



PVDOMICS STUDY

Drop-Out - Form #412

Instructions: This form is completed when it is determined that a participant who enrolled in the PVDOMICS Study (based on the Enrollment Form 100) drops out *and/or becomes ineligible*. (If the participant is transplanted and/or dies prior to end of PVDOMICS Study, complete Forms 400 and 401.) Send the completed form by email (pvd-systems@bio.ri.ccf.org) to the DCC for data entry.

Use Forms 410-Extension Request and/or F411-Exception Request to obtain further missing data, if possible. However, if there is some missing data that will never be obtained, complete Form 420 Comments and Q10 to explain reason for missing data. In certain cases, center may receive some reimbursement for available data.

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1. Identification Number

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2. Alphacode

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3. Date dropped: mm/dd/yyyy

Reason(s) Participant Dropped (*see list of possible reasons below*)

4. Primary reason this participant dropped from PVDOMICS Study ____ ____
5. Secondary reason this participant dropped from PVDOMICS Study (if applicable) ____ ____

1 = More than six weeks (from Form 100-Date of Enrollment) passed. Center did not submit a request for extension and no further data captured. Either no data other than F100 is available or very limited data.

7 = Participant does not have pulmonary hypertension and is not a comparator or healthy control (confirmed by RHC)
Note: This reason can be indicated after a Form 102 was reviewed by the adjudication committee and a recommendation was made to drop the participant from the study.

9 = Participant is a total consent withdrawal – no longer wants anything at all to do with the study and requests that all data is deleted and biosamples discarded – no further contact ever

If a new reason is identified, notify the DCC via e-mail at pvd-DCCclin@ccf.org and a new code will be assigned.

Comments:

For DCC Use Only:

Code for primary reason DCC dropped participant:

20=DCC dropped due to insufficient study data

21=DCC dropped due to participant refused to collect OMICS C1 and C2.

200. Date this form completed (mm/dd/yyyy)..... ____/____/____

201. Username of person reviewing completeness of this form..... _____

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ____/____/____

Username of person entering this form _____