Scientific Quality Initiatives, the NCI Clinical Trials Working Group (CTWG) recommended establishing a funding mechanism as well as a prioritization process for correlative studies and QOL/PRO studies that are incorporated into the fundamental design of a clinical trial and are not currently supported by the U10/UG1 funding mechanisms. The purpose of the BIQSFP is to ensure that the most important, scientifically meritorious biomarker, imaging, QOL/PRO, and CEA studies within appropriate NCI clinical trials can be initiated in a timely manner.

Targeted biological studies, imaging, and quality of life studies embedded in clinical trials should have the potential to modify standard of practice. The assays/tests/instruments must be reliable, provide interpretable answers that are of benefit to patients, and lead to the validation of targets, reduction of morbidity, prediction of treatment effectiveness, enhanced clinical trial design and the identification of populations that might benefit from treatment or lead to improvements in clinical trial accrual and retention.

V. Mechanism of Support

BIQSFP is managed through the Coordinating Center for Clinical Trials (CCCT) within the NCI Office of the Director (OD). The number of anticipated awards is contingent upon the availability of FY17 BIQSFP funding and the number of meritorious proposals submitted. NCI committed $10M to BIQSFP funding in FY 2016. Applicants may submit more than one trial concept with associated biomarker, imaging, QOL/PRO, or CEA studies, provided that they are scientifically distinct. However, both the scientific merit of the parent clinical trial concept and the scientific merit of the biomarker, imaging, QOL/PRO, or CEA study proposals must be approved by the appropriate review/evaluation entity (NCI SC, CTEP or DCP) in order to be eligible for BIQSFP funding.

VI. Requirements and Definitions

A. Eligible trial types for BIQSFP funding are:

- Trials conducted by NCTN Groups and NCORP Research Bases
- Phase 2 (≥100 patients) and 3 treatment trials with integral or integrated biomarker or imaging studies
- Phase 3 cancer prevention clinical trials with integral or integrated biomarker or imaging studies
- Randomized symptom science/supportive care clinical trials with efficacy endpoints
- In terms of CEA proposals, the parent concept must be a randomized phase 3 treatment or prevention clinical trial with a comparator arm or a symptom science/supportive care clinical trial with a comparator arm.

B. NCI Treatment Trials test the effectiveness of new treatments or new ways of using existing treatments in people who have cancer. The treatments tested may include drugs, vaccines, approaches to surgery or radiation therapy, or combinations of treatments including some to boost the immune system. Many newer treatment trials require people to have their tumors tested for

genetic changes first to see if treatments targeting specific changes might work better for them than standard treatments.

C. NCI Cancer Prevention Trials are studies involving healthy people. In most prevention trials, the participants either do not have cancer but are at high risk for developing the disease or have had cancer and are at high risk for developing a new cancer. These studies look at cancer risk and ways to reduce that risk. BIQSFP study applications within Treatment Trials are submitted to **CTEP PIO** for evaluation by the appropriate NCI Steering Committee.

D. NCI Symptom Science/Supportive Care Trials test interventions to improve the quality of life of cancer patients, especially those who have side effects from cancer and its treatment, such as pain, nutrition problems, infection, nausea and vomiting, sleep disorders, depression, and other cancer and treatment related symptoms and toxicities.

Symptom Science/Supportive Care trials might test drugs, such as those that help with depression or nausea, or they might test lifestyle, behavioral or psychological interventions (e.g., exercise, yoga, cognitive behavioral therapy, and/or coping interventions).

BIQSFP study applications within Cancer Prevention and Symptom Science/Supportive Care Trials are submitted to **DCP PIO** for evaluation by the appropriate NCI Steering Committee.

Further details on the preceding definitions can be found at: **http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/types**.

E. EXCEPTIONS: In rare cases, INTEGRAL and INTEGRATED biomarker, imaging and quality of life studies associated with protocols that are still in development, recently approved concepts, and in some cases, active trials may be eligible for BIQSFP funding IF the study component is considered by NCI to be of significant scientific and clinical merit.

