



BURNETT
SCHOOL of MEDICINE

SCIENTIFIC REVIEW BOARD (SRB) ADMINISTRATIVE GUIDELINES

**ANNE BURNETT MARION SCHOOL OF MEDICINE
AT TEXAS CHRISTIAN UNIVERSITY**



TABLE OF CONTENTS



SCHOOL OF MEDICINE SCIENTIFIC REVIEW BOARD (SRB)..... 3

ADMINISTRATIVE GUIDELINES..... 3

PURPOSE AND SCOPE OF SCIENTIFIC REVIEW BOARD.....3

SCIENTIFIC REVIEW BOARD MEMBERSHIP.....4

SUBMISSION OF PROPOSALS..... 6

EXPECTATIONS FOR INCLUSION OF TCU SCHOOL OF MEDICINE MEDICAL STUDENTS.....7

 USE OF SCHOOL OF MEDICINE STUDENT DATA..... 7

 SURVEY MONITORING..... 7

ASSIGNMENT OF REVIEWERS..... 8

USE OF EXTERNAL CONSULTANTS IN THE REVIEW..... 8

REQUEST FOR REVIEW BY THE FULL SRB..... 8

SRB REVIEW OUTCOMES..... 9

 1. ACCEPT PROPOSAL WITHOUT REVISION..... 9

 2. RECOMMEND APPROVAL PENDING ACCEPTABLE REVISIONS..... 9

 3. REVISE AND RESUBMIT..... 9

REVIEWER’S EXPECTATIONS.....10

FEEDBACK TO RESEARCHER..... 10

APPROVAL, VOTE OF SRB..... 11

APPROVAL FOR RESEARCH PROPOSAL TO BE SUBMITTED TO TCU IRB.....11

APPROVAL FOR EXTERNAL FUNDING PROPOSAL TO BE SUBMITTED TO TCU OFFICE OF
RESEARCH FROGFLOW..... 11

TRACKING OF SRB REVIEWS..... 12

APPENDIX A: PROPOSAL REVIEW AND FEEDBACK..... 13

PROPOSAL REVIEW.....14

SRB REVIEW DECISION (SELECT ONE)..... 15

EVALUATION CRITERIA..... 16

SCHOOL OF MEDICINE SCIENTIFIC REVIEW BOARD (SRB) ADMINISTRATIVE GUIDELINES



The Purpose and Scope of the Scientific Review Board

The Scientific Review Board (SRB) is established with the primary purpose of reinforcing the institutional mission of promoting scholarship through research excellence, ensuring all protocols from the School of Medicine (SOM) have been vetted and optimized for submission.

The SRB will review research and funding proposals to ensure that they meet an acceptable standard of scientific rigor and merit prior to their being submitted for TCU IRB review or to any extramural funding agency.

Research proposals that do not require review by the TCU IRB and grant proposals that do not require approval by TCU Office of Research do not need to be reviewed by the School of Medicine SRB. In addition, School of Medicine Scholarly Pursuit and Thesis (SPT) research projects do not require SRB review.

The Scientific Review Board (SRB) ensures that the scientific question(s) being asked within a protocol is (are) relevant and that the design of the protocol is appropriate to answer the research question(s). The SRB review will primarily focus on the elements of good scientific study design. Proposals will be evaluated for the following criteria:

- clarity of the research question
- appropriateness and efficiency of design
- rigor and feasibility of methods
- qualifications and expertise of the research team
- scholarship and pertinence of background material and rationale
- adequacy of sample size and relevance of controls
- the validity of the statistical analysis plan
- resources available to the research team necessary to conduct the research
- adequacy of inter-institutional agreements necessary to facilitate the research

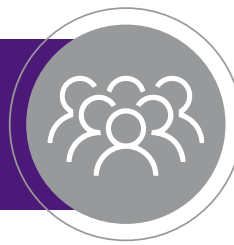
In addition, the SRB may desire to comment on the proposal's scientific relevance, compelling ethical or participant safety issues, and resource utilization and setting.

The SRB reviewers will submit a summary of their evaluation to the SRB Chair and report their final determination to the researcher and departmental chair as (1) accept proposal without revision; (2) recommend approval pending acceptable revision; (3) revise and resubmit to SRB at which time the researcher must address required revisions and re-submit to the SRB for review. See below for more information on these outcomes. For further information, email us at MDSRB@tcu.edu.

