Staff Study Information

Staff Member (Last Name, First Name)

_____

Role

◯ CRC
◯ RC
◯ RA

Disease Center

◯ Brain
◯ Breast
◯ Community
◯ Gyne
◯ GI
◯ GU
◯ Head & Neck
◯ Heme
◯ IDDC
◯ Lung
◯ Melanoma
◯ Rad Onc

HCC #

_____

Patient's Initials (First name initial, Last name initial)

_____

Patient's year of birth

_____

Date review/check initiated

_____

QA Team Member Completing Review

_____

Reason for eligibility review

◯ Orientation completion
◯ Yearly
◯ For Cause
◯ 2nd Check
◯ 3rd Check
◯ Other

If other, specify reason for performing eligibility review

Step of protocol

☐ Step 0
☐ Step 1
☐ Step 2
☐ N/A

Consent Information

This is a cooperative group study

◯ Yes
◯ No
◯ Yes, but consent not required to be entered (i.e. performing check on same patient, in between step 1 and 2 registrations)

Cooperative Group Protocol

_____
(Provide Protocol name, (e.g., BR004, A013759, or EA3112))

Patient ID

_____
(Add subject's on study ID)

Is this a consent or reconsent?

◯ Initial consent
◯ Re-consent

Provide the date the consent was signed by the patient

_____

Provide the protocol version date for this consent

_____

Provide the expiration date of this consent

_____

Were there questions for the patient to answer on this consent?

◯ Yes
◯ No

How many questions are on the consent form?

_____

Question 1: Enter Question Language

_____

Patient's answer to Question 1

◯ Yes
◯ No

Question 2: Enter Question Language

_____

Patient's answer to Question 2

◯ Yes
◯ No

Question 3: Enter Question Language

_____

Patient's answer to Question 3

◯ Yes
◯ No

Question 4: Enter Question Language	_____
Patient's answer to Question 4	◯ Yes ◯ No
Question 5: Enter Question Language	_____
Patient's answer to Question 5	◯ Yes ◯ No
Question 6: Enter Question Language	_____
Patient's answer to Question 6	◯ Yes ◯ No
Comments	_____ (Provide any additional information about this consent)

Informed Consent Process

(1) Most current, IRB approved version of the consent(s) used

- Review eREG to ensure correct consent version was signed
- For cooperative group studies only (Alliance, ECOG-ACRIN, NRG, SWOG, Theradex), review CTSU for current version of consent. If the version in CTSU does not match ours, email the Regulatory Specialist to ask whether the updated protocol/consent is in the process of being approved for our site and whether the patient will need to reconsent on the updated version. Based on that, decide if reconsent is needed before registering or if just before treatment. Note: we have 30 days from posted date on CTSU to implement
- To confirm version of consent in CTSU, enter in the protocol in the "Protocols" tab > Select "Documents"

◯ Yes
◯ No
◯ N/A (e.g., second step registration/randomization)

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(2) All pages of the consent are present

◯ Yes
◯ No

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(3) Consent expiration date was within timeframe of patient signing consent

Note: If patient signed an expired consent, they will need to resign consent prior to registration

◯ Yes
◯ No

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(4) Consent signed within 28 days (or number of days as applicable to the study) of patient registration/randomization/enrollment/treatment start

◯ Yes
◯ No
◯ No, but patient was reconsented or considered in active screening

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(5) If consent is outside of 28 day window (or window specified per protocol), the patient was reconsented

◯ Yes
◯ No
◯ Other

Specify other for reason patient not reconsented if consent is outside of 28 day window

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(6) If consent signed greater than 28 days and patient is considered to be in active screening, there is a CRC/RC/RA note covering ongoing consent dialogue

◯ Yes
◯ No
◯ N/A

(7) All questions within the informed consent were answered per the consent format (i.e. circled, checked, or initialed/dated)

- If a question was missed, there is documentation in CRC/RC/RA note that the question was reviewed/discussed with the patient and the patient's response

◯ Yes
◯ No
◯ N/A

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(8) Consent(s) complete with subject's (or legally authorized representative's) signature, date, time, printed name (as applicable), and any other field as required per the consent

- If the patient recorded an incorrect date or time, there is documentation in CRC/RC/RA note that addresses this
- If the patient answered a portion of the consent that is N/A, there is documentation in CRC/RC/RA note that addresses this

◯ Yes
◯ No
◯ N/A - Non-English, blind, physical limitation

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(9) Consent(s) complete with physician's (or designee's) signature, date, time, printed name (as applicable), and any other field as required per the consent

