

PVDOMICS EVENTS REPORTING FORMS 400-402

Coordinator Training March 1st 2018

NHLBI Pulmonary Vascular Disease Phenomics Program

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Form 400-Event Notification

Event	Report on Form		Phone call and e-mail to DCC co-PIs ¹⁾	Report to Local IRB as required	Auto e-mail sent to :	
	400 (report immediately upon learning of the event)	401			400	401
Any SAE within 24 hours of study procedure (regardless of relatedness or expectedness) ²⁾	X	X (within 1 week of learning of the event)	X	X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
A) Any death ²⁾ OR B) Life-threatening SAE that is: - possibly, probably or definitely related to a study procedure <u>AND</u> - unexpected or expected, but of greater severity than described in consent ²⁾	X	X (within 1 week of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
Non-fatal, non-life-threatening SAE or unanticipated adverse event that is: - possibly, probably or definitely related to a study procedure <u>AND</u> - unexpected or expected, but of greater severity than described in consent	X	X (within 2 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC NHLBI OSMB Chair
Non-fatal event that happened more than 24 hours after study procedure and is: - not related or unlikely to be related to a study procedure OR - possibly, probably or definitely related to a study procedure but is expected and accurately described in the consent	X	X (within 4 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC

Form 400-Event Notification Continued

- You should fill out this form as soon as the center identifies that a participant event has occurred.
- Events that occur during the study period or within 2 weeks of study completion should be reported.
- The type of event (death, hospitalization, life threatening event, prolonged hospitalization and other) is asked
- The date of the event.
- In the Physician's judgment was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
- If the event was possibly, probably or definitely caused by any procedure or device, done as part of the PVDOMICS protocol, was it described in the consent.
- For SAE within 24 hours of a study procedure: **the Clinical Center PI must notify the DCC Co-PIs immediately by call and email (see Footnote 1 on Form 400).**

Form 401-Detailed Serious Adverse/Adverse Event

- This form is under revision.
- The purpose of this form is to provide details about the SAE and AEs
- Reporting should follow the guidelines by the PVDOMICS OSMB and NHLBI Adverse event and Unanticipated Problem Reporting Policy.
- You should fill out this form within the timelines given in the instructions. Add further details and final outcomes later if need be.
- It is up to the physician's clinical judgment to decide when a AE or SAE has occurred.
- The Event Review Committee will review all events to make final determination whether will count as a study SAE.

FORM 402- EVENT INFORMATION SENT TO THE DCC

- This is filled out **after** Form 401.
- The DCC will notify the clinical center staff to complete and enter this form. Do not send the packets until notified to do so.
- The date the event packet is scanned and sent to the DCC is recorded
- The type of information scanned and transferred to the DCC is asked (Discharge summary, ER note, Expiration summary, Autopsy and other documentation) is asked.