

**Vanderbilt-Ingram Cancer Center
Scientific Review Committee (SRC)
Policies and Procedures**

SUBJECT: Mission Statement

The purpose of the Scientific Review Committee (SRC) is to ensure that all cancer treatment trials conducted under the auspices of the Vanderbilt-Ingram Cancer Center meet peer-reviewed standards of scientific design, including appropriate scientific rationale, specific aims, study endpoints, biostatistical analysis, and adequate ability to accrue patients. These criteria exist in order to ensure that the study is conducted in accordance with the scientific principles and integrity maintained by the Vanderbilt-Ingram Cancer Center, that the scientific aims of the study can reasonably be met, and that Cancer Center resources used to support clinical investigation are appropriately and wisely used.

APPROVED: _____
Chair, Scientific Review Committee/12/31/98

**Vanderbilt-Ingram Cancer Center
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SUBJECT: SRC Membership

POLICY and PROCEDURE:

1. The SRC is composed of the following voting members: (1) a minimum of 8 physician members (see below), (2) a minimum of 2 oncology nursing members, (3) the Cancer Center biostatistician, (4) a representative of the Chemotherapy Pharmacy, and (5) one or more representatives of the Cancer Center Clinical Trials Shared Resource (CTSR). The SRC Office Assistant is an Ex-officio (non-voting) member.
2. Physician members of the SRC are derived from the membership of the Vanderbilt Cancer Center, and are nominated by the Chair of the SRC, subject to approval by the Cancer Center Director.
3. The standard term of appointment of physician members to the SRC is 36 months; however; members who choose to continue to participate beyond the end of a 36 month term may do so, subject to approval by the SRC Chair. Memberships are staggered such that one third of SRC members complete their term each year.
4. Members of the SRC are discouraged from simultaneous participation in the Vanderbilt Institutional Review Board (IRB).
5. Members of the SRC are expected to serve as a reviewer for a minimum of one protocol per quarter, and to attend a minimum of fifty percent of committee meetings, in order to remain in good standing.
6. The SRC meets on the second and fourth Wednesdays of each month.
7. A quorum of *eight* committee members is required in order for the SRC to conduct protocol reviews or other business.
8. Members of the SRC who consistently fail to meet their membership obligations as defined above are subject to dismissal by the SRC Chair.

APPROVED: _____
Chair, Scientific Review Committee/2/8/2006

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SUBJECT: SRC Chair and Vice-Chair

POLICY and PROCEDURE:

1. The Chair and Vice-Chair of the SRC shall be appointed by the Cancer Center Director from the membership of the Vanderbilt Cancer Center.
2. The terms of appointment of the SRC Chair and Vice-Chair are 18 months; however, the Chair and/or Vice-Chair may continue to serve beyond the end of the 18 month term, at the discretion of the Cancer Center Director.
3. The Chair is responsible for ensuring that an adequate number of members are appointed to the SRC to allow timely review of submitted protocols.
4. The Chair is responsible for ensuring that all protocols submitted to the SRC receive a timely review; ideally within three weeks of submission.
5. The Chair is responsible for assigning protocols submitted to the SRC to committee members for review; this responsibility may be delegated to the SRC Coordinator by the Chair.
6. The Chair is responsible for leading and facilitating the discussion at committee meetings of protocols under review by the committee, and for calling a vote on protocols, which have completed review.
7. The Chair is responsible for summarizing the Committee's review of a protocol in a letter to the Principle Investigator (PI), indicating either (1) approval of the protocol or (2) the Committee's concerns, which must be addressed and resolved prior to final approval by the SRC.
8. The Chair is responsible for reviewing the PI's responses to Committee reviews and determining if administrative approval of a protocol is appropriate.
9. The Vice-Chair of the SRC shall execute the responsibilities of the Chair in the absence of the Chair, or as delegated by the Chair.

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SUBJECT: SRC Coordinator

POLICY and PROCEDURE:

1. The SRC Coordinator is responsible for receiving, cataloguing and tracking all new protocols conducted under the auspices of the Vanderbilt-Ingram Cancer Center.
2. Following receipt of a protocol, the Coordinator conducts an initial administrative review to ensure that all requisite components of the protocol are present before enlisting reviewers for the protocol or before forwarding the protocol to the SRC Chair for reviewer assignment.
3. Following assignment of reviewers, the Coordinator contacts the reviewers and forwards to them all relevant materials.
4. The Coordinator performs follow-up with reviewers to ensure that the protocols receive a timely review.
5. The Coordinator schedules SRC meetings and notifies committee members of meeting times.
6. The Coordinator records all minutes and committee votes in written form, and maintains appropriate records and other documentation within the CTO.
7. The Coordinator manages and oversees all committee correspondence and all committee-related clerical duties.
8. The Coordinator maintains active files on all open protocols conducted under the auspices of the Cancer Center, and works with the CTO to obtain accrual data for the SRC's semi-annual accrual monitoring function.
9. The Coordinator performs other committee-related business delegated by the Chair.