VII. Biomarker and Imaging Studies

Two types of biomarker and imaging studies are eligible for consideration – **integral** and **integrated**.

A. Integral Studies - Defined as assays/tests that must be performed in order for the trial to proceed. Integral studies are inherent to the design of the trial from the onset and must be performed in real time for the conduct of the trial. Integral biomarkers require a CLIA-certified laboratory.

Integral studies have the highest funding priority.

Categories and examples of eligible integral studies are as follows:

- Tests to establish eligibility – e.g., ERCC-1 to determine protocol eligibility for patients with gastric cancer or imaging assessment of hypoxia for trials of drugs effective in hypoxic tissues such as tirapazamine
- Tests for patient stratification – e.g., measurement of 18qLOH and MSI for assignment of risk in stage 2 colon cancer
- Tests to assign patients to a treatment arm of a trial, including surrogate endpoints for assignment of treatment during a trial – e.g., FLT3/ITD ratio for assignment of pediatric AML patients to a study arm; eradication of the BCR-ABL clone in CML to determine whether to continue treatment; FDG-PET scan after initial course of therapy to assess early response to determine whether to continue treatment where third-party payers would not cover the cost

- Non-reimbursable imaging tests to measure a primary endpoint or to stratify patients based on imaging response – e.g., PET scans for non-Hodgkin's lymphoma response to chemotherapy
- QOL studies utilizing an assay/imaging test for eligibility, stratification, or response

B. Integrated Studies – Defined as studies of assays/tests that are clearly identified as part of the clinical trial from the outset and are intended to identify or validate assays or markers and imaging tests that are planned for use in future trials. Integrated studies in general should be designed to test a hypothesis, not simply to generate a hypothesis.

The number of trial subjects included in the integrated assays/tests performed should be sufficient to obtain scientifically valid outcomes during the trial. The application should include complete plans for specimen collection, laboratory measurements, establishing cutpoints, and statistical analysis.

One example would be predictive biomarker assays that are measured either *in vitro* or *in vivo* where the assay result is not used for eligibility, treatment assignment, or treatment management in the trial; a second example would be the use of an imaging test to detect biologic modification of the target but the image is not used as a primary study endpoint.

Eligible categories of integrated studies and examples are as follows:

- Studies to establish and validate clinical utility (including cutpoints) for assays/tests that show promise for future INTEGRAL studies
- QOL/PRO studies to validate assays/tests in understudied populations, such as pediatrics and adolescent/young adults experiencing disease or treatment related symptoms, such as chemotherapy induced peripheral neuropathy, fatigue, and pain.

C. Criteria for Review of Biomarker and Imaging Studies

Prioritization and evaluation criteria include:

- The strength of the preliminary data for both test utility and performance characteristics including cutpoints
- The potential of the test to change practice and have high impact on patient care (e.g., the impact of the test itself or the change of therapy indicated by the results of the trial)
- The ability of the test to yield well-defined and validated interpretations that will guide decision-making
- The extent of standardization of the tests as to be transferable to the non-research setting
- The adequacy of the process for specimen collection or image acquisition including feasibility data
- A description of potential cost-sharing approaches that can be developed with entities that would eventually commercialize the test

Clinical assays that are used to assign or significantly modify a patient's treatment in the proposed clinical trial must have undergone rigorous analytic validation and sufficient clinical validation to warrant inclusion in a clinical trial. Such assays will ordinarily be performed in CLIA-accredited laboratories and will need FDA review as well.

It is not intended that any priority or particular level of merit is assigned to one criterion over another but rather the proposals are evaluated based on the totality of the information and strength of the data.

Applications for biomarker studies will include a completed Biomarker Study Checklist, Budget, and Budget Justification. Applications for imaging studies will include a completed Imaging Study Checklist, Budget, and Budget Justification.

