



**BURNETT**  
SCHOOL of MEDICINE

# **GUIDELINES FOR STUDENTS AS PARTICIPANTS AND SUBJECTS IN MEDICAL EDUCATION RESEARCH**

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# INTRODUCTION



Medical education research plays a critical role in advancing our understanding of teaching and learning in academic medicine. In conducting medical education research, it is essential that faculty adhere to the highest ethical standards to protect the rights and well-being of students, who often serve as research participants. Upholding these ethical principles not only safeguards student privacy and autonomy but also enhances the credibility and impact of the research within the academic community.

These guidelines provide an overview of School of Medicine philosophies and safeguards related to use of medical students as participants in medical education research. Our aim is to support faculty in designing and conducting research while protecting the rights of our students. Faculty conducting research involving students should comply with institutional policies, ethical standards, and legal regulations to protect the rights and confidentiality of students.

# 1. GENERAL PRINCIPLES



## **ETHICAL STANDARDS**

All research involving students must adhere to ethical standards of human subjects research, including obtaining appropriate approvals from the School of Medicine Scientific Review Board (SRB) and TCU Institutional Review Board (IRB).

## **STUDENT INVOLVEMENT IN MEDICAL EDUCATION RESEARCH**

Burnett medical students may not formally or informally participate as researchers on any research project that solely relies on Burnett student data whether it is survey, qualitative, or performance data.

## **USE OF EVALUATION DATA**

Faculty may not use qualitative comments collected from the Office of Assessment as part of the scheduled evaluation processes for research, as these are collected with assurances of anonymity and limited use for program evaluation.

## **INFORMED CONSENT**

For any proposed research study, students must be fully informed about the research, including its purpose, potential risks, and how their data will be used prior to data collection. Participation should be voluntary, with no coercion or undue influence, and students must be provided the opportunity to withdraw with no repercussions at any time.

If there is a study that proposes use of retrospective consent, the SRB will convene to review the research proposal and provide approval to the faculty. Typically, retrospective consent is not approved.

## **ANONYMITY AND CONFIDENTIALITY**

Measures must be in place to protect student identity and confidential information, including the anonymization of data wherever possible.

Purpose (internal Audit and QI vs. Dissemination): Internal audit and quality improvement (QI) activities, such as program evaluation, curriculum revisions, or compliance audits, focus on enhancing internal processes are not designed for public dissemination and therefore are not classified as research activities.

# 1. GENERAL PRINCIPLES



Conversely, research activities intended to generate knowledge with the ultimate goal of dissemination to the academic community, such as evaluating the effectiveness of a flipped classroom model or assessing the impact of a student wellness policy, require SRB and IRB approval.

## **AVOIDING COERCION**

Faculty must be mindful of the inherent power dynamic in the faculty-student relationship and take steps to account for this imbalance. Students should not feel that participation in research is tied to their grades, academic progress, or future opportunities. To protect against this, scheduled curricular time or the learning management system cannot be used to recruit, consent, or engage in research endeavors. The PI must describe recruitment and data collection measures, ensuring that there is no use of institutional resources for data collection (e.g., Office of Assessment or the Educational Affairs team).

## **MITIGATING BIAS**

Faculty members conducting research on their own students should take steps to mitigate any perceived or actual bias, such as using third parties to collect or analyze data, especially when it involves student evaluations or performance scores.

## **TRANSPARENCY**

Research findings should be reported in a transparent manner, ensuring that individual student identities are not revealed.

## **DATA SHARING**

When sharing research findings or data, ensure that student confidentiality is maintained in compliance with institutional guidelines and FERPA regulations. Only de-identified data should be shared publicly.

## 2. USE OF STUDENT ASSIGNMENTS IN MEDICAL EDUCATION RESEARCH



### PERMISSION AND INFORMED CONSENT

Faculty should obtain explicit consent prior to data collection from students if their assignments are to be used for research purposes. Students should be informed that their academic work will be used in a study and be given the option to opt out of the study at any point during the study. Best practice is to have another faculty member not associated with the project administer the consent to further remove any potential bias or coercion.

### NO IMPACT ON GRADES

The use of student assignments in research should not affect their grades or academic standing in any way. Faculty should ensure that students do not feel pressured to participate as part of their academic evaluation.

