Protocol Title:	**Activation Date:** **Protocol Version:** **National Accrual:** **NCT Number:** **Cancer Type for CRCWM website:**

SCHEMA

STUDY OVERVIEW

CRCWM RN REVIEWER COMMENTS

FEASIBILITY REVIEW
DATE:

CLINICAL/TREATMENT		
• Physician interest	☐ Yes ☐ No	
• Eligibility issues	☐ Yes ☐ No	
• Unique pre-study requirements	☐ Yes ☐ No	
• Non-routine tests	☐ Yes ☐ No	
• AE/dose mod issues	☐ Yes ☐ No	
• Treatment concerns	☐ Yes ☐ No	

Insert Summary from CTSU

REGULATORY		
• FDA Registration study	☐ Yes ☐ No	
• Pre-study central review/testing	☐ Yes ☐ No	
• More than 1 consent (e.g., screening)	☐ Yes ☐ No	
• Reproductive language restrictions	☐ Yes ☐ No	
• DCP eligible	☐ Yes ☐ No	
• MD/RN/CRA protocol training	☐ Yes ☐ No	
•	☐ Yes ☐ No	

CIRB PATIENT MATERIALS • Recruitment materials • Educational materials • Wallet card • QOLs/Surveys	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
RADIATION • Radiation IROC credentialing • Dosimetry data submission via TRIAD	 ☐ Yes ☐ No ☐ Yes ☐ No	
RADIOLOLGY • Radiology credentialing • RECIST/other tumor response • Imaging transfer via TRIAD	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
PATHOLOGY	☐ Yes ☐ No	
PHARMACY • Provided drugs • Drug order/prep/distribution issues • Medication diaries • **Study drug supplier**	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	Sponsor: PMB ☐ McKesson☐ Other - _____ ☐
Conflict of Interest (COI)	☐ Yes ☐ No	Physician(s):
FINANCE • Sponsor funded labs/procedures • Non-billable labs/procedures • Funding for non-billable items	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
Qualified clinical trial (Medicaid Attestation form) ☐ Yes ☐ No RSH EPIC linking ☐Yes ☐No **FUNDING in OPEN** *Insert from CTSU*		
SPECIMENS	☐ Yes ☐ No	

• Biospecimens (i.e. tissue, blood, urine, bone marrow, stool) • Kits provided • Study manual/equipment/training • Shipping information • Tracking system	☐ Yes ☐ No ☐ Yes ☐ No	
ADVANCE TO CAC ☐ Yes ☐ No **RARE/JUST IN TIME** ☐ Yes ☐ No		

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
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This guide was developed in collaboration with the SWOG ORP Liaison Committee and the SWOG Protocol Coordinators Operations Office. The purpose of the guide is to facilitate a thorough review of a NCI NCTN Group Clinical Trial for the following purposes; determining site feasibility, protocol implementation planning and a study aide for research staff training. Each section is organized to follow the process for learning and planning the implementation of the trial at your site. You may need to update the specific study guide as new amendments are generated.

Suggested documents to include during the clinical trial review: Study protocol. Consent, Funding memorandum, National coverage analysis, Local Coverage Analysis, Data collection forms and other trial related documents as needed.

To ensure accurate and current information, update this form with new protocol amendments as needed and include the specific section or page of the protocol for a quick reference.

