Research Compliance and Quality Assurance Program (RCQA):
Audit Checklist – Subject Specific

Protocol Title / Code:	
Sponsor:	
PI Name:	
Auditor Name:	
Audit Date(s):	
Subject #:	

Key Dates:

Date participant was identified:
Date of Initial Consent:
Date of Optional Consent:
Date of Re-consent(s):
Date of Enrollment:

Arm (if applicable):
Date of First Dose:
Date Off Study:
Date of Last Dose:
Date of Death (if applicable):

Consent					
Verification of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Each consent process is well documented, confirming all GCP requirements are met.	☐	☐	☐	☐	
Correct version of ICF(s) used for all consenting.	☐	☐	☐	☐	
Sufficient time was given to the patient to make a decision, and this is evident in source documentation.	☐	☐	☐	☐	

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Re-consent, when required, was done in a timely fashion, following REB approval of the new information.	☐	☐	☐	☐	
Consent withdrawal, if any, was documented (including the extent of withdrawal).	☐	☐	☐	☐	
No protocol-specific tests (including screening) have been done prior to patient signing the consent.	☐	☐	☐	☐	
Eligibility/Registration					
Verification of the following:	**☑**	**☒**	**N/A**	**Not Reviewed**	**Comments**
All inclusion and exclusion criteria are met, and confirmed by an investigator on the study.	☐	☐	☐	☐	
If contraception is an eligibility criterion, discussion of this requirement was documented in notes.	☐	☐	☐	☐	
Screening assessments for confirming eligibility are completed within protocol-specified timeline.	☐	☐	☐	☐	
Eligibility checklist was signed and dated by the person who completed it, and was signed off by a study investigator, if required. All signature dates are within required timeline.	☐	☐	☐	☐	
Eligibility / registration related correspondence was filed.	☐	☐	☐	☐	
IVRS and/or sponsor confirmation of screening and registration were filed.	☐	☐	☐	☐	

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Patient did not receive study treatment prior to registration confirmation from the sponsor.	☐	☐	☐	☐	
If applicable (and permitted), all signed and dated eligibility waivers were filed.	☐	☐	☐	☐	
Participant Chart/File Organization + Other General Items					
Verification of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Participant charts are organized in a logical fashion; documents can be easily located.	☐	☐	☐	☐	
Packages of documents are correctly paginated.	☐	☐	☐	☐	
No loose sheets in participant research (source) charts; all documents are bound.	☐	☐	☐	☐	
Source documentation signed / initialed and dated by the person who performed the task or recorded the information.	☐	☐	☐	☐	
Source worksheets do not contain blank spots / fields that have not been closed / crossed off.	☐	☐	☐	☐	
All corrections have been managed appropriately: a single line through incorrect information, initial, date and state reason of change, if applicable.	☐	☐	☐	☐	
All late entries are documented accordingly, with explanation if applicable.	☐	☐	☐	☐	
Personnel documenting study-specific source information are listed on the delegation log and the dates match.	☐	☐	☐	☐	

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No patient identifiers have been inappropriately disclosed. De-identification must be done with a china marker.	☐	☐	☐	☐	
Pencil and whiteout (for revisions to data) were not used.	☐	☐	☐	☐	
Telephone communications were documented in the Electronic Patient Record (EPR)or in the narrative notes.	☐	☐	☐	☐	
Queries have been resolved within established timelines.	☐	☐	☐	☐	
Vitals and Physical Exams					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Vitals were performed as per protocol schedule.	☐	☐	☐	☐	
Physical exams (PEs) were performed as per protocol schedule and criteria, by qualified personnel. All required body systems were reviewed and documented.	☐	☐	☐	☐	
PE and visit specific worksheets are filed and signed off by the person completing it.	☐	☐	☐	☐	
Physician dictation and coordinator/nursing narrative note are written for each clinic visit.	☐	☐	☐	☐	
Treatment/Investigational Agent					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**

