SCIENTIFIC REVIEW COMMITTEE

STANDARD OPERATING PROCEDURES
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Function of the Scientific Review Committee

The Scientific Review Committee (SRC) is a subcommittee of the Protocol Review and Monitoring Committee (PMRC) at the Stephenson Cancer Center (SCC). The PRMC has the overall responsibility for reviewing, approving, and monitoring all cancer-related protocols at the SCC for scientific merit, study feasibility, resource prioritization, data quality, safety and progress. The PRMC has delegated these functions to the following three subcommittees:

- Scientific Review Committee (SRC) – Review for scientific merit and feasibility; SCC resource allocation (initial assessment)
- Protocol Monitoring Committee (PMC) – Review for progress towards enrollment targets; SCC resource utilization (ongoing assessment); review for data quality
- Data and Safety Monitoring Committee (DSMC) – Data and safety monitoring for trials that require institutional-level monitoring

All cancer-related protocols involving a University of Oklahoma Health Sciences Center (OUHSC) faculty member or an SCC affiliate member require review by the Scientific Review Committee. The specific functions of the SRC are to:

- Review the scientific merit of cancer-related research involving human subjects at the SCC
- Foster the development of innovative, collaborative, and scientifically-sound studies that focus on the prevention, detection, diagnosis, and treatment of cancer as well as long-term follow-up and care
- Review the proposed utilization of SCC resources including, but not limited to, personnel, human responses, patient entry, tissue, blood and data
- Assist SCC investigators in the development of scientifically- and clinically-sound research through well-written and well-conducted clinical trials
- Provide a standard format for review of scientific feasibility and merit

The SRC is complementary to the Institutional Review Board (IRB), but it does not duplicate or overlap the responsibilities of the IRB, which focus on the protection of human subjects. The
OUHSC IRB will not approve any cancer-related study involving human subjects without first receiving notice of approval from the SRC, as mandated by the OUHSC Provost.

**Committee Composition**

SRC members are appointed by the SCC Director for three (3) year appointments. At least ten (10) members will serve on the SRC with representative members from each the following: Pediatric Hematology / Oncology, Adult Hematology / Oncology, Nursing, Obstetrics and Gynecology, Radiation Oncology, Surgery, Pharmacy, Statistics and Behavioral Science.

Members are invited to participate based on disciplinary expertise as well as expertise in the design, conduct and analysis of specific trials. At-large members may be appointed to the SRC based on the areas of research and expertise needed for protocol review. A statistician and the CTO Administrative Director will also be standing members of the SRC. The CTO will provide administrative support for the SRC.

The SRC Chair is appointed by the SCC Director for a three (3) year appointment. The responsibilities of the Chair include the following: conducting bi-monthly SRC meetings; corresponding with PIs with regard to initial review and committee actions; assigning reviews to SRC members; maintaining the integrity, quality, and records of the SRC; and reporting SRC activities to the SCC leadership. The SRC Co-Chair is appointed by the SCC Director for a three (3) year appointment. The Co-Chair performs the responsibilities of the Chair in the absence of, or as delegated by, the latter.

A meeting quorum requires the presence of 50% of voting members. Each SRC member will have one (1) vote. On issues where an SRC member is a PI, Co-PI, or sub-PI, the SRC member is permitted to discuss, but not vote. The SRC meets on alternating Wednesdays to precede the OUHSC IRB Board 2 (Cancer Board) meeting on the following Monday. The yearly schedule of the SRC will be distributed in January of that year.

The SRC will be supported by a Coordinator whose responsibilities include: maintaining a database and tracking sheet of protocols reviewed by the SRC; maintaining files on all active protocols reviewed by the SRC; assisting PIs in preparing submissions to the SRC to assure that all documentation is complete; maintaining records concerning appointment and term of SRC members; documenting meetings through generating and distributing minutes; providing other administrative support as required by the SRC Chair or committee.
**SRC Review Process**

The SRC Chair assigns committee members to review protocols based upon member expertise. Any SRC member serving as a PI of a protocol coming before the committee for scientific review will not be allowed to serve as a reviewer for that protocol. The Coordinator will send the protocol and the SRC Reviewer’s Form (Appendix A) to the reviewers one week before the SRC meeting. Additionally, the assigned statistician will receive the protocol for review.

