

## **Biomarker, Imaging, & Quality of Life Studies Funding Program (BQSFP)** National Cancer Institute / Coordinating Center for Clinical Trials (NCI/CCCT)

### **Website**

<http://www.cancer.gov/about-nci/organization/ccct/other-programs/bqsfp>

### **I. BQSFP Submission and Evaluation Process**

- A. BQSFP study applications are only accepted from** NCI National Clinical Trials Network (NCTN) Groups or NCI Clinical Oncology Research Program (NCORP) Research Bases.
- B. All BQSFP study applications **must** be evaluated by an NCI Steering Committee (SC).** If an appropriate NCI SC does not exist, the study will be evaluated by an ad hoc evaluation committee.
- C. INTEGRAL** proposal packages must be submitted with the parent concept and will be evaluated concurrently with the parent concept.
- D. INTEGRATED** studies should be included in the concept as a secondary objective and noted on the concept submission form.
- E. INTEGRATED** studies that need real time assays/tests or special sample collection or processing and cannot be stored and batched should be submitted following concept approval. Integrated studies that do NOT need real time assays/tests, etc. will be accepted only after the trial has reached at least 75-percent of the protocol-specified accrual goal and no later than six months following the publication date of the trial's primary outcome.
- F. BQSFP requests receiving a favorable evaluation for scientific merit from the NCI Steering Committee (or the ad hoc evaluation committee) will be recommended to the NCI Clinical and Translational Research Operations Committee (CTROC) for funding.** CTROC approves, disapproves, and/or modifies BQSFP proposals. The respective NCTN Group or NCORP Research Base will be notified of the results of the CTROC review by the CTEP/DCP PIO.

### **II. Key Changes for 2018**

- A. Submission of INTEGRATED studies that require real-time assays/tests or special sample collection or processing within *3 months of concept approval* is encouraged but no longer required (see *VII. B. INTEGRATED Studies* - page 3 and *X. BQSFP Proposal Package & Submission* – page 7).**
- B. Submission of INTEGRATED studies that do NOT require real-time assays/tests or special sample collection or processing has been modified (see *I.E. BQSFP Submission and Evaluation Process* – page 1; *VII.B. INTEGRATED Studies* - page 3; and *X.A. BQSFP Proposal Package & Submission* – page 7).**
- C. Quality of Life/Patient Reported Outcomes (QOL/PRO) proposals must include a letter from the Division of Cancer Prevention (DCP) indicating that the proposed costs exceed allowable DCP credits/resources and that DCP has agreed that the study should be considered for BQSFP funding (see *IX.B. Quality of Life/Patient Reported Outcome Studies* – page 6).**
- D. New *Statistical Requirements* and a *Statistical Evaluation Template* have been added to assist in the statistical evaluation of BQSFP studies (see *VIII. Statistical Requirements for BQSFP Study Applications* – page 4)**
- E. Randomized phase 2 cancer prevention clinical trials with integral or integrated biomarker or imaging studies are eligible for BQSFP funding.**
- F. Changes to the requirements for annual progress reports (see *XIII. Terms and Conditions for Funding* – page 8)**
- G. Requests for INTEGRAL and INTEGRATED biomarker assays and imaging tests now use separate checklists.**

### III. Overview and Summary

The NCI invites NCTN Groups and NCORP Research Bases to apply for funding to support biomarker, imaging, and quality of life/patient reported outcome (QOL/PRO) studies as well as cost-effectiveness analysis (CEA) proposals. All study applications must be associated with NCI clinical trial concepts or protocols.

BQSFP applications may be submitted anytime during the calendar year. BQSFP guidelines are subject to annual NCI/CCCT review and revision.

### IV. Purpose

The NCI Clinical Trials Working Group (CTWG), as part of its Prioritization and Scientific Quality Initiatives, recommended establishing a funding mechanism and prioritization process for correlative studies and QOL/PRO studies that are inherent in the design of a clinical trial and are not currently supported by the U10/UG1 funding mechanisms. The purpose of BQSFP 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.

Precision medicine, immunology, 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 and provide interpretable answers that are of benefit to patients. In addition, they need to lead to the validation of targets, reduction of morbidity, prediction of treatment effectiveness, enhanced clinical trial design or identification of populations that might benefit from treatment.

