

**THE OU CANCER INSTITUTE
SCIENTIFIC REVIEW COMMITTEE
STANDING OPERATING PROCEDURE**

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- I. Function - The function of the Scientific Review Committee (SRC) is to oversee the scientific aspects and conduct of the cancer-related research involving human subjects at the OU Cancer Institute at the University of Oklahoma Health Sciences Center. All cancer-related protocols involving a University of Oklahoma Health Sciences Center faculty member or a OU Cancer Institute affiliate member require review by the SRC. The function of the SRC is complementary to that of the Institutional Review Board (IRB), but it does not duplicate or overlap the responsibilities of the IRB, which focuses on the protection of human subjects. The University of Oklahoma Health Sciences Center IRB will not issue a full approval for any cancer related study involving human subjects without first receiving notice of approval from the SRC, as mandated by the Provost of The University of Oklahoma Health Sciences Center. The SRC focuses on the scientific merit, prioritization, and progress of cancer-related research involving human subjects at the OU Cancer Institute. The specific objectives of SRC are as follows:
 - A. Review the scientific merit of cancer-related research involving human subjects at OU Cancer Institute.
 - B. Foster the development of innovative, collaborative, and scientifically sound studies which focus on the prevention, detection, diagnosis, and treatment of cancer as well as long-term follow-up and care.
 - C. Review the proposed utilization of OU Cancer Institute (and State) resources including but not limited to human responses, patient entry, tissue, blood and data.
 - D. Assist investigators in the development and clinically feasible research through well written, and well conducted clinical trials.
 - E. Monitor progress of protocols relative to study objectives, accrual, data collection, and safety.
 - F. Provide a standard protocol format for submission and review.

II. Membership and Responsibilities

A. Committee Membership:

Members will be appointed by the Board of Directors of the OU Cancer Institute for a 2 year appointment. A total of 14 members will serve on the SRC with representative members from each OU Cancer Institute "department" excluding the Chairperson. The departments represented on the SRC may include, but are not be limited to, Pediatric Hematology/Oncology, Adult Oncology/Hematology, Nursing, Obstetrics and Gynecology, Radiation

Oncology, Surgery, Pharmacy, and Behavioral Science. The members appointed will be invited to participate based on expertise for clinical areas as well as design, conduct and analysis of such trials. At-large members may be appointed to the committee based on the areas of research and expertise needed for protocol review. A Biostatistician and the Supervisor of the CRO will also be standing members of the SRC. The meeting will be attended by the SRC Coordinator who serves as secretary for the committee.

1. Chairperson - The Chairperson of the SRC is appointed by the Director of OU Cancer Institute for a 3 year appointment. The responsibilities of the Chairperson include:
 - A. Conduct monthly SRC Meetings.
 - B. Correspond with Investigators with regard to initial review and continuing reviews.
 - C. Assign reviews to committee members III conjunction with the SRC Coordinator.
 - D. In collaboration with Coordinator of the SRC, maintain the integrity, quality, and records of the SRC with the assistance of the Supervisor of the CRO.
 - E. Report the status of the SRC to the Director of the OU Cancer Institute.
 - F. Document the meeting through the generation and distribution of minutes from the meeting.
2. Coordinator - The Coordinator of the SRC is appointed by the Director of OU Cancer Institute. The responsibilities of the coordinator include:
 - A. Maintain a database of protocols reviewed by the Scientific Review Board.
 - B. Maintain files on all active protocols reviewed by the SRC.
 - C. Assists Investigators in preparing submissions to the SRC to assure that all documentation is completed in accordance with the appropriate guidelines.
 - D. Correspond with Investigators in regard to initial review and continuing reviews.
 - E. Assign reviews to committee members III conjunction with the SRC Chairperson.

- B. Quorum - A quorum requires the presence of 51 % of voting members. Each committee member will have one vote. On issues where a committee member is a principal or sub-investigator, the committee member will be permitted to discuss, but not vote.
- C. Meeting - The SRC will meet on alternating Wednesdays to precede the IRB Board 2 meeting on the following Monday. This is done to Tuesdays and Thursdays every 2 weeks to accommodate the bimonthly meetings of the IRB Board 2 meeting. The yearly schedule of the SRC will be distributed in January of that year.
- D. Committee Responsibilities:
1. Review of new protocols - All cancer-related protocols involving human subjects must be received by IRB office according to their operating procedure. The IRB will not approve any cancer-related protocols involving human subjects, instead forwarding these protocols to the Chairperson or Coordinator of the SRC. Subsequently, the IRB will receive a notice of approval [or other action taken by the SRC] prior to approving the protocol.