The SRB Chair will submit an annual report to the Dean of the School of Medicine regarding submitted proposals and outcomes.

Please note: Researchers should only forward proposals to TCU IRB or the Office of Research when final decision is "accept proposal without revision".

SCIENTIFIC REVIEW BOARD MEMBERSHIP



Membership consists of a Chair and a minimum of five (5) faculty from the School of Medicine faculty with research experience and complimentary professional expertise (e.g., cross disciplinary). Members will also have different areas of research experience (e.g. basic science, population health, educational research). They will be appointed by the dean for three-year terms that are renewable without expiration.

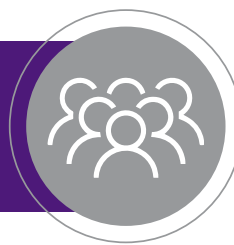
As necessary for specific protocols, ad hoc (non-voting consultant) members may be added to the SRB when specific content expertise is needed. Any member of the SRB may request assistance of faculty or other external reviewers who possess specific expertise relevant to the research project if there are questions concerning the relevance of the proposed study or other technical issues which is beyond the expertise of the board members. When this need is identified, either by the chair or the primary reviewer in consultation with the chair, the chair will contact the Division or Department head for assistance in identifying a willing and available ad hoc SRB member.

The SRB chair (or delegate) is responsible for identifying and contacting the reviewers to ensure that they:

- Possesses the requisite expertise
- Is not a research team member on the proposal that is subject to review or has an apparent conflict of interest pertinent to the proposed research.
- Is available to perform the review in a timely manner and willing to undertake the task.

Once the consultant has been identified, the SRB will invite the consultant to review the proposal. The assigned SRB reviewers will schedule a meeting with the consultant to finalize the final review. If the proposal is routed to the larger SRB board for full discussion, the consultant may be invited to attend the SRB meeting as a non-voting member.

SCIENTIFIC REVIEW BOARD MEMBERSHIP



Membership Roster:

Name	Department	Email	Expertise and Skills
Jennifer Allie, PhD, MPA, SRB Chair	Office of Faculty Affairs and Development	j.allie@tcu.edu	Qualitative methodology; survey design; educational research; policy analysis
Michael Bernas, MS	Medical Education	m.bernas@tcu.edu	Quantitative methodology; student research projects
Jo Anna Leuck, MD	Medical Education	j.leuck@tcu.edu	Emergency medicine; resuscitation; cardiac arrest; sepsis; airway management; acute trauma management; MedEd, most specifically simulation
Gregory Kearns, PharmD, PhD	Medical Education	g.kearns@tcu.edu	Pediatric clinical pharmacology and toxicology; pharmacokinetics; pharmacodynamics; pharmacogenetics; early phase clinical trial design
Imran Siddiqui, PhD	Medical Education	i.siddiqui@tcu.edu	Medical biochemistry; educational research design
Kevin Kidder, PhD	Medical Education	k.kidder@tcu.edu	Educational research; quantitative, qualitative, mixed methods
Angela Cantrell, PhD	Medical Education	angela.cantrell@tcu.edu	Anatomical sciences; neuroscience; curricular development & evaluation; medical education research; quantitative data analysis; basic science research; small animal research
Kimberly Washington, MD	Surgery	k.l.washington@tcu.edu	General surgery, hepato-pancreato-biliary surgery, clinical trial design
Lee Flood, PhD	Medical Education	l.d.flood@tcu.edu	Educational Research; Program Evaluation; Mixed-Methods; Applied Statistics; Qualitative Analysis (e.g. thematic analysis, grounded theory, code mapping)

SUBMISSION OF PROPOSALS



1. Researchers must ensure that the respective School of Medicine department chair has reviewed and approved any research or funding proposal prior to submitting proposals to the SRB.
2. Final drafts of research or funding proposals must be submitted to the SRB using the online submission form.
 - All submissions must be in Word format. Please do not submit a PDF or other non-editable file format.
 - Researchers should submit a full research proposal (see [template](#)) along with all required forms for TCU IRB or the funding proposal.
 - Submissions should be submitted at least 15 business days before the scheduled date of TCU IRB submission or submission to an external funding agency.
 - Please note that any external funding proposals must be submitted through [TCU FrogFlow](#) for review and approval by the TCU Office of Research. This approval is anticipated to add an additional 5-7 business days to the timeline.