- If the physician recorded an incorrect date or time, there is documentation in CRC/RC/RA note that addresses this
- If the physician dated/timed the consent prior to the patient, there documentation in CRC/RC/RA note that addresses this and includes confirmation that the MD did sign after the patient
- If the physician answered a portion of the consent that is N/A, there is documentation in CRC/RC/RA note that addresses this

◯ Yes
◯ No

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(10) If consent(s) signature dates differ, there is an appropriate CRC/RC/RA note explaining this

◯ Yes
◯ No
◯ N/A

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(11) If a consent has "Signature of Witness" line, it should be completed as N/A unless required due to a patient impairment (e.g., blindness, deafness) or the use of an interpreter

◯ Yes
◯ No
◯ N/A

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(12) For special circumstance consent (Non-English, blind, physical limitation), consent completed per CRS SOP or IRB guidelines as applicable

For physical limitation: Refer to HCC-CRS-CLIN-001

For Non-English, Deaf, Blind: Refer to the CRS Training Portal > Informed Consent > Non-English (includes deaf & blind)

◯ Yes
◯ No
◯ N/A

(13) HIPAA/ancillary/correlative consent completed

◯ Yes
◯ No
◯ N/A

(14) HIPAA/ancillary/correlative consent with issues noted

Consent(s) complete with patient's and physician's (or designee's) signature, date, time, printed name (as applicable), and any other field as required per the consent

- If the patient/physician recorded an incorrect date or time, there is documentation in CRC/RC/RA note that addresses this
- If the physician dated/timed the consent prior to the patient, there documentation in CRC/RC/RA note that addresses this and includes confirmation that the MD did sign after the patient
- If the patient/physician answered a portion of the consent that is N/A, there is documentation in CRC/RC/RA note that addresses this A separate HIPAA Consent is required for all NCTN consents (Alliance, ECOG-ACRIN, NRG, SWOG, NCI, Theradex)

◯ Yes
◯ No

(15) Consent(s) scanned into EMR

◯ Yes
◯ No
◯ N/A (do not have access to EMR)

(16) Physician has training documented in eReg with a date prior to consent date

If unable to locate date in eReg, Regulatory Working Drive reviewed for training. If unable to locate, reach out to the Regulatory Specialist.

Regulatory Working Drive: CRS > Regulatory > WorkingDrive

The training will be located in the study specific folder in the folder marked then as "Regulatory".

◯ Yes
◯ No

(17) CRC/RC has training documented in eReg with a date prior to consent date

If unable to locate date in eReg, Regulatory Working Drive reviewed for training. If unable to locate, reach out to the Regulatory Specialist.

Regulatory Working Drive: CRS > Regulatory > WorkingDrive

The training will be located in the study specific folder in the folder marked then as "Regulatory".

◯ Yes
◯ No

RA has training documented in eReg with a date prior to consent date

If unable to locate date in eReg, Regulatory Working Drive reviewed for training. If unable to locate, reach out to the Regulatory Specialist.

Regulatory Working Drive: CRS > Regulatory > WorkingDrive

The training will be located in the study specific folder in the folder marked then as "Regulatory".

◯ Yes
◯ No
◯ N/A

(18) Consent Process Form provided

◯ Yes
◯ No

(19) CRS Consent Process Form is complete and accurate

- Subject identifiers are complete and accurate
- All lines are complete
- Form is electronically signed and dated by the CRC/RC/RA

◯ Yes
◯ No

(20) Consent Process Form lists the same number of optional questions as consent document and the correct patient response was documented

◯ Yes
◯ No
◯ N/A

(21) CRC/RC/RA consent note includes documentation of physician involvement

OR the MD has documentation in their note supporting their involvement in the consent discussion

◯ Yes
◯ No

(22) CRC/RC/RA consent note confirms that contraception teaching as per protocol is documented

◯ Yes
◯ No
◯ N/A

There are other issues with the informed consent process not addressed above

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Reconsent Process

Did this study have any re-consent events applicable to this subject?