Reviews are assigned by the SRC Chairperson and Coordinator based upon expertise. Any SRC member serving as a primary investigator 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 provide copies of the protocol and the SRC Protocol Review Form (Appendix A) to the reviewers one week before the meeting of the SRC. Additionally, the Biostatistician will receive a copy of the protocol for review.

Protocol Definitions (12/01/2009):

- A. Investigator-initiated protocol - Requires a primary and secondary review and a statistical review.
- B. Cooperative Group Cancer Therapy Evaluation Program (CTEP)/ National Institute Health (NIH) Protocol (protocols that can demonstrate evidence of external peer review at the CTEP or NIH level) - Requires a review for priority. The Chair will have the discretion of approving these studies without a vote from the committee. 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 review and subsequent approval by the IRB. These protocols may undergo full SRC review if directed by the Cancer Center Director or IRB chair. The SRC has the prerogative to assign national trials lower priority scores if they compete with ongoing institutional sponsored trials or are thought to have a lower scientific merit.

C. Industry Protocol- Requires a primary review and a statistical review and must receive a majority vote by the SRC for approval.

D. Exempt/expedited protocols - Institutional protocols that meet criteria for IRB exempted research requires a primary reviewer's recommendation and vote by the SRC for approval.

E. Other protocols- Trials conducted solely for the purpose of collecting information (registry trials) without addressing a specific scientific question or hypothesis may be considered by the SRC for review. Examples of these types of studies include compassionate use trials (agent or device made available for rare patient who may benefit), post marketing trials which seek to collect additional safety or efficacy data through expanded use, tissue collection/tissue banking protocols which seek to provide a resource for later analysis or study. In general, these types of trials seek to collect additional information and offer no specific scientific hypothesis. 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 be administratively reviewed and approved by the SRC Chair or Co-Chair. The Chair has the discretion to request full committee review for any study.

2. Review Process - A summary of the protocol will be presented by the primary reviewer. Comments and recommendation will be made by the primary reviewer and where applicable, by the secondary reviewer. Statistical considerations will be addressed by the SRC's statistician. All therapeutic protocols will be reviewed by at least one physician member of the SRC.
3. Review Criteria - Recommendations relative to protocol approval by the SRC will be based upon the criteria listed below:
 - A. Accepted for submission to the IRB - The study is scientifically sound and acceptable as written and may be forwarded to the IRB without modifications.
 - B. Accepted with minor revisions - The study is scientifically sound and acceptable if certain clarifications are provided. The investigator must submit a copy of any revised protocol outlining changes directly to the SRC. Upon SRC approval by the primary and secondary reviewer, the SRC will forward to the Chairperson or Coordinator for submission.

- C. Approval with major revisions - The study is scientifically sound and acceptable if the investigator can make modifications to the protocol and/or provide clarifications as requested by the SRC. The protocol must return to the SRC for full board review and approval before IRB submission.
 - D. Tabled - The protocol was not reviewed and must return to the SRC for full review and approval before IRB submission.
 - E. Disapproved - The study is not scientifically sound, not ethical, not acceptable as written, or not within the mission of the OU Cancer Institute.
4. Recording of the Committee's Activities - The actions of SRC will be recorded by the Chairperson or Coordinator of the SRC in the form of minutes and will be distributed to all committee members **within seven days of the meeting.**
 5. Notification - The recommendations of the SRC will be forwarded by the Chairperson or Coordinator via letter to the Principal Investigator within seven days of the SRC meeting.
 6. Subsequent Review and Approval Process - The Principal Investigator must submit a copy of any revised protocol directly to the SRC at least one week before the next scheduled meeting. Review will occur as outlined above.
 7. Change in Protocol - **All substantive changes to investigator-initiated and industry-sponsored cancer-related protocols must be reviewed and approved by the SRC before approval by the IRB.** Major changes in protocol (examples include 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 board review. Minor changes in protocol will be reviewed administratively.
 - A. **All requests for changes in protocol should be submitted independently to the SRC and IRB by the investigator in conjunction with the CRO/PRO.**
 - B. It should be noted that when a change is necessary to better protect research subjects, the IRB is obligated to approve that change immediately and IRB approval will, therefore, not be contingent upon SRC approval.
 - C. **An Investigator may petition the SRC for an expedited review of a major change in protocol. The Principal Investigator must contact the SRC**