VIII. QOL/PRO Studies

A. QOL/PRO studies, other than biomarker and imaging, should be submitted for DCP Cancer Control credits. However, scientifically meritorious QOL/PRO studies may be considered for BIQSFP funding when the collection of data requires funding beyond the usual Cancer Control credits.

B. Criteria for Review of QOL/PRO Studies

Prioritization and evaluation criteria include:

- The proposed costs exceed allowable DCP credits/resources
- The proposed QOL/PRO study has been discussed with DCP and approved for consideration for BIQSFP funding
- The potential to impact patient morbidity and quality of life with clinically meaningful benefit
- The potential to move science forward in cancer related symptom science/supportive care by adding critical knowledge
- The strength of the preliminary data supporting the hypothesis(es) to be tested and methods proposed
- A clearly defined process for data and specimen collection
- A statistical plan with adequate power for testing the QOL/PRO correlative study hypothesis(es)
- Measures that are reliable, valid, and appropriate to the population of interest
- Feasibility of the proposal such that completion can be accomplished efficiently and in a reasonable time frame

IX. Cost-Effectiveness Analysis (CEA) Studies

Cost-Effectiveness Analysis (CEA) provides useful information to help health care payers manage the use of costly medical technologies in order to maximize the health of their patient populations when facing constrained budgets, and to clinicians and patients to help guide treatment decisions based on CEA's unique endpoints, perspectives (e.g., societal, clinical, or third-party), and time horizon (e.g., within trial or long-term survivorship).

To be most useful to decision-makers, CEA of new cancer therapies must have maximal feasibility, be timely, and have high internal validity. CEA funding may also apply to Symptom Science/Supportive Care clinical trials.

CEA studies are considered INTEGRATED studies and must be submitted **within three (3) months** of the PI receiving notification by the respective CTEP/DCP PIO, that the concept was approved.

Conducting a CEA alongside a clinical trial can achieve these goals and also offers the benefit of efficiency by utilizing the existing structure of the trial to collect additional data for the economic analysis. It is not required that a CEA proposal be included with each clinical trial concept submitted. However, in some instances the addition of CEA may be recommended during evaluation review of the clinical trial concept.

The CEA evaluation criteria are intended to help guide the selection of cancer clinical trials that warrant additional funds for a CEA. The CEA study should be a secondary endpoint of the parent concept. NCI SCs evaluate CEA proposals paired with clinical trial concepts through their concept review and prioritization processes. NCI SCs will make use of an ad hoc CEA expert(s) as well as other resources available at the NCI, to evaluate CEA proposals included in clinical trial concepts.

Criteria for Review of CEA Proposals

Researchers should consider pairing a CEA proposal to phase 3 treatment or prevention clinical trials, or symptom science/supportive care clinical trials when the following conditions are met:

- The results of the clinical trial are expected to substantially influence clinical practice
- The cost-effectiveness study would be of high impact as judged by substantial budget implications for health care systems, either in terms of overall cost savings or added costs to the system
- It is feasible to conduct a high quality CEA as part of the clinical trial. Specific issues to consider include:
  - The comparator arm should be relevant to current clinical practice.
  - The trial should be of sufficient duration with respect to the follow-up of patient outcomes, that consequences of interest to economic evaluation can be captured either directly or through modeling.
  - There is reasonable statistical power for the key cost-effectiveness analysis
- Because of the high cost of the experimental treatment, there is a reasonable degree of uncertainty regarding the outcome of the CEA even if the clinical outcome favors the experimental treatment.

Modeling is a pivotal part of the CEA proposal. CEA proposals should describe the general type of model that will be used. If a model is to be developed, the expertise of the model developer, timeline for model development, calibration, and validation (if relevant) must be included in the proposal. This may include but not be limited to all model inputs that are needed as well as the respective sources for the inputs, what provisions are needed to document the model structure, assumptions, data inputs, parameter estimations as well as intermediate and final outputs so that replication of the CEA would be possible by an external analyst.

