Monitoring Checklist

HCC#	Disease Center	Monitoring Date
Subject Initials (F,M,L)	**Subject ID#**	**Date DCF given to Disease Center**

INFORMED CONSENT	SOURCE VERIFIED	Remember to look for the following: (Add any findings and request clarifications In Findings email)
Consent Process		
Patient Study Chart	☐Y ☐N	○ Confirm that chart cover sheet is completed in its entirety with accurate patient information ○ Confirm that chart has a side tab with accurate patient information
CRS Consent Process complete and accurate?	☐Y ☐N	○ Confirm subject identifiers are complete and accurate ○ Confirm all lines are complete ○ Confirm form is signed and dated by the CRC/RA
Consent Process Form lists the same number of optional questions as consent document?	☐Y ☐N	○ Confirm all optional questions are accounted for and accurately recorded on the source doc. **If the Consent Process Form does not match the IRB approved consent form, update source document and send to QA Manager for posting on the Final Drive.
CRC/RA consent process note present?	☐Y ☐N	○ Confirm CRC/RA note includes documentation of physician involvement of the consent process ○ Confirm contraception teaching is documented
CRC/RA has training documented in CTMA?	☐Y ☐N	○ Confirm CRC/RA training date is prior or equal to consent date
Consent Document(s)		
Consent(s) the most current version, IRB approved and within 28 days of subject registration?	☐Y ☐N	○ Review the CRS Final Drive and CTSU website to ensure correct consent version was signed ○ Confirm consent expiration date ○ Confirm all pages of the consent are present **NOTE:** If a patient's original consent times out per CRS policy when they sign another consent follow the reconsent process
Ancillary consents, HIPAA, and/or correlative consent(s) completed and meet above requirements?	☐Y ☐N ☐N/A	○ **A separate HIPAA Consent is required for all NCTN consents signed after 2/14/2019**
All optional questions are answered (i.e. correlative samples, biopsies, QOL, etc)?	☐Y ☐N ☐N/A	○ Review each page of the consent document as questions may be located throughout the consent document ○ Confirm the subject appropriately answered the questions per the consent format (i.e. circled, checked, or initialed/dated, etc.)

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INFORMED CONSENT	SOURCE VERIFIED	Remember to look for the following: (Add any findings and request clarifications In Findings email)
Consent(s) complete with signature, date, time, and printed name?	☐Y ☐N	○ Confirm physician and subject both completed: ○ Signature ○ Date ○ Time ○ Printed Name (as applicable)
If consent(s) signature dates differ, is there an appropriate CRC note explaining this?	☐Y ☐N ☐N/A	○ Confirm no research procedures were completed prior to physician signature
Signed consent(s) scanned into EMR?	☐Y ☐N	○ Confirm via ARIA *Notes* tab
Physician has training documented in CTMA?	☐Y ☐N	○ Confirm physician training date is prior or equal to consent date

RE-CONSENT(S)	SOURCE VERIFIED	Remember to look for the following: (Add any findings and request clarifications In Findings email)
Did this study have any Reconsent events applicable to this subject?	☐Y ☐N	○ Review regulatory working drive *IRB* folders for amendments and *Re-consent Process Checklist* to determine if reconsent was required **NOTE:** Patients who time out from original ICF and need to resign an ICF is a **Reconsent,** a note on the process form will include reason for reconsent due to first ICF timing out, other than protocol amendment/addendum
Reconsent Process – skip this section if reconsent not applicable (If original consent times out must RE-consent)		
Reconsent Process Form complete and accurate?	☐Y ☐N	○ Confirm subject identifiers are complete and accurate ○ Confirm all lines are complete ○ Confirm form is signed and dated by the CRC/RA
Reconsent Process Form lists the same number of optional questions as consent document?	☐Y ☐N	○ Confirm all optional questions are accounted for and accurately recorded on the source doc **If the Consent Process Form does not match the IRB approved consent form, update source document and send to QA Manager for posting on the Final Drive
CRC/RA re-consent process note present?	☐Y ☐N	○ Confirm physician involvement in the reconsent process is documented
CRC/RA has training documented in CTMA?	☐Y ☐N	○ Confirm CRC/RA training date is prior or equal to consent date
Reconsent Document(s) – skip this section if reconsent not applicable		