**Risk Assignment**

New protocols submitted to the SRC are first reviewed by the CTO administrative staff to assure that all required components of a research protocol are included. They are then forwarded to the appropriate Clinical Research Disease Site Group for review and approval. Protocols are then reviewed by the SRC. At this time the SRC Chair determines the study risk as one of two levels:

- **Low Risk:** Studies involving no therapeutic intervention – i.e., studies involving patient questionnaires, blood draws, or other low-risk tissue sampling (i.e., hair, urine, sputum), voice or video recordings, moderate exercise, existing data, documents, pathologic or diagnostic specimens, behavioral, cognition or perception. Studies involving intervention with standard doses of nutritional agents available over the counter (i.e., vitamins, minerals).

- **High Risk:** Studies involving cancer-directed chemotherapy, biologic therapy, radiation therapy, or surgical intervention. Studies involving higher-risk tissue sampling (i.e., bone marrow, or sampling requiring any type of anesthesia). Studies involving non-standard doses of agents available over the counter.

The SRC Chair also records whether the study is covered by an external Data and Safety Monitoring Board.

**Levels of SRC Review**

There are two levels of SRC review: Full Review and Expedited Review. The SRC Chair determines the level of review according to the type of trial.
**Full Review:** For Full Review, the SRC Chair identifies a primary reviewer, a secondary reviewer (if required), and a statistician (if required). The entire protocol or amendment is made available for review, and the assigned reviewer is required to comment on specific items regarding the scientific merit of the study and submit their remarks on the SRC Reviewer’s Form (see Appendix A). The SRC can take one of the actions defined below. Protocols that require Full Review include:

- **Investigator-Initiated Protocols (Phase I-III):** Requires a primary and secondary reviewer, a statistical reviewer, and must receive a majority vote by the SRC for approval.

- **Industry-Sponsored Protocols (Phase I-III):** Requires a primary reviewer, a statistical reviewer, and must receive a majority vote by the SRC for approval.

- **IRB Exempt / Expedited Protocols:** An institutional protocol that meets the criteria for IRB exempted research requires a primary reviewer’s recommendation and majority vote by the SRC for approval.

**Expedited Review:** Studies or amendments subject to Expedited Review are reviewed by the SRC Chair, who is responsible for approval or disapproval. The outcomes of Expedited Reviews are reported to the full committee at the next scheduled meeting. Protocols that require only Expedited Review include:

- **National Cooperative Group / CTEP Protocols:** These protocols must demonstrate evidence of external peer-review at the CTEP or National Cooperative Group level. The Chair has the discretion to approve through Expedited Review. These protocols may be submitted and will be reviewed on a rolling basis. The Expedited Review will be done in an effort not to delay the process of subsequent IRB review and approval. These protocols may undergo Full Review if directed by the Chair.

- **Other Protocols:** Trials conducted solely for the purpose of collecting information without addressing a specific scientific question. Examples of these studies include:
  
  - Compassionate Use Trials – involving an agent or device made available for rare patient who may benefit
o Post-Marketing Trials – seek to collect additional safety or efficacy data through expanded use
o Tissue Collection / Banking Trials – seek to provide a resource for later analysis or study.

Data generated from these trials may be useful / important despite the absence of a specific scientific question, and may provide a resource for later evaluation. Trials fitting into this category may receive an Expedited Review by the SRC Chair. The Chair has the discretion to request a Full Review for any study.

Committee Actions

For protocols requiring a Full Review, a summary will be presented by the assigned primary reviewer. Comments and recommendations will be made by the primary reviewer and, where applicable, the secondary reviewer. Statistical considerations will be addressed by the assigned statistician. All therapeutic protocols will be reviewed by at least one physician member of the SRC. Recommendations relative to protocol approval by the SRC will be based upon the criteria listed below:

- **Accepted for Submission to the IRB**: The protocol is scientifically-sound and acceptable as written and may be forwarded to the IRB without modifications.