CEA proposals included in clinical trial concepts should be developed by NCTN Groups/NCORP Research Bases. NCTN Groups/NCORP Research Bases intending to submit a CEA proposal, should annotate their plans on the respective CTEP/NCORP *Trial Concept Submission Form (see Appendix #1 and #2)* at the time of parent concept submission.

X. Studies Ineligible for BIQSFP Funding

- Studies that do not meet the definitions for eligible trials (e.g., phase 1 concepts, phase 2 concepts with <100 patients, and all non-randomized concepts)
- Studies that are still within the discovery phase or pre-clinical development stage focusing on assay development
- Studies that are considered exploratory
- Studies that can be conducted in the future on stored specimens (retrospective studies), except if the results are critical to the stated primary or secondary objectives of the trial
- Studies eligible for DCP Cancer Control Credits or other DCP funding
- Cohort studies or longitudinal observational studies
- Studies that include assays, tests, or instruments that are standard of care and normally reimbursed by third-party payers
- INTEGRATED studies and CEA studies submitted **more than three (3) months** after the PI receiving notification by the respective CTEP/DCP PIO, that the concept was approved.

XI. BIQSFP Proposal Package & Submission

INTEGRAL studies must be embedded into the parent concept. The BIQSFP Proposal Package must be submitted at the time of parent concept submission.

Anticipated/planned **INTEGRATED** studies and CEA studies should be annotated on the respective CTEP/NCORP *Trial Concept Submission Form* (see Appendix #1 and #2) at the time of parent concept submission and must be submitted **within three (3) months** of the PI receiving notification by the respective CTEP/DCP PIO, that the concept was approved.

All resources needed for completion of the BIQSFP Proposal Package can be found on the BIQSFP website at: **https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp**. The site also includes the BIQSFP Guidelines, Frequently Asked Questions (FAQs), Concept Checklists, Budget and Budget Justification information, and Program Contacts. All of the BIQSFP Funded Studies are also available on the website.

A. BIQSFP Proposal Package
What is required?

- Cover letter signed by the NCTN Group/NCORP Research Base Chair indicating submission of a biomarker, imaging, QOL/PRO, or CEA study proposal in response to the 2017 BIQSFP Guidelines.
- **Cover letter should include**:
  - The title(s) of the BIQSFP project(s)
  - Brief description of the project(s) indicating whether the study(s) is integral or integrated
  - Type of study(s) proposed (biomarker, imaging, QOL/PRO and/or CEA)
  - Total budget figure requested for each project (biomarker, imaging, QOL/PRO CEA)
  - Duration of the study
- Detailed budget as described in the **Budget Preparation** section (below)
- Parent clinical trial concept wherein the biomarker, imaging, QOL/PRO, and/or CEA proposal is embedded

B. Biomarker: A separate document is required describing the characteristics and performance of each biomarker assay test proposed for funding and its role in the trial. Applicants should refer to the *Study Checklist for Clinical Trials with Biomarker Assays for Treatment/Symptom Science/ Supportive Care Studies* (**https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp**) for instructions on what information is needed. This section is not to exceed five (5) pages for each assay.

Applicants are encouraged to submit a laboratory SOP(s) as an Appendix in order to support validation of the assay(s) being proposed.

Integral and integrated studies require a separate BIQSFP Proposal Package as indicated above.

For additional explanations and definitions, investigators are also encouraged to visit **Performance Standards Reporting Requirements for Assays in Clinical Trials** at: **http://cdp.cancer.gov/scientific_programs/pacct/PACCT_Assay_Standards_Document.pdf**

Additional information regarding validation of integral biomarkers can be found at NCI's Cancer Diagnosis Program (CDP) website: **https://cdp.cancer.gov/resources/drdr/default.htm**

C. Imaging: A separate document is required describing the characteristics and performance of each imaging test proposed for funding and its role in the trial. Applicants should refer to the *Study Checklist for Clinical Trials with Imaging Assays for Treatment/Symptom Science/ Supportive Care Studies* (**https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp**) for instructions on what information is needed. This section is not to exceed five (5) pages for each imaging test. If both integral and integrated

studies are proposed within the same concept being submitted, each study will require a separate BIQSFP Proposal Package as indicated above.