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RE-CONSENT(S)	SOURCE VERIFIED	Remember to look for the following: (Add any findings and request clarifications In Findings email)
Reconsent signed prior to additional treatment/ study procedures?	☐Y ☐N	○ Confirm consent expiration date ○ Confirm all pages of the consent are present
Ancillary reconsents, HIPAA, and/or correlative consent(s) completed and meet above requirements?	☐Y ☐N ☐N/A	○ **A separate HIPAA Consent is required for all NCTN consents signed after 2/14/2019**
All optional questions are answered (i.e. correlative samples, biopsies, QOL, etc)?	☐Y ☐N ☐N/A	○ Review each page of the consent document as questions may be located throughout the consent document ○ Confirm the subject appropriately answered the questions per the consent format (i.e. circled, checked, or initialed/dated, etc.)
Did subject responses for optional questions change from original consent? If yes, was sponsor notified of changes?	☐Y ☐N ☐ N/A	○ Compare original consent to reconsent
Consent(s) complete with signature, date, time, and printed name?	☐Y ☐N	○ Confirm physician and subject both completed: ○ Signature ○ Date ○ Time ○ Printed Name (as applicable)
If consent signature dates differ, is there an appropriate CRC note explaining this?	☐Y ☐N ☐N/A	○ Confirm no research procedures were completed prior to physician signature
Signed consent(s) scanned into EMR?	☐Y ☐N	○ Confirm via ARIA *Notes* tab
Physician has training documented in CTMA?	☐Y ☐N	○ Confirm physician training date is prior or equal to consent date

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ELIGIBILITY / SCREENING	**SOURCE VERIFIED**	**Remember to look for the following:** **(Add any findings and request clarifications In Findings email)**
CRS Eligibility Checklist complete and accurate?	☐Y ☐N	○ Confirm each line of the checklist is addressed ○ Confirm all dates are appropriately calculated for prior treatment washouts, as applicable ○ Confirm all first/second reviewer initials are completed **If the CRS Eligibility Form needs to be updated or have additional information added, update source document and send to QA Manager for posting on the Final Drive
Protocol specific checklist complete and accurate (i.e. ECOG-ACRIN form)?	☐Y ☐N ☐N/A	○ Confirm each field on the checklist is addressed ○ Confirm physician signature and date are completed
NCTN OPEN Enrollment Form and *CRS Cooperative Group Enrollment Form* completed?	☐Y ☐N ☐N/A	○ Confirm the appropriate NCTN registration form is accurately completed (download from CTSU website and provide to disease center staff if it was not provided in the screening packet) ○ Confirm the *CRS Cooperative Group Enrollment Form* is accurately completed and start of treatment date is documented
Source documents present to support all inclusion/exclusion criteria?	☐Y ☐N	○ Confirm a CRC/RA note is present to document any criteria without a separate source document (i.e. no history of live vaccine, clinical indication for HIV/HEP testing, etc.)