- **Accepted with Minor Revisions**: The protocol is scientifically-sound and acceptable pending clarification on the part of the PI of specific points. The PI must submit a copy of any protocol revisions to the Chair for Expedited Review and approval.

- **Approval with Major Revisions**: The study is scientifically-sound and acceptable if the PI can make modifications to the protocol and / or provide clarifications as requested by the SRC. The protocol must return to the SRC for Full Review and approval before IRB submission.

- **Tabled**: The protocol was not reviewed and must return to the SRC for Full Review and approval before IRB submission.

- **Disapproved**: The study is not scientifically-sound, not ethical, and not acceptable as written, or not within the mission of the SCC.
The actions of SRC will be recorded in the form of minutes and will be distributed to all SRC members at the following SRC meeting. The recommendations of the SRC will be forwarded by the Chair via email to the protocol PI within seven (7) days of the SRC meeting.

The PI must submit a copy of any revised protocol directly to the SRC at least one (1) week before the next scheduled meeting. Review will occur as outlined above. All substantive changes to investigator-initiated and industry-sponsored protocols must be reviewed and approved by the SRC before approval by the IRB. Major protocol changes (e.g., modifications in drug dosage or delivery, change in methods, procedure or study design, changes in exclusion or inclusion criteria, addition / reduction of subject accrual goals, etc.) will be held for the next SRC meeting and must receive Full Review. Minor protocol changes will receive Expedited Review.

All requests for protocol changes should be submitted to the SRC Chair by the PI. When a change is related to the protection of research subjects, the IRB is obligated to review the request immediately. In this event, IRB approval will not require SRC approval. A PI may petition the SRC for an Expedited Review of a major change in protocol. The PI must contact the SRC Chair and demonstrate that delaying implementation of the protocol change until the next scheduled SRC meeting would seriously impede the research project. The SRC Chair may decide to grant approval of the change pending Full Review or may convene three (3) or more SRC members to perform an ad hoc Expedited Review.

**Protocol Format and Submission Requirements**

All investigator-initiated protocols must be submitted in the SCC format defined in Essential Elements of a Protocol (Appendix B).

National cooperative group and industry protocols may be submitted without conversion to SCC format provided they contain the key elements required by the SRC for scientific review.

All investigator-initiated protocols must involve a statistician before submission to the SRC. Principal Investigators who are SCC members may request statistical assistance through the following:

SCC Biostatistics Core
SCC-Biostat@ouhsc.edu
Protocols should be submitted to the SRC through the Coordinator at least ten (10) days before the next scheduled SRC meeting. The Coordinator may be contacted at the following:

PRMC Coordinator
405-271-6813
SCC-PRMC@ouhsc.edu

Assistance in preparing a protocol in SCC format may be obtained through the Coordinator. Any requests for SRC Expedited Review should be forwarded directly to the SRC Chair.

National cooperative group and industry protocols can be submitted simultaneously to the SRC and the IRB; however, the IRB will not approve any cancer-related protocol involving human subjects without prior SRC approval.

SRC Documentation

A. Minutes – Minutes from SRC meetings will be recorded and kept by the SRC Chair or Coordinator.

B. SRC Reviewer’s Forms – Forms will be completed by reviewers before the SRC meeting and will be given to the Coordinator on the same day as the SRC meeting.

C. Protocol Records – The SRC Coordinator will maintain records / copies each protocol submission, protocol identification number, the SRC Reviewer’s Forms, SRC recommendations and correspondence to PIs.

D. Protocol Database – The Clinical Trials Office will maintain a database of information relative to protocol priority, eligibility criteria, accrual, continuing review, and audits.