Applicants are encouraged to submit an imaging SOP(s) as an Appendix in order to support validation of the test(s) being proposed.

D. QOL/PRO: A separate document is required describing the characteristics and performance of each measure that validates a QOL/PRO assessment and/or an instrument proposed for funding and its role in the trial. Applicants should refer to the *Study Checklist for Clinical Trials with QOL/PRO Endpoints* (see BIQSFP website) for instructions on what information is needed. This section is not to exceed five (5) pages for each assay, test, or endpoint. If both integral and integrated studies are proposed within the same concept being submitted, each will require a separate BIQSFP Proposal Package as indicated above.

Applicants are encouraged to submit a symptom science/QOL/PRO SOP(s) as an Appendix in order to support validation of the test/tool/instrument(s) being proposed.

E. Cost-Effectiveness Analysis: A separate document is required outlining the rationale behind the request for funding of the CEA proposal. The CEA proposal should be a secondary endpoint of the parent concept. Applicants should refer to the *Study Checklist for Randomized Clinical Trials with a Comparator Arm and Cost-Effectiveness Analysis (CEA) Component(s)* (**https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp**) for instructions on including the required information. This section is not to exceed eight (8) pages. The CEA budget justification should include:

- Evidence of institutional capacity and/or experience in health economic analysis
- Evidence of training, expertise and/or experience in health economic analysis and related expertise (e.g., instrument development, medical abstraction, administrative coding, cost analysis, etc.) by the proposed investigator(s) and/or staff
- An activity analysis for each year of the proposed study, (e.g., how much and what kind of resources/personnel will be required for relevant phases of the study in each year, model development, data abstraction, data acquisition, analysis, etc.)
- Evidence that the timeframe of the proposed CEA study is consistent with the timeframe of the parent concept. For example, will data abstraction instruments needed for the CEA be developed and validated in time for data acquisition in the parent trial? Will results from the parent trial on health outcomes that are necessary inputs to the CEA be available when needed? If there is a delay in the availability of trial outcomes beyond the timeframe of the proposed CEA study, what provisions will be made to ensure that the CEA will be completed?

F. Budget Preparation

- All BIQSFP study proposals must include a budget at the time of submission that clearly details the costs (Direct and Indirect) for each biomarker, imaging, QOL/PRO and/or CEA study proposal submitted.
- A total composite budget must be provided for the entire cost of the BIQSFP project. The budgets for the project should use the Form PHS 398 along with a narrative justifying each requested cost (**http://grants.nih.gov/grants/funding/phs398/phs398.html**).
- Covered BIQSFP costs may include but not be limited to procurement of and completion of research assays on blood or tissue, central pathology or image reading, and shipping.
- Costs associated with QOL/PRO assessments that are conducted as part of CEA may be included.
- Costs for the PI of the clinical trial concept/study and/or NCTN Group/NCORP Research Base leadership are not covered under the BIQSFP program.

- The Budget packet must include a completed NIH biosketch form for each study PI. Form SF424 can be found at: **http://grants.nih.gov/grants/funding/424/index.htm#format**. Additional information on the new biosketch requirements can be found at: **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html**.
- NCTN Group/NCORP Research Base investigators are encouraged, where applicable, to explore options for reducing the cost of assays and tests to be supported by BIQSFP funding. These cost sharing options might include billing third party payers or partial funding from commercial partners, or choosing between academic vs. commercial laboratories. Investigators' use of commercially available laboratory tests may aid in reducing budgetary requirements. Cost sharing with other funders will have a positive impact on the evaluation.
- For all BIQSFP applications, the signature of the institutional business official is not required at the time of initial submission of the total composite budgets. Institutional approval and sign-off is required once the final funding has been approved by the NCI.