<table>
<tr><td colspan="4">This Section may be completed in collaboration with a business administrator.</td></tr>
<tr><td colspan="2">Intervention / Therapeutic ☐</td><td colspan="2">Non-Interventional ☐ NCT#: Click or tap here to enter text.</td></tr>
<tr><td colspan="2" rowspan="2">NCI Anticipated Accrual: Click or tap here to enter text.</td><td colspan="2">NCTN Group credit assignment(s): 1 group or split between the following:</td></tr>
<tr><td colspan="2">☐ SWOG ☐ Alliance ☐ NRG ☐ ECOG ☐ CCTG</td></tr>
<tr><td colspan="2">Site Reimbursement Considerations:</td><td colspan="2">Base Award: Click or tap here to enter text.
Credits: Click or tap here to enter text.
See attached funding memo for specific reimbursement</td></tr>
<tr><td colspan="4">Participating Site(s): Click or tap here to enter text.</td></tr>
<tr><td>National CA Available?</td><td>☐ Yes
☐ No</td><td colspan="2">Are there any special billing or contractual considerations?
Local CA considerations: Click or tap here to enter text.
Patient billing contact: Click or tap here to enter text.
* Patient Billing Considerations: Is your local CA consistent with the National CA and do you need any further institutional approvals for non- funded clinical services?</td></tr>
<tr><td>Is this an FDA Registration Trial?</td><td>☐ Yes
☐ No</td><td colspan="2">What is the monitoring plan? Click or tap here to enter text.</td></tr>
<tr><td colspan="2">Are there additional regulatory requirements?
Consider additional resources and /or training to comply with any additional regulatory requirements.
(i.e., Master Trial File) ☐ Yes ☐ No</td><td colspan="2">Click or tap here to enter text.</td></tr>
<tr><td colspan="4">Study Objectives
Objectives and rationale provide a framework for the rest of the review and insight into trial compliance requirements. Include or reference the protocol section for this section. Provide a clear statement of study objectives with specific reference to all study modalities and type of data needed to correlate with objectives (i.e., survival, disease response, disease-free interval).</td></tr>
<tr><td colspan="4">Primary:</td></tr>
</table>

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

Click or tap here to enter text.

Secondary:

Click or tap here to enter text.

Additional:

Click or tap here to enter text.

Background

Provide rationale for doing the study. Should include history of toxicities from previous studies to allow some assessment of expected toxicities and severity. This will provide a reference point for development of study parameters, case report forms and eligibility. (For protocol development reviewer: Are the references applicable for the patient population?)

Notes:

Click or tap here to enter text.

Non-Treatment Studies: Schema and/or Plan (*ONLY complete this section for non-therapeutic/cancer control trials*).

Protocol Section: Click here to enter text.

Include the protocol sections/ pages where you found the information for future reference.

Guide Questions	Review	Site Implementation Plan / Considerations
How will patients be identified and screened for this study?	Click or tap here to enter text.	Click or tap here to enter text.
What if any departments need to be involved in conducting the trial?	Click or tap here to enter text.	Click or tap here to enter text.
Are there any supplies or equipment provided for this study?	Click or tap here to enter text.	Click or tap here to enter text.
Required training?	Click or tap here to enter text.	Click or tap here to enter text.

Study Participant Selection (eligibility, staging, stratification) **Protocol Section:** Click here to enter text.

A great quick reference section for information including staging, related references and time frames. What are the histological classifications and staging?

Click or tap here to enter text.

Are there any compatible trials for this patient population that are appropriate for co-enrolling? *Consider any studies which the patients could co-enroll and if there are any potential related issues.* **If yes, list protocol number:** Click or tap here to enter text.	☐ Yes ☐ No

Treatment Plan and Schedule of Events (study calendar) **Protocol Section:** Click here to enter text.

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

May want to append a copy of the schedule of events. While reviewing this section consider collaborating with the treatment staff, clinical manager or pharmacy. Assess the resource needs from a clinical perspective.