Chairperson and demonstrate that delaying implementation of the protocol change until the next scheduled meeting of the SRC would seriously impede the research project. The SRC Chairperson may decide to grant approval of the change pending full SRC review or may convene 3 or more SRC members to perform an expedited review.

8. Continuing Review - Continuing reviews will be conducted on all industry sponsored and investigator-initiated SRC protocols that are actively accruing patients. Continuing reviews occur annually to determine if sufficient progress is being made and to monitor protocol compliance, serious adverse events, accrual, revisions and modifications to the protocol, and changes in the study priority. The necessary data for review will be provided by the PRO. The SRC is empowered to close a protocol at continuing review if the Principal Investigator fails to demonstrate sufficient progress without extenuating circumstances. The continuing review should be submitted to the SRC and IRB in the same month. The IRB must reapprove all active protocols no later than 12 months from the date of last review. Federal regulations require suspension of any study which is not reapproved within the 12 month period. The IRB notifies Investigators of the requirement for continuing review two months before expiration. The PRO will notify the SRC of the need for continuing review.

9. Monitoring Accrual- One of the functions of the SRC is to monitor accrual on all cancer-related protocols. Accrual will be monitored during the annual review of the protocol by the SRC.

10. Protocol Termination Process

A recommendation for protocol termination may be made during the continuing review or audit processes. Reasons for protocol termination include:

- A. Insufficient accrual within the projected time period, defined as less than 30% of the projected accrual.
- B. Failure to appropriately obtain consent.
- C. Failure to adhere to IRB approved clinical trial.
- D. Poor data quality/collection.
- E. Serious adverse events, where appropriate, beyond what would be expected for the procedure.

The Principal Investigator will be notified of termination of the study along with the reason(s) for termination. The Investigator will have 30 days to

appeal the termination and respond in writing relative to the reasons for termination. The Investigator's appeal will be reviewed at the next meeting of the SRC. If the Investigator does not or cannot adequately respond to the SRC's satisfaction (determined by a majority vote), the protocol is terminated and results in loss of access to OU Cancer Institute shared resources. At that time, the IRB will be immediately notified and no further patients may be enrolled to the study.

E. Protocol Format and Submission Requirements

All Investigator-initiated protocols must be submitted in the Cancer Center protocol format (Appendix B) and must be accompanied by the Standard of Care Form (Appendix C) with the corresponding table outlining protocol parameters and monitoring of patients and a TSG Protocol Priority Sheet (Appendix D). Cooperative group and industry protocols may be submitted without conversion to cancer center format provided they contain the key elements required by the SRC for scientific review along with a completed Standards of Care Form and attachment and a TSG Protocol Priority Sheet.

All investigator-initiated protocols must involve a statistician before submission to the SRC. Request for statistical assistance may be forwarded to the OU Cancer Institute (Biostatistics Shared Resource) Statistical Office.

Protocols are to be submitted to the SRC through the Protocol Office **at least 10 days before the next SRC meeting.** Assistance in preparing a protocol in cancer center format may be obtained through the protocol office. Protocol submissions must be accompanied by a completed Standard of Care Form and a TSG protocol Priority Sheet. The protocol will be then reviewed at the next SRC meeting. Any requests for expedited SRC review should be forwarded directly to the chairman of the SRC.

