SWOG CANCER RESEARCH NETWORK

April 1, 2022

TO: ALL NATIONAL CLINICAL TRIALS NETWORK MEMBERS; CTSU

FROM: SWOG Quality Assurance Department (E-mail: qamail@swog.org)

RE: Best Practices for SWOG Studies

MEMORANDUM – Updated Best Practices for SWOG Studies

The purpose of this memorandum is to inform sites that the Best Practices for SWOG Studies has been updated. The following is a summary of the changes:

Eligibility affirmation

- Revised to allow electronic signature
- Revised to allow an APP to sign when serving as the registering investigator

Specimen submission

- Updated the shipping requirements

Data submission

- Added rationale for continuing to submit data for ineligible patients

Documentation requirements

- Updated with source documentation requirements
- Added menstrual, sexual and contraceptive use history to required documentation for the History and Physical

Withdrawal of consent

- Provided clarification that information from the local EMR may be used to report follow-up status for patients lost to follow-up if no formal withdrawal of consent has occurred.
- Clarified that data collected on a subject prior to the point of withdrawal remains part of the study database and is subject to audit or FDA inspection.

The updated Best Practices document along with other Quality Assurance resources can be found under the Clinical Trials section of the SWOG website (in the Additional Resources section on the Quality Assurance & Audits page). For comments or questions, please contact the Quality Assurance Manager at the SWOG Operations Office at (210) 614-8808 or qamail@swog.org.