- Review OnCore - Reviews - Details to review amendments and Re-consent Process Checklist to determine if reconsent was required
- Review eReg - IRB

◯ Yes
◯ No

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(23) Re-consent signed prior to additional treatment/study procedures

◯ Yes
◯ No

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(24) Most current, IRB approved version of the consent(s) used

◯ Yes
◯ No

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(25) All pages of the consent are present

◯ Yes
◯ No

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(26) Consent expiration date was within timeframe of patient signing consent

◯ Yes
◯ No

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(27) Consent signed within 28 days (or number of days as applicable to the study) of patient registration/randomization/enrollment/treatment start

◯ Yes
◯ No
◯ No, but patient was reconsented or considered in active screening

---

(28) If consent signed greater than 28 days and patient is considered to be in active screening, is there a CRC/RC/RA note covering ongoing consent dialogue

◯ Yes
◯ No
◯ N/A

---

(29) All questions within the informed consent were answered per the consent format (i.e. circled, checked, or initialed/dated)

- If a questioned was missed, there is documentation in CRC/RC/RA note that the question was reviewed/discussed with the patient and the patient's response

◯ Yes
◯ No
◯ N/A

Subject responses for optional questions changed from original consent

◯ Yes
◯ No

(30) If there were changes in the way the patient answered optional questions, there is documentation to support that the sponsor was notified of changes

◯ Yes
◯ No
◯ N/A

(31) Consent(s) complete with subject's (or legally authorized representative's) signature, date, time, printed name (as applicable), and any other field as required per the consent

- If the patient recorded an incorrect date or time, there is documentation in CRC/RC/RA note that addresses this
- If the patient answered a portion of the consent that is N/A, there is documentation in CRC/RC/RA note that addresses this

◯ Yes
◯ No
◯ N/A - Non-English or blind consent

(32) Consent(s) complete with physician's (or designee's) signature, date, time, printed name (as applicable), and any other field as required per the consent

- If the physician recorded an incorrect date or time, there is documentation in CRC/RC/RA note that addresses this
- If the physician dated/timed the consent prior to the patient, there documentation in CRC/RC/RA note that addresses this and includes confirmation that the MD did sign after the patient
- If the physician answered a portion of the consent that is N/A, there is documentation in CRC/RC/RA note that addresses this

◯ Yes
◯ No

(33) If consent(s) signature dates differ, there is an appropriate CRC/RC/RA note explaining this

◯ Yes
◯ No
◯ N/A

(34) If a consent has "Signature of Witness" line, it should be completed as N/A unless required due to a patient impairment (e.g., blindness, deafness) or the use of an interpreter

◯ Yes
◯ No
◯ N/A

(35) For special circumstance consent (Non-English, blind, physical limitation), consent completed per CRS SOP or IRB guidelines as applicable

For physical limitation: Refer to HCC-CRS-CLIN-001

For Non-English, Deaf, Blind: Refer to the CRS Training Portal > Informed Consent > Non-English (includes deaf & blind)

◯ Yes
◯ No
◯ N/A

(36) HIPAA/ancillary/correlative consent completed

◯ Yes
◯ No
◯ N/A

(37) HIPAA/ancillary/correlative consent with issues noted

Consent(s) complete with patient's and physician's (or designee's) signature, date, time, printed name (as applicable), and any other field as required per the consent

- If the patient/physician recorded an incorrect date or time, there is documentation in CRC/RC/RA note that addresses this
- If the physician dated/timed the consent prior to the patient, there documentation in CRC/RC/RA note that addresses this and includes confirmation that the MD did sign after the patient
- If the patient/physician answered a portion of the consent that is N/A, there is documentation in CRC/RC/RA note that addresses this A separate HIPAA Consent is required for all NCTN consents (Alliance, ECOG-ACRIN, NRG, SWOG, NCI, Theradex)

◯ Yes
◯ No

(38) Re-consent scanned into EMR

◯ Yes
◯ No
◯ N/A (do not have access to site's EMR)

(39) Physician has training documented in eReg with a date prior to consent date

If unable to locate date in eReg, Regulatory Working Drive reviewed for training. If unable to locate, reach out to the Regulatory Specialist.

Regulatory Working Drive: CRS > Regulatory > WorkingDrive
The training will be located in the study specific folder in the folder marked then as "Regulatory".

◯ Yes
◯ No

(40) CRC/RC/RA assisting with reconsenting the patient has training documented in eReg with a date prior to consent date

If unable to locate date in eReg, Regulatory Working Drive reviewed for training. If unable to locate, reach out to the Regulatory Specialist.

