

## Data Collection Worksheet

**Please Note:** The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

**Interview Instructions:** I am going to ask you questions about how your relative has been feeling during the past week. I am interested in changes you have noticed and the duration of these changes.

### A. Mood Related Signs

**1. Anxiety:** (*anxious expression, ruminations, worrying*) Has your relative been feeling anxious this past week? Has s/he been worrying about things s/he may not ordinarily worry about, or ruminating over things that may not be that important? Has your relative had an anxious, tense, distressed, or apprehensive expression?

**2. Sadness:** (*sad expression, sad voice, tearfulness*) Has your relative been feeling down, sad, or blue this past week? Has s/he been crying at all? How many days out of the past week has s/he been feeling like this? For how long each day?

**3. Lack of reactivity to pleasant events:** If a pleasant event were to occur today (i.e., going out with spouse, friends, seeing grandchildren), would your relative be able to enjoy it fully, or might his/her mood get in the way of his/her interest in the event or activity? Does your relatives mood affect any of the following:

- his/her ability to enjoy activities that used to give him/her pleasure?
- his/her surroundings?
- his/her feelings for family and friends?

**4. Irritability:** (*easily annoyed, short tempered*) Has your relative felt short-tempered or easily annoyed this past week? Has s/he been feeling irritable, impatient, or angry this week?

### B. Behavioral Disturbance

**5. Agitation:** (*restlessness, handwringing, hairpulling*) Has your relative been so fidgety or restless this past week that s/he was unable to sit still for at least an hour?

Was your relative so physically agitated that you or others noticed it? Agitation may include such behaviors as playing with ones hands, hair, hand-wringing, hair-pulling, and/or lip-biting: have you observed any such behavior in your relative during the past week?

**6. Retardation:** (*slow movements, slow speech, slow reactions*) Has your relative been talking or moving more slowly than is normal for him/her? This may include:

- slowness of thoughts and speech
- delayed response to your questions
- decreased motor activity and/or reactions.

**7. Multiple physical complaints:** In the past week, has your relative had any of the following physical symptoms? (in excess of what is normal for him/her):

- indigestion?
- constipation?
- diarrhea?
- stomach cramps?
- belching?
- joint pain?
- backaches?
- muscles aches?
- frequent urination?
- sweating?
- headaches?
- heart palpitations?
- hyperventilation (shortness of breath)?

If you have observed any of these physical symptoms, how much have these things been bothering your relative? How severe have the symptoms gotten? How often have they occurred in the past week?

**Rating guideline:** *Do not rate symptoms that are side effects from medications or those symptoms that are only related to gastrointestinal ailments.*

**8. Acute loss of interest:** (*less involved in usual activities*) How has your relative been spending his/her time this past week (not including work and chores)? Has your relative felt interested in his/her usual activities and hobbies? Has your relative spent any *less* time engaging in these activities?

If s/he is *not* as interested, or has not been that engaged in activities during the past week: Has your relative had to push him/herself to do the things s/he normally enjoys?

Has your relative *stopped* doing anything s/he used to do? Can s/he look forward to anything or has s/he lost interest in many of the hobbies from which s/he used to derive pleasure?

**Rating guideline:** *Ratings of this item should be based on loss of interest during the past week. This item should be rated 0 if the loss of interest is long-standing (longer than 1 month) and there has been no worsening during the past month. This item should be rated 0 if the patient has not been engaged in activities because of physical illness or disability, or if the patient has persistent apathy associated with dementia.*

### C. Physical Signs

**9. Appetite loss:** *(eating less than usual)* How has your relative's appetite been this past week compared to normal? Has it decreased at all? Has your relative felt less hungry or had to remind him/herself to eat? Have others had to urge or force him/her to eat?

**Rating guideline:** *Rate 1 if there is appetite loss but still s/he is eating on his/her own. Rate 2 if eats only with others encouragement or urging.*

**10. Weight loss:** Has your relative lost any weight in the past month that s/he has not meant to or been trying to lose? (If not sure: are your relative's clothes any looser on him/her?) If weight loss is associated with present illness (i.e., not due to diet or exercise): how many pounds has s/he lost?

**Rating guideline:** *Rate 2 if weight loss is greater than 5 lbs. in past month.*

**11. Lack of energy:** *(fatigues easily, unable to sustain activities - score only if change occurred acutely, or in less than one month)* How has your relative's energy been this past week compared to normal? Has s/he been tired all the time? Has s/he asked to take naps because of fatigue? This week, has your relative had any of the following symptoms due to lack of energy only (**not** due to physical problems):

- heaviness in limbs, back, or head?
- felt like s/he is dragging through the day?

