

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

**Membership Requirements**

**Scientific Reviewer Requirements and Responsibilities**

1. Reviewers will be required to attend 80% (minimum of 10) of all monthly meetings per year.
2. Reviewers will submit written comments on assigned full board protocols to the STI PRC/DSMB Coordinator by noon on the day of the scheduled committee meeting. Reviewers will submit data safety monitoring written comments on protocols not assigned to full board review to the STI PRC/DSMB Coordinator within seven (7) business days of receipt.
3. Reviewers who are assigned as “Primary Reviewers” will provide an oral summary and review of the protocol at the meeting and provide a recommendation for the committee’s vote and approval. The reviewer who is assigned as “Secondary Reviewer” will orally communicate to the committee their review. All scientific reviewers, even if not assigned a protocol, are permitted to provide written and/or oral comments on any protocol submitted.
4. Reviewers will remain anonymous to all investigators (principal investigator, co-investigators, and research coordinator) of the study. No communication will occur between a scientific reviewer and the principal investigator, co-investigators, or research coordinator of the study about any STI PRC/DSMB deliberations. As a STI PRC/DSMB member, all discussions and communications will remain confidential.

**Research Coordinator Requirements and Responsibilities**

1. STI Research Coordinators will be required to attend 80% (minimum of 10) of all monthly meetings per year.
2. STI Research Coordinators will submit written comments on assigned full board protocol to the STI PRC/DSMB Coordinator by noon on the day of the scheduled committee meeting. Reviewers will submit data safety monitoring written comments on protocols not assigned to full board review to the STI PRC/DSMB Coordinator within seven (7) business days of receipt.
3. STI Research Coordinators will orally communicate to the committee their reviews of a protocol. All Research Coordinators, even if not assigned a protocol, are permitted to provide written and/or oral comments on any protocol submitted.
4. STI Research Coordinator Reviewer will remain anonymous to all investigators (principal investigator, co-investigators, and research coordinator) of the study. No communication will occur between a research coordinator and the principal investigator, co-investigators, or research coordinator of the study about any STI PRC/DSMB deliberations. As a STI PRC/DSMB member, all discussions and communications will remain confidential.

### **Non-Voting Member Requirements and Responsibilities**

1. STI PRC/DSMB non-voting members will be required to attend 80% (minimum of 10) of all monthly meetings per year.
2. Non-voting members are permitted to review and provide written and/or oral comments on any protocol submitted.
3. No communication will occur between a non-voting member and the principal investigator, co-investigators, or research coordinator of the study about any STI PRC/DSMB deliberations. As a STI non-voting PRC/DSMB member, all discussions and communications will remain confidential.