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ELIGIBILITY / SCREENING	**SOURCE VERIFIED**	**Remember to look for the following:** **(Add any findings and request clarifications In Findings email)**
Screening Tests/ Evaluation section of Eligibility Checklist complete and accurate?	☐Y ☐N	○ Confirm all forms that require a physician's signature have been signed and dated ○ Confirm all lab reports printed from ARIA are the *Approved* version ○ Confirm calculated dates are accurate ○ Confirm tests/procedures/evaluations will not time out prior to registration/treatment, as applicable ○ If an assessment needed to be repeated for eligibility, confirm the correct date is reflected on the checklist ○ Look for common oversights: ○ Height and vitals documented per protocol and meet eligibility criteria ○ All baseline QOLs/correlatives required at screening have been collected or confirmed ○ If confirmation of pathology is required for eligibility, confirm source is present from the pathology department ○ Confirm the date of collection is present on the pathology report (reports printed from ARIA generally do not include a date of service). The report must be reprinted if the date service is not documented.
ALL study-specific requirements completed after consent signed?	☐Y ☐N	○ Review protocol/FRIAR if a question of timing of a procedure/test
Insurance Verification (IVFC) completed *and* patient accepted estimated costs?	☐Y ☐N	○ Review IVFC for completeness and accuracy ○ Confirm patient acceptance is documented ○ If multimodality trial, confirm IFVC was submitted to appropriated departments (Med Onc, Surg Onc, Rad Onc), as appropriate
Eligibility Checklist is signed and dated by First Reviewer, Second Reviewer and Investigator?	☐Y ☐N	○ Confirm each field on the checklist is addressed ○ Confirm all signatures and dates are completed prior to subject registration
CRS SOURCE DOCUMENTS		

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ELIGIBILITY / SCREENING	SOURCE VERIFIED	Remember to look for the following: (Add any findings and request clarifications In Findings email)
Baseline Medical Problems Form complete and accurate?	☐Y ☐N	○ Confirm the correct CTCAE version is checked/conditions are graded appropriately ○ Confirm page numbers are accurately completed ○ Confirm all current or ongoing issues that the subject is experiencing are listed ○ Confirm all start dates are listed with at least an approximate year (baseline is not acceptable as a date) ○ Confirm abnormal lab results from the screening labs are included (i.e. anemia, decreased lymphocyte count) ○ Confirm abnormal vital signs (i.e. HTN, tachycardia, bradycardia) are included ○ Confirm all medications listed in the *Action Taken* column are on the Con Med Log ○ Confirm the treating physician signature and date are completed (date must be on or after start date of all problems)
Baseline Assessment Form complete and accurate?	☐Y ☐N	○ Confirm all headers and footers are accurately completed ○ Confirm all Past Medical History (PMH) outlined in physician notes and other source documents are listed with the appropriate start and stop dates ○ Confirm the Prior Systemic Therapy, Radiation, and Surgery checkboxes are completed appropriately ○ Confirm all past biopsies, surgeries, and treatments (drug, radiation, etc.) are listed with start and stop dates (don't list radiology) ○ Confirm prior drug administration records (not just MD notes) are included with the other screening documents ○ If oral drug was last treatment, confirm there is adequate documentation of last dose ○ Confirm all pathology reports are in the screening packet and support diagnosis and treatment history
Baseline Physical Exam Form complete and accurate?	☐Y ☐N	○ Confirm all headers and footers are accurately completed ○ Confirm Performance status is recorded ○ If "see dictation" is written, confirm all applicable organ systems were reviewed per protocol ○ Confirm signature and date are completed **If the additional Performance Status' are listed or the form needs to be updated or have additional information added, update source document and send to QA Manager for posting on the Final Drive.

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ELIGIBILITY / SCREENING	**SOURCE VERIFIED**	**Remember to look for the following:** **(Add any findings and request clarifications In Findings email)**
Con Med Log complete and accurate?	☐Y ☐N	○ Confirm all fields are completed including Dosage, Route, and Frequency of medication, Start dates, Reason for Use ○ *Supplement* or *Prophylaxis* can be listed for *Reason for Use* as appropriate ○ OTC is not acceptable as dosage ○ Confirm *Baseline* is listed in the Cycle/Day Column ○ Confirm all over the counter medication(s) including herbal medications and supplements are listed completely as above ○ Confirm all Baseline Conditions listed in the *Reason for use* column are on the Baseline Medical Problems Form ○ Confirm page numbers are completed
Tumor Measurement Form complete and accurate?	☐Y ☐N ☐ N/A	○ Confirm the correct method of disease assessment was completed (RECIST v1.1, iRECIST, RANO, mesothelioma, etc.) ○ Confirm the correct diameters were used to calculate response (i.e. short axis for Lymph Nodes) ○ Confirm all calculations are correct ○ Confirm all fields on form are completed accurately ○ Confirm all sites of disease listed in the radiology report are addressed on the form (lesions can be grouped as non-target lesions i.e. *multiple pulmonary mets*) ○ Confirm appropriate special forms are used as required. (i.e., Serological Response Form = prostate)