### V. Mechanism of Support

BQSFP is managed through the Coordinating Center for Clinical Trials within the NCI Office of the Director. The number of anticipated awards is contingent upon the availability of funds. NCI committed \$10 million to BQSFP funding in fiscal year 2018. Approved BQSFP studies are funded as administrative supplements to the NCTN Group/NCORP Research Base grants.

### VI. Eligibility

**A. Eligible trials** are those conducted by NCTN Groups and NCORP Research Bases, reviewed by NCI Steering Committees, and include:

- Randomized phase 2 and phase 3 NCTN treatment trials
- Randomized phase 2 and phase 3 NCORP cancer prevention clinical trials
- Randomized symptom science/supportive care clinical trials with efficacy endpoints
- CEA proposals, if part of a randomized phase 3 treatment or prevention clinical trial concept with a comparator arm, or a symptom science/supportive care clinical trial with a comparator arm

#### **B. Trial Types**

- **NCI Treatment Trials** test the effectiveness of new cancer treatments or new ways of using existing cancer treatments in people who have cancer. The treatments tested may include drugs, vaccines, approaches to surgery or radiation therapy, or combinations of treatments including immunotherapy modalities.
- **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 or recurrence. These studies look at cancer risk and ways to reduce that risk.
- **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 fatigue, pain, nutrition problems, infection, nausea and vomiting, sleep disorders, depression, and other cancer and treatment related symptoms and toxicities.

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

## VII. Integral and Integrated Studies

Two types of studies embedded in NCTN or NCORP trials 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 or to support the primary analysis. Integral studies are inherent to the design of the trial and must be performed on all participants, usually in real-time. The assay/test must support one of the trial's primary hypotheses. **Integral studies have the highest funding priority.**

Examples of integral studies include:

- Tests to establish eligibility, randomization, stratification, or treatment assignment in a treatment, imaging, prevention or symptom science trial
- Functional imaging or molecular characterization linked to execution of primary analysis, such as non-reimbursable PET scans or biomarker evaluation

- B. Integrated Studies** – These are intended to validate markers, imaging tests or tools, or QOL/PRO instruments for possible use as an integral marker in future trials or in clinical practice. Integrated studies should test a specific hypothesis with a preplanned statistical design, and are not hypothesis-generating or exploratory. Integrated studies must be included in the protocol as a secondary objective.

**Real Time (RT) Integrated Studies** -- Some integrated studies may require that assays or tests be performed during the trial, for example, biomarker assays that require a fresh tumor biopsy or real time processing of a blood or tissue sample, or imaging tests to measure treatment response.

Integrated RT studies should be submitted after the principal investigator (PI) receives notification by the CTEP or DCP PIO that the concept was approved, preferably within 3 months.

**Non-Real Time (NRT) Integrated Studies** -- Other integrated studies do not require real time assays/tests or sample collection or processing. Examples of NRT integrated assays/tests include tools to analyze scans collected as part of standard treatment, gene expression studies that correlate with outcome, and PD-L1 assays performed on diagnostic tumor samples where the results are not used for eligibility, treatment assignment, or treatment management.

Integrated NRT studies will be accepted only after the trial has reached at least 75-percent of the protocol-specified accrual goal and no later than six months following the date of publication of an abstract or manuscript on the primary outcome results of the trial (whichever occurs first).

Examples of integrated studies include:

- Studies to establish or validate clinical utility (including cutpoints) for assays/imaging tests or tools that show promise for future use as integral biomarkers or imaging tests.
- QOL/PRO studies to validate instruments 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.
- CEA studies that rely on database data collection such as Medicare usage and do not require documentation of patient resource utilization may be NRT integrated studies.