Prior to initiating a proposal routing form in **FrogFlow**, you will need to access **FrogFlow** and establish the Office of Research tile on your [my.tcu.edu](#). Instructions for accessing **FrogFlow**, creating the tile, initiating a proposal form, video of a demonstration of the system and other helpful guides can be found in our "How To" folder on box:

FrogFlow How To Folder

It is strongly recommended that researchers leverage peer-review of all proposals prior to submitting them to the SRB. This is not a mandate, but rather reinforces the best practices for ensuring successful research proposals. Peer-review prior to SRB submission may limit the number of revisions and ensure that proposals are finalized and approved within the 15-day window. The SRB review committee may need additional time if proposals need significant revisions and mentoring meetings are required.

Once proposals are approved, the researcher should report progress to their departmental chair no later than every 12-month period from the formal approval of the project. Additionally, any and all granting of continuation approval, modifications, and/or revisions should also be reported to the departmental chair and SRB chair within four academic weeks of such action.

EXPECTATIONS FOR INCLUSION OF TCU SCHOOL OF MEDICINE STUDENTS



Any studies that anticipate using student participants or using student performance data must be approved by Senior Leadership which includes the Dean, Executive Dean, Associate Dean for Educational Affairs; Senior Associate Dean for Faculty; Senior Associate Dean for Strategy; and Senior Associate Dean for Finance. Following SRB review, the proposal will be routed to this group for consideration.

Currently enrolled students at the Burnett School of Medicine will not be approved to conduct research projects using only Burnett School of Medicine student populations.

Use of School of Medicine Student Data

Proposals which include TCU School of Medicine medical student data should include a description of the plan to coordinate with the School of Medicine Office of Assessment and Evaluation to ensure confidentiality of student data. All proposals received that include medical student level data will be routed to the Assistant Dean for Assessment and Evaluation to verify the plan.

Considerations for Studies Conducted in the Learning Environment

For studies that use student information, the proposal must fully elucidate the rationale for conducting the research within the school and for limiting participants to our population. Further, if research is to occur in the classroom, the proposal should describe the ethical implications and protections that will be used to protect the confidentiality and anonymity of student level data. PIs should ensure that the proposal fully explains the justification for site and population selection.

Survey Monitoring

The SRB will consider the impact of proposed surveys on all resources, including but not limited to students, staff, and the curriculum and provide this feedback to the researcher. The SRB will use a rubric to assess the anticipated impact on resources, and balance this with the potential impact on expanding knowledge in the discipline in considering the approval and scheduling of medical student survey research designs.

SUBMITTED PROPOSAL REVIEWERS



Assignment of Reviewers

The chair of the SRB, or delegate, will identify at least two (2) reviewers from the SRB. Reviewers will independently assess the proposal, using the SRB proposal feedback rubric.

Use of External Consultants in the Review

SRB reviewers may determine that they require external consultant review as part of the review process. Reviewers should notify the SRB chair within five (5) business days of request to engage external consultants in the review process. This request should be communicated to the researcher within 2 days of notification by the SRB chair. PIs should be informed that the request for external consultants may add an additional ten (10) days for review and decision.

In cases in which the SRB calls upon consultants with content expertise relevant to review a given proposal, the opinion of the consultant(s) will be taken into consideration when developing the final SRB report.

If a consultant is used in review of a proposal, this will be noted in the letter to the researcher.

Request for Review by the full SRB

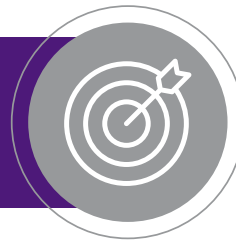
Reviewers may request that proposals be routed to the larger SRB for full review and discussion. These requests should be communicated to the chair of the SRB within five (5) business days of receipt.

The SRB chair will then schedule a full SRB meeting as soon as possible. The SRB members will receive a copy of the proposal and feedback rubric. In the event that this meeting cannot occur prior to the seven (7) day anticipated deadline, the chair will communicate with the PI on this delay and identify an anticipated response timeline to the PI.

