1. Have you ever given birth or fathered a child? (Include current pregnancy and any pregnancies that resulted in early pregnancy loss, whether by choice or not)

[ ]  Yes (Please go to question 2)

[ ]  No (Women, please go to Menstruation/Pregnancy section below)

[ ]  Unknown (Stop, you are finished)

1. Please describe the outcome of each pregnancy, of yourself or your partner, starting with the most recent.

Table for Recording Pregnancy Data

| # | Pregnancy Outcome | Date(mm/yyyy) |
| --- | --- | --- |
| 1 | [ ]  Currently pregnant[ ]  Live birth[ ]  Miscarriage[ ]  Therapeutic abortion or elective termination[ ]  Still birth | /  |
| Data to be entered by site | [ ]  Currently pregnant[ ]  Live birth[ ]  Miscarriage[ ]  Therapeutic abortion or elective termination[ ]  Still birth | / |
| Data to be entered by site | [ ]  Currently pregnant[ ]  Live birth[ ]  Miscarriage[ ]  Therapeutic abortion or elective termination[ ]  Still birth | / |
| Data to be entered by site | Other comments and outcomes (such as twins, use of fertility drugs or in vitro fertilization, etc.): | Data to be entered by site |

Please answer the following questions regarding your hormonal cycles (women only, men are finished):

## Menstruation/Pregnancy

1. Are you of child-bearing potential? [ ]  Yes [ ]  No [ ]  Unknown
2. Have you ever had a menstrual period? [ ]  Yes [ ] No (If No, you are finished)

If Yes, what age was your first period?

1. Do you use any forms of contraception (periods may be regular or irregular)?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, indicate all forms of contraception used (choose all that apply):

**[ ]**  Oral contraceptives – combined pill (“the pill”)

**[ ]**  Oral contraceptives – progestin-only pill (“Minipill”)

**[ ]**  Transdermal patch (i.e., Ortho Evra)

**[ ]**  Shot/injection (i.e., Depo-Provera)

**[ ]**  Vaginal ring (i.e., NuvaRing)

**[ ]** Implantable devices with hormone (i.e., ParaGuard, Mirena)

**[ ]** Abstinence

**[ ]** None of these

1. Are you currently pregnant? [ ]  Yes [ ]  No [ ]  Unknown

If Yes, indicate your due date: // mm/dd/yyyy

## Menopause

1. Do you believe you are currently experiencing menopause? [ ]  Yes [ ]  No
	1. If Yes, indicate the approximate date of your last menstrual period: // mm/dd/yyyy
	2. Have you taken hormonal therapy? [ ]  Yes [ ]  No
		1. If Yes, specify name of hormonal therapy taken:
		2. If Yes, indicate which years you started and stopped hormonal therapy:

Date Started: // mm/dd/yyyy Date Stopped: // mm/dd/yyyy

## Post-menopause

1. Are you post-menopausal? [ ]  Yes [ ]  No [ ]  Unknown

If Yes, indicate cause:

[ ]  Natural

[ ]  Surgical (complete hysterectomy – ovaries and uterus removed), date: // mm/dd/yyyy

[ ]  Surgical (partial hysterectomy – only uterus removed), date: // mm/dd/yyyy

[ ]  Medications or chemotherapy

## Other hormone-related syndromes

1. Any other known hormone-related/endocrine syndromes or disorders?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, specify:

[ ]  Polycystic ovary syndrome

[ ]  Hyperthyroidism

[ ]  Cushing’s syndrome

[ ]  Other, specify

## General Instructions

This form contains data elements that are collected to describe the fertility and hormonal status of participants. Fertility is relevant to drug toxicity and may be a long-term outcome measure of the intrusiveness of MS. Long term studies are most likely to include these measures.

Other elements are to categorize female hormonal status as this may impact efficacy and safety outcomes.

Responses are obtained from self-report when possible or obtained from parent/legal guardian interview.

All elements on this CRF are classified as Supplemental and should be collected if the research team considers them appropriate for their study.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Have you ever given birth or fathered a child? Choose yes or no (Include current pregnancy and any pregnancies that resulted in early pregnancy loss, whether by choice or not)
* Please describethe outcomeof each pregnancy, of yourself or your partner, starting with the most recent. Complete the table for each known pregnancy.
* Have you ever had a menstrual period? Women only, Choose yes or no. If No is selected, form is complete.
* What age was your first period? Indicate age
* Do you use any forms of contraception (periods may be regular or irregular)? Choose all that apply
* Are you currently pregnant? Women only. Choose yes or no. If yes indicate due date.
* Do you believe you are currently experiencing menopause? Choose yes, no or unknown. If yes, indicate the approximate date of the participants last menstrual period and if yes indicate if the participant has taken hormonal therapy. If yes indicate start and stop dates.
* Are you post-menopausal? Choose yes, no or unknown. If yes, indicate the reason. If surgical provide date of surgery.
* Any other known hormone-related/endocrine syndromes or disorders? Choose yes, no or unknown. If yes, specify type.