REGISTRATION	**SOURCE VERIFIED**	**Remember to look for the following:** **(Add any findings and request clarifications In Findings email)**
NCTN Group to receive accrual credit confirmed?	☐Y ☐N ☐ N/A	○ Group receiving credit should be the sponsor of trial, unless SWOG study. If SWOG study, confirm with QA Manager correct cooperative group given credit
Subject registered in OPEN?	☐Y ☐N ☐ N/A	○ Registration confirmation email in chart ○ Confirm a copy of the sponsor registration form(s) is in the chart ○ MD signatures as appropriate ○ Do the registration form and printout from the database agree ○ Confirm CTMA is updated with the *Subject Study ID #* and *Registering Cooperative Group*, *Registering Coordinator*, and *3rd Check* via *Edit/View Details*

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REGISTRATION	SOURCE VERIFIED	Remember to look for the following: (Add any findings and request clarifications In Findings email)
Were baseline activities completed prior to treatment start?	☐Y ☐N ☐ N/A	○ Tissue (Ensure requisitions and shipping documents are filed in the chart) ○ Labs (Ensure requisitions and shipping documents are filed in the chart) ○ PROs/ QOLs, etc
Did Treatment start within protocol mandated time frame?	☐Y ☐N ☐ N/A	○ Confirm that C1D1 treatment occurred within the protocol time frame from registration

TREATMENT (REVIEW EACH ITEM FOR EVERY CYCLE)	SOURCE VERIFIED	REMEMBER TO LOOK FOR THE FOLLOWING: (ADD ANY FINDINGS AND REQUEST CLARIFICATIONS ON THE DCF) CHECK THAT ACTIVITY IS BEING REVIEWED BASED ON THE PROTOCOL VERSION ACTIVE AT TIME OF TREATMENT
Cycle #: Start Date:		
Treatment Visit Requirement Form complete and accurate?	☐Y ☐N	○ Confirm subject identifiers are complete and accurate ○ Was a reconsent completed, if due? ○ Confirm all tick boxes are checked and have source to verify completion ○ Confirm tumor assessment information is filled in correctly ○ Confirm RTC date is correct ○ Confirm form is signed and dated by the CRC/RA

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TREATMENT (REVIEW EACH ITEM FOR	SOURCE VERIFIED	**REMEMBER TO LOOK FOR THE FOLLOWING:** (ADD ANY FINDINGS AND REQUEST CLARIFICATIONS ON THE DCF) CHECK THAT ACTIVITY IS BEING REVIEWED BASED ON THE PROTOCOL VERSION
Physical Exam Form complete and accurate?	☐Y ☐N ☐N/A	○ Confirm all headers and footers are accurately completed ○ Confirm Performance Status is recorded ○ If "see dictation" is written, confirm a copy of the dictation is in the chart and all applicable organ systems were reviewed per protocol ○ Confirm MD reviewed labs box is ticked ○ Confirm Tumor assessment is filled out as appropriate ○ Confirm information about patient continuing treatment is answered ○ Confirm signature and date are completed **If the additional Performance Status' are listed or the form needs to be updated or have additional information added, update source document and send to QA Manager for posting on the Final Drive
Con Med Log updated and accurate?	☐Y ☐N	Review Con Med Log to ensure all Con Meds are accurately recorded, all columns are completed with appropriate start/stop dates, baseline is not to be used as a start date.
AE Log updated and accurate?	☐Y ☐N	○ Confirm per protocol when AE reporting begins (post-ICF/C1D1) ○ Review AE Log to ensure all AEs are accurately recorded and have appropriate start/stop dates, (baseline is not a date), in real time ○ AE's with dose modification &/or SAE indications correctly assessed, documented &/or reported. ○ Confirm AEs are graded per the correct CTCAE version
CRC note complete and accurate?	☐Y ☐N	○ Copy of note should be in chart ○ Note can include patient's current ECOG status; review of meds; review of hospitalizations; discussion of any adverse events since last visit; any questions the patient may have; review of pill diary, protocol timeline and upcoming testing; and patient willingness to continue treatment. ○ Patient self-assessments (QOLs, PROs) completed per protocol ○ Confirm any changes to meds are documented on Con Med form ○ Confirm adverse events are added to AE log and MD has evaluated them for seriousness, attribution, CS/NCS ○ Confirm documentation of CRC to treating RN hand-off ○ If any CRC vs. MD note discrepancies, must be clarified in EMR and a NTF