Regulatory Working Drive: CRS > Regulatory > WorkingDrive
The training will be located in the study specific folder in the folder marked then as "Regulatory"

◯ Yes
◯ No

(41) Re-consent Process Form provided

◯ Yes
◯ No

(42) Re-Consent Process Form is complete and accurate

- Subject identifiers are complete and accurate
- All lines are complete
- Form is electronically signed and dated by the CRC/RC/RA

◯ Yes
◯ No

(43) Re-Consent Process Form lists the same number of optional questions as consent document and the correct patient response was documented

◯ Yes
◯ No
◯ N/A

(44) CRC/RC/RA consent note includes documentation of physician involvement

OR the MD has documentation in their note supporting their involvement in the consent discussion

◯ Yes
◯ No

(45) CRC/RC/RA consent note confirms that contraception teaching as per protocol is documented

◯ Yes
◯ No
◯ N/A

There are other issues with the reconsent process not addressed above

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Cooperative Group Studies

This is a cooperative group study

◯ Yes
◯ No
◯ N/A (for second step registration/randomization)

Type of cooperative group

◯ Alliance
◯ ECOG-ACRIN
◯ SWOG
◯ Theradex
◯ NRG

Confirmed registering site's NCI code

CRS Central (SharePoint) > CRS Disease Centers > Regulatory Hub > Links > Regulatory Template Forms > CRS Sites and Staff Directory

Click on the Hospital+NetworkSites_Directory tab

◯ Yes
◯ No

Issue regarding registering site's NCI code

Protocol is active in CTSU

• Look up study - Protocol tab
• Confirm if any portion of the study is closed to accrual.

◯ Yes
◯ No

Comment regarding active status of protocol

There is a DTL for this study

• Look up study - Protocol tab
• Home screen - if there is a checkmark in the DTL column there is a DTL

◯ Yes
◯ No

All research personal are listed on the DTL

• Go to the Delegation Log tab - Task Assignment - select site and protocol
• For consenting MD and treating MD, ensure the following are listed: Consenting Person, Eligibility Assessment, End Point Assessment, Enrolling Person/Treating Investigator, HP Assessments, IND Prescribing, Tox Assessment
• For you, ensure you are listed as OPEN Registrar
• For the CRC/RC, ensure they are listed as Consenting Person and Rave CRA (if they will be entering data)
• If anyone is not listed on the DTL, email the Regulatory Specialist

◯ Yes
◯ No

Comment regarding staff not listed on DTL

Correct version of the enrollment form is being used

• Look up study - Protocol tab
• Go to "Protocol Related Documents"

- Filter based on either "Patient Enrollment" or "Case Report Forms" - After selecting, make sure to click "Apply filters" • If newer documents, email to Regulatory Specialist to have them added to eReg

◯ Yes
◯ No

Comment regarding enrollment form

If there is not a DTL or if staff is not listed on the DTL, staff are listed on the roster for the site you are registering to - includes treating MD(s), CRC, RC, RA, yourself

• Go to the Rums tab
• Select the Cooperative Group from the top left drop down box
• Ensure staff has site you are registering to listed along with an "ACTIVE" status

- RA, RC, and Community CRCs should have roles of Rave CRA and Triad Site User
- You should have the role of Rave CRA and Registrar
- CRCs at HCC do not need a role listed • If someone is not listed, email Denise Stromoski and/or Mary Horak

◯ Yes
◯ No
◯ N/A

Comment regarding staff and roster

Registration status is listed as approved

• Go to the Regulatory tab - Site registration - Type in site number and protocol
• If the site registration status is not approved, use the Snipping Tool to snip the table with "status reason" listed and send to the Regulatory Specialist for guidance

◯ Yes
◯ No

Registration status comment

RTF number confirmed
NOTE: RTF number is only required for studies that have a radiation component, require upload of radiation plan to TRIAD, and RTF is required in OPEN at time of registration/randomization.

To check if RTF required:
*Go to "Protocols" tab and type in protocol
*On the "Home" screen if there is a check in the IROC/TRIAD box, review the protocol for language regarding IROC

To find the RTF number:
• Go to Regulatory - Provider Associations
• Select the site.
• Click on the blue "i" icon to see the site's address.
The site number does not appear on this screen, to confirm that it is for the site you are registering to scroll to the bottom to locate the address. Compare this address to what is listed for the site on the CRS Sites and Staff Directory.

◯ Yes
◯ No
◯ N/A

RTF number issue

Modality approved for the site

• Go to Regulatory - Provider Associations
• Select the site.
• Click on the blue "i" icon to confirm what modality is approved for the protocol (and the options you will have to select in OPEN).
If study is not listed, email Brie Marino

◯ Yes
◯ No
◯ N/A

Modality comment

Notes/Comments for Internal Use ONLY

Baseline Assessment Form

(46) Baseline Assessment form provided without request

◯ Yes
◯ No
◯ N/A

(47) Patient's medical/surgical history provided, documented, and/or documented as being reviewed (MD note, CRC/RC note)

Reminders:

- Does not require source documentation unless required for eligibility purposes
- The CRC/RC/RA can discuss with the patient that their past medical/surgical history was reviewed and that the form was completed to the best of the patient's recollection

◯ Yes
◯ No
◯ N/A

(48) PAST MEDICAL HISTORY

All past medical/surgical history outlined in physician notes and other source documents are listed with the appropriate start and stop dates

Reminders:

- For start and stop dates, an approximate year is okay unless a more accurate date is required for eligibility purposes
- Mammograms, colonoscopies, endoscopies, etc, that have negative results and were performed to screen for cancer should not be listed
- Test that was performed to actively rule out metastatic sites of the current cancer but have negative results, should be included
- Prior/resolved cancer diagnoses not related to current/target cancer diagnosis are to be included -In general, list the cancer with the start and stop dates (at minimum, years to be listed) -Under comments, list the treatment provided for that cancer (e.g. name of chemotherapy, surgery, radiation)
- If concurrent/active secondary malignancy, then each procedure, treatment, etc., should be listed on its own line. Of note: If there is specific eligibility criteria regarding lifetime max dose of a chemotherapeutic agent or total dose of radiation a patient can have received to once site, then those treatments for the prior cancer are to be listed on separate lines with the required information; source documentation is then required.

◯ Yes
◯ No
◯ N/A

(49) If patient has a prior/resolved cancer diagnosis or has a concurrent/active secondary malignancy, pathology reports are provided

◯ Yes
◯ No
◯ N/A

(50) Past biopsies, surgeries, and treatments related to current cancer diagnosis are listed

◯ Yes
◯ No

(51) Drug treatment history documented without issues

- For the Event Name, the name of the drug or the line of treatment is documented (one row on the form is used to capture the line of treatment)
- If patient was on a prior research protocol, the names of the medications the patient received are to be listed under Event Name
- If a medication was not an FDA approved med, list the mechanism of action in the comments
- For the start date, the date when the patient received the first dose of medication in the line of treatment was entered
- For the end date, the date the last dose of medication was administered/taken in the line of treatment was entered
- Comments include the number of cycles completed
- Exact start and stop dates are listed
- If unable to locate exact start or stop date for oral medications, the month and year are listed

◯ Yes
◯ No
◯ N/A

(52) Prior drug administration records for each treatment given are included

- For IV medications, these are to be infusion records - MD notes are not sufficient.

- If oral medications, MD notes or other documentation (i.e. Nursing notes) are included to support start and stop dates.

Note: If records were not able to be obtained, there is sufficient documentation to support that attempts at obtaining records were made and that the treatment and dates were completed based on current information available and/or patient recollection.

◯ Yes
◯ No
◯ N/A

(53) If oral drug was last treatment, there is adequate documentation to support when the last dose was taken

◯ Yes
◯ No
◯ N/A

(54) RADIATION - TREATMENT HISTORY

Radiation treatment history documented without issues

- Event Name include the type/modality and site radiated
- Comments include the total Gy and number of fractions

◯ Yes
◯ No
◯ N/A

(55) Source for radiation treatment included

- This should be the radiation treatment summary
- If treatment summary is not available, there is source that confirms
- The start and stop dates
- Area(s) treated
- Total amount of radiation received Note: If records were not able to be obtained, there is sufficient documentation to support that attempts at obtaining records were made and that the treatment and dates were completed based on current information available and/or patient recollection.

◯ Yes
◯ No
◯ N/A

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(56) SURGERY - TREATMENT HISTORY

Surgery treatment history documented without issues

- Event Name lists the anatomical location and/or type of surgery performed
- Start and stop dates are listed with the date of the surgery
- If multiple surgical procedures are performed, main surgical procedure is listed for the Event Name
- Comments list the brief pathology results
- Prophylactic surgical procedures to manage current diagnosis (e.g., hysterectomy in certain breast cancers) are included

◯ Yes
◯ No
◯ N/A

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(57) BIOPSY - TREATMENT HISTORY

Biopsy treatment history documented without issues

- Event Name lists the anatomical location that was biopsied and/or imaging method
- Start and start dates are listed with the date of the biopsy
- Comments lists the brief pathology results

◯ Yes
◯ No
◯ N/A

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(58) All pathology reports are present, support diagnosis and treatment history, and have date of collection present in the report

Reminder: Aria does not print date for cytology reports. The report needs to be printed from EPIC or eRecord (PowerChart)

◯ Yes
◯ No

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(59) OR reports and/or biopsy reports included in the packet with date listed on the report

Note: If records were not able to be obtained, there is sufficient documentation to support that attempts at obtaining records were made and that the treatment and dates were completed based on current information available and/or patient recollection.