Has your relative been fatigued more easily this week?

*week prior to the interview.*

*This item should be rated 0 if the lack of energy is longstanding (longer than 1 month) and there has been no worsening during the past month.*

### D. Cyclic Functions

**12. Diurnal variation of mood:** *(symptoms worse in the morning)* Regarding your

relatives mood (his/her feelings and symptoms of depression), is there any part of the day in which s/he usually feels better or worse? (or does it not make any difference, or vary according to the day or situation?)

If **yes** to a difference in mood during the day: Is your relatives depression worse in the morning or the evening?

If worse in the morning: Is this a mild or a very noticeable difference?

**Rating guideline:** *Diurnal variation of mood is only rated for symptoms that are worse in the morning. Variation of mood in the evening can be related to sundowning in patients with dementia and should not be rated.*

**13. Difficulty falling asleep:** *(later than usual for this individual)* Has your relative had any trouble falling asleep this past week? Does it take him/her longer than usual to fall asleep once s/he gets into bed (i.e., more than 30 min)?

**Rating guideline:** *Rate 1 if patient only had trouble falling asleep a few nights in the past week. Rate 2 if s/he has had difficulty falling asleep every night this past week.*

**14. Multiple awakenings during sleep:** Has your relative been waking up in the middle of the night this past week? How long is s/he awake?

If **yes:** does s/he get out of bed? Is this just to go to the bathroom and then s/he goes back to sleep?

**Rating guideline:** *Do not rate if waking is only to go to the bathroom and then is able to fall right back asleep. Rate 1 if sleep has only been restless and disturbed occasionally in the past week, and has not gotten out of bed (besides going to the bathroom). Rate 2 if s/he gets out of bed in the middle of the night (for reasons other than voiding), and/or has been waking up every night in the past week.*

**15. Early morning awakenings:** *(earlier than usual for this individual)* Has your relative been waking up any earlier this week than s/he normally does (without an alarm clock or someone waking him/her up)?

If **yes:** how much earlier is s/he waking up than is normal for him/her? Does your relative get out of bed when s/he wakes up early, or does s/he stay in bed and/or go back to sleep?

**Rating guideline:** *Rate 1 if s/he wakes up on his/her own but then goes back to sleep. Rate 2 if s/he wakes earlier than usual and then gets out of bed for the day (i.e., s/he cannot fall back asleep).*

## **E. Ideational Disturbance**

**16. Suicide:** (*feels life is not worth living, has suicidal wishes, or makes suicide attempt*) During the past week, has your relative had any thoughts that life is not worth living or that s/he would be better off dead? Has s/he had any thoughts of hurting or even killing him/herself?

**Rating guideline:** *Rate 1 for passive suicidal ideation (i.e., feels life isn't worth living but has no plan). Rate 2 for active suicidal wishes, and/or any recent suicide attempts, gestures, or plans. History of suicide attempt without current passive or active suicidal ideation is not scored.*

**17. Self-depreciation:** (*self-blame, poor self-esteem, feelings of failure*) How has your relative been feeling about him/herself this past week? Has s/he been feeling especially critical of him/herself, feeling that s/he has done things wrong or let others down? Has s/he been feeling guilty about anything s/he has or has not done? Has s/he been comparing him/herself to others, or feeling worthless, or like a failure? Has s/he described him/herself as "no good" or "inferior"?

**Rating guideline:** *Rate 1 for loss of self-esteem or self-reproach. Rate 2 for feelings of failure, or statements that s/he is "worthless," "inferior," or "no good".*

**18. Pessimism:** (*anticipation of the worst*) Has your relative felt pessimistic or discouraged about his/her future this past week? Can your relative see his/her situation improving? Can your relative be reassured by others that things will be okay or that his/her situation will improve?

**Rating guideline:** *Rate 1 if s/he feels pessimistic, but can be reassured by self or others. Rate 2 if feels hopeless and cannot be reassured that his/her future will be okay.*

**19. Mood congruent delusions:** (*delusions of poverty, illness, or loss*) Has your relative been having ideas that others may find strange? Does your relative think his/her present illness is a punishment, or that s/he has brought it on him/herself in some irrational way? Does your relative think s/he has less money or material possessions than s/he really does?