**C. Studies Ineligible for BIQSFP Funding**

- Studies that are not embedded in an eligible trial type (e.g., phase 1 concepts, non-randomized phase 2 studies, etc.)
- Biospecimen and imaging studies still within the discovery phase or pre-clinical development stage focusing on assay/test development
- Studies considered exploratory or hypothesis-generating
- Studies eligible for DCP Cancer Control Credits or other DCP or DCTD funding
- Studies that include assays, tests, or instruments that are standard of care and normally reimbursed by third-party payers
- Collection of cost data that solely compares the costs between comparator and experimental arms
- Studies proposed more than 6 months after the primary results are reported

**VIII. Statistical Requirements for BIQSFP Study Applications**

It is recommended that this section be developed in consultation with a biostatistician, ideally one who is familiar with the specific trial data elements relevant to the proposed BIQSFP study. While the examples in this section are mainly for biomarker studies, all BIQSFP applications should include a statistical section explaining the endpoint, case selection, statistical analysis, and sample size.

**A. Endpoints**

Precisely define the the clinical endpoints and the biomarker/imaging measurements involved in the analysis; for time-to-event outcome variables, be sure to clearly indicate the types of events included in each endpoint definition.

**B. Case Selection**

If the trial's entire patient population will not be included in the BIQSFP study, specify the proposed case selection method, including inclusion/exclusion criteria, and whether stratification or matching will be used. If a complex case selection strategy (e.g., matched or adaptive selection) will be used, then the specific algorithm should be described.

**C. Statistical Analysis Plan**

The statistical analysis plan should describe how the primary objectives will be addressed in a quantifiable and statistically evaluable way. Indicate the general statistical framework (e.g., estimation, association, comparison, prediction). The following information should be provided, as applicable:

- Statistical methods for the primary analyses (e.g., Cox proportional hazards regression, conditional or unconditional logistic regression, etc.)
- Transformations applied to variables
- Methods for marker cutpoint validation
- Variable selection procedures (including a list or description of the variables initially considered for inclusion in the model)
- List of standard clinical variables to be incorporated into models or other analyses
- Multiple-comparison adjustment methods
- For complex studies, methods that will be used to validate the analysis results, or a rationale for not performing a validation study
- Any other information necessary to understand and evaluate the proposed primary analyses

**D. Justification for Sample Size**

Based on the stated primary analyses and proposed statistical analysis plan, provide a justification (rationale) for the number of assays/tests. The rationale should include a clear explanation (or cited reference) for the method of sample size determination along with a statement of all assumptions required to perform that calculation so that an independent statistician would be able to reproduce the estimates from the information provided in the application.

Typically, a sample size estimate will require assumptions about the following:

- Anticipated distribution of marker values in the targeted population(s) (e.g., marker positivity rate if the marker is dichotomous)
- Assay success rates (based on anticipated rates of technical failures, degraded or insufficient biospecimens, etc.)
- Event rates or number of events anticipated for the cases included in the primary analysis
- Expected differences in outcomes or magnitudes of associations (e.g., hazard ratio or other “effect” size)

These assumptions and estimates need to be supported by preliminary data or previous studies, which should be described either in this section or in the background section.

**IX. Review Criteria**

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

**A. Biomarker and Imaging Studies**

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 must be performed in CLIA-accredited laboratories (if they are reported to the patient or their physician) and may need FDA review as well. Prioritization and evaluation criteria include:

- The strength of the preliminary data for both test utility and performance characteristics including cutpoints
- Adequacy of statistical plans, including power, stringency, and subset analyses if indicated
- 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 assays/tests/tools as to be transferable to the non-research setting
- The adequacy of the process for specimen collection or image acquisition or analysis including feasibility data
- A description of cost-sharing with entities that would eventually commercialize the test

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>

For additional explanations and definitions related to biomarker assays, see **Performance Standards Reporting Requirements for Assays in Clinical Trials** at:

[http://cdp.cancer.gov/scientific\\_programs/pacct/PACCT\\_Assay\\_Standards\\_Document.pdf](http://cdp.cancer.gov/scientific_programs/pacct/PACCT_Assay_Standards_Document.pdf)

**B. Quality of Life/Patient Reported Outcome Studies**

Most QOL/PRO studies (which use previously validated instruments) 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. Both integral and integrated QOL/PRO studies are eligible for BIQSFP funding.