Guide Questions	Site Implementation Plan / Considerations
Treatment setting (outpatient, inpatient, home)	Click or tap here to enter text.
Overall duration of study:	Click or tap here to enter text.
Are there provisions for missed study events and scheduling issues?	Click or tap here to enter text.
Duration of each treatment dose for scheduling purposes.	Click or tap here to enter text.
Concurrent administration of agents, timing of pre-meds and hydration.	Click or tap here to enter text.
Is sequencing of therapies routine if multiple agents, is sequencing of agents clearly specified and whether there needs to be rest period between administration?	Click or tap here to enter text.
Are supportive therapies specified in the protocol? Are they non-routine?	Click or tap here to enter text.
Are any medications contraindicated with this treatment?	Click or tap here to enter text.
Are guidelines for dose calculations / rounding / capping (i.e., maximum BSA, Cr Cl estimation, actual weight vs ideal weight vs adjusted weight) provided?	Click or tap here to enter text.
Administrative considerations, central vs peripheral venous access.	Click or tap here to enter text.
If drug is available via PO/IV, and there is institutional standard, does the protocol specify whether one route or other is required?	Click or tap here to enter text.
Are there special considerations for patients to manage during their treatment?	Click or tap here to enter text.
What type of staff education is needed for administering treatment?	Click or tap here to enter text.
What type of patient education is needed?	Click or tap here to enter text.
Is drug administration congruent with known site institutional standards/package insert? If deviation, please comment / or specify.	Click or tap here to enter text.
Are treatment plan order sets needed / study aides	Click or tap here to enter text.

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

Registration Section: Click here to enter text. *Focus on the **TECHNICAL ASPECT** of registering a patient to the study: What are the steps? What is the timeframe in relationship to registering the patient? Consider scheduling treatments and procuring the investigational agent.*	
Guide Questions	**Site Implementation Plan / Considerations**
Is there a pre-study testing requirement routine? ☐ Yes ☐ No If not, is there funding identified to cover, and is this adequately addressed in the cost of the funding memorandum? Refer to funding memo and coverage analysis.	Click or tap here to enter text.
Patient Registration: System used: OPEN ☐ or Other ☐ Click or tap here to enter text.	
Is there more than 1 registration step? ☐ Yes ☐ No **If yes, what are the time frames?**	Click or tap here to enter text.
Time frame from registration to treatment and / or drug delivery.	Click or tap here to enter text.
How will patients be identified and screened for this study.	Click or tap here to enter text.
Site Credentialing Requirements **Protocol Section:** Click here to enter text. **Note: For SWOG, this may also be included / addressed in Section 13 or 15 of the protocol.** *Detail how this study impacts ancillary clinical services (Rad/Lab/Path/Surgery, etc.) and what are the specific needs in order to implement the trial from their perspective. Indicate specific needs as this information is in connection with the implementation plan (last section of the Guide).* ***INCLUDE DEPARTMENT CONTACTS***	
Are there site certifications requirements for modalities?	Click or tap here to enter text.
Radiology **Credentialing** ☐ Yes ☐ No **Protocol training** ☐ Yes ☐ No **Phantom scans required** ☐ No ☐ Yes When: Click or tap here to enter text. **Central confirmatory review for imaging** ☐ Yes ☐ No	Specific needs: Click or tap here to enter text.

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

Site or Sponsor Contact: Click or tap here to enter text.	
Laboratory and Pathology Site training required ☐ Yes ☐ No Central confirmatory review required ☐ Yes ☐ No **Time point**: Click or tap here to enter text. **Clinical lab contact**: Click or tap here to enter text. **Pathology contact**: Click or tap here to enter text.	Specific needs: Click or tap here to enter text.
Surgical **Credentialing** ☐ Yes ☐ No **Surgical contact**: Click or tap here to enter text.	Specific needs: Click or tap here to enter text.
Radiation Therapy **Credentialing** ☐ Yes ☐ No **Radiation contact**: Click or tap here to enter text.	Specific needs: Click or tap here to enter text.
Contacts from other departments that need to be involved.	Click or tap here to enter text.

Investigational Drug(s) Supply and Administration Information. **Protocol Section:** Click here to enter text.

This section assists with developing your institutional treatment plans (clinical order sets).

Drug	Guide Review	
1. Click here to enter text.	**Drug formulation and administration requirements**	Click or tap here to enter text.
	Supportive drug administration requirements (ex. hydration, premeds, etc.)	Click or tap here to enter text.
	Are drug self- administration diaries required or included?	Click or tap here to enter text.
	Duration of each treatment dose for scheduling purposes.	Click or tap here to enter text.
Drug Supplier: **Sponsor NCI** ☐ **Commercial** ☐	**NCI supply procurement timelines.** **NCI investigational drug storage.**	Click or tap here to enter text.

