Implementing a Quality Improvement Review Board for Oversight of Non-Human Subjects Research Projects

Toni L. Denison, M.S., CPHQ

RESEARCH INTEGRITY OFFICE | QUALITY IMPROVEMENT REVIEW BOARD

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER™

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Introduction

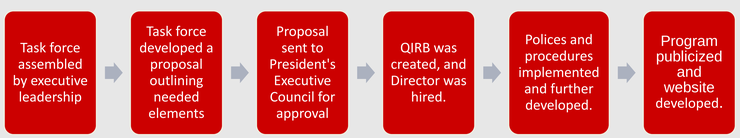
Appropriate review and oversight of projects not meeting the definition of human subjects research was a challenge that Texas Tech University Health Sciences Center (TTUHSC) sought to address with the implementation of a Quality Improvement Review Board (QIRB).

Quality Improvement (QI) projects are fundamentally distinct from Human Subjects Research (HuSR); however, the differences between them are subtle and highly nuanced. Determining whether a project meets the definition of QI or qualifies as HuSR, thus requiring Institutional Review Board (IRB) review, can be confusing and frustrating.

QIRB review helps project leaders understand the difference between QI and HuSR and establish the correct path toward either QIRB or IRB review. This ensures that HuSR is not mistakenly conducted under the label of a QI project, and strengthens the scholarly rigor of QI projects. During our 2018 AAHRPP site visit, the QIRB and related processes were noted as an Area of Distinction for TTUHSC.

Creating a QIRB

The first step for establishing a new review board was to gain support from the University President's office. With support from the Senior Vice President for Research and Associate Provost, an interprofessional team of faculty came together and developed a plan to present to the President's Executive Council for approval at the highest level of the University. The QIRB plan included its mission, organizational structure, composition of the QIRB, and a policy to guide QIRB activities.



Initial and continuous costs associated with the QIRB include salary and fringe benefits of one full time employee.

QIRB Submission and Review Process

The submission process is designed to be quick and user-friendly in order to facilitate the fast-paced and dynamic nature of QI projects.

The Director addresses issues with the team during initial review, and can obtain HRPP advice as needed. Then, one board member is assigned as a secondary reviewer before the project is approved.

Review Criteria

Project review evaluates the intent, design, participants, risks, and benefits inherent to the project to determine whether it is QI or HuSR. When a project contains design elements that could indicate that the project may be HuSR, the QI Director consults with TTUHSC's Human Research Protection Program (HRPP). It also may be held that certain projects, e.g., Program Evaluations or Needs Assessments, fall outside the criteria for either QI or HuSR and there is no required review and approval by an oversight committee.

Required for approval as QI

- Specific prospective improvement goal
- Evidence-based intervention offered to all participants
- Cyclical design; Data analysis measures change over time
- No risks outside those of receiving care; Participants should benefit

Triggers HRPP consult

- Project goal is to fill gap in the literature
- Project appears to address a research question
- Design appears to include a control group; the intervention is withheld from some participants for purpose of comparison.

"Other" project types

- Project goal is to evaluate the performance of a program, or establish baseline performance.
- Does not include an intervention
- Does not monitor for change over time

Roles and Responsibilities

QIRB Director

- Full time
- Review all submissions, make initial outcome determinations, provide outcome letters, maintain accurate database, coordinate quarterly board meetings, conduct educational outreach and advise project leaders on appropriate QI design.

QIRB Chairperson

- Attend quarterly board meetings. Conduct secondary project reviews.
- Offer advice on challenging project determinations, work with Director on ongoing QIRB policy and program development.

Board Members

- Attend quarterly board meetings. Conduct secondary project reviews.
- Offer advice in area of expertise as needed.

AVP Research Integrity

- Attend quarterly board meetings. Conduct secondary project reviews.
- Advise on HRPP policies. Guide ongoing policy and program development and improvement.

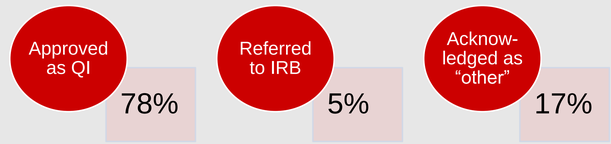
QIRB Policies

Essential elements of QIRB policies include:

- The board will consist of at least one member from each of the schools and at least one member will also be a member of the IRB.
- Project leaders must have a faculty appointment greater than 50%.
- Projects conducted at non-TTUHSC sites must include a letter of support from the site.
- Projects that are neither QI or HuSR are offered an acknowledgement letter for their records.
- QIRB approval is valid for 2 years. The Director follows up with teams at the one year and two year marks.

QIRB Performance

During the seven years from 2017-2023, the distribution of review outcomes is as follows:



Upon follow up, 75% of project leaders report that their QI projects have been successful and resulted in publication or presentation of the results.

Via educational outreach, the QIRB Director conducts on average 5 to 10 educational presentations annually to faculty, residents, and students.

Discussion

TTUHSC has found that the benefits of separate QIRB review include:

- **Reduced burden on the IRB**
- **Improved support for QI scholarly activity**
- **Improved rigor of QI project design**
- **Reduced risk of HuSR conducted without IRB approval**

Projects submitted to the QIRB that were determined to require IRB review demonstrates that in the absence of a QIRB, project leaders may have conducted HuSR without IRB approval.

Continuing QIRB program development includes:

- Growth of community understanding via educational outreach
- Publication of a QIRB Policy Manual
- Quality control under HRPP quality assurance processes within a newly drafted internal Quality Improvement Program in order to provide accountability of QIRB Board's decisions.