DATE: 13-Jul-2017
TO: Patrick A Stanko
CC: Allen, Pearette A
     Wirtanen, Emily A
     Heagerty, David A
RE: IRB PROTOCOL #: 823083
TITLE: PAS 6-19 Reliance Agreement App for PennERA testing
SPONSORING AGENCY: NO SPONSOR NUMBER
REVIEW BOARD: IRB #2

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IRB SUBMISSION: NOTICE OF CEDED REVIEW

Dear Dr. Stanko

The above referenced protocol was administratively reviewed by the Institutional Review Board on 20-Jun-2017.

The University of Pennsylvania has ceded initial and ongoing review of this study to the Chesapeake IRB.

Note:
1) Please provide the central IRB approval letter and stamped consent once they are available.
2) The contract review is not done yet and the Penn IRB will review the consent form once the contract has been finalized.

The following documents were included in this review:
- HS ERA Initial Application, confirmation code cdghfbdd, submitted 4/22/17
- Clinical Study Protocol (Version 1.0) dated 08 September 2016
- Investigator Brochure for Guadecitabine (SGI-110) (Version Number: 7.0) dated 18 August 2016
- Informed Consent Form and HIPAA Authorization (Version 1.0)
- Informed Consent Form for Data Collection Related to the Pregnancy of a Subject's Partner that Occurred While the Subject Was Participating in a Clinical Research Trial and HIPAA Authorization (For Participant's Partner) (Version 1.0)
- EQ-5D-5L Health Questionnaire
- Q2Solutions Laboratory Manual dated 15 February 2016
- Patient Alert Card (Version 1.0) dated 1 Nov 2016
- Pharmacy Manual dated 07-Dec-2016

INVESTIGATOR RESPONSIBILITIES: Please refer to the PI assurance document included in your application for guidance on the additional responsibilities of Penn investigators when IRB review has been ceded to an external IRB.

CONTINUING REVIEW: Ongoing review of this study will not be conducted by the Penn IRB. However, please submit all continuing review approval letters to the Penn IRB prior to the date of expiration so that the University of Pennsylvania Human Research Protections Program can accurately track the approval of the protocol.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.upenn.edu/IRB/directory.

***This letter constitutes official University of Pennsylvania IRB correspondence. ***