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Chair, Scientific Review Committee/12/31/98

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SUBJECT: Definition of protocols which require SRC review

POLICY and PROCEDURE: Being revised



The Chair of the SRC shall have final discretion as to whether a cancer treatment protocol must undergo SRC review.

APPROVED: _____
Chair, Scientific Review Committee/12/31/98

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SUBJECT: Procedure for submission of protocols to the SRC

POLICY and PROCEDURE:

1. Protocols are submitted to the SRC for review via the Cancer Center Clinical Trials Office (CTO) Protocol Submission Form (see attached). Items which are required for submission include: (1) name of the principle investigator (PI), (2) identification of the Cancer Center Clinical Team which is sponsoring the protocol, (3) expected duration of the study, (4) expected accrual to the study at each of the sites associated with the Cancer Center, (5) objective evidence for the expected accrual, (6) an indication as to whether eligibility criteria overlap with other open protocols, and (7) the signature of the Cancer Center Clinical Team Leader.
2. To be considered for review by the SRC, each protocol must include: (1) scientific rationale with appropriate supporting references to the medical literature, (2) one or more clearly stated scientific aims, (3) clearly stated protocol eligibility criteria, (4) a clearly stated treatment plan, (5) one or more clearly stated study endpoints, and (6) copies of the data forms to be used. All protocols must also include valid statistical design and analysis where appropriate. The VICC Biostatistician, who serves as a member of the SRC, is available for consultation to PIs in regard to studies, which require statistical design or revision. A grant application or completed CPHS/IRB proposal does **not** meet the above criteria for consideration as a protocol by the SRC. Proposals submitted without a protocol meeting the above criteria will be returned to the PI and will not be reviewed until a valid protocol is submitted.

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SUBJECT: Procedure for review of protocols

POLICY and PROCEDURE:

1. All investigator-initiated and industry-sponsored studies will be screened for adherence to SRC protocol guidelines at the time of protocol submission to the CTSR/SRC. Protocols which are found to be lacking in one or more elements required for committee review will be returned for revision to the principal investigator, without undergoing SRC review. Protocols will be accepted for review only when all elements required for review are included in the protocol (see Protocol Requirements policy for listing of the necessary elements).
2. The Chair is responsible for assigning protocols submitted to the SRC to committee members for review; this responsibility may be delegated to the SRC Coordinator by the Chair.
3. Studies are reviewed for validity and integrity in regard to: (1) scientific rationale, including appropriate references to the medical literature (2) study design, including adequate scientific aims, eligibility criteria, study endpoints, and treatment information (3) biostatistical design, (4) study duration, (5) evidence of ability to accrue to the protocol, (6) scientific priority, and (7) adequacy of data collection forms (see attached Reviewer Form).
4. Each protocol is reviewed by two physician reviewers (a “Primary Reviewer” and “Secondary Reviewer”), the Cancer Center biostatistician, an oncology nurse, a chemotherapy pharmacy representative, and a CTO staff member. At least one of the two physician reviewers is required to attend the meeting at which the submitted protocol is to be reviewed, in order to present a brief synopsis of the protocol. If the second physician reviewer is unable to attend the meeting at which the submitted protocol is to be reviewed, he/she will provide a review by submitting a completed review form to the SRC Coordinator prior to the meeting.
5. Following the presentation of a protocol for review by one of the two reviewers and discussion among committee members, a vote is called by the Chair. A protocol must receive an affirmative vote from two-thirds or more of the voting members of the SRC in order to receive approval.
6. A reviewed protocol may receive one of the three following designations: (1) **final approval**; (2) **preliminary approval** pending minor revisions; or (3) not approved

pending major revision (s); and (4) **rejection**. Studies receiving preliminary approval pending minor revisions may receive final approval by the SRC Chair after administrative review of the PI's response to one or more minor concerns (such as lack of evidence of ability to accrue or lack of an indication of prioritization in regard to other overlapping studies). Studies, which are not approved, must undergo re-review by the full committee after suitable revision by the PI. A protocol will not receive approval from the CPHS/IRB until it has received final approval from the SRC.

