THOMAS E. STARZL TRANSPLANTATION INSTITUTE
PROTOCOL REVIEW COMMITTEE

Protocol Submission Form

Incomplete information may delay protocol processing and review by the Thomas E. Starzl Transplantation Institute Protocol Review Committee (PRC).

Required Documents: ***Full protocol and/or OSIRIS protocol***
Consent form(s)
Data safety monitoring plan
Investigator's brochure, if applicable
List of competing protocols
STI Financial support letter, if applicable

Principal Investigator:
Campus Address:
Telephone Number:
FAX #:
Email:

Title of Protocol:

Co-investigators:

Research Coordinator:

Does the principal investigator, any co-investigator, or research coordinator involved in this study have a conflict of interest in participating in the study? ☐ Yes ☐ No

Financial Sponsor of Study:

- ☐ STI-sponsored (Include a financial support letter from Clinical Director or Scientific Director)
- ☐ Industry-initiated and industry-sponsored
- ☐ Investigator-initiated and industry-sponsored
- ☐ NIH-sponsored
- ☐ Foundation-sponsored
- ☐ Other sponsor (specify):_____

Is this a multi-center study that is locked into the design as provided? ☐ Yes ☐ No

Is there an FDA / IND number for any study drug or device? ☐ Yes ☐ No
If yes, provide the IND#_____
Also, provide a copy of the Investigator's Brochure with submission

Is an investigator IND application required? ☐ Yes ☐ No

If yes, have you contacted the University of Pittsburgh Office for Investigator IND and IDE Support (O3IS) for assistance with the IND process? ☐ Yes ☐ No

How many patients does the principal investigator expect to see in clinic that would meet the eligibility criteria of this protocol? /year
What is the anticipated accrual rate for this study? /year

Number of patients to be enrolled at STI?
Number of patients to be enrolled in entire study (if applicable)?

Does this study require services of the CTRC? ☐ Yes ☐ No

Is radiation involved for research purposes in this study? ☐ Yes ☐ No

Does this study involve recombinant DNA (rDNA)? ☐ Yes ☐ No
If yes, have you contacted the University of Pittsburgh rDNA Office? ☐ Yes ☐ No

Have you included a Data Safety Monitoring Plan with this protocol? ☐ Yes ☐ No
This plan is required for the STI PRC protocol review.