



PVDOMICS STUDY

Request for Exception(s) - Form #411

Instructions: Use Form 411 to request that an exception be made for two conditions:

- 1) If an historical test is outside the established window of protocol/MOP acceptability;
And/Or,
- 2) If a test was done for clinical reasons but not using criteria established for PVDOMICS study tests/measurements.

(Use Form 410 to request a study extension to complete study measurements.)

Once this form is entered and saved in the database, an email notice will be sent from the database to individuals who will review this case for approval within 2 business days.

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1. Identification Number

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2. Alphacode

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3. Date of exception(s) requested: mm/dd/yyyy

For column a: identify study component for which an exception is being requested.

01=Sleep Study

02=ECHO

03=Cardiac MRI

04=Chest CT

-Contact DCC for other study component

05=V/Q Scan

06=PFT

07=RHC

08=CPET

09=Other center lab (F200-205)

10=HRQOL

11=W/H or BIA

12=ECG

13=6MWT

For column b, identify the date a test was performed that falls outside of an established study guideline, if applicable. Otherwise leave date blank.

a. Test/Measure

**b. Date of Test
to be used**

**210. DCC
Use only**

4. Exception request #1. / .. /

Rationale:

5. Exception request #2. / .. /

Rationale:

Continued on next page

a. Test/Measure

b. Date of Test
to be used210. DCC
Use only

6. Exception request #3. ____/____/____

Rationale:

7. Exception request #4. ____/____/____

Rationale:

100. Username of center physician who reviewed this request*

(*This should be the center PI or Co-PI and have a Form 10 entered into the database.)

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

201. Username of person completing/reviewing completeness of this form

Clinical Center Use Only

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

Username of person entering this form

For DCC Use Only:

For column 210. Exception(s) approval given?

1=Exception(s) granted and okay with window

2=Exception(s) granted and okay with clinical study

3=Exception not granted

211. Date of DCC decision

212. DCC Comments: _____