7. One or more concerns may be identified by the SRC in regard to a multi-institutional protocol in which one or more VICC institutions is a participating member, where the multi-institutional protocol cannot be modified in response to the committee's concerns. The protocol will be considered to be amended and will receive final approval following receipt of a letter, to be appended to all copies of the protocol, from the PI, which adequately addresses the SRC's concerns in regard to VICC participation.
8. Any aspect of a protocol's design which is perceived as presenting a significant threat to patient safety has an inherent impact on the scientific validity of the study, and thus is appropriate for consideration by the SRC during its review process.

APPROVED: _____
Chair, Scientific Review Committee/2/10/00

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SUBJECT: Monitoring of accrual to open protocols

POLICY and PROCEDURE:

1. The SRC monitors patient accrual onto all VICC protocols on semi-annual basis. Evidence of an investigator's ability to adequately accrue a sufficient number of patients to a protocol to ensure its timely completion and to justify use of Cancer Center resources to open the protocol is required at the time of protocol submission. Monitoring of accrual to open protocols is conducted to ensure that continued use of Cancer Center Resources is warranted, and that the scientific objectives of the study are being met in a timely fashion. The SRC's accrual monitoring is based on Cancer Center Team accrual data prepared by the CTO and reviewed at Team meetings.
2. The SRC Chair will notify each Clinical Team Leader, in writing, of all protocols which, at the time of initial review, do not meet the minimal accrual standard set by the SRC (see attached Draft Letter #1). The minimal accrual standard is presently defined as 50% of the number of patients scheduled to be accrued to date, based on (1) the projected accrual number and (2) projected study duration, both of which are provided by the study PI at the time of protocol submission. An explanation of the basis for substandard accrual is requested from the Team Leader, and notification that continued substandard accrual will result in study closure upon second review in six months is provided to the Team Leader. Accrual to the study may continue if the committee's concerns are adequately addressed by the Team Leader.
3. Accrual for all protocols which did not meet the minimal accrual standard set by the SRC upon initial review undergo a second review approximately six months after the initial review. The SRC Chair shall again notify each Clinical Team Leader, in writing, of all protocols which continue to fail to meet the minimal accrual standard set by the SRC (see attached Draft Letter #2). An explanation of the basis for substandard accrual, or appropriate revision of the projected accrual goal for the protocol, is requested from the Team Leader, in writing, within two weeks of the second review.
4. All protocols, which continue, fail to meet the minimal accrual standard, and for which an explanation deemed suitable by the SRC is not provided, will be closed to further accrual by the SRC.

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SUBJECT: Prioritization of competing or overlapping protocols

Date of Revision: 05/29/02

POLICY and PROCEDURE:

1. A patient treated at a participating VICC institution may not simultaneously participate in more than one therapeutic study involving investigational agents.
2. In order to ensure unbiased accrual to clinical trials conducted at the VICC, it is the policy of the SRC that two or more clinical trials cannot simultaneously compete for a common or overlapping population of patients. In situations where a protocol submitted to the SRC for review has eligibility criteria which overlap, either partially or completely, with another protocol currently open to accrual, *it is the responsibility of the Clinical Team Leader to establish a clear prioritization for these clinical trials.*
3. Each Clinical Team Leader will develop a disease-specific prioritization flow diagram, in collaboration with the VICC Cancer Information Program staff, which clearly illustrates the prioritization of studies by stage, presence or absence of prior therapy, and other relevant clinical parameters. Disease-specific prioritization flow diagrams should be developed and revised in the context of scheduled disease-specific team meetings.
4. A hand-written revision of the currently approved prioritization flow diagram, indicating the proposed prioritization of the submitted study, is required as a part of the protocol submission information for all new protocols submitted to the SRC.
5. The Clinical Team Leader staff will submit revisions of prioritization flow diagrams to the VICC Computer Graphic Design staff, who will generate a printed, web-ready document file. The completed file will be sent to (1) the VICC Cancer Information Program staff for review, and (2) the responsible Clinical Team Leader for formal sign-off.
6. Following approval of a study by both the SRC and IRB, the revised prioritization flow diagram will be posted on the VICC website.
7. It is expected that **all** patients eligible for each of two (or more) conflicting or overlapping studies will first be offered participation in the study of highest priority. Accrual to competing studies is monitored by the SRC as a part of its NCI mandate. Violation of this policy may lead to suspension of the involved study by the SRC.