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TREATMENT **(REVIEW EACH ITEM FOR**	SOURCE VERIFIED	**REMEMBER TO LOOK FOR THE FOLLOWING:** (ADD ANY FINDINGS AND REQUEST CLARIFICATIONS ON THE DCF) CHECK THAT ACTIVITY IS BEING REVIEWED BASED ON THE PROTOCOL VERSION
Vital Signs	☐Y ☐N	○ Confirm VS performed at the correct times for the study ○ Confirm out of range results are added to AE log and MD has evaluated them for seriousness, attribution, CS/NCS
Labs	☐Y ☐N	○ Confirm all required labs were done within protocol timeframes and that the printout is the final/approved version ○ Confirm out of range labs are reported on AE log ○ Confirm lab abnormalities are graded per the correct CTCAE version ○ Documentation of Research labs drawn and sent is in chart (Ensure requisitions and shipping documents are filed in the chart)
Tumor Measurement Form complete and accurate?	☐Y ☐N ☐ N/A	○ Confirm the correct method of disease assessment was completed (RECIST v1.1, *i*RECIST, RANO, mesothelioma, etc.) ○ Confirm the correct diameters were used to calculate response (i.e. short axis for Lymph Nodes) ○ Confirm diameters were added correctly in the *Sum of Target Lesions* field ○ Confirm all fields on form are completed accurately ○ Confirm all sites of disease listed in the radiology report are addressed on the form (lesions can be grouped as non-target lesions i.e. *multiple pulmonary mets*) ○ Confirm appropriate special forms are used as required. (i.e., Serological Response Form = prostate)
Diagnostic tests	☐Y ☐N ☐N/A	○ Confirm copies of any testing performed since last visit are in chart ○ Confirm documentation of MD review of results and effect on patient's study participation is documented ○ Confirm abnormal results are added to AE log and MD has evaluated them for seriousness, attribution, CS/NCS in real time

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TREATMENT (REVIEW EACH ITEM FOR	**SOURCE VERIFIED**	**REMEMBER TO LOOK FOR THE FOLLOWING:** (ADD ANY FINDINGS AND REQUEST CLARIFICATIONS ON THE DCF) CHECK THAT ACTIVITY IS BEING REVIEWED BASED ON THE PROTOCOL VERSION
Treatments	☐Y ☐N ☐N/A	○ Confirm treatment parameters were met ○ Dose modification indicated and implemented? ☐ N/A ○ Physician orders ○ Confirm orders correct per protocol ○ All pages of orders signed and dated by PI or Co-Investigator ○ Dose accurate and complete? (BSA, calculations, rounding) ○ Drug dosing worksheet e.g., carboplatin dosing form ☐ N/A ○ IVRS confirmation ☐ N/A ○ Infusion/administration records ○ All drugs documented as given in correct dose, route and time? ○ Supportive therapy (growth factors, abx, steroids) administered per protocol? ○ Drug diary ☐ N/A ○ Complete, accurate & assessment of all AE's recorded on the diary by the patient documented and recorded on AE log (if applicable) ○ Signed, dated and timed by CRC and Patient ○ Pill count reconciliation form filled out ○ Radiation records ☐ N/A

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Did an SAE occur?	☐Y ☐N ☐N/A	o SAE checklist complete and accurate? o SAE Blue Sheet filed in appropriate cycle SAE occurred. o Was a study specific report submitted per protocol? o CTEP-AERS o Study specific form o CRS form o AE report within protocol mandated time frame o Confirm SAE is signed and dated by PI o If "Please mark if the PI has confirmed approval electronically" has been checked on the CRS form, review safety folder to confirm source of electronic signature o Confirm all source documents are printed and in chart o Confirm AE log and Con med log are updated o Confirm SAE term(s) are graded per the correct CTCAE version o Confirm attribution(s) to study drug(s) listed on SAE forms match the attributions on the AE log
Protocol deviations identified?	☐Y ☐N ☐N/A	o Was a Protocol Deviation indicated & report submitted?
Has the patient's study status changed?	☐Y ☐N ☐N/A	o If yes, confirm patient disposition is documented (Confirm a consent withdrawal form is completed as applicable o Confirm CTMA is updated and the correct status has been selected (i.e. Off Trial Intervention, Completed Trial Intervention, etc.)

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FOLLOW-UP (REVIEW EACH ITEM FOR EVERY FU VISIT)	SOURCE VERIFIED	**REMEMBER TO LOOK FOR THE FOLLOWING:** (ADD ANY FINDINGS AND REQUEST CLARIFICATIONS ON THE DCF)
Treatment Visit Follow-Up Form complete and accurate?	☐Y ☐N ☐N/A	○ Confirm follow-up parameters met? (labs, vitals, etc) ○ Confirm CT scans were performed per protocol
DATA SOURCE VERIFICATION **(SOURCE VERIFY DATA ACCURACY FOR ALL TIMEPOINTS)**		**REMEMBER TO LOOK FOR THE FOLLOWING:** (ADD ANY FINDINGS AND REQUEST CLARIFICATIONS ON THE DCF) **CHECK THAT ACTIVITY IS BEING REVIEWED BASED ON THE PROTOCOL VERSION ACTIVE AT TIME OF TREATMENT**

Was all data entered accurately and per protocol?	☐Y ☐N
	☐N/A
		○ Review each folder and confirm that entries in EMR are accurate and reflect the source in the chart
		○ Open all scanned documents and check source for proper redaction.
		○ Confirm that all protocol required activities have been reported
		  ○ AEs were graded per the correct CTCAE version
		  ○ PROs/QOLs are scanned or emailed as required
		  ○ Lab value ranges are correct
		  ○ Scan submission per TRIAD (confirmation documentation must be filed in the chart)
		○ For Theradex Studies, review the *Theradex Rave data entry cheatsheet*, *Theradex Rave Reference Sheet*, and *Theradex Rave User Guide Version 1* to ensure accurate data entry

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Findings Review

Email sent to CRC/RA with list of findings and Manager copied?	☐Y ☐N	○ Subject line of email must be: Audit Results - HCC XX-XXX – XX (patient initials) (i.e. Audit Results - HCC 18-195 – RN) ○ Attach DCF form to email ○ Print a copy of DCF and place in chart, return to CRC/RA ○ Include in email expectation of timeline for return of chart with updates (should be within 5 working days, per CRS policy)
All findings fully addressed by CRC/RA?	☐Y ☐N ☐ N/A	○ Review updates and sign off ○ Scan a copy of the fully reviewed DCF to auditing folder ○ Save the completed Monitoring Checklist form in the auditing folder
Enter chart audit in CTMA	☐Y ☐N	○ Enter study #, Event Monitoring, Clinical Workflow, Audit folder: Open Add button. Enter date. Event dropdown box choose "Internal Monitoring Completed" Enter patient subject number, initials and what part of the chart was audited (e.g.: SCR/REG/C1-C4/ EOT/ FU + RAVE).

NCTN OPEN FUNDING	Completed	To be completed and verified by QA auditor
Review OPEN Funding and complete any applicable funding	☐Y ☐N ☐N/A	○ Review the protocol, protocol Funding sheet on the CTSU website, and specimen tracking system, as applicable, to ensure the correct samples were collected ○ Enter applicable date on the Funding page

QA/QA Training Coordinator Signature: _____ Date: _____