E. Correspondence – Copies of all correspondence related to actions and conduct of the SRC will be maintained by the Chair or Coordinator of the SRC.
F. Annual Report – An Annual Report will be prepared by the SRC Chair and will be submitted to the Committee, the PRMC Chair and SCC Director at the end of each fiscal year. The SRC Annual Report will detail the activities of the SRC including protocol submissions, protocol reviews and committee actions.
Appendix A - SRC Reviewer’s Form
SRC REVIEWER’S FORM

PROTOCOL TITLE:

PI:

REVIEWER:

REVIEW DATE:

OVERALL CRITIQUE:

Reviewer Recommendation:

1. Accepted for IRB submission
2. Accepted with Minor Revisions (Administrative review by SRC)
3. Accepted with Mandatory Revisions (Full SRC re-review required)
4. Not accepted

Y N N/A Are there overlapping protocols in the disease site group? The PI should point out any potential overlap with ongoing trials at SCC and, if overlap exists, describe how patients will be allocated to each study.

Y N N/A Purpose / Specific Aims – Are the specific aims and hypothesis clearly stated to include the broad, long-term objectives of the research project?

COMMENTS:

Y N N/A Background and Rationale – Is there a detailed description of the background so that the rationale for the study is clear? Is there a critical evaluation of existing knowledge, work accomplished by the PI and others, a recent review of the literature with analysis, and specific identification of the gaps that the clinical trial is intended to fill? There should be a discussion of the potential difficulties and limitations of the proposed treatment procedures and alternative approaches to achieve the aims.
COMMENTS:

Y  N  N/A  **Specific Location of Study** – Has the PI identified the study sites, including the hospital(s) and affiliate investigator offices, if allowable?

- SCC only
- SCC Partners / Affiliates
- Other_____________

COMMENTS:

Y  N  N/A  **Probable Duration of the Project** – Has the PI provided a reasonable estimate of the time for completion of the entire study and is it realistic? (See Statistics Section)

COMMENTS:

**Research Plan**

Y  N  N/A  **Experimental Design and Methods** – Should include study design (open-label, single-, double-blind), type of design (randomized, control), an outline of the procedures, treatments, hospitalizations, etc. that are part of the experimental design and that effect individual patients. Will this be appropriate to accomplish the specific aims of the project? A schema would be helpful.

COMMENTS:

Y  N  N/A  **Patient Eligibility Criteria** – Must include the following: population to be studied (i.e., tumor type and stage, prior therapy, measurability of disease). Do the inclusion and exclusion criteria include disease-related criteria, medical history, performance status, organ function,
concomitant therapy, and other illnesses?

COMMENTS:

Y  N  N/A  Procedures for Patient Entry - includes procedures for entry of patients on study (mechanisms for registration, and procedure for verification of eligibility status, randomization).

COMMENTS:

Y  N  N/A  Pre-Treatment Evaluation – Should include the tests and timing of the tests required for eligibility determination and other tests required for pre-treatment.

COMMENTS:

Y  N  N/A  Study Parameters and Monitoring of Patients – This section must include all study tests, their timing / frequency, and interim tests for therapeutic effect (Does the test and monitoring schedule coincide with the treatment plan or does it complicate the plan?) Are response assessments specified to occur at times that coincide with definitions of response (i.e., if two assessments two months apart are required for response categorization, are these assessments made as described?) Are tests to be obtained when the patient is removed from the study clearly outlined? A table of study parameters must be provided to identify standards of care.

COMMENTS:

Y  N  N/A  Treatment Plan – Does the protocol include the regimen (drugs, doses and schedule by which the treatment will be given)? Are the drug administration guidelines clearly written (the route of administration, infusion solution and concentration, rate of infusion)? Is there a treatment code (if applicable) with procedures for breaking
the treatment code? Abbreviations for drug names are not acceptable.

**COMMENTS:**

**Y N N/A**  Dose Modifications or Escalations – Are there criteria for modification of therapy based on toxicity (intermittent holding, discontinuation, or dose reduction of study agent)? Are there instructions regarding required action if no criteria are listed for a particular toxicity? Instructions for dose escalation, if allowed, should also be provided. Are the criteria for dose modification of each drug clearly stated?