G. A complete **Proposal Package**, including attachments, must be emailed via pdf attachment to the relevant Program office.

NCORP Research Base non-treatment clinical trial proposals must be e-mailed to:

NCI DCP Protocol Information Office - ncidcppio2@mail.nih.gov
cc: Worta McCaskill-Stevens, MD, MS - wm57h@nih.gov
Ann O'Mara, PhD. - omaraa@mail.nih.gov

NCTN Group/NCORP Research Base treatment clinical trial proposals must be e-mailed to:

NCI CTEP Protocol Information Office - PIO@ctep.nci.nih.gov
cc: Margaret Mooney, M.D. - mooneym@ctep.nci.nih.gov

Study submissions must reference **"BIQSFP"** in the Subject line of the email.

XII. Terms and Conditions for Funding

BIQSFP Administrative Supplements are provided annually via the parent U10/UG1 Cooperative Agreement for the study and will be administered by CCCT in conjunction with the appropriate NCI program (e.g., CTEP or DCP). All the terms and conditions of the of the parent U10/UG1 award apply to
this funding. Recipients of a BIQSFP administrative supplement are required to include an annual progress report for each funded BIQSFP study, with the *Type 5* parent grant's progress report.

Funding is restricted for the purpose of the approved project. Similarly, any carryover requests for this award are limited to the approved project unless written approval is obtained in advance by the relevant NCI program official. Funding is dependent on continuance of the clinical trial protocol and adequate progress.

XIII. Publication of BIQSFP-Funded Studies

Upon completion of BIQSFP-funded studies, publications should acknowledge the funding source as follows:

"This clinical study was supported in whole or in part by funding from the Biomarker, Imaging, & QOL Studies Funding Program (BIQSFP) awarded by the National Cancer Institute".

XIV. Inquiries

Questions regarding responsiveness of the proposed studies to the BIQSFP should be directed to the one of the following NCI Program Staff:

For CTEP:

Margaret M. Mooney, MD
Chief, Clinical Investigations Branch
National Cancer Institute
9609 Medical Center Drive
Room 5W-412
Bethesda, MD 20892-9737
For non-USPS mail (FedEx, UPS, etc.)
Rockville, MD 20850-9737
Phone: 240-276-6560
Email: mooneym@ctep.nci.nih.gov

For DCP:

Worta J. McCaskill-Stevens, MD, MS
Chief, Community Oncology and Prevention Trials Research Group
Head, Breast Cancer Prevention
Division of Cancer Prevention
National Cancer Institute
9609 Medical Center Drive
Room 5E-446
Bethesda, MD 20892-9744
For non-USPS mail (FedEx, UPS, etc.)
Rockville, MD 20850-9744
Phone: 240-276-7075
Email: wm57h@nih.gov

Ann M. O'Mara, PhD, RN
Head, Palliative Care Research
Community Oncology and Prevention Trials Research Group
National Cancer Institute
9609 Medical Center Drive
Room 5E-444
Bethesda, MD 20892
For non-USPS mail (FedEx, UPS, etc.)
Rockville, MD 20850-9744
Phone: 240-276-7050
Email: omaraa@mail.nih.gov

Questions regarding cancer imaging studies:

Lalitha K. Shankar, MD, PhD
Chief, Clinical Trials Branch
Cancer Imaging Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
9609 Medical Center Drive
Room 4W-346
Bethesda, MD 20892-9729
For non-USPS mail (FedEx, UPS, etc.)