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

	Commercial drug procurement local considerations. **Institutional Formulary** ☐ Yes ☐ No **2. Specialty Pharmacy**: Click here to enter text.	**Specific needs** Click or tap here to enter text.
IND status: ☐ **Exempt** ☐ **Non-Exempt** ☐ N/A **If Non-Exempt, who sponsors the IND?** Click or tap here to enter text. **IND#**: Click or tap here to enter text. **If Exempt, do you need an exemption letter for your IRB?** ☐ Yes ☐ No ☐ N/A		
2. Click here to enter text.	**Drug formulation and administration requirements.**	Click or tap here to enter text.
	Supportive drug administration requirements (ex. hydration, premeds, etc.)	Click or tap here to enter text.
	Are drug self- administration diaries required or included?	Click or tap here to enter text.
	Drug formulation and administration requirements.	Click or tap here to enter text.
Drug Supplier: **Sponsor NCI** ☐ **Commercial** ☐	**NCI supply procurement timelines.** **NCI investigational drug storage.**	Click or tap here to enter text.
	Commercial drug procurement local considerations. **Institutional Formulary** ☐ Yes ☐ No **2. Specialty Pharmacy**: Click here to enter text.	**Specific needs** Click or tap here to enter text.
IND status: ☐ **Exempt** ☐ **Non-Exempt** ☐ N/A **If Non-Exempt, who sponsors the IND?** Click or tap here to enter text. **IND#**: Click or tap here to enter text. **If Exempt, do you need an exemption letter for your IRB?** ☐ Yes ☐ No ☐ N/A		
3. Click or tap here to enter text.	**Drug formulation and administration requirements.**	Click or tap here to enter text.

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

	Supportive drug administration requirements (ex. hydration, premeds, etc.)	Click or tap here to enter text.
	Are drug self- administration diaries required or included?	Click or tap here to enter text.
	Duration of each treatment dose for scheduling purposes.	Click or tap here to enter text.
Drug Supplier: **Sponsor NCI** ☐ **Commercial** ☐	**NCI supply procurement timelines.** **NCI investigational drug storage.**	Click or tap here to enter text.
	Commercial drug procurement local considerations. **Institutional Formulary** ☐ Yes ☐ No **2. Specialty Pharmacy**: Click here to enter text.	**Specific needs** Click or tap here to enter text.

IND status:

☐ **Exempt** ☐ **Non-Exempt** ☐ N/A

If Non-Exempt, who sponsors the IND? Click or tap here to enter text. **IND#**: Click or tap here to enter text.

If Exempt, do you need an exemption letter for your IRB? ☐ Yes ☐ No ☐ N/A

Local pharmacy contact information:	Click or tap here to enter text.
Implementation considerations:	Click or tap here to enter text.

Safety Monitoring and Dose Modifications. Protocol Section: Click here to enter text.

Complete thoroughly or include protocol pages section for quick reference. Data in this section details what should be considered for inclusion in the treatment plan. Are there any special considerations for non-routine reporting for SAE events?

CTCAE: ☐ **Version:** Click here to enter text.

☐ Other: Click here to enter text.

Drug Toxicities: Refer to consent and protocol section: Click here to enter text.

Notes:

Click or tap here to enter text.

Are dose modifications consistent with standard of care and known drug toxicities? Are dose mods clear and consistent throughout the sections? (e.g., if multiple agents, is it clear when to hold/re-start therapy with each agent?)

Click or tap here to enter text.

Criteria for holding, re-instituting, discontinuing or escalating treatment clearly stated.

Click or tap here to enter text.

Clinical Trial Review Guide

Site Study ID: Click or tap here to enter text.	**Protocol ID**: Click or tap here to enter text.	**Version:** Click or tap here to enter text.
Title: Click or tap here to enter text.		