**COMMENTS:**

**Y N N/A**  Toxicity Monitoring and Adverse Event Reporting – Are the toxicity criteria included? Is there a definition of dose-limiting versus non-dose limiting toxicities, if applicable (Phase I)? Is there a description of the grade of toxicities that must be reported by telephone within 24 hours, the person(s) and telephone number to report such toxicities, the toxicities that must be reported by writing and the time frame for written reports, the procedures for submitting written reports, the names and addresses of all organizations that must receive written reports, and the methods to assess relationship of adverse events to study drug?

**COMMENTS:**

**Y N N/A**  Treatment Evaluation / Response Criteria – Does the section include methodology for tumor measurements and / or evaluation of no measurable disease, and definition of response assessments (duration and criteria for response), or methods to evaluate other endpoints?

**COMMENTS:**
Y  N  N/A  Removal of Patients from Study – Are the criteria by which patients are to be removed from the study (disease progression, need for concomitant additional therapy, toxicity, acute illness, non-compliance, deemed in the best interest of the patient, subject withdrawal, etc.) outlined?

COMMENTS:

Y  N  N/A  Laboratory / Pharmacokinetic Studies – Are the laboratory or pharmacokinetic studies, if planned, described, and is how the samples will be obtained, processed, stored and, if shipped, addressed?

COMMENTS:

Y  N  N/A  Pharmaceutical Information – Does the protocol contain the drug name, manufacturer / availability, storage, dose / preparation, drug preparation / administration guidelines (the route of administration, infusion solution and concentration, rate of infusion), dose calculations (calculation of drug dose based on real versus ideal body weight, rounding up or down of doses, if necessary) and associated toxicities? Is it clear from where the drug will be obtained and who is responsible for the cost?

COMMENTS:

Y  N  N/A  Data Collection Procedures / Records to be Kept – Are there specific documents to record data, where they are to be sent, and on what schedule?

COMMENTS:
Y N N/A **Statistical Considerations** – Is the statistical method of how each specific aim, or at least the primary aim, will be evaluated clearly defined? Will the treatment response be evaluated as disease free survival, time to death / recurrence, marker reduction from baseline, or simply the proportion of complete / partial responders vs. non-responders? For a feasibility study, is it clear how the feasibility will be assessed when the study is complete? For a pilot study, is it clear how this data will help prepare for a main study? For phase I trials, is there expected (hypothesized) toxicity rates for each dose level? For a phase II protocol, is there a sample size and an interim decision rule?

**COMMENTS:**

Y N N/A **Economic Considerations** – Does the PI explain who is financially responsible for pharmacokinetic studies or other laboratory assays, all other associated costs of therapy, monitoring and follow-up that are not a part of the standard-of-care of a patient with this particular malignancy? Are the medications being provided free-of-charge or will they be the responsibility of the patient?

**COMMENTS:**

**Human Subjects** – Are each of the following sections adequately addressed?

1. Subject Population Y N N/A
2. Potential Risks Y N N/A
3. Consent Procedures Y N N/A
4. Protection of Subjects Y N N/A
5. Potential Benefits Y N N/A
6. Risk-Benefit Ratio Y N N/A
7. Gender and Minorities Y N N/A

**COMMENTS:**
Y  N  N/A  **Bibliography** – Are all references provided, with full citations including titles?

**COMMENTS:**

Y  N  N/A  **Appendix** – Does it include performance status definitions, toxicity criteria, ideal body weight (if applicable) or other data that is referenced in the protocol?

**COMMENTS:**
Appendix B - Essential Elements of a Protocol
Essential Elements of a Protocol

Title Page / Face Sheet – Contains the title of the study, Principal Investigator including name, institution / Cooperative group, address, and phone number, and names of co-investigators.

A. Purpose / Specific Aims – The specific aims and hypothesis should be clearly stated to include the broad, long-term objectives of the research project.

B. Background and Rationale – Include a detailed description of the background so the rationale for the study is clear. This should contain a critical evaluation of existing knowledge, work accomplished by you and others, a recent review of the literature with analysis, and specific identification of the gaps that the clinical trial is intended to fill. Discuss the potential difficulties and limitations of the proposed treatment procedures and alternative approaches to achieve the aims. Point out any potential overlap with ongoing trials at the Stephenson Cancer Center and, if there is overlap, describe how patients will be allocated to each study.