## **Patient Interview**

Ratings of some patient interview items should be based principally on direct observation, i.e., anxiety, sadness, irritability, agitation, retardation. Questions to the patient can provide additional information on these items. The remaining items are scored based on the interview behavior and the patient's response to direct inquiry.

**Interview Instructions:** I am going to ask you some questions about how you have been feeling during the past week.

## A. Mood Related Signs:

**1. Anxiety:** (*anxious expression, ruminations, worrying*) Does the subject have an anxious, tense, distressed, or apprehensive expression?

*Ask the patient:* Have you been feeling anxious this past week? Have you been worrying about things you may not ordinarily worry about, or ruminating over things that may not be that important?

**2. Sadness:** (*sad expression, sad voice, tearfulness*) Does the patient have a sad expression or sad voice? Is the patient tearful?

*Ask the patient:* Have you been feeling down, sad, or blue this past week? Have you been crying at all? How many days out of the past week have you been feeling like this? For how long each day?

**3. Lack of reactivity to pleasant events:** Is the patient able to respond to friendly or supportive remarks or to humor?

*Ask the patient:* If a pleasant event were to occur today (i.e., going out with your spouse, friends, seeing your grandchildren), would you be able to enjoy it fully, or might your mood get in the way of your interest in the event or activity? Does your mood affect any of the following:

- your ability to enjoy activities that used to give you pleasure?
- your surroundings?
- your feelings for your family and friends?

**4. Irritability:** (*easily annoyed, short tempered*) Observe whether the patient is easily annoyed and short-tempered during the interview.

*Ask the patient:* Have you felt short-tempered or easily annoyed this past week? Have you been feeling irritable, impatient, or angry this week?

## B. Behavioral Disturbance

**5. Agitation:** (*restlessness, handwringing, hairpulling*): Observe the patient for behaviors such as playing with his/her hands, hair, hand-wringing, hair-pulling, and/or lip-biting.

*Ask the patient:* Have you been fidgety or restless this past week? Have you been unable to sit still for at least an hour? Were you so physically agitated to the point that others noticed it?

**6. Retardation:** (*slow movements, slow speech, slow reactions*) This item should be scored *exclusively on the basis of the raters observations*. Retardation is characterized by:

- slow speech
- delayed response to questions
- decreased motor activity and/or reactions.

**7. Multiple physical complaints:** In the past week, have you had any of the following physical symptoms in excess to what is normal for you:

- indigestion?
- constipation?
- diarrhea?
- stomach cramps?
- belching?
- joint pain?
- backaches?
- muscles aches?
- frequent urination?
- sweating?
- headaches?
- heart palpitations?
- hyperventilation (shortness of breath)?

If **yes** to any of the above: How much have these things been bothering you? How bad have they gotten and how often have they occurred in the past week?

**Rating guideline:** Do not rate symptoms that are side effects from taking medications or those that are only related to gastrointestinal ailments.

**8. Loss of interest:** (less involved in usual activities - score only if change occurred acutely, or in less than one month) How have you been spending your time this pastweek (not including work and chores)? Have you felt interested in what you usuallylike to do? Have you spent any less time engaging in these activities?

If **not** as interested, or has not been engaged in activities during the past week: Have you had to push yourself to do the things you normally enjoy? Have you *stopped* doing anything you used to do? Can you look forward to anything or have you lost interest in many of the hobbies from which you used to derive pleasure?

**Rating guideline:** Ratings of this item should be based on loss of interest during the past week. This item should be rated 0 if the loss of interest is long-standing (longer than 1 month) and there has been no worsening during the past month. This item should be rated 0 if the patient has not been engaged in activities because of physical illness or disability or if the patient has persistent apathy associated with his/her dementia.

## C. Physical Signs

**9. Appetite Loss:** (*eating less than usual*) How has your appetite been this past week compared to normal? Has it decreased at all? Have you felt less hungry or had to remind yourself to eat? Have others had to urge or force you to eat?

*Rate 1 if appetite loss but still eating on his/her own. Rate 2 if eats only with others encouragement or urging.*

**10. Weight Loss:** Have you lost any weight in the past month that you have not been trying to lose? (If not sure: are your clothes any looser on you?) If weight loss is associated with present illness (i.e., not due to diet or exercise): how many pounds have you lost?

*Rating guideline: Rate 2 if weight loss is greater than 5 lbs. in past month.*

**11. Lack of energy:** (*fatigues easily, unable to sustain activities - score only if change occurred acutely, or in less than one month*) Does the patient appear fatigued or drained of energy?

