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THOMAS E. STARZL TRANSPLANTATION INSTITUTE
DATA SAFETY MONITORING BOARD

Data Safety Monitoring Plan Progress Report

Principal Investigator:

Protocol Title:

IRB Number:

Type of Review: ☐ DSMP (three member review) ☐ DSMB (full board review)

1. What is the original IRB approval date?
2. Has this study previously had a different IRB number?
   ☐ No ☐ Yes, specify:
3. What is the approved duration of entire study?
4. How many participants were approved for this study?
5. How many participants have been enrolled to date?
6. How many participants were enrolled during this renewal period?
7. How many participants dropped out or withdrew during this renewal period?
   Reason:

8. Type of study:
   ☐ single center
   ☐ multi-center (include report from the central IRB)

9. What is the current status of your protocol?
   ☐ open
   ☐ closed to enrollment
   ☐ data analysis only
   ☐ closed
   ☐ on hold
   ☐ suspended

10. What are your plans for the study?
    ☐ continue with enrollment as planned
    ☐ modify accrual plans and continue the study [explain modification(s)]

☐ close study

11. Describe the data safety monitoring plan that was approved for the study.

12. Did you strictly adhere to your approved data safety monitoring plan?

☐ Yes
☐ No (explain data safety monitoring plan deviations in detail)

Attach to this form documentation of your study team's data safety monitoring meetings and discussions.

13. List all adverse events (AEs) for this renewal period.

14. Explain each adverse event, how many participants were affected, how it was resolved, and any corrective actions.

15. Has any new information been identified that requires a modification to the protocol and/or consent document?

☐ No
☐ Yes, explain in detail:

16. List all protocol deviations and violations for this renewal period.

17. Explain each protocol deviation/violation, how it was resolved, and any corrective actions.

18. Have there been any breaches in confidentiality?

☐ No
☐ Yes, explain in detail:

For Starzl Transplantation Institute Data Safety and Monitoring Board (STI DSMB) use only:

Risk/Benefit Ratio: ☐ unfavorable ☐ favorable

Study should: ☐ terminate ☐ proceed: ☐ as written ☐ with modifications

Signature of Chair or Designee: Date: