



## Vanderbilt University

Institutional Review Board

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[www.mc.vanderbilt.edu/irb](http://www.mc.vanderbilt.edu/irb)

August 19, 2014

James E. Loyd, M.D.  
Medicine - Allergy, Pulmonary and Critical Care  
T-1218 MCN 2650

Lisa Wheeler  
Medicine - Allergy, Pulmonary, and Critical Care Medicine  
T-1217 MCN 2650

**RE: IRB# 9401 "Genetic, Hormonal, and Metabolic Signaling Interactions in PAH /Caveolar Defects Underlie the Genetic Origins in PAH"** (RFA-HL-04-019; NIH-1K23HL098743-01A1; R01HL111259; Entelligence-Actelion Pharmaceuticals)

Dear [James E. Loyd, M.D.](#):

At the meeting on [8/19/2014](#), the Institutional Review Board reviewed the Application for Continuing Review for the research study identified above. The Committee determined the study poses [Greater than Minimal Risk](#) to participants.

**The Consent Form(s) have been stamped with the approval and expiration date and this copy should be used when obtaining the participant's signature.** Federal regulations require the original copy of the participant's consent be maintained in the principal investigator's files and that a copy be given to the participant at the time of consent. An additional record (i.e., case report form, medical record, database, etc.) of the consent process should also be maintained in a separate location for documentation purposes.

Please note the requirement for annual VU IRB Human Subjects Training is not current or will soon expire for some key study personnel (KSP) associated with this study. It is the Principal Investigator's responsibility to ensure that all KSP have met the annual training requirement (see IRB Procedure VI.B.1). Please log in to DISCOVER-E at <https://irb.mis.vanderbilt.edu/pls/htmldb/f?p=106:20>, select the "Studies" tab and review the "IRB Training Status for Study Personnel" view to identify those needing to renew training. Those individuals may then access the CITI Basic and Refresher Courses at <https://www.citiprogram.org>.

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants or others. The IRB Adverse Event reporting policy III.L is located on the IRB website at <http://www.mc.vanderbilt.edu/irb/>.

**Please note that approval is for a [12-month](#) period.** According to federal regulations, this period is calculated from the date of the convened meeting as noted above. Any changes to the research study must be presented to the IRB for approval prior to implementation.

**DATE OF IRB APPROVAL: [8/19/2014](#) DATE OF IRB EXPIRATION: [8/18/2015](#)**

Sincerely,



James A.S. Muldowney III, M.D., Chair  
Institutional Review Board  
Health Sciences Committee #3  
JSM/th

**Electronic Signature:** James Muldowney III/VUMC/Vanderbilt : (819C320F52BC7ACDBAB300A300103864)

**Signed On:** 08/20/2014 03:37:32 PM CDT