The following is a brief description of the content of each section contained in a SWOG protocol *with special notes in red text regarding NCORP Studies.*

Title page

Lists the study number and title, the current version date, the NCT number, the agent(s) *or intervention(s)* used in the study and their commercial vs investigational status, the study chairs(s), and statistician(s). In addition, if it is a registration study, this would also be listed here. *For some NCORP studies, there may be a clinical nurse coordinator listed who serves as a trainer and contact for study-specific procedures.*

Participants

Provides information on which Network Groups or institutions can participate in the study. *Pay special attention to this section as some NCORP studies may only be open to limited institutions and only institutions that are listed are allowed enrollment of patients.*

Protocol Contact Information

Provides contact information for questions about eligibility, data submission, specimens, medical queries, CTEP-IAM, OPEN, patient transfers, SAEs, and the CTSU Helpdesk. *For NCORP studies, contact cancercontrolquestion@crab.org for eligibility and data submission questions or if unsure who to contact.*

Schema

Provides a diagrammatic overview of a protocol from registration to the end of the protocol treatment.

1.0 Objectives

States the study purpose, a brief outline of the i*ntervention* under evaluation and the endpoints of interest (survival, response, time to progression, *adherence, adverse events, symptoms,* etc.)

2.0 Background

Supplies justification for conducting the study and cites results of similar studies or pilot data. This section provides a detailed explanation of why it is felt that this approach is potentially better than the current standard of care.

3.0 Drug Information

Describes the drugs used in the study, their known toxicities, storage requirements, drug stability, administration, and supply information. CAEPR table with exceptions to SAE reporting (SPEER). *For NCORP trials, if applicable, may state "drug information is not applicable to this study" if study does not have a drug intervention, or may state that therapy/effects being studied is at the discretion of investigator. Some NCORP trials may list investigational device information in this section.*

4.0 Staging Criteria

When required, this section details staging criteria used in the study. Diagnostic criteria may also be included in this section, as appropriate.

5.0 Eligibility Criteria

Outlines participant and disease characteristics required or excluded for participation in the study. There are **NO WAIVERS** to these criteria. *As a reminder, it is important to confirm all criteria and timing are still met on the day of registration as NCORP studies may have particular timing and eligibility requirements. All participants registered are followed per protocol criteria regardless if the participant met eligibility criteria.*

6.0 Stratification Factors

Stratification factors are *pre-intervention* participant characteristics which are balanced across *intervention* arms. These factors must be documented PRIOR to randomization.

7.0 Treatment Plan

Provides a description of the *intervention* or study plan, including precautions, prohibited medications, pre-medications, dose, schedules, number of cycles, study specific procedures for disease *or study* assessment, and reasons for discontinuing *study intervention*. Pre-medication and supportive care are also included, as appropriate. *For NCORP studies, the section title may vary to adapt to the specific trial. It is important to thoroughly review this section prior to registration as some trials may require procedures or evaluations to be done in a certain order prior to registration, and during and after intervention. This section may also list the allowable standard of care therapies that are allowed and details or references to instructions for special evaluations or procedures. Follow-up length and details are also included in this section.*

8.0 Toxicities Monitored & Dosage Modifications

Lists the anticipated toxicities and guidelines for dosage adjustment and serious adverse event reporting requirements, including additional events to be reported that fall outside of the reporting requirement tables *when applicable to the study.*

9.0 Study Calendar

General snapshot of study requirements for all tests, procedures, and *intervention* administration required while the participant is on study. *For NCORP studies (and for some therapeutic studies), patient reported outcomes forms and required timepoints are also listed. It is important to refer to the appropriate protocol sections referenced in the calendar for complete study details.*

10.0 Criteria for Evaluation & Endpoint Definitions

Provides instructions for measuring disease response *or intervention*, participant performance status, and study endpoints.

11.0 Statistical Considerations

Reiterates the study objectives, defines accrual goals and describes the study design used to address the objectives of the study. Guidelines for early closure and data and safety monitoring will also be outlined.

12.0 Discipline Review

Includes information regarding pathology, radiation therapy, imaging or surgery review requirements and, when required, includes details regarding submission of materials.

13.0 Registration Guidelines

Provides detailed *participant/*patient registration instructions including when and how to register, how many registration steps are required for the study, registration policies, the requirement for the Registration Worksheet to be completed. *For NCORP studies, there may be protocol-specific requirements (PSR) for sites to complete before the first participant from the site may be registered to the trial (requirements such as site application for trial participation or trial-specific training).*

14.0 Data Submission Schedule

Provides a detailed schedule for all required data submission, and how to submit them. Generally, source documentation is uploaded in RAVE and radiology scan images are submitted to TRIAD. *For NCORP studies, special requirements for data submission will be described in this section. A link to the Oncology Research Professional (ORP) Manual is often found in this protocol section as an additional resource. Contact cancercontrolquestion@crab.org with any questions.*

15.0 Special Instructions

Outlines other aspects of protocol participation, including special instructions or protocol specific training, specimen shipping or handling procedures or other materials, if applicable. *Note that instructions and training for administration of participant questionnaires are in this section.*

16.0 Ethical and Regulatory

Describes ethical and regulatory issues for the study. Informed consent, IRB, and drug accounting information are presented.

17.0 Bibliography

Lists references used in the protocol.

18.0 Appendices

Contains all appendices referenced in the text. Examples of Appendices:

- Instructions for the SWOG Biospecimen Bank
- Participant Diaries
- Quality Assurance Audit/Monitoring plans
- New York Heart Association Criteria
- Drug Interaction Examples
- Live Vaccine Examples
- Participant Drug Information Handout and Wallet Card
- Algorithms for Immune Related Reactions
- *Descriptions of PRO instruments and scoring*
- *Telephone recruitment or consent scripts*
- *Remote consent procedures*
- *Study flow charts*
- *SWOG study amendments/memos/revision notifications*

Additional NCORP Study-Specific Protocol Reminders:

1. *For NCORP CCDR Studies such as S1912CD and S2108CD, the NCORP Practice Survey of Site-Level Attributes Survey must be submit to CTSU before being allowed to register participants in OPEN.*

2. *Be familiar with special data submission instructions listed in Protocol Section 14. For example, S1501 requires ECHOS to be submitted using AG Mednet and not TRIAD.*

3. *The following study-specific appendices can be found in Protocol Section 18*
   - *S1912CD Staff Talking Points and Video Link information*
   - *S2010 Symptom Management Recommendations*
   - *S2013 Medidata patient cloud ePRO information and Site checklist for activities prior to consenting a participant to the study*
   - *S2108CD Physician Interview Guide script and the Genomic Tumor Board standing operating procedures*

4. *Email cancercontrolquestion@crab.org with data submission or eligibility criteria questions for the following SWOG NCORP studies. Include the SWOG Study ID # and SWOG Participant/Subject ID in the email subject line. Be sure no PHI is included in email communication.*
   - *S0820*
   - *S1204*
   - *S1316*
   - *S1501*
   - *S1600*
   - *S1614*
   - *S1703*
   - *S1714*
   - *S1820*
   - *S1823*
   - *S1904*
   - *S1912CD*
   - *S2010*
   - *S2013*
   - *S2108CD*
   - *S2205*

   These studies are in the five SWOG NCORP Committees:
   - *Cancer Survivorship*
   - *Cancer Care Delivery Research*
   - *Palliative and End of Life Care*
   - *Prevention & Epidemiology*
   - *Symptom Control and Quality of Life.*