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.

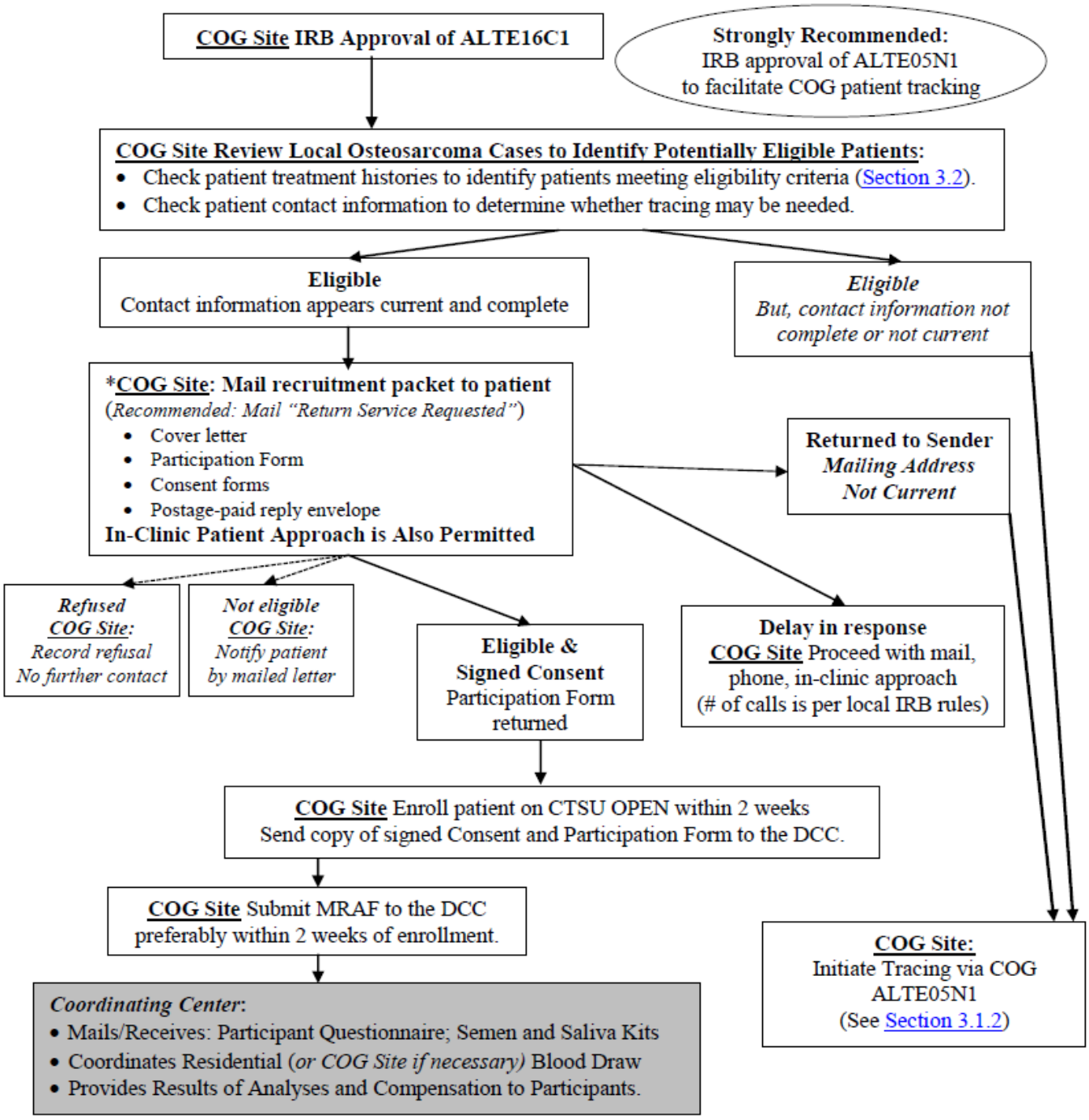
___5. Diagnosis
Osteosarcoma survivors without a systemically treated relapse or subsequent malignancy.
Note: *history of relapse or second malignancy is permitted if treated with local therapy only (e.g. surgery, radiation).*

___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.



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