### DE-IDENTIFICATION OF WORK

When possible, assignments should be de-identified so that individual students cannot be identified in the research results. This is especially important if the research involves public dissemination of findings.

### GRADING OF ASSIGNMENTS

The PI and co-investigators should refrain from grading the assignments. A separate set of assessors, who have no connection to the research, should evaluate the student assignments. To avoid coercion, students should be informed that the assessors have no connection with the research and will provide the investigators with de-identified grades.

### USE OF ARCHIVED ASSIGNMENTS

If using previously submitted assignments, investigators must retrospectively obtain consent unless prior consent for future research use was obtained. Any archived data may only be used if it is de-identified, with approval from the SRB and/or IRB required in all cases.

## 3. USE OF STUDENT SURVEYS IN RESEARCH



### APPROVAL AND RECOMMENDATIONS FOR SURVEY DISTRIBUTION

For all proposals that include a survey of students, the survey tool must have been reviewed and approved for distribution by the Assistant Dean for Assessment and Evaluation. The Assistant Dean will consider survey design to ensure anonymity and confidentiality of participants as well as considerations for survey fatigue. The Assistant Dean may consider recommendations to the PI for timing of the distribution to avoid over saturation of surveys. Further, the Assistant Dean may alert the PI to any unintended biases within the survey design.

The PI should clearly define the recruitment strategy in their proposal, which must include approval for distribution to the relevant students using the approved School of Medicine medical student distribution lists. The Assistant Dean for students will not approve distribution of any student surveys without approval of the SRB.

### VOLUNTARY PARTICIPATION

Participation in surveys must be completely voluntary, and students should not be penalized for opting out. PI should describe the strategies in place to ensure that students feel no obligation to participate due to power dynamics, such as the faculty-student relationship.

### INFORMED CONSENT

Students must be informed about the purpose of the survey, what data will be collected, and how it will be used. They must be made aware of their right to withdraw at any time without penalty.

### ANONYMITY

Where possible, surveys should be anonymous to avoid the identification of individual students. This helps prevent potential bias or repercussions.

### USE OF INCENTIVES

Any incentives offered to encourage participation should not be so large as to unduly influence a student's decision. If incentives are provided, they should not be linked to academic performance or standing. Any incentives must be approved by the Assistant Dean for Admissions and the Director of Financial Aid to ensure there are no conflicts with student financial aid.

## 4. USE OF STUDENT PERFORMANCE DATA (EVALUATIONS, SCORES, ETC.) IN RESEARCH



### GENERAL PRINCIPLES

Faculty should consider what additional data beyond Burnett SOM student performance data is available to strengthen their study. This may include other data/documents and the inclusion of other medical schools in the study design. Faculty are encouraged to reach out to any SRB member to discuss their research study and to explore ways to broaden the depth of data within a student-focused research project.

### APPROVAL TO USE STUDENT PERFORMANCE/OUTCOME DATA

Any research that requests to use student data must be coordinated with and approved by the Assistant Dean for Assessment and Evaluation. The Assistant Dean will ensure compliance with all policies and regulations related to student data and work with the PI on a strategy for anonymizing and aggregating the data to protect students.

*Research that relies on USMLE step scores, NBME medicine shelf exams, or course exam data will typically not be approved.*

### INFORMED CONSENT AND TRANSPARENCY

Students should be made aware if their performance data will be used in research, and their consent should be obtained.

### ACCESS TO DATA

Only authorized individuals should have access to confidential performance data. Access to data must be coordinated with and managed by the Assistant Dean for Assessment and Evaluation. The PI must describe in detail the steps that will be taken to securely store and manage student data to prevent unauthorized access or breaches.

### USE OF AGGREGATE DATA

Whenever possible, faculty should use aggregate data that does not identify individual students. This is particularly important when sharing results with a wider audience or publishing the findings.





FOR MORE INFORMATION OR QUESTIONS ABOUT THE SRB PROCESS OR REQUIREMENTS, CONTACT THE SRB CHAIR, DR. JENNIFER ALLIE, AT [J.ALLIE@TCU.EDU](mailto:J.ALLIE@TCU.EDU).