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

F. Documentation

1. SRC Minutes of the SRC meeting will be recorded and kept by the Chairperson or Coordinator of the SRC.
2. SRC Review Forms - SRC review forms will be completed by reviewers before the SRC meeting and will be given to the Chairperson or Coordinator of the SRC on the same day as the SRC meeting. (See Appendix A.)
3. Protocol Records - The SRC Chairperson or Coordinator will maintain records of each protocol submission, protocol identification number, SRC

4. SRC Database - The Cancer Clinical Trials Office will maintain a database of information relative to protocol priority, protocol eligibility criteria, protocol accrual, protocol continuing reviews, and protocol audits. The Cancer Center must be able to monitor accrual on all Investigator-initiated, non-industry, therapeutic protocols.
5. Correspondence - Copies of all correspondence emanating directly from the actions and conduct of the SRC will be maintained by the Chairperson or Coordinator of the SRC.
6. Annual Report - An SRC Annual Report will be prepared by the SRC Chairperson and the Coordinator of the SRC and will be submitted to the SRC and the Director of the OU Cancer Institute. The SRC Annual Report will detail the activities of the SRC including protocol submissions, protocol reviews, and continuing reviews.

Appendix A - SRC Protocol Review Form

SRC PROTOCOL REVIEW 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 TSG? The PI should point out any potential overlap with ongoing trials at The OU Cancer Institute and if there is an overlap, 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 which 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 investigators offices, if allowable?

ρ **OU Cancer Institute only**
ρ **OU Cancer Institute Partners/Affiliates**
ρ **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, there 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 a part .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 outlines? A table of study parameters must be provided to identify standards of care.
COMMENTS:
- Y N N/A Treatment Plan - Does it 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 of the treatment code? Abbreviations for drug names are not acceptable.
COMMENTS:

- Y N N/A Dose Modifications or Escalation's - 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 - Is there 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 it 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? Is it clear where the drug will be obtained from and who is responsible for the cost?
COMMENTS:
- Y N N/A Data Collection Procedures/Records to be Kept - Are there specific documents where data is to be recorded, 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 which 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 Cancer Institute of New Jersey and if there is an 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. Same as above
 - 4. Procedures for patient entry - includes procedures for entry of patients on study (mechanisms for registration, and procedure for verification of eligibility status).

5. Pre-Treatment Evaluation - includes the tests and timing of the tests required for eligibility determination and other tests required pre-treatment.
6. Study Parameters and Monitoring of Patients - includes study tests, the timing for monitoring of patients for toxicity, and interim tests for therapeutic effect (does coincide with definitions of response (i.e. - if two assessments two months apart are required for response categorization, are these assessments made as described?), and tests to be obtained when the patient is removed from the study. A table form of study parameters is recommended.
7. 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).
8. Dose Modifications or Escalation's - 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 is listed for a particular toxicity. Instructions for dose escalation, if allowed.
9. 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 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.
10. 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.
11. 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.).
12. Laboratory/Pharmacokinetic Studies - describe laboratory or pharmacokinetic studies, if planned. How samples will be obtained, processed, stored and, if

13. Same as above

14. Pharmaceutical Information - provided by the pharmacist, the Industrial 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.

15. 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 - Standard of Care Form

THE CASE CANCER CENTER
SCIENTIFIC REVIEW BOARD
PROTOCOL REVIEW FORM

Date: _____

Study Title:

Investigator: _____

Check one:

_____ The drug for this protocol is included or approved for inclusion in the latest official edition of one of the following publications:

1. American Hospital Formulary Service Drug Information
2. American Medical Association Drug Evaluations
3. United States Pharmacopoeia Drug Information (USPDD)

_____ Use for this drug is supported by clinical research that appears in Peer Reviewed Medical Literature, such as the following publications:

1. American Journal of Medicine
2. Annals of Internal Medicine
3. The Journal of the American Medical Association
4. Journal of Clinical Oncology
5. Blood
6. Journal of the National Cancer Institute
7. The New England Journal of Medicine
8. British Journal of Cancer
9. British Journal of Hematology
10. British Medical Journal
11. Cancer
12. Drugs
13. European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
14. Lancet
15. Leukemia
16. Other. _____

_____ There is no evidence of effectiveness for the planned clinical use.

Signature of SRC Representative

Date Signed

Appendix D - TSG Protocol Priority Sheet

TSG Protocol Priority Sheet

Principal Investigator:

Protocol:

Reviewed and accepted by TSG: _____ / _____ / _____

Prioritization: List all currently active and pending protocols and prioritization.

Signature of PI

Date Submitted