C. Specific Location of Study – Identification of study sites including the hospital(s) and affiliate investigators offices, if allowable.

D. Probable Duration of the Project – An estimate of the time to completion of the entire study.

E. Research Plan

1. Experimental Design and Methods – Includes study design (open-label, single-, double-blind), type of design (randomized, control), an outline of the procedures, treatments, hospitalizations, etc., that are part of the experimental design and that effect individual patients. How will these be used to accomplish the specific aims of the project?

2. Patient Eligibility Criteria – Population to be studied (i.e., tumor type and stage, prior therapy, measurability of disease. Inclusion and exclusion criteria to include, but not limited to, disease-related criteria, medical history, performance status, organ function, concomitant therapy, and other illnesses)

3. Procedures for Patient Entry – Includes procedures for entry of patients on study (mechanisms for registration, and procedure for verification of eligibility status).

4. Pre-Treatment Evaluation – Includes the tests and timing of the tests required for eligibility determination and other tests required pre-treatment.

5. Study Parameters and Monitoring of Patients – Includes study tests, the timing for monitoring of patients for toxicity, and interim tests for therapeutic effect. Do tests
coincide with definitions of response (i.e., if two assessments two months apart are
required for response categorization, are these assessments made as described)?
Tests to be obtained when the patient is removed from the study. A table format of
study parameters is recommended.

6. Treatment Plan – Includes the regimen (drugs, doses and schedule by which the
treatment will be given), drug administration guidelines (the route of administration,
infusion solution and concentration, rate of infusion, how the drug is labeled and
packaged) and guidelines which detail procedures that must be followed when the
drug is administered by affiliate investigators, if allowable, and location of treatment
code (if applicable) with procedures for breaking of the treatment code. Also
includes any laboratory or pharmacokinetic studies to be performed on the trial
(may refer to appropriate sections for detailed description).

7. Dose Modifications or Escalations – Criteria for modification of therapy based on
toxicity (intermittent holding, discontinuation, or dose reduction of study agent), and
instructions regarding required action if no criteria are listed for a particular toxicity.
Instructions for dose escalation, if allowed.

8. Toxicity Monitoring and Adverse Event Reporting – Includes definition of toxicity
criteria, definition of dose-limiting versus non-dose limiting toxicities, if applicable
(Phase I). Describes the grade of toxicities that must be reported by telephone
within 24 hours, the person(s) and telephone number to report such toxicities, the
toxicities that must be reported by writing and the timeframe for written reports, the
procedures for submitting written reports, the names and addresses of all
organizations that must receive written reports, and the methods to assess
relationship of adverse events to study drug.

9. Treatment Evaluation / Response Criteria – Includes methodology for tumor
measurements and / or evaluation of non-measurable disease, and definition of
response assessments (duration and criteria for response), or methods to evaluate
other endpoints.

10. Removal of Patients from Study – Criteria by which patients are to be removed
from the study (disease progression, need for concomitant additional therapy,
toxicity, acute illness, non-compliance, deemed in the best interest of the patient,
subject withdrawal, etc.)

11. Laboratory / Pharmacokinetic Studies – Describe laboratory or pharmacokinetic
studies, if planned. How samples will be obtained, processed, stored and, if
shipped, mechanism and address.

12. Pharmaceutical Information – Provided by the pharmacist, the industry sponsor, or
the NCI. Contains the drug name, manufacturer / availability, storage, dose /
preparation, drug preparation / administration guidelines (the route of
administration, infusion solution and concentration, rate of infusion), dose calculations (calculation of drug dose based on real versus ideal body weight, rounding up or down of doses, if necessary) and associated toxicities.

13. Data Collection Procedures / Records to be Kept – Specification of documents on which each of the following is to be recorded, where it is to be sent, and on what schedule: study information; flow sheets or forms for interim monitoring; specialty forms for pathology, radiation, or surgery; off-study summary sheet; Annual Report.

