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 the next question)

No (Women, please go to question 3)

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 | Live birth  Miscarriage  Therapeutic abortion or elective termination  Still birth | / |
| Data to be entered by site | 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)
   1. If Yes, what age was your first period?
3. Do you use any forms of contraception (periods may be regular or irregular)?

Yes  No  Unknown

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

Oral contraceptives – combined pill (“the pill”)

Oral contraceptives – progestin-only pill (“mini-pill”)

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
   1. If Yes, indicate your due date: // m m/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: // m m/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: // m m/dd/yyyy Date Stopped: // m m/dd/yyyy

## Post-menopause

1. Are you post-menopausal? Yes  No  Unknown
   1. If Yes, indicate cause:

Natural

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

Surgical (partial hysterectomy – only uterus removed), date: // m m/dd/yyyy

Medications or chemotherapy

## Hypoglycemia

1. Has there ever been clinical concern for hypoglycemia?
   1. If Yes, specify all the apply:

Fasting

Post-prandial

Laboratory blood glucose < 50 mg/dL

Symptomatic? If so, specify:

Symptoms improved after feeding

## Bone Health

1. Have there ever been bone fractures?  Yes  No  Unknown
   1. If Yes, specify:
2. Have you ever been diagnosed with any condition or abnormality of the spine or skeleton?  Yes  No  Unknown
   1. If Yes, specify:
3. Has a DXA scan ever been performed?  Yes  No  Unknown
   1. If Yes, specify indication and results:
4. Have you ever been told that you had rickets or ever taken high dose vitamin D (>= 20,000 IU daily, or >= 50,000 IU weekly)?  Yes  No  Unknown
5. For adults between the ages of 40 – 90, World Health Organization (WHO) Fracture Risk Assessment tool (FRAX) score:

## Short Stature/Growth Hormone Deficiency

1. Have you ever been diagnosed with short stature?

Yes  No  Unknown

1. Have you ever been diagnosed with growth hormone deficiency?

Yes  No  Unknown

* 1. If Yes, did you receive growth hormone?  Yes  No  Unknown

## Other Endo

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

Yes  No  Unknown

* 1. If Yes, indicate all that apply:

Polycystic ovary syndrome: Age at diagnosis:

Constitutional delay of growth and puberty: Age at diagnosis:

Hypogonadotropic hypogonadism: Age at diagnosis:

Hyperthyroidism: Age at diagnosis:

Hypothyroidism: Age at diagnosis:

Cushing’s syndrome: Age at diagnosis:

Hypoparathyroidism: Age at diagnosis:

Adrenal insufficiency: Age at diagnosis:

Dyslipidemia: Age at diagnosis:

Exocrine pancreatic insufficiency: Age at diagnosis:

Diabetes (see separate diabetes-specific CRF) : Age at diagnosis:

Other, specify: Age at diagnosis:

## General Instructions

This form contains data elements that are collected to describe the fertility and hormonal status of participants.

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.

## 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.
* Hypoglycemia questions are intended as a screen; more detailed questions may be necessary for study-specific purposes.
* For bone health evaluation, in particular, for collection and reporting of densitometry in pediatrics and adults, please see detailed guidelines at: [International Society for Clinical Densitometry](http://www.iscd.org/).
* WHO Fracture Risk Assessment Tool can be accessed at: [FRAX Tool](http://www.shef.ac.uk/FRAX)
* Any other known hormone-related/endocrine syndromes or disorders? Choose yes, no or unknown. If yes, specify type.

## References:

Zemel BS, Kalkwarf HJ, Gilsanz V, Lappe JM, Oberfield S, Shepherd JA, Frederick MM, Huang X, Lu M, Mahboubi S, Hangartner T, Winer KK. Revised reference curves for bone mineral content and areal bone mineral density according to age and sex for black and non-black children: results of the bone mineral density in childhood study. J Clin Endocrinol Metab. 2011 Oct;96(10):3160-9.