Prioritization and evaluation criteria include:

- The proposal includes a letter from DCP indicating that the proposed costs exceed allowable DCP credits/resources and that DCP has agreed that the study should be considered for BIQSFP funding. DCP will provide this letter to the NCORP Research Base for the application.
- The potential to impact patient morbidity and quality of life with clinically meaningful benefit
- The potential to move science forward 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 collection
- A statistical plan with adequate power for testing the QOL/PRO study hypothesis(es)
- Instruments are reliable, valid, and appropriate to the population of interest or are in the process of validation

**C. Cost-Effectiveness Analysis (CEA) Studies**

CEA studies provide 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, health care sector), and time horizon (e.g., within trial or long-term survivorship). To be most useful to decision makers, CEA studies must have maximal feasibility, be timely, and have high internal validity. 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. The CEA evaluation criteria are intended to help guide the selection of cancer clinical trials that warrant additional funds for a CEA.

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 sufficient 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 crucial 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.

## X. BIQSFP Proposal Package & Submission

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/bigsfp>. The site also includes the BIQSFP Guidelines, Frequently Asked Questions (FAQs), Submission Checklists, Budget and Budget Justification information, and Program Contacts.

### A. When to Submit

- **INTEGRAL** studies must be embedded in the parent concept. The BIQSFP Proposal Package must be submitted with the parent concept. Concept submission forms can be found at:
  - **CTEP** ([https://ctep.cancer.gov/protocolDevelopment/docs/Concept\\_Submission.docx](https://ctep.cancer.gov/protocolDevelopment/docs/Concept_Submission.docx))
  - **DCP NCORP Clinical Trials Document Submission Worksheet v3.1** ([https://prevention.cancer.gov/sites/default/files/uploads/clinical\\_trial/NCORP-Clinical-Trials-DSW-02272017.docx](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/NCORP-Clinical-Trials-DSW-02272017.docx))
- BIQSFP proposals for **RT INTEGRATED** studies should be submitted after the principal investigator (PI) receives notification by the CTEP or DCP PIO that the concept was approved, preferably within 3 months.
- BIQSFP proposals for **NRT INTEGRATED** studies will be accepted only after the trial has reached at least 75-percent of the protocol-specified accrual goal and no later than six months following the date of publication of an abstract or manuscript on the primary outcome results of the trial (whichever occurs first). The requirement for 75-percent of the protocol-specified accrual goal may be re-considered if a trial is stopped earlier based on a Data Safety Monitoring Committee recommendation (usually due to an interim analysis).

### B. 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 2018 BIQSFP Guidelines. The cover letter should include:
  - Title(s) of the BIQSFP project(s)
  - Title and protocol number of the parent clinical trial concept associated with the biomarker, imaging, QOL/PRO, and/or CEA proposal
  - 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 requested for each project
  - Duration of each study
- Detailed budget
  - Total composite budget that details the costs (direct and indirect) for *each* biomarker, imaging, QOL/PRO and/or CEA study proposal submitted
  - Use the Form PHS 398 (<http://grants.nih.gov/grants/funding/phs398/phs398.html>)
  - Include a narrative justifying each requested cost
  - Covered BIQSFP costs may include, but are not 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
  - Salary and meeting travel costs for the PI of the clinical trial/study and/or NCTN Group/NCORP Research Base leadership are **not** covered under the BIQSFP program.
  - Investigators are encouraged to explore options for reducing the cost of assays and tests to be supported by BIQSFP funding, perhaps by billing third party payers, obtaining partial funding from commercial partners, or choosing the lowest priced laboratory.
  - The signature of the institutional business official is not required at the time of initial submission of the total composite budget. Institutional approval and sign-off is required once the final funding has been approved by the NCI.
- Study Checklist -- Submit the appropriate checklist based on the type of request: (<https://www.cancer.gov/about-nci/organization/ccct/funding/biqsfp>)
    - **Integral Biomarker:** A separate document (no more than 5 pages per assay) is required describing the characteristics and performance of **each** biomarker assay test proposed for funding and its role in the trial. Applicants should follow the *Study Checklist for Integral Biomarker Assays*.
    - **Integrated Biomarker:** A separate document (no more than 5 pages per assay) is required describing the characteristics and performance of **each** biomarker assay test proposed for funding and its role in the trial. Applicants should follow the *Study Checklist Integrated Biomarker Assays*.
    - **Integral Imaging:** A separate document (no more than 5 pages per imaging study) is required describing the characteristics and performance of **each** imaging test proposed for funding and its role in the trial. Applicants should follow the *Study Checklist for Integral Imaging Tests*.
    - **Integrated Imaging:** A separate document (no more than 5 pages per imaging study) is required describing the characteristics and performance of **each** imaging test proposed for funding and its role in the trial. Applicants should follow the *Study Checklist for Integrated Imaging Tests*.
    - **QOL/PRO:** A separate document (no more than 5 pages per instrument) 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 follow the *Study Checklist for QOL/PRO Assessments*.
    - **CEA:** A separate document (no more than 8 pages) is required outlining the rationale behind the request for funding of the CEA proposal. Applicants should refer to the *Study Checklist for Cost-Effectiveness Analysis (CEA)*.
  - Standard Operating Procedures (SOP) -- Applicants are encouraged to submit an SOP(s) as an appendix when the SOP informs on precision, accuracy, and specificity needed for validation of the assay(s), imaging tests or QOL/PRO instruments being proposed.
  - NIH Biosketch -- 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: <https://grants.nih.gov/grants/forms/biosketch.htm>
- C.** A complete **Proposal Package** as a **PDF** must be emailed to the relevant Program office. Study submissions must reference "BIQSFP" in the subject line of the email.

