



## 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.

### Screener and Baseline questions

1. Are you currently in a stable relationship with a male partner?

1  YES

2  NO (END OF SCREENER)

2. Are you currently pregnant?

1  YES (END OF SCREENER)

2  NO

99  Don't know

3. Are you or your male partner currently using any form of birth control or protection against pregnancy?

1  YES (Go to 5a)

2  NO

4. Please give the approximate date when you stopped using all forms of birth control or protection against pregnancy:

Month [Jan to Dec] (drop-down menu)

Year [2010 to 2013] (drop-down menu)

5. Are you currently trying to get pregnant?

1  YES

2  NO (Go to 5a)

5a. When do you think you will start trying to become pregnant? (We will send you

an invitation later to participate)

About 1-2 months from now (END OF SCREENER)

About 3-4 months from now (END OF SCREENER)

About 5-6 months from now (END OF SCREENER)

5b. What is your e-mail address? \_\_\_\_\_

6. For how many months have you been trying to get pregnant?

|\_\_|\_\_| MONTHS

[If you have experienced a miscarriage before your current attempt to get pregnant, please state the number of months you have been trying since the miscarriage.]

7. Are you currently using any fertility treatments (e.g., clomiphene citrate [clomid]), gonadotropins, donor insemination) or assisted reproductive technologies (e.g., in vitro fertilization)?

1  YES (END OF SCREENER)

2  NO (go to next section)

If respondent answers “NO (2)” to questions 1, or 5, “YES” to 2, 3 or 7, or is outside required age range, please write: “thank you for your interest-we are sorry, but you are not eligible for the present study at this time.” If 5a is completed, please write: “thank you for your interest-we will contact you in the near future and invite you to participate in our study.”

### Baseline and Follow-up Questions

The next several questions are about your menstrual periods.

B1. Are you having your menstrual period right now?

1  YES

2  NO(GO TO B3)

B2. What was the date it started?

Month [Jan to Dec] (drop-down menu)

Day [1 to 31] (drop-down menu)

Year [options: 2012, 2013, 2014] (drop-down menu) (GO TO B4)

[The first day of bleeding, not just spotting. If your period began yesterday or today, please provide yesterday or today's date.]

**DO NOT ALLOW FUTURE DATES. IF THEY GIVE A FUTURE DATE DO NOT LET WOMEN PROCEED WITH QUESTIONNAIRE.**

B3. What was the date your last menstrual period started? (Please estimate exact date as best as you can) [The first day of bleeding, not just spotting.]

Month [Jan to Dec] (drop-down menu)

Day [1 to 31] (drop-down menu)

Year [2011, 2012, 2013, 2014-allow up to current year] (drop-down menu)

**DO NOT ALLOW FUTURE DATES. IF THEY GIVE A FUTURE DATE DO NOT LET WOMEN PROCEED WITH QUESTIONNAIRE.**

B4. How long do you expect it will be before you get your next period unless you become pregnant?

1  Less than 7 days

2  7-14 days

3  15-21 days

4  More than 21 days

B5. How many times have you had your menstrual period since you stopped using birth control or protection against pregnancy?

|\_\_|\_\_|

# times

99  Don't Know

[Please only count the periods when you were actively trying to get pregnant. In addition, if you have experienced a miscarriage before your current attempt to get pregnant, please state the number of periods you have had since the miscarriage (subtracting off the periods when you weren't trying).]

B6. At what age did you have your first menstrual period?

\_\_ \_\_ (drop-down menu: range from 8 to 18)

AGE

B7. Did your period become regular on its own without the use of hormonal contraceptives like the pill, patch, implants, or injectables (regular in a way so you can usually predict about when the next period will start)?

1  YES

2  NO (GO TO B12)

3  CANNOT SAY BECAUSE I WAS TAKING HORMONES MOST OF THE TIME(GO TO B10)

B8. How old were you when your menstrual periods became regular?

|\_\_|\_\_| (drop-down: 8-21; GO TO B12)

AGE

99  Don't know (GO TO B12)

90  Never became regular (GO TO B12)

*B9 omitted.*

B10. What is the main reason you started using hormonal contraceptives? (Check all that apply)

1  To regulate my menstrual periods

2  To prevent pregnancy

3  To reduce menstrual pain

4  To treat acne

5  Other- What other reason?\_\_\_\_\_

*B11 omitted.*

B12. Within the past couple of years, has your menstrual period been regular? Please think about those times you were not using hormonal contraceptives?

1  YES (GO TO B14)

2  NO (GO TO B13)

3  CANNOT SAY BECAUSE I WAS TAKING HORMONES MOST

OF THE TIME (GO TO B14)

[regular in a way that you could usually predict about when the next period would start]

B13. What were the main reasons that your periods were irregular during this time?  
(Check all that apply.)

I was not ovulating (GO TO B15) PCOS/Polycystic Ovary Syndrome (GO TO B15)

Hormonal abnormality (GO TO B15)

Stress (GO TO B15)

Exercise/Diet/Weight-related (GO TO B15)

Pregnancy/Breastfeeding (GO TO B15)

Other

Please Specify: \_\_\_\_\_ (GO TO B15)

Don't Know (GO TO B15)

B14. Thinking about the time(s) when you have not used hormonal contraceptives, what is your typical menstrual cycle length? That is, the number of days from the **first day** of one menstrual period to the **first day** of your next menstrual period?

# DAYS \_\_\_\_ (GO TO B15)

99  Don't Know (GO TO B15)

[If you have a range of days, please pick midpoint of range. For example, if your cycle ranges from 26-28 days, the midpoint would be 27 days.]

[If the number entered is less than 22 or above 40, the following will pop up:

“Information on menstrual cycle length is very important for the accuracy of this study. Please double check that you have entered your information correctly.”]

B15. About how many menstrual periods do you have in one year (12 months)?

|\_\_|\_\_|

# PERIODS

99  DON'T KNOW

B16. How many days does your menstrual period usually flow (bleeding, not spotting)?

1  Less than 3 days

2  3 days

3  4 days

4  5 days

5  6 days

6  7 or more days

B17. How would you classify the total amount of your menstrual flow?

1  Light (10 or fewer pads or tampons per period)

2  Moderate (11 to 20 pads or tampons per period)

3  Moderate/heavy (21-30 pads or tampons per period)

4  Heavy (more than 30 pads or tampons per period)

B18. Do you usually experience pain during your menstrual period? Please focus on the times when you were not using hormonal contraceptives.

1  YES

2  NO (GO TO END)

B19. How much pain do you usually have with your menstrual period?

1  Mild cramps, with medication seldom needed

2  Moderate cramps, with medication usually needed

3  Severe cramps, with medications and bed rest required

### How to Calculate Time to Pregnancy

Time-to-pregnancy (TTP) was estimated by using data from the questionnaires completed by females (screening, baseline, and follow-up). Women reported their pregnancy attempt time (in months and in menstrual cycles) at baseline. Women who reported regular menstrual cycles (defined as being able to “usually predict about when the next period will start”) were asked to report their usual menstrual cycle length. For women with irregular cycles, estimated cycle length was based on date of LMP at baseline and on prospectively-reported LMP dates during follow-up. TTP estimates were in cycles, using the following formula: [(menstrual cycles of attempt time at baseline) + [(LMP date from most recent follow-up questionnaire - date of baseline questionnaire)/cycle length] + 1].

Protocol source: <https://www.phenxtoolkit.org/protocols/view/100403>