At the conclusion of the SRB meeting, the reviewers will finalize the feedback rubric and submit this to the chair of the SRB and the dean.

The SRB should make a determination on the decision regarding the proposal and this should be noted on the feedback rubric.

SRB REVIEW OUTCOMES



Upon independent review, the reviewers should convene and draft a final evaluation rubric. SRB reviewers may identify one of these outcomes from this first review:

1. Accept Proposal Without Revision

- Proposals approved for submission to the TCU IRB or to TCU Office of Research FrogFlow (external funding proposals, as written).
- The final feedback rubric and reviewer comments will be forwarded to the chair of the SRB and the dean.
- The dean will approve the review and sign the feedback rubric.
- The dean will then communicate to the researcher, cc'ing the department chair the outcomes and recommendations of the SRB review.
- The researcher may submit their proposal to the TCU IRB of TCU Office of Research FrogFlow.

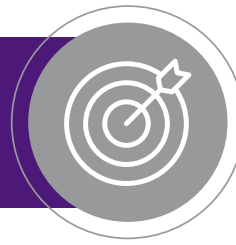
2. Recommend Approval Pending Acceptable Revisions

- The final feedback rubric and reviewer comments will be forwarded to the chair of the SRB and the dean.
- The dean will approve the review and sign the feedback rubric.
- The dean will then communicate to the researcher, cc'ing the department chair the outcomes and recommendations of the SRB review.
- Revision suggestions should be fully described in the feedback rubric.
 - SRB Reviewers should indicate revisions that are recommended and revisions that are required.
 - Researchers should consider all recommended revisions, and must address all required revisions in the resubmission.
- The researcher may request a consultation with the SRB reviewers prior to resubmission, but this is not required.
- The researcher will forward an updated proposal, with track changes, and any responses to required revisions to the SRB reviewers.
 - Resubmission of the proposal will initiate the second review and restart the review timeline described here.
 - SRB reviewers should complete subsequent review within five (5) business days.
- At the conclusion of the review of revisions, SRB reviewers will propose either:
 - Accept Proposal Without Revision (see outcome 1 above); or
 - Revise and Resubmit (see outcome 3 below).

3. Revise and Resubmit

- Revise and Resubmit decisions should trigger a request for a mentoring discussion with the researcher and the SRB reviewers.
- The mentoring discussion should clarify purpose and methodology and the researcher will be asked to revise and resubmit to the SRB reviewers for second review, cc'ing the chair of the SRB.

SRB REVIEW OUTCOMES



- The final feedback rubric and reviewer comments will be forwarded to the the chair of the SRB and the dean.
- The dean will then communicate to the researcher, cc'ing the department chair, the outcomes and recommendations of the SRB review.
- Researchers should be instructed to review the feedback rubric, make appropriate revisions, and resubmit the proposal with track changes and responses to all required revisions to the SRB reviewers for second review, cc'ing the SRB chair and the dean.
- Resubmissions of the proposal will initiate the second review and restart the review timeline described herein.
- At the conclusion of the review of revisions, SRB will propose either:
 - Accept Proposal Without Revision (see outcome 1 above); or
 - Accept Proposal Pending Revisions (see outcome 2 above); or
 - Revise and Resubmit.
 - In the event of a resubmission that also scores a “Revise and Resubmit” decision, the reviewers will request a full SRB review meeting as described above.

Reviewer's Expectations

The SRB will make every effort to review a complete protocol and communicate the review recommendations to the researcher within seven (7) business days of protocol submission to the SRB.

This timeline does not apply to incomplete protocols or when the SRB awaits for corrections, clarifications, modifications or additional materials from the researcher. Revise and Resubmit decisions may delay this timeline by up to 10 business days depending on researcher and reviewers' schedules.

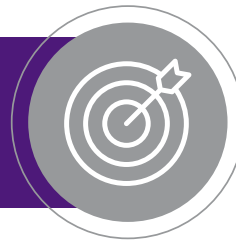
To ensure that the SRB review process can be completed within the aforementioned timeline, assigned SRB reviewers must complete their final feedback rubric within five (5) business days of being assigned and notify the chair of the SRB of the outcomes of this first review.

SRB reviewer outcomes and feedback should be forwarded to the chair of the SRB and the dean by end of business day on the fifth day.

