



PVDOMICS STUDY

Clinical Center Alternative Sleep Study

Report Transmission - Form #155

Instructions: This form is completed by clinical center personnel to document a historical or current clinical sleep study that did not follow PVDOMICS protocol. A historical sleep study report can be used if it is less than one year from date of initial PVDOMICS study enrollment and with no change in nighttime oxygen or sleep disorder therapy, no more than 10% weight loss or gain, and in the opinion of the investigator, no change in patient condition that would impact results, then the clinically available data may be considered adequate for inclusion in the case. Contact the Sleep Study Core if you have any questions.

--	--	--	--	--	--

1. Identification Number

--	--

2. Alphacode

--	--	--	--	--	--	--	--

3a. Start date of alternative sleep study: (mm/dd/yyyy)

3. b. Type of study
 (1=Historical, 2=Current clinical (not following PVDOMICS protocol) (if Q3b =2, skip to Q6).

4. a. Does PVDOMICS study staff know if there has been a change in nighttime oxygen or sleep disorder therapy since this **historical** study was completed?
 0=No (no change in nighttime oxygen or sleep disorder therapy since historical study completed)
 1=Yes (a change in nighttime oxygen or sleep disorder therapy was identified since historical study completed)
 9=Unknown (unknown if any changes to therapy since historical study completed)

b. Does PVDOMICS study staff know if there has been a 10% change in weight since this **historical** study was completed?
 0=No, participant reports no 10% change in weight since historical study completed
 1=Yes, participant reports that there was a weight gain of more than 10% since the historical study was completed
 2=Yes, participant reports that there was a weight loss of more than 10% since the historical study was completed
 9=Unknown whether or not there was 10% weight gain or loss.

5. Does center physician think there is a change in the participant's clinical condition that would impact results from the historical study?
 0=No, center physician does not believe there is a change in participant's clinical condition that would have an impact on historical study results
 1=Yes, center physician does believe there is a change in participant's clinical condition that impacts historical study results

6. Date final report transmitted to Sleep Core (mm/dd/yyyy) / /

7. Comments for Sleep Core personnel:

199. Username* of PVDOMICS staff member transmitting report to Core
 *Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu)

200. Date 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