F. Statistical Considerations – Includes the maximum number of patients to be accrued over a defined period of time, the statistical power of the study to test the major hypothesis, summary of plans for statistical analysis, and the timing and method of interim analysis of the study, if planned, and criteria for closing the protocol.

G. Economic Considerations – Explain who is financially responsible for pharmacokinetic studies, laboratory assays, and all other associated costs of therapy, monitoring and follow-up.

H. Human Subjects

1. Subject Population
2. Potential Risks
3. Consent Procedures
4. Protection of Subjects
5. Potential Benefits
6. Risk-Benefit Ratio
7. Gender and Minorities

Bibliography – Includes full references

Appendix – Should include references, performance status definitions, toxicity criteria, ideal body weight (if applicable)

Consent Form – In lay terminology, includes statements that the study involves research and purpose of research; expected duration of subject’s participation; description of procedures, including experimental procedures; description of potential risks and benefits and disclosure of alternative treatments; costs statement; statement regarding extent of confidentiality and statement that the FDA may inspect records; explanation as to whether compensation for participation will be given, including compensation in the event of injury, and whom to contact for information regarding research subject’s rights and research-related injury; statement that participation is voluntary, and that refusal to participate or subject discontinuation involves no penalty or loss of benefits.
Appendix C – New Protocol Notification Form
Clinical Trials Office
New Protocol Notification Form

I. General Information

Date: ____________________________

Principal Investigator: ____________________________

Primary Contact: ____________________________

Primary Contact Phone: ____________________________

Primary Contact Email: ____________________________

Protocol Title: ____________________________

II. Appropriate Clinical Research Disease Site Group (choose one):

- [ ] Breast Cancer
- [ ] Hepatocellular Carcinoma
- [ ] Dermatologic Cancers
- [ ] Lung Cancer
- [ ] G. I. and Colorectal Cancers
- [ ] Neurologic Cancers
- [ ] Gynecologic Cancers
- [ ] Orthopedic Oncology
- [ ] Head and Neck Cancers
- [ ] Pediatric Cancers
- [ ] Hematologic Cancers
- [ ] Urologic Cancers
- [ ] Phase I
III. Attached documents available at this time (check all that apply):

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<tbody>
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<td></td>
<td>Confidentiality Disclosure Agreement (CDA)</td>
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<td>Protocol Synopsis</td>
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<td>Informed Consent</td>
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<td>Protocol Budget</td>
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<td>Other:</td>
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Appendix D – Protocol Review Form
Clinical Trials Office  
Protocol Review Form

Section I

1. General information:
   - Date:  
   - PI/Study Chair Name:  
   - Study Number:  
   - Protocol Title:  

2. Sponsor Type (Choose one of the following):
   - National Cooperative Group: GOG, CALGB, RTOG, SWOG, ACRIN, COG, etc.
   - Externally Peer Reviewed: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Koman Foundation, etc.
   - Institutional: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.
   - Industrial: Design and implementation of the study is controlled by the pharmaceutical company.

3. Clinical Trial Type (choose one of the following):
   - Therapeutic Trial: Clinical trials with therapeutic intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions.
   - Prevention Trial: Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.
   - Supportive Care Trial: Clinical trials intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.
   - Screening, Early Detection or Diagnostic Trial: Clinical trials directly testing the efficacy of devices, techniques, procedures, or tests for earlier or more accurate detection or diagnosis of disease.
   - Epidemiologic, Observational or Outcome Trial: Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants (e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies).
   - Ancillary Trial: Auxiliary studies that are stimulated by, but are not a required part of, a main clinical trial / study, and that utilize patient or other resources of the main trial / study to generate information relevant to it. Ancillary studies included must be linked to an active trial or epidemiologic or other study and should include only patients accrued to that trial or study. Only studies that can be linked to individual patients or participant data should be reported.
   - Correlative Trial: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patients or participant data should be reported.
   - Other: Chart review or other retrospective study.
4. Clinical Trial Type (choose one of the following):
   - Phase I
   - Phase I/II
   - Phase II
   - Phase II/III
   - Phase III
   - Phase IV
   - NA

5. Study Complexity:
   - Yes
   - No
   - Is this a multi-center trial?
   - Does the study require PKs?
   - Does the study require EKGs?
   - Does the study require / permit biospecimen collection?
   - Does the study involve gene therapy?
   - Does the study involve medical imaging that requires pre-qualification or certification?
   - Does the study involve a quality of life question?

