RUSH UNIVERSITY MEDICAL CENTER
1653 WEST CONGRESS PARKWAY,
CHICAGO, ILLINOIS, 60612-3833

OFFICE OF RESEARCH AFFAIRS
312.942.5498
312.942.2874 (FAX)

RUSH UNIVERSITY MEDICAL CENTER

Full Accreditation

Sync Review

Principal Investigator: Parikshit Sharma
Department:

IM - Administration

IM - Cardiology

ORA Number: 22051809-Sync01
Project Title: Cardiac Resynchronization Therapy DeliveRy guided non-Invasive electrical and VEnous anatomy assessment (CRT-DRIVE)
Project Start Date: 6/28/2022 3:20 PM

This letter must be included in the IRB amendment submission when submitting an amendment to the IRB to address the sync findings noted below.

Hi Study Team

During ORA-Sync review, we noted the following findings:

Good Morning Study Team,

I have conducted a ORA Sync of your study and sync findings were noted. Please note that the study is in “Awaiting updates” state in the sync workspace. The study team will need to respond to the sync findings noted below. To respond to sync findings please use the “submit update” button from the sync workspace.

If you have any questions regarding sync process, please contact sync team via “email sync” button from the sync workspace.

ORA sync findings:
1) The budget is not consistency with other documents reviewed. The itemized budget provided shows “Caregiver Travel Reimbursement” on line 61 of the “Study Procedures Tab” however, the CTA, ICF and the IRB Application does not mention compensation/reimbursement for study participation and travel.

- The ICF cost section, page 7 states that: Any research-related tests, procedures, or services that you may receive solely for the purposes of this study and which would not be performed otherwise will be provided to you free of charge by the study Sponsor, XSpline S.p.A.

Specifically, these include CTA (Computed Tomography Angiography) and pregnancy test for women of childbearing potential. You or your insurance will be responsible for paying for the cost of any routine medical care that you would receive whether you participate in this study or not, unless you are told that such item or services will be supplied at no cost. If you have health insurance, the insurance may or may not pay for the costs associated with your participation in this study. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires. Before you decided to be in this study, you should contact your insurance provider to verify coverage,

- Will you be paid for your participation in this study? You will not be paid for being in this study. Your participation in this study may contribute to the development of commercial products from which the Sponsor company or others may derive financial benefit. There are no plans to pay you for any of these developments.

- The Clinical Trial Agreement (CTA) reviewed named "UPDATED_ACTA_BUDGET_FINAL_REVISED_12.6.19_XSpline_Revised RUMC Edits 05242023_CLEAN" is silent regarding subject reimbursement.

If required, please revise any appropriate study document(s) for consistency or provide reasonable rationale for what may appear to be inconsistencies between the study documents (ICF, IRB application, and CTA/budget). Any changes/revision done to the ICF and IRB application will require IRB review. Please notify me if a revision is submitted.

Any assistance that you can provide with this inquiry would be greatly appreciated.
As a friendly reminder, please complete financial review signoff (FRS) in OnCore for this study as soon as possible. Please note, although this will not impact sync completion for this study, a non-completion of FRS may delay the revenue cycle sync signoff (RCS) process and calendar release. If you have any questions or need assistance/education regarding this reminder, please contact Priya Mishra at Priya_Mishra@rush.edu. Thank you.

Thank you,
Omo

Please notify the assigned sync team if/after an amendment has been submitted via sync workspace and remember to use the sync workspace for all communications regarding ORA Sync. If you have any questions regarding the ORA Sync process, please contact sync team via "Email Sync Specialist" button from the sync workspace.

If changes to the IRB application and/or consent document will be requested based on the sync findings, you are required to submit this letter and the consent changes to the IRB for review and approval prior to enrolling participants.

Kindest Regards,

Solomon

Solomon_Adelowo@rush.edu