Any special instructions for treating adverse events? Click or tap here to enter text.
Timeframe for reporting AEs and SAEs in relation to last dose. Click or tap here to enter text.
Non-routine requirements for SAE reporting. Click or tap here to enter text.
Any special assessments and reporting for commercial drugs. Click or tap here to enter text.
Other considerations, ex. documentation tools, etc. Click or tap here to enter text.

Criteria for Evaluation and Endpoints. **Protocol Section: Click here to enter text.**

How long are patients followed? What is the procedure for discontinuing therapy?

Guide Questions	Site Implementation Plan / Considerations
Disease response criteria: ☐ RECIST ☐ Other: Click here to enter text.	Click or tap here to enter text.
Criteria for removal from study routine? (Section: Click or tap here to enter text.)	Click or tap here to enter text.
Procedure for discontinuing patient from study.	Click or tap here to enter text.
Other:	Click or tap here to enter text.
Documentation considerations.	Click or tap here to enter text.

Data Submission Schedule and Considerations. **Protocol Section:** Click here to enter text.

Guide Questions	Site Implementation Plan / Considerations
Data capture system:	☐ RAVE Medidata ☐ Other (specify): Click here to enter text.
Is timeframe for data reporting routine? If not, then explain.	Click or tap here to enter text.
Data submission effort. Does the study require remote monitoring or additional data preparation or submission?	Click or tap here to enter text.
Is additional data required that is not routine? (i.e., ECG monitoring.)	Click or tap here to enter text.

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Title: Click or tap here to enter text.		

Pathology submission requirements.	Click or tap here to enter text.
Imaging:	☐ TRIAD: Click here to enter text. ☐ Other: Click here to enter text.
QOL submissions? ☐ Yes ☐ No	Click or tap here to enter text.
PRO surveys (effort involved, special arrangements: paper or electronic). Are there survey tools provided? If electronic, does special arrangements need to be made? **Who is the PRO contact for the study?**	Click or tap here to enter text. Click or tap here to enter text.
Documentation considerations.	Click or tap here to enter text.
Data Management Quality Plan	Review the need for the following 1. Study Calendar 2. AE Log 3. Con Med Log 4. ECOG PS version 5. Inter-departmental Communication/ Coordination Tools 6. Smart Phrases 7. Data Reporting timelines 8. Reporting Period

Correlative Studies. **Protocol Section:** Click here to enter text.

Guide	Site Implementation Plan / Considerations
Biologic specimens.	Click or tap here to enter text.
Are kits provided?	Click or tap here to enter text.
Specimen processing, storage, shipping considerations.	Click or tap here to enter text.
Are there multiple time points for collections? Over what period of time?	Click or tap here to enter text.
Resource studies (example: economic)	Click or tap here to enter text.
Are any of these studies optional?	Click or tap here to enter text.

Recruitment and Marketing Strategies

Recruiting materials generally attached in the appendices (Section 18 of the protocol).

Click or tap here to enter text.

Clinical Trial Review Guide

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Title: Click or tap here to enter text.		

Reviewer Name: Click or tap here to enter text.	**Date:** Click or tap here to enter text.
Implementation Plan and Effort Analysis	

Study Team Click or tap here to enter text.

Clinical Departments that will be involved with this clinical trial:

Click or tap here to enter text.

Clinical Trial Acuity

Clinical Coordination Resources: Click here to enter text.

Regulatory Management Resources: Click here to enter text.

Data Management Resources: Click here to enter text.

Implementation Planning Notes:

Click or tap here to enter text.

Additional Implementation Planning by Milestones (optional)

This section may be used to develop a work plan to implement the clinical trial. Consider using this when collaborating with other study team members, departments, etc.

Study Milestones	Schedule of Events / Requirements	Implementation Plan	Comments
Start Up Considerations and Research Team Training Needs	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Clinical Staff Study Training and Implementation Considerations	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Screening/eligibility	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Randomization	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

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Title: Click or tap here to enter text.		

Treatment period	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
AE reporting	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Disease response	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Correlative studies	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
End of treatment	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Follow up	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Study Close Out	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.