Feedback to Researcher

Scholarship and research are iterative processes. Researchers should anticipate that the SRB process may also be an iterative review. If researchers are asked to revise and resubmit their proposals, the 2nd review process may identify additional items that complicate the study, particularly with the redesign of methodology. Researchers that have questions or concerns should request a face-to-face meeting with their SRB reviewers to discuss this 2nd review.

SRB REVIEW OUTCOMES



Reviewers should score the overall proposal using the rubric and recommend to the SRB chair and dean whether the proposal is 1) approved to be submitted to TCU IRB or TCU Office of Research FrogFlow, or 2) approved pending revisions; or 3) Revise and Resubmit.

Reviewer feedback related to methodology should be considered as suggestions. Faculty investigators are encouraged to consider these suggestions, but final design decisions are at the discretion of the individual researcher or research team. However, the SRB and the dean will expect that all required revisions are fully addressed and discussed in the resubmission materials. Failure to adequately respond to required revisions may result in proposals being rejected by the SRB and the dean.

The SRB commits to ensuring that all feedback returned to the faculty is crafted in a way that facilitates respectful dialogue, and SRB comments will presume a mentoring, formative feedback tone.

The dean will review the final rubric and comments on the proposal and email final recommendation from the SRB to the respective researcher, cc'ing the department chair.

Approval, Vote of SRB

Typically, approval of proposals will include the recommendation of the assigned reviewers and the chair of the SRB. Recommendations of the SRB will be based on consensus.

In the event that the reviewers request full SRB review, a quorum of three (3) voting members is necessary to render final disposition of a proposal.

Final approval of all proposals is at the discretion of the chair who will take into account the recommendations of the SRB members.

Approval for Research Proposal to be Submitted to TCU IRB

Only proposals that have been scored as "Accept Proposal Without Revision" may be forwarded to the TCU IRB or the TCU Office of Research FrogFlow.

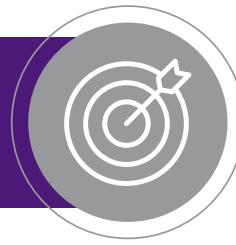
Funding proposals may not be submitted to external funding agencies until proposals have approvals from both SRB and TCU Office of Research.

Approval for External Funding Proposal to be Submitted to the TCU Office of Research FrogFlow

External Grant Funding Proposals must be routed to TCU Frog Flow for TCU Office of Research review and approval before submitting to external funding agency. Please allow for 5-7 business days for TCU Office of Research review and approval. For more information see:

<https://research.tcu.edu/sponsored-programs/>

SRB REVIEW OUTCOMES



Tracking of SRB Reviews

All proposals will be tracked by the administrative assistant to the dean, to include the PI's name; title of study; date proposal is received; review status; and SRB and IRB approval date. This project log will also track whether projects use student performance data, use medical students as participants, and whether IRB review is warranted. A status report will be shared with the SRB quarterly and the dean annually by the chair of the SRB, and the project log will be maintained on a shared BOX folder.

APPENDIX A: PROPOSAL REVIEW AND FEEDBACK



Proposal Information

Primary Investigator (PI) Name:	
Proposal Title:	
Date Submitted to SRB:	
Date of Review by SRB:	
SRB Reviewers Names and Email Addresses:	

APPENDIX A: PROPOSAL REVIEW AND FEEDBACK



Proposal Review

Criteria	Rating (1 Unacceptable; 4 Exceptional)	Feedback/Suggested Revisions Rationale
1. Proposal is clearly written and in format so that person with no former prior knowledge of the subject may make an informed judgement as to scientific or scholarly merit of the proposed project.		
2. Proposal clearly describes what is intended by the PI, how the PI intends to reach objectives, and anticipated implications of the project's findings.		
3. The proposed project clearly exhibits application of sound investigative methodology.		
4. Analysis procedures are specified AND are demonstrably linked to the research questions/hypotheses being investigated.		
5. Whether for basic or applied research, the proposal demonstrates evident value. The project has potential for producing a quality scholarly product or publication.		
6. The proposal is supported by relevant scholarly literature.		
7. Research design does not have negative impact, specifically the anticipated time for participation is not overly burdensome on participants.		
8. All required IRB documentation and supporting forms are included with proposal. Forms may be found at: https://research.tcu.edu/research-compliance/irb/irb-forms-templates/		
Total Score (out of 32):		

APPENDIX A: PROPOSAL REVIEW AND FEEDBACK



Student Survey Request: Y / N

If yes, frequency of survey distribution:

If yes, please include instructions to researchers to work with the Office of Student Affairs to distribute to students using the student list-servs. Researchers must submit final approved IRB Proposal and recruitment timeline to Student Affairs prior to distributing email communications with survey links.

