COG-ALTE16C1: Effects of Modern Chemotherapy Regimens on Spermatogenesis and Steroidogenesis in Adolescent and Young Adult (AYA) Survivors of Osteosarcoma

**FAST FACTS**
Eligibility Reviewed and Verified By

______________________ MD/DO/RN/LPN/CRA Date 

______________________ MD/DO/RN/LPN/CRA Date 

Consent Version Dated___________

**PATIENT ELIGIBILITY:**

**Important note:** The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient's medical research record which will serve as the source document for verification at the time of audit.

1. Gender
   - Male

2. Age
   - Patients must be ≥ 18 and ≤ 50 years of age at the time of enrollment

3. Previous Treatment
   - Received upfront therapies for Osteosarcoma, which included cisplatin (with or without other agents).

4. Timing from Cancer Treatment to Study Entry
   - Patient must have completed cancer treatment ≥ 2 years prior to study enrollment.

5. Diagnosis
   - Osteosarcoma survivors without a systemically treated relapse or subsequent malignancy.
   - Note: history of relapse or second malignancy is permitted if treated with local therapy only (e.g. surgery, radiation).

6. Language
   - Able to speak, read and write in English, French or Spanish.

**TREATMENT PLAN:**

COG Sites review medical records to identify osteosarcoma survivors, confirm patient eligibility and then proceed with patient approach (by mail or in clinic). For patients consented to Future Contact through ACCRN07 or APEC14B1, Sites may request support with patient approach from the Data Coordinating Center (DCC). Once consented, patients are enrolled by the Site via CTSU OPEN and initial enrollment forms and documents transmitted to the DCC. After initial enrollment steps are completed, the DCC is responsible for working with study participants to facilitate completion of the Men’s Health Questionnaire and semen, blood, and saliva specimen collection processes.
EXPERIMENTAL DESIGN SCHEMA
Shaded boxes are the responsibility of the Coordinating Center. CIRB-approved templates of forms and letters are provided on the study website.

**COG Site IRB Approval of ALTE16C1**

**COG Site Review Local Osteosarcoma Cases to Identify Potentially Eligible Patients:**
- Check patient treatment histories to identify patients meeting eligibility criteria (Section 3.2).
- Check patient contact information to determine whether tracing may be needed.

**Eligible**
Contact information appears current and complete

- **Refused COG Site:** Mail recruitment packet to patient
  (Recommended: Mail “Return Service Requested”)
  - Cover letter
  - Participation Form
  - Consent forms
  - Postage-paid reply envelope

- **Not eligible COG Site:** Notify patient by mailed letter

- **In-Clinic Patient Approach is Also Permitted**

- **Eligible & Signed Consent**
  Participation Form returned

**COG Site:** Enroll patient on CTSU OPEN within 2 weeks
Send copy of signed Consent and Participation Form to the DCC.

**COG Site Submit MRAF to the DCC**
preferably within 2 weeks of enrollment.

**Coordinating Center:**
- Mails/Receives: Participant Questionnaire; Semen and Saliva Kits
- Coordinates Residential (or COG Site if necessary) Blood Draw
- Provides Results of Analyses and Compensation to Participants.

**Strongly Recommended:**
IRB approval of ALTE05N1 to facilitate COG patient tracking

**Eligible**
But, contact information not complete or not current

**Returned to Sender**
Mailing Address Not Current

**Delay in response**
Proceed with mail, phone, in-clinic approach
(# of calls is per local IRB rules)

**COG Site:** Initiate Tracing via COG ALTE05N1
(See Section 3.1.2)

**REMINDER:** For patients consented to Future Contact through ACCRN07 or APEC14B1,
Sites may request DCC support with patient approach (see Section 4.2.3).