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
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>If yes, have you contacted the University of Pittsburgh Office for Investigator IND and IDE Support (O3IS) for assistance with the IND process?</td>
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<td>How many patients does the principal investigator expect to see in clinic that would meet the eligibility criteria of this protocol?</td>
<td>year</td>
<td></td>
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<td>What is the anticipated accrual rate for this study?</td>
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<td>Number of patients to be enrolled at STI?</td>
<td></td>
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<td>Number of patients to be enrolled in entire study (if applicable)?</td>
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<td>Does this study require services of the CTRC?</td>
<td>Yes</td>
<td>No</td>
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<td>Is radiation involved for research purposes in this study?</td>
<td>Yes</td>
<td>No</td>
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<td>Does this study involve recombinant DNA (rDNA)?</td>
<td>Yes</td>
<td>No</td>
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<td>If yes, have you contacted the University of Pittsburgh rDNA Office?</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Have you included a Data Safety Monitoring Plan with this protocol?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

*This plan is required for the STI PRC protocol review.*