Rockville, MD 20852-4910
Phone: 240-276-6510
Email: shankarl@mail.nih.gov

Questions regarding the prioritization, evaluation, and Administrative Supplements funding processes should be directed to:

Raymond A. Petryshyn, PhD
Program Director
Coordinating Center for Clinical Trials
National Cancer Institute
9609 Medical Center Drive
Room 6W-608
Bethesda, MD 20892-9744
Phone: 240-276-6160
Fax: 240-276-7868
Email: petryshr@mail.nih.gov

Questions regarding Cost-Effectiveness Analysis should be directed to:

O. Wolf Lindwasser, PhD
Program Director
Coordinating Center for Clinical Trials
National Cancer Institute
9609 Medical Center Drive
Room 6W-620
Bethesda, MD 20892-9744
Phone: 240-276-6160
Fax: 240-276-7868
Email: wolf.lindwasser@nih.gov

8/08,3/09,3/10,3/11,3/12,4/13,11/13,12/14,12/15,2/17

BIQSFP APPENDIX #1	**PHASE 2, 2/3 and 3 TRIAL CONCEPT SUBMISSION, Version 4.2**	CLINICAL INVESTIGATIONS BRANCH
	National Cancer Institute **Division of Cancer Treatment and Diagnosis** **Cancer Therapy Evaluation Program** **August 26, 2015**	

NOTES: Concepts must be submitted in electronic format (tables or schema may be converted to .pdf format to assure accurate transfer). To complete the form electronically, use the mouse pointer or the Tab key to navigate. Select and enter text for each text field (the INSERT key must be set to OFF) or follow instruction when given. Submit by e-mail to PIO@CTEP.NCI.NIH.GOV.

If this is a Phase 2/3 or a Phase 3 study that involves an IND agent or IDE biomarker, then the concept will be forwarded to the FDA to receive regulatory comments to assist with completion of the protocol. For Phase 2/3 and Phase 3 drug studies which do not fit this category, we will also send the concept to the FDA, but for purely informational purposes.

Each of the scientific sections should be sufficient to briefly describe the major elements of the study. Within these principles as a guide, there are no specific requirements or limitations on length; however, concept proposals should be concise (recommended maximum length 8 to 10 pages). The concept proposal is NOT meant to be a draft of the protocol document and the sections below should NOT be excessive or encyclopedic.

I. ADMINISTRATIVE

Title of Concept: [Click here to enter title]

Sponsoring Organization's Local Protocol Number: [Click here to enter local number]

Concept Version Date: [Click here to enter a date]

Study Chair Name (printed): [Click here to enter name]

Study Chair Signature (optional): _____ Date: [Click here to enter a date]

Study Chair Address: [Click here to enter address information]
[Click here to enter street adress]
[Click here to enter city, state, zip]

Study Chair Phone: [Click here to enter phone number]

Study Chair Fax: [Click here to enter fax number]

Study Chair e-mail: [Click here to enter e-mail address]

Name(s) of co-chairs or discipline chairs, if any: [Click here to enter name]

Group Chair/Cooperative Agreement Name: [Click here to enter name]

Group Chair Signature (optional): _____ Date: [Click here to enter a date]

Group Chair Address: [Click here to enter address information]
[Click here to enter street adress]
[Click here to enter city, state, zip]

Group Chair Phone: [Click here to enter phone number]

Group Chair Fax: [Click here to enter fax number]

Group Chair e-mail: [Click here to enter e-mail address]

NIH Grant Number: [Click here to enter grant number]

Study Statistician Name: [Click here to enter name]

Study Statistician E-mail: [Click here to enter e-mail address]

II. PHASE OF STUDY

Specify what type of phase this study will be conducted under (2 or 3).

2 ☐ **3** ☐ **2/3** ☐

III. DISEASE AND INTEGRAL MARKER SPECIFIC SECTION

Specify the Name and Code of all the Study Diseases below (MeDRA Code Disease list available on CTEP Web site, http://ctep.cancer.gov/protocolDevelopment/codes_values.htm.

1. If study involves multiple diseases, please provide Disease Name and Disease Code for each disease.
   [Click and enter Disease Name] [Click and enter Disease Code]
   [Click and enter Disease Name] [Click and enter Disease Code]
   [Click and enter Disease Name] [Click and enter Disease Code]

2. If this disease is under a Steering Committee, please indicate if this Concept version has already been reviewed by the Task Force? **Yes** ☐ **No** ☐ **Not Known** ☐

3. Does the study involve any investigational (non-standard of care) integral marker(s) (e.g., laboratory test, imaging test) defined as test(s) that must be performed in order for the trial to proceed or for the trial data to be analyzed with respect to the primary endpoint?
   Yes ☐ **No** ☐ **Not Known** ☐

   If yes, please describe briefly below (not to exceed 1 page) the integral purpose for the marker (e.g., eligibility criterion, assignment to treatment, stratification variable, risk classification or score, etc.) and how the marker will be funded for the study. Also provide the main supporting background information on the characteristics, performance, and validation of the investigational integral marker and whether an IDE will be required.

   Information on investigational integral marker:
   Purpose:
   Description:
   Does this investigational device require an IDE?
   If the above requires an IDE, please provide what entity will hold the IDE:

4. For Network Groups of the NCTN Program Only: BIQSFP STUDY APPLICATION
   a) Is a BIQSFP application being submitted in conjunction with this concept for an **INTEGRAL** study(ies)?

Yes ☐ No ☐

If a BIQSFP application is being submitted with the concept, the information on the investigational integral study(ies) must be provided in the application and not in this concept form.

b**)** Will an **INTEGRATED** BIQSFP application be submitted in conjunction with this concept?

Yes ☐ No ☐

If so, please identify each proposed integrated study assay/test/assessment/instrument _____ _____.

NOTE: The completed BIQSFP integrated study application packet must be received by the CTEP PIO **within three (3) months after PI notification of concept approval.**

BIQSFP APPENDIX #2

NCI Community Oncology Research Program (NCORP) Clinical Trials Document Submission Worksheet v3.1

Protocol Information Office, DCP, NCI
Phone: 240-276-7130
Submit documents electronically to:
nci_dcp_pio@mail.nih.gov

SECTION 1: GENERAL INFORMATION

1. A. Overview of Document Information

Please indicate type of submission: ☐ Concept ☐Revised Concept ☐ New Protocol ☐Revised Protocol ☐Amendment ☐Other

Research Base Concept/Protocol No.: _____ If new protocol submission, indicate the Concept number:_____

Study Title:

_____

_____

Name of Research Base: _____ NCI Institution Code:_____

Study Chair Name: _____ NCI Investigator No.: _____

Study Chair Phone: (____) _____ Study Chair Email: _____

Study Coordinator Name: _____E-mail: _____ Phone No.: (_____)_____

Will this study be in RSS? ☐ yes ☐ no CTSU? ☐ yes ☐ no OPEN? ☐ yes ☐ no RAVE? ☐ yes ☐ no

Is this study monitored by a Data Monitoring Committee? ☐ yes ☐ no

1. B. Funding Information

Is this study supported by a federally funded grant? ☐ Yes ☐ no Grant Number: _____
Is this study supported by a non-federally funded grant (PCORI, ACS, etc.)? ☐ Yes ☐ no Please specify: _____

a) Is a BIQSFP study application being submitted in conjunction with this concept for an **INTEGRAL** study(ies)?

Yes ☐ No ☐

If a BIQSFP application is being submitted with the concept, the information on the investigational integral study(ies) must be provided in the application and not in this concept form.

b) Will an **INTEGRATED** BIQSFP study application be submitted in conjunction with this concept?

Yes ☐ No ☐

If so, please identify each proposed integrated study assay/test/assessment/instrument

_____

_____.

NOTE: The completed BIQSFP integrated study application packet must be received by the DCP PIO **within three (3) months after PI notification of concept approval.**

1. C. Study Type:

☐ Interventional

☐ Observational

☐ Expanded Access

Study Phase (check one) ☐ 1/2 ☐ 2 ☐ 2/3 ☐ 3 ☐ N/A Is NCORP credit requested? ☐ Yes ☐ no