

**THOMAS E. STARZL TRANSPLANTATION INSTITUTE
PROTOCOL REVIEW COMMITTEE / DATA SAFETY MONITORING BOARD**

Criteria and Guidelines for Protocol Review

Protocol Review

When reviewing the submitted protocol, evaluate the following for approval by the STI PRC for submission to the University of Pittsburgh Institutional Review Board (IRB):

Proposed Study

- scientific merit
 - research question
 - specific aims
 - significance
 - study design and methods
 - data collection and statistical considerations
- risk-to-benefit ratio
- qualifications of investigators to conduct study

Resources

- clinical care and patient management
 - availability of resources to achieve endpoints and complete study
 - availability of patients
 - competition with other approved protocols
 - adequacy of patient population to achieve defined subject accrual within the specified time frame

When reviewing the submitted protocol, evaluate the following points, so that recommendations can be made to the investigative team, if necessary, to enhance the

quality of the protocol. Any suggestions or recommendations concerning the following areas will NOT be required for protocol approval by the STI PRC.

- storage and labeling of samples and data
- appropriateness of costs and payments
- inclusion of a data safety monitoring plan

Consent Review

When reviewing the submitted consent form(s), evaluate the following to enhance the quality of the consent process. Any suggestions or recommendations for the consent form(s) will NOT be required for protocol approval by the STI PRC.

- level of study description (8th grade level or younger)
- completeness and clarity of risks and benefits (informed consent)
- inclusion and completeness of the following sections:
 - Defined Alternative Treatments
 - New Information
 - Costs and Payments
 - Compensation for Injury
 - Confidentiality
 - Right to Withdraw
 - Voluntary Consent
 - Investigator's Certification
- consistency with protocol

**THOMAS E. STARZL TRANSPLANTATION INSTITUTE
PROTOCOL REVIEW COMMITTEE / DATA SAFETY MONITORING BOARD**

Criteria and Guidelines for Data Safety Monitoring

Data Safety Monitoring

After a protocol has been approved by the University of Pittsburgh IRB, the study will be evaluated at least yearly by three members of the STI DSMB. However if the IRB mandates a data safety monitoring board for the study, then the study will be evaluated by the STI DSMB (full board) at a regularly scheduled meeting. When reviewing the study for data safety monitoring, evaluate the following:

- progress of the study
- all study related adverse and unanticipated events and protocol deviations as reported by the investigative team
- data quality and timeliness
- risk-to-benefit ratio
- participant recruitment and accrual rates
- subject safety
- confidentiality of subject participation and data as reported by the investigative team
- STI's performance in the study as reported by the investigative team
- ethics of the study in relation to new and relevant information
- documentation of study-specific data safety monitoring meetings and discussions

Any recommended changes in the protocol or consent forms after IRB-approval that are unrelated to the data safety monitoring outlined above will be considered suggestions to enhance the quality of the materials and will not be required for protocol approval by the STI DSMB.

Supporting Documents and IRB Required Forms

Review the submitted supporting documents and IRB required forms to ensure appropriateness, completeness, and consistency with protocol and consent form(s). Any suggestions or recommendations made for the supporting documents and IRB-required forms will not be required for protocol approval by the STI PRC/DSMB.

**THOMAS E. STARZL TRANSPLANTATION INSTITUTE
PROTOCOL REVIEW COMMITTEE / DATA SAFETY MONITORING BOARD**

Guidelines for Submitting Written Comments

Reviewer's written comments on assigned full board protocols are due electronically to the STI PRC/DSMB Coordinator by noon on the day of the scheduled committee meeting. Informal email communications will not be accepted. A signed copy of the written comments will be collected at the committee meeting.

Reviewer's data safety monitoring comments on protocols not assigned to full board review are due electronically within seven (7) days of receipt. Informal email communications will not be accepted. A signed copy of the written comments will be collected at the next committee meeting.

The following format is suggested for the reviewer's written (and oral) comments:

Part I:

Title of Protocol
Principal Investigator's Name

Part II:

Narrative Summary of Study - include type of review (new, renewal, modification, etc.), type of study (prospective, retrospective, randomized, etc.), hypothesis/goal, specific aims, brief study design and methods, and endpoints.

Define subject population (sex, age range, why a subject) and number to enroll (if renewal – include number enrolled to date and during current renewal period)

Address risk-to-benefit ratio (Important!) – favorable, unfavorable, etc.

If a renewal, include information on subject withdrawals, subject complaints, adverse events, unexpected problems, and breaches in confidentiality. Address adherence to data safety monitoring plan. Based on the points defined in *Data Safety Monitoring* (page 3), provide a recommendation on whether the study should continue or be terminated.

If modifications, summarize the requested changes.

Part III:

- A. List your comments, requested changes, and questions concerning the protocol that are required to be addressed for approval.
- B. List your suggestions and recommendations for the protocol, consent(s), supporting documents, and IRB-required forms that are not required for approval of the protocol but would enhance the quality of the IRB submission.

Part IV:

Provide recommendation to the STI PRC/DSMB:

Approval for submission to IRB – no comments

Approval subject to responses to questions/comments outlined in Part III

Reconsideration – requires re-review by the STI PRC/DSMB Full Board

Disapproval

Part V:

Reviewer's Name (Printed)

Reviewer's Signature

Date of Review