6. Main Inclusion Criteria (Top 3 - such as primary treatment and recurrence):
   -
   -
   -

   Main Exclusion Criteria
   -
   -
   -

7. Appropriate Clinical Research Disease Site Group (choose one):
   - Breast Cancer
   - Dermatologic Cancers
   - G. I. and Colorectal Cancers
   - Gynecologic Cancers
   - Head and Neck Cancers
   - Hematologic Cancers
   - Phase I Cancers
   - Hepatocellular Carcinoma
   - Lung Cancer
   - Neurologic Cancers
   - Orthopedic Oncology
   - Pediatric Cancers
   - Urologic Cancers

8. Patient Population and Study Prioritization:
   - SCC Projected Total Accrual: ________
   - National Planned Total Accrual: ________
   - SCC Projected Annual Accrual: ________
   - Expected Duration of the Accrual Period (months): ________

   Does the study have competing protocols currently active?  Yes ☐ No ☐

   If yes, the PI must attach a written justification for opening this protocol. Prioritization of competing protocols should be discussed and adjudicated in the appropriate Clinical Research Disease Site Group.
9. Primary Disease Site (choose one):

<table>
<thead>
<tr>
<th>Primary Disease Site</th>
<th>Other Disease Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lip, OralCavity &amp; Pharynx</td>
<td>Breast-Female</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Breast-Male</td>
</tr>
<tr>
<td>Stomach</td>
<td>Cervix</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>Corpus Uteri</td>
</tr>
<tr>
<td>Colon</td>
<td>Ovary</td>
</tr>
<tr>
<td>Rectum</td>
<td>Other Female Genital</td>
</tr>
<tr>
<td>Anus</td>
<td>Prostate</td>
</tr>
<tr>
<td>Liver</td>
<td>Other Male Genital</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Urinary Bladder</td>
</tr>
<tr>
<td>Other Digestive Organ</td>
<td>Kidney</td>
</tr>
<tr>
<td>Larynx</td>
<td>Other Urinary</td>
</tr>
<tr>
<td>Lung</td>
<td>Non-Hodgkin's Lymphoma</td>
</tr>
<tr>
<td>Other Respiratory &amp; Intrathoracic Organs</td>
<td>Multiple Myeloma</td>
</tr>
<tr>
<td>Bones &amp; Joints</td>
<td>Hodgkin's Lymphoma</td>
</tr>
<tr>
<td>Soft Tissue</td>
<td>Lymphoid Leukemia</td>
</tr>
<tr>
<td>Melanoma, skin</td>
<td>Myeloid &amp; Monocytic Leukemia</td>
</tr>
<tr>
<td>Kaposi's Sarcoma</td>
<td>Leukemia, other</td>
</tr>
<tr>
<td>Mycosis Fungoides</td>
<td>Leukemia, not otherwise specified</td>
</tr>
<tr>
<td>Other Skin</td>
<td>Other Hematopoietic</td>
</tr>
<tr>
<td>Eye &amp; Orbit</td>
<td>Other Endocrine System</td>
</tr>
<tr>
<td>Brain &amp; Nervous System</td>
<td>Unknown Sites</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Ill-Defined Sites (Multiple Sites)</td>
</tr>
<tr>
<td></td>
<td>NA</td>
</tr>
</tbody>
</table>

10. Study Contact Information (to include in campus protocol book and web protocol listing):

   Name: 

   Campus phone and extension: 

   Email Address: 

Last Revised - 07/16/2012
IMPORTANT! Please sign and return before the next SRC meeting deadline:

Required Signature: Principal Investigator

________________________  _________________________
Principal Investigator       Date

Required Signature: Clinical Research Disease Site Group Chair

________________________  _________________________
CRDSG Chair                 Date