



PVDOMICS STUDY

Event(s) Notification Form #400

Instructions: This form is completed as soon as the Clinical Center identifies that a participant event has occurred. An event can be an adverse event (AE) and/or serious adverse event (SAE) such as but not limited to: life threatening condition, hospitalization, death or other event. Events that occur during the study period or within 2 weeks of study completion should be reported. The timeline and procedures for AE/SAE reporting follow the guidelines by PVDOMICS OSMB and NHLBI Adverse Event and Unanticipated Problem Reporting Policy.

Events Reporting Timelines

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

¹⁾ For SAEs within 24 hours of study procedure:

The clinical center PI must notify the DCC **immediately** upon learning about the event as follows:

- Call one of the DCC co-PIs [Dr. Beck at (216) 444-9927 or Dr. Erzurum at (216) 312-3116] AND
- Send an e-mail to both Drs. Beck and Erzurum (beckg@ccf.org, erzurum@ccf.org). Be sure to use the option in your e-mail software that requests a delivery receipt.

²⁾ These classes of safety events are subject to expedited reporting to NHLBI and the OSMB. All other safety events are reported to NHLBI and the OSMB as part of routine reports.



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1. Identification Number

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2. Alphacode

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3. Date center first heard of event: mm/dd/yyyy

Type of event that occurred:

4. Death (0=No, 1=Yes, requires expedited reporting)

a. Date of death (mm/dd/yyyy)..... / /

b. Occurred within 24 hours of a study procedure? (0=No, 1=Yes).....

5. Hospitalization (0=No, 1=Yes)

a. Date of admission (mm/dd/yyyy)..... / /

b. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting)

6. Life-threatening event (0=No, 1=Yes)

a. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting)

7. Prolonged hospitalization (0=No, 1=Yes)

a. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting)

8. Other SAE (0=No, 1=Yes)

Note: Event that occurred during hospitalization that in itself would have triggered a hospitalization, lead to persistent disability, congenital abnormality, or inability to conduct normal life functions

a. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting)

9. Was this an adverse event only (0=No, 1=Yes)

10. a. In the Clinical Center Physician's judgment*, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)

b. If the event was possibly, probably, or definitely caused by any procedure or device, done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent?

1=Unexpected – not mentioned in the consent

2=Expected, but of greater severity than mentioned in the consent

3=Expected and accurately described in the consent

* Judgment questions in 10a & b are repeated on Form 401. Only Form 401 responses will be used for reporting purposes. Documents that help with determining judgment should be submitted using Form 402 when requested by the DCC.

11. Provide a brief comment in the box below concerning event(s) that occurred:

200. Date form completed (mm/dd/yyyy) ____/____/____
201. Username of person completing/reviewing completeness of this form..... _____
202. Username of physician reviewing accuracy and completeness
of this form _____
(Username is the first 6 letters of physician's last name and first initial.)

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ____/____/____

Username of person entering this form _____