**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.