**Email NCTN Group BIQSFP proposals to:**

NCI CTEP Protocol Information Office - [PIO@ctep.nci.nih.gov](mailto:PIO@ctep.nci.nih.gov)  
**cc:** Margaret Mooney, M.D. - [mooneym@ctep.nci.nih.gov](mailto:mooneym@ctep.nci.nih.gov)  
BIQSFP mailbox – [NCIBIQSFP@mail.nih.gov](mailto:NCIBIQSFP@mail.nih.gov)

**Email NCORP Research Base BIQSFP proposals to:**

NCI DCP Protocol Information Office - [ncidcppio2@mail.nih.gov](mailto:ncidcppio2@mail.nih.gov)  
**cc:** Wortá McCaskill-Stevens, MD, MS - [wm57h@nih.gov](mailto:wm57h@nih.gov)  
BIQSFP mailbox – [NCIBIQSFP@mail.nih.gov](mailto:NCIBIQSFP@mail.nih.gov)

**XI. Conditions for Funding**

BIQSFP studies are funded via Administrative Supplements to the parent U10/UG1 Cooperative Agreement for the study and are 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. This includes adherence to the NIH data sharing policy, even if BIQSFP study results are negative. [https://grants.nih.gov/grants/policy/data\\_sharing/](https://grants.nih.gov/grants/policy/data_sharing/)

Funding is restricted to the approved project and dependent on continuance of the clinical trial and adequate progress on the BIQSFP-funded study. Carryover requests must receive written approval from the relevant NCI program official.

A progress report for each funded BIQSFP study must be included with the parent grant's noncompeting renewal. The progress report should indicate the number of assays/tests/instruments completed in the previous budget period, the number of patients screened, and/or the number of patients enrolled, as appropriate for each study. It should also identify any problems with the BIQSFP study or enrollment in the trial.

Any requested changes to the study budget (e.g., the sample size increased or additional tests were added during protocol development, the cost of the test increased, etc.) should be described in the budget narrative and require BIQSFP program approval.

**XII. 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".*

**XIII. Inquiries**

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

**For NCTN Trials:**

Margaret M. Mooney, MD  
Chief, Clinical Investigations Branch  
Cancer Therapy Evaluation Program  
Division of Cancer Treatment and Diagnosis  
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](mailto:mooneym@ctep.nci.nih.gov)

**For DCP Trials:**

Worta J. McCaskill-Stevens, MD, MS  
Chief, Community Oncology and Prevention Trials Research Group  
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](mailto:wm57h@nih.gov)

**Direct questions regarding prioritization, evaluation, and administrative supplements to:**

BIQSFP Program Director  
Coordinating Center for Clinical Trials  
National Cancer Institute  
9609 Medical Center Drive  
Bethesda, MD 20892-9744  
Phone: 240-276-6160  
Fax: 240-276-7868  
Email: [NCIBIQSFP@mail.nih.gov](mailto:NCIBIQSFP@mail.nih.gov)