*Ask the patient:* How has your energy been this past week compared to normal?

Have you been tired all the time? Have you needed to take naps because of fatigue?

Have you had any of the following symptoms due to lack of energy only (*not due to physical problems*):

- heaviness in limbs, back, or head?
- felt like you are dragging through the day?

*Rating guideline: Ratings of this item should be based on lack of energy during the week prior to the interview. This item should be rated 0 if the lack of energy is longstanding (longer than 1 month) and there has been no worsening during the past month.*

## D. Cyclic Functions

**12. Diurnal variation of mood:** (*symptoms worse in the morning*) Regarding your mood (feelings and symptoms of depression), is there any part of the day in which you usually feel better or worse? (Or does it not make any difference, or vary according to the day or situation?)

If **yes** to a difference in mood during the day: Is your depression worse in the morning or the evening? If worse in the morning: is this a mild or a very noticeable difference?



**Rating guideline:** *Diurnal variation of mood is only rated for symptoms that are worse in the morning. Variation of mood in the evening can be related to sundowning inpatients with dementia and should not be rated.*

**13. Difficulty falling asleep:** *(later than usual for this individual)* Have you had any trouble falling asleep this past week? Does it take you longer than usual to fall asleep once you get into bed (i.e., more than 30 min)?

**Rating guideline:** *Rate 1 if only the subject had trouble falling asleep a few nights in the past week. Rate 2 if s/he has had difficulty falling asleep every night this past week.*

**14. Multiple awakenings during sleep:** Have you been waking up in the middle of the night this past week more than usual? If **yes:** do you get out of bed? Is this just to go to the bathroom and then you go back to sleep?

**Rating guideline:** *Do not rate if waking is only to go to the bathroom and then is able to fall right back asleep. Rate 1 if sleep has only been restless and disturbed occasionally in the past week, and has not gotten out of bed (besides going to the bathroom). Rate 2 if s/he gets out of bed in the middle of the night (for reasons other than voiding), and/or has been waking up every night in the past week.*

**15. Early morning awakenings:** *(earlier than usual for this individual)* Have you been waking up any earlier this week than you normally do (without an alarm clock or someone waking you up)? If **yes:** how much earlier are you waking up than is normal for you? Do you get out of bed when you wake up early, or do you stay in bed and/or go back to sleep?

**Rating guideline:** *Rate 1 if s/he wakes up on his/her own but then goes back to sleep. Rate 2 if s/he wakes earlier than usual and then gets out of bed for the day (i.e., s/he cannot fall back asleep).*

## **E. Ideational Disturbance**

**16. Suicide:** *(feels life is not worth living, has suicidal wishes, or makes suicide attempt)* During the past week, have you had any thoughts that life is not worth living or that you would be better off dead? Have you had any thoughts of hurting or even killing yourself?

**Rating guideline:** *Rate 1 for passive suicidal ideation (i.e., feels life isn't worth living). Rate 2 for active suicidal wishes, and/or any recent suicide attempts, gestures, or plans. History of suicide attempt in a subject with no passive or active suicidal ideation does not in itself justify a score.*

**17. Self-depreciation:** *(self-blame, poor self-esteem, feelings of failure)* How have you been feeling about yourself this past week? Have you been feeling

especially critical of yourself, feeling that you have done things wrong or let others down? Have you been feeling guilty about anything you have or have not done? Have you been comparing yourself to others, or feeling worthless, or like a failure? Have you felt "no good" or "inferior"?

**Rating guideline:** Rate 1 for loss of self-esteem or self-reproach. Rate 2 for feelings of failure, or statements that s/he is "worthless," "inferior," or "no good."

**18. Pessimism:** (*anticipation of the worst*) Have you felt pessimistic or discouraged about your future this past week? How do you think things will work out for yourself? Can you see your situation improving? Can you be reassured by others that things will be okay or that your situation will improve?

**Rating guideline:** Rate 1 if s/he feels pessimistic, but can be reassured by self or others. Rate 2 if feels hopeless and cannot be reassured that his/her future will be okay.

**19. Mood congruent delusions:** (*delusions of poverty, illness, or loss*) Have you been seeing or hearing things that others do not see or hear? Has your imagination been playing tricks on you in any way, or have you been having ideas that others may not understand? Do you think that your present illness is a punishment, or that you have brought it on yourself in some way? Do you think you have a lot less money or material possessions than others say that you have?

Protocol source: <https://www.phenxtoolkit.org/protocols/view/121703>