**Reproductive/hormonal status:**

Females only:

## Have you ever had a menstrual period? Yes No

1. If no, section is complete. Do not proceed to further questions.
2. Are you currently on, or have you been on within the past year, sex hormone-related therapy? (Includes, but not limited to, hormonal contraceptives, including hormone-releasing contraceptive devices; hormone replacement therapy, eg, estrogens, progestins; testosterone): Yes No

If yes, please list for each medication or hormone-releasing device:

|  |  |  |  |
| --- | --- | --- | --- |
| Medication/device name | Dose/frequency (if applicable) | Start date | End date (if stopped) |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site |

**Pregnancy Status**

1. Pregnant? Yes No Unsure
2. If yes, estimated due date: mm/dd/yyyy
3. If no, pregnant within past year? Yes No  Unknown

**Nursing Status**

1. Nursing? Yes No
2. Menstrual periods: Regular Irregular Not applicable
3. Do you believe you are currently experiencing menopause (perimenopausal)? Yes No Unsure
4. If Yes, indicate the approximate date of your last menstrual period: // m m/dd/yyyy
5. Are you post-menopausal? Yes No Unknown
   1. If Yes, indicate cause:

Natural

Surgical (both ovaries removed – eg, during total hysterectomy), date last ovary removed: // mm/dd/yyyy

Medications or chemotherapy

Male only:

History of low testosterone: Yes No

**General Endocrine History**

1. Polycystic ovary syndrome: Yes No Unknown
   1. If yes, age at diagnosis:
2. Hyperthyroidism: Yes No Unknown
   1. If yes, age at diagnosis:
3. Hypothyroidism: Yes No Unknown
   1. If yes, age at diagnosis:
4. Cushing’s syndrome: Yes No Unknown
   1. If yes, age at diagnosis:
5. Adrenal insufficiency: Yes No Unknown
   1. If yes, age at diagnosis:
6. Diabetes Mellitus: Yes No Unknown
   1. If yes, age at diagnosis:
   2. Type: 1 2 Unknown Other, specify:
7. Diabetes Insipidus: Yes No Unknown
   1. If yes, age at diagnosis:
   2. Type: Central Nephrogenic Other, specify:

## GENERAL INSTRUCTIONS

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

The female/reproductive section, or questions from this section, may be used if the study is looking at measures that are looking at outcomes that are potentially impacted by hormonal status, or if safety (eg, due to pregnancy, nursing) could be an issue.

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.