Scientific Review Board feedback and suggestions for revisions:

Strengths:

Limitations:

Revisions Suggested:

Revisions Required (must be included for “Approval Pending Acceptable Revision or Revise and Resubmit” outcomes):

SRB Review Decision (Select one):

	<p>Accept Proposal Revision</p> <p>Submit their proposal to the TCU IRB or TCU Office of Research FrogFlow</p>
	<p>Approval Pending Acceptable Revisions</p> <p>Researcher should forward updated proposal, with track changes, and any responses to required revisions to the SRB reviewers.</p>
	<p>Revise and Resubmit</p> <p>Researcher is encouraged to schedule a mentoring discussion with the SRB reviewers and should review the feedback rubric, make appropriate revisions, and resubmit the proposal with track changes and responses to all required revisions to the SRB reviewers for second review</p> <p>Second review that results in Revise and Resubmit must trigger full SRB Review Meeting</p>

SRB Approval:

Jennifer L. Allie, PhD
Professor, Medical Education
Chair of Burnett School of Medicine Scientific Review Board

Date

APPENDIX A: PROPOSAL REVIEW AND FEEDBACK



Evaluation Criteria:

Exceptional (4):

The proposal's research questions, design and methodology, and proposed analyses are exceptionally clear and appropriate. The proposed study demonstrates the feasibility and expertise needed to ensure scientific rigor and successful completion of the proposed outcomes. The literature review includes pertinent and recent background material supporting a strong rationale for the current study's inquiries. The methodology employs appropriate design, sample characteristics, and controls to ensure the proposed results. The statistical analysis plan is valid, and it is clear that the resources needed to successfully conduct and complete the study are available. The study results will likely expand the knowledge base in the field under investigation.

Acceptable (3):

The proposal's research questions, design and methodology, and proposed analyses are acceptably clear and appropriate. In most sections, the study demonstrates the feasibility and expertise needed to ensure scientific rigor and successful completion of the proposed outcomes. The literature review includes most of the pertinent and recent background material that supports an acceptable rationale for the study's inquiries. The methodology employs acceptable design, sample characteristics, and controls to ensure the proposed results. The statistical analysis plan is valid in most areas, and the resources needed to successfully conduct and complete the study are acceptable. The study results may expand the knowledge base in the field under investigation.

Marginal (2):

The proposal's research questions, design and methodology, and/or proposed analyses lack clarity and needed details. Deficiencies in several sections question whether the study is feasible and whether there is expertise to ensure scientific rigor and successful completion of the proposed outcomes. Pertinent and recent background material is missing from the literature review that is needed to support the study's rationale and inquiries. The methodology is missing key information, sample characteristics, controls, and/or may include design flaws that may preclude the proposed results. The statistical analysis plan is unclear or inappropriate in several areas, and there is doubt as to whether the resources needed to successfully conduct and complete the study are in hand. The study results are unlikely to expand the knowledge base in the field under investigation.

Unacceptable (1):

The proposal's research questions, design & methodology, and proposed analyses are unclear and/or inappropriate. The proposed study fails to demonstrate the feasibility and expertise needed to ensure scientific rigor and successful completion of the proposed outcomes. The literature review does not include pertinent and recent background material and does not support a strong rationale for the current study's inquiries. The methodology employs inappropriate design, sample characteristics, and controls to ensure the proposed results. The statistical analysis plan is invalid, and it is unclear that the resources needed to successfully conduct and complete the study are available. It is unclear as to whether the study results will expand the knowledge base in the field under investigation.



BURNETT
SCHOOL of MEDICINE

FOR MORE INFORMATION ABOUT THE BURNETT
SCHOOL OF MEDICINE SCIENTIFIC REVIEW BOARD,
PLEASE CONTACT THE OFFICE OF FACULTY
DEVELOPMENT AT MDFACULTYDEV@TCU.EDU.