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Oral drug: participant medication diaries are completed and filed.	☐	☐	☐	☐	
Oral drug: study staff attests to the review of all medication diaries, and return of medication containers.	☐	☐	☐	☐	
Oral drug: if there are missing elements from pill diaries, documentation of patient education on compliance was done.	☐	☐	☐	☐	
IV drug: infusion records filed in patient chart are complete, with correct start and stop times (if required by protocol).	☐	☐	☐	☐	
Medical devices: [For medical device studies, enter device-specific requirements in this section. Add more lines as applicable.]	☐	☐	☐	☐	
Study drug orders for all protocol-required doses are completed, signed off by a study investigator (check dates), and filed.	☐	☐	☐	☐	
Treatment confirmations (e.g. IVRS confirmations or similar forms) have been filed.	☐	☐	☐	☐	
Dose was properly adjusted according to protocol dose modification table, if applicable.	☐	☐	☐	☐	
Adverse Events (AEs) / Concomitant Medications (CMs)					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**

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AE Log: timely sign-off by investigator for assessment and confirmation of causality and seriousness.	☐	☐	☐	☐	
AEs are assigned attributions as required.	☐	☐	☐	☐	
Documentation of review of AEs and CMs is complete for each visit, as per protocol.	☐	☐	☐	☐	
Lab AEs are recorded as per protocol specified criteria (e.g. anemia, hyperkalemia, proteinuria).	☐	☐	☐	☐	
ECG abnormalities are recorded as per protocol specified criteria (e.g. QT prolongation, sinus tachycardia).	☐	☐	☐	☐	
Abnormalities detected from vitals and weight are recorded as per protocol specified criteria (e.g. hypertension, fever, weight loss).	☐	☐	☐	☐	
Abnormalities detected from physical exams / physician dictations are recorded as per protocol specified criteria (e.g. edema).	☐	☐	☐	☐	
CM indications and dates (for those that are NOT prophylactic or PRN) match the AEs recorded.	☐	☐	☐	☐	
Symptoms reported on pill diaries, Patient Reported Outcomes (PROs), and drug administration records are consistent with those captured on AE Log.	☐	☐	☐	☐	
Participant did not take any prohibited medications while on study.	☐	☐	☐	☐	

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Protocol-required pre-meds and/or symptom management meds were given.	☐	☐	☐	☐	
SAEs					
Verification of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
All AEs that meet the serious criteria are reported to sponsor within protocol required timeline (i.e. 24 / 48 hours).	☐	☐	☐	☐	
SAE follow-ups are reported as per protocol.	☐	☐	☐	☐	
Confirmation (e.g. email or fax) of SAE submissions filed.	☐	☐	☐	☐	
SAE term, dates, grade and attribution are consistent with those recorded on the AE Log.	☐	☐	☐	☐	
Tumour Measurements (TMs) (for Oncology Trials)					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Baseline and all follow-up scans done as per protocol schedule.	☐	☐	☐	☐	
Consistent imaging method used throughout trial (e.g. always contrast CT, or always MRI, etc.).	☐	☐	☐	☐	
Follow-up TMs done in a timely fashion (ASAP following scans).	☐	☐	☐	☐	
TMs are signed off by the investigator (and radiologist, if applicable) in a timely fashion.	☐	☐	☐	☐	

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Response assessment meets protocol-required criteria.	☐	☐	☐	☐	
Scrapbook images corresponding to all target lesions printed and filed for each assessment.	☐	☐	☐	☐	
Labs/ECGs/Etc.					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Clinical significance assessment for abnormal labs/ECGs is done in a consistent manner.	☐	☐	☐	☐	
Labs/ECGs/Etc. done according to protocol Schedule of Events (esp. time, if specified).	☐	☐	☐	☐	
Central or outside lab reports filed.	☐	☐	☐	☐	
Participant questionnaires, if required , are completed as per schedule and filed.	☐	☐	☐	☐	
Correlatives					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Correlative sample source documents and/or requisitions were filed and meets source documentation standards (e.g. complete with signature and date of the person collecting the samples).	☐	☐	☐	☐	
Documentation that all required correlative specimens were obtained. Timed samples are recorded and meets protocol requirement.	☐	☐	☐	☐	

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Processing and shipping documents were completed for all samples and filed.	☐	☐	☐	☐	
Follow-Up (FU)					
Verifications of the following:	☑	☒	**N/A**	**Not Reviewed**	**Comments**
Long term FU completed as per protocol.	☐	☐	☐	☐	
All protocol-required FU assessments were completed within timeline.	☐	☐	☐	☐	
If required by the protocol, documentation for resolution/stabilization of AEs.	☐	☐	☐	☐	

Additional Notes: