

Certification of Approval for a Project Involving Human Subjects

Date: 21-Aug-2018

Protocol Number: 25286
PI: DIAMOND, ADAM
Review Type: FULL COMMITTEE
Approved On: 21-Aug-2018
Approved From: 21-Aug-2018
Approved To: 20-Aug-2019
Committee: A1
School/College: Temple Affiliates
Department: Temple Hospital
Sponsor: VELOXIS PHARMACEUTICALS, INC.
Project Title: Dosing strategies for de novo once-daily extended release tacrolimus (LCPT) in kidney transplant recipients

The IRB approved the protocol 25286.

If the study was approved under expedited or full board review, the approval period can be found above. Otherwise, the study was deemed exempt and does not have an IRB approval period.

If applicable to your study, you can access your IRB-approved, stamped consent document or consent script through ERA. **Open the Attachments tab and open the stamped documents by clicking the Latest link next to each document.** The stamped documents are labeled as such. Copies of the IRB approved stamped consent document or consent script must be used in obtaining consent.

Before an approval period ends, you must submit the Continuing Review form via the ERA module. Please note that though an item is submitted in ERA, it is not received in the IRB office until the principal investigator approves it. Consequently, please submit the Continuing Review form via the ERA module at least 60 days, and preferably 90 days, before the study's expiration date.

Note that all applicable Institutional approvals must also be secured before study implementation. These approvals include, but are not limited to, Medical Radiation Committee ("MRC"); Radiation Safety Committee ("RSC"); Institutional Biosafety Committee ("IBC"); and Temple University Survey Coordinating Committee ("TUSCC"). Please visit these Committees' websites for further information.

Finally, in conducting this research, you are obligated to submit the following:

- **Amendment requests - all changes to the study must be approved by the IRB prior to the implementation of the changes unless necessary to eliminate apparent immediate hazards to subjects**

- **Reportable new information - using the Reportable New Information form**, report new information items such as those described in the Investigator Guidance: Prompt Reporting Requirements HRP-801 to the IRB **within 5 days**
- **Closure report** - using a closure form, submit when the study is permanently closed to enrollment; all subjects have completed all protocol related interventions and interactions; collection of private identifiable information is complete; and Analysis of private identifiable information is complete.

For the complete list of investigator responsibilities, please see the Policies and Procedures, the Investigator Manual, and other requirements found on the Temple University IRB website: : <http://research.temple.edu/irb-forms-standard-operating-procedures#POLICY>

Please contact the IRB at (215) 707-3390 if you have any questions