◯ Yes
◯ No
◯ N/A

(60) PROCEDURES - TREATMENT HISTORY

Procedures treatment history documented without issues

- For events that are related to cancer treatment but do not fit the other treatment history labels - this includes port placements
- Start and stop dates are listed with the date of the procedure
- For ports, only the current port placement is included (not prior port insertions/removals) - site of port not required unless needed for eligibility purposes

◯ Yes
◯ No
◯ N/A

(61) Source document provided for procedures performed (i.e. IR report for port placement)

Note: If records were not able to be obtained, there is sufficient documentation to support that attempts at obtaining records were made and that the treatment and dates were completed based on current information available and/or patient recollection.

◯ Yes
◯ No
◯ N/A

(62) ALLERGY

Allergies were included and documented appropriately

- Event Name lists the name of the drug or food the patient is allergic to
- Start and end dates are listed as "N/A"
- Comments include the reaction the patient experienced (as applicable)
- Each drug/food allergy is listed on a separate line
- Only drug and food allergies are listed - seasonal, dust, and pollen allergies do not need to be listed
- If the patient does not have an allergy, "NKA", "NKDA", etc, was entered

◯ Yes
◯ No

(63) Appropriate selection of the Type of Subject History

Note: Use the surgery label if the patient had a prophylactic surgical procedure to manage their cancer diagnosis (e.g., hysterectomy in certain breast cancers).

◯ Yes
◯ No

There are other issues with the Baseline Assessment Form not addressed above

This may include items such as:

- Spelling errors
- Item that needs to be removed

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Baseline Medical Problems Form

(64) Baseline Medical Problems Form provided without request

◯ Yes
◯ No
◯ N/A

(65) If there are no baseline medical problems to capture, there is an entry stating there are no AEs

◯ Yes
◯ No
◯ N/A

(66) Source provided for baseline medical problems (AEs) being reviewed with the patient

◯ Yes
◯ No

(67) Correct CTCAE version selected

◯ Yes
◯ No

(68) All current or ongoing issues that the subject is experiencing are listed

This includes any symptom, diagnosis, etc. noted in MD note, CRC/RC/RA note, other notes as applicable

NOTE: If per protocol AEs noted from QOLs/PROs are to be captured, these are also listed

◯ Yes
◯ No
◯ N/A

(69) Abnormal results from screening labs are included

Note: For CKD (Chronic Kidney Disease), this is only listed if the patient has an actual diagnosis and meets the CTCAE grading

◯ Yes
◯ No
◯ N/A

(70) Abnormal vital signs are included (e.g., bradycardia, tachycardia, hypertension, hypotension, obesity)

◯ Yes
◯ No
◯ N/A

(71) AEs noted from testing performed are captured

Reminders:

- Do not include incidental findings unless there is a specific CTCAE term for the finding (e.g., ascites, pleural effusion, atelectasis, pericardial effusion)
- Exception: If the finding is captured on the Tumor Measurement Form (RECIST, RANO, etc), do NOT list
- If there is a finding for which the patient is experiencing a symptom related to the incidental finding, the symptom is listed

◯ Yes
◯ No
◯ N/A

(72) Correct CTCAE term utilized to capture the symptom/abnormality/finding (e.g.,. pneumonia is captured under the CTCAE term of lung infection)

- If there is not a specific CTCAE term, then a CTCAE system and the "other" category is selected (e.g., for Type II diabetes, it is listed as "Endocrine disorders, other - Type II diabetes)

◯ Yes
◯ No

(73) Correct grade selected/entered

◯ Yes
◯ No

(74) Start dates are correct and are listed with a least an approximate year

- Start date to match source
- Start date to be consistent with con med log as applicable (i.e. patient cannot start a medication prior to the start of the AE)
- If patient-reported symptom or diagnosed medical condition, year at minimum is entered
- If a lab abnormality or any abnormality noted on a screening tests/procedure, the date of the test is entered

◯ Yes
◯ No

(75) Stop date either remains blank or an exact end date is listed (i.e. Month/Day/Year)

- The stop date is only entered if the AE resolved or changed grade during the screening period. Otherwise, the stop date is left blank.

◯ Yes
◯ No

(76) "Action Taken" column completed appropriately

- All medications/interventions the patient is taking for the AE are listed
- The medication name listed here should match the con med log (e.g. Tylenol is on the con med log, this is listed in the action taken and not acetaminophen)
- Only includes medications and interventions (i.e. foley, oxygen)
- If there is not a medication or intervention, "Monitor" is listed

◯ Yes
◯ No

(77) Any medication/intervention listed in the "Action Taken" column is captured on the Con Med Log

◯ Yes
◯ No
◯ N/A

(78) Patient ID entered (will only be applicable if patient ID known)

◯ Yes
◯ No
◯ N/A

(79) Physician has signed the form electronically

The Controlled, Related to Disease, and Related to Prior Anti-cancer Therapy columns are completed as applicable

Reminders:

- Items marked as erroneous do not need to be re-approved by MD/PI prior to registration
- If performing a check for a second step and only patient ID added (confirmed by looking at version history), MD does not need to approve prior to the second step registration/randomization NOTE: If there were no AEs at baseline, Physician signed the entry confirming no AEs

◯ Yes
◯ No
◯ Known pending at time of review

There are other issues with the Baseline Medical Problems Form not addressed above

This may include items such as:

- Spelling errors
- Item that needs to be removed

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Con Med Log

(80) Con Med Log provided without request

◯ Yes
◯ No
◯ N/A

(81) Source provided for con meds being reviewed with the patient

- For medications listed in MD notes but not on the con med log, in general, a CRC/RC note that documents the con meds were reviewed is okay
- HOWEVER, if there is a specific eligibility criterion regarding a medication, we need explicit documentation (i.e. a medication listed in MD note that is prohibited per protocol)
- If confirmation of a start date is required for registration, this is to be specified in CRC/RC note (i.e. ADT therapy prescribed to patient - need confirmation that CRC/RC confirmed with the patient when they started taking the ADT)
- If a medication was prescribed, need documentation if the patient started taking the medication (i.e. if script for antiemetic provided for when the patient starts chemo so that they can fill it ahead of time, note needs to document that script given but patient has not taken)

◯ Yes
◯ No

(82) All medications the patient is currently taking are listed

- This includes all prescriptions, over-the-counter medications, vitamins, and herbal supplements Note: If a patient has been prescribed a medication but has not yet started taking the medication, this should not be listed. It will only be added to the form once the patient indicates/confirms that they have started taking the medication.

◯ Yes
◯ No
◯ N/A

(83) All interventions used to treat baseline medical problems are listed (e.g., oxygen, blood transfusion, BiPAP, nutritional supplements)

Note: Interventions used to prevent a medical problem or AE are not listed (e.g., compression stockings, nutritional supplements as prophylaxis)

◯ Yes
◯ No
◯ N/A

(84) All entries have dose, route, and frequency completed appropriately

- If the mediation has multiple ingredients (e.g., multivitamin), it is acceptable to write in the amount (e.g., 1 tablet)
- if the dose is set up as a sliding scale (e.g., insulin), the range is listed for the dose
- if patient is receiving a morning and evening dose of the medication and the dose is the same, this is captured on one line and 'twice a day' can be entered for the frequency

◯ Yes
◯ No

(85) All entries have at least approximate start date listed and match source as applicable

◯ Yes
◯ No

(86) End date either remains blank or an exact end date is listed (i.e. Month/Day/Year)

- The end date is only entered if the AE resolved or changed grade during the screening period. Otherwise, the end date is left blank.

◯ Yes
◯ No

(87) All entries include reason for use

- Reason for use is the exact and complete CTCAE term that is listed on the Baseline Medical Problems Form
- Exception to the exact CTCAE term: If the AE term is listed under the "Other" category, only enter in the AE term (e.g. "Endocrine disorders, other - Diabetes Type II" is listed on BMP form, on the con med log, only list "Diabetes Type II")
- If the medication is being used as a supplement or for prophylaxis, "Supplement" or "Prophylaxis" is entered

◯ Yes
◯ No

(88) All baseline conditions listed in the Reason for Use column are on the Baseline Medical Problems Form

◯ Yes
◯ No
◯ N/A

(89) If a cycle/day column is included on the form, "Baseline" is written in

◯ Yes
◯ No
◯ N/A

(90) "Prohibited Medication from Protocol" column completed

- If the protocol has a prohibited medication section, the section number is written in
- If the protocol has no prohibited mediation section, "N/A" is entered

◯ Yes
◯ No

(91) IDS pharmacy review completed and email present on chart

◯ Yes
◯ No
◯ N/A

(92) If there were prohibited/precautionary medications, MD has reviewed and commented and/or documentation present to support that patient educated to stop medication(s)

- If patient was required to stop a medication, there is source present to support the date of the last dose and a stop date was entered for the medication

◯ Yes
◯ No
◯ N/A

There are other issues with the Con Med Log not addressed above

This may include items such as:

- Spelling errors
- Item that needs to be removed

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Disease Assessment

(93) Disease assessment form provided in packet without request (i.e. RECIST, RANO)

◯ Yes
◯ No
◯ N/A

(94) Correct imaging modality utilized for disease assessment

◯ Yes
◯ No
◯ N/A

(95) Correct method of disease assessment(s) was completed as per protocol (i.e. RECIST, RANO, Lugano, study specific)

◯ Yes
◯ No
◯ N/A

(96) Correct diameters used to calculate response

◯ Yes
◯ No
◯ N/A

(97) All calculations are correct

◯ Yes
◯ No
◯ N/A

(98) For RECIST v1.1, a maximum of 5 target lesions are identified with a maximum of two per organ

◯ Yes
◯ No
◯ N/A

(99) All sites of disease listed in radiology report are addressed on the form (can be listed as target or non-target)

◯ Yes
◯ No
◯ N/A

(100) For Imaging Core reads, the form has been electronically signed by the radiologist and the signature audit trail has been printed

◯ Yes
◯ No
◯ N/A or known pending at time of review

(101) Appropriate special/study specific forms used as required

◯ Yes
◯ No
◯ N/A

(102) All fields on form(s) are completed

◯ Yes
◯ No

(103) Treating MD has either signed the form or has documentation in their note that the scans/testing were reviewed

◯ Yes
◯ No

There are other issues with the disease assessment form not addressed above

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Screening

(104) All study specific requirements completed after consent signed

For tests/assessment completed prior to signing of consent:

- If the test/assessment was done as part of Standard of Care, it is okay unless specified in the protocol that the test/assessment needed to be completed after signing of consent
- If the test/assessment was for study purpose, a deviation is to be filed

◯ Yes
◯ No
◯ N/A

---

(105) Source for screening labs provided

◯ Yes
◯ No
◯ N/A

---

(106) All screening labs completed as per protocol within protocol allowable window

◯ Yes
◯ No
◯ N/A

---

(107) Lab reports are electronically approved
Aria: "Approved"
Epic: "Provider Status: Reviewed"

◯ Yes
◯ No
◯ N/A or known pending at time of review

---

(108) If labs performed at an outside facility, report was reviewed by the MD

Either

- MD initialed/signed, dated, and marked CS or NCS for all pages of report
- OR
- Labs uploaded to Aria/Epic and electronically signed/reviewed by the MD

◯ Yes
◯ No
◯ N/A or known pending at time of review

---

(109) Source for all screening tests/procedures (i.e. scan, ECG, PFT, ECHO, Vital Signs, PE) provided

◯ Yes
◯ No
◯ N/A

---

(110) All screening tests/procedures (i.e. scan, ECG, PFT, ECHO, Vital Signs, PE) performed as per protocol and within protocol allowable window

For imaging, this includes that the correct imaging modality was performed as per protocol.

◯ Yes
◯ No
◯ N/A

(111) Screening tests/procedures reviewed by/electronically reviewed/approved by appropriate MD

This includes but not limited to:

- MD notes are approved
- ECHOs are approved/reviewed

◯ Yes
◯ No
◯ N/A or known pending at time of review

---

(112) Physician signature or initials present on any test/procedure that required physician signature (i.e. ECG)

- NCS/CS should be marked for any abnormal results

◯ Yes
◯ No
◯ N/A

---

(113) Screening QOLs done as per protocol

For cooperative group studies where the QOLs are completed on paper, ensure the most recently approved version of the PROs/QOLs are being used.

Go to CTSU > type in the protocol in the "Protocols" tab > Click "Documents" > While under the "CIRB Approved Documents" section, filter the "Support Documents"

◯ Yes
◯ No
◯ N/A

---

(114) QOL forms completed appropriately

- If performed on paper, patient's name (or patient ID if known) and date of completion are provided on each page
- Each question was answered by the patient; if not, this was addressed in CRC/RC/RA note

◯ Yes
◯ No
◯ N/A

---

(115) Source for archival tissue provided

If archival tissue is required per protocol (this includes if the patient consented to optional banking/tissue collection), the following must be provided:

- Archival tissue request form with email from Tissue Support confirming review
- Source that the archival tissue request was sent to path department
- NOTE: If archival tissue is part of eligibility criteria, confirmation of tissue availability must be present (e.g., email confirmation from pathology department, tissue request form signed by pathologist, or CRC/RC/RA providing written source that they have tissue in hand)

◯ Yes
◯ No
◯ N/A

(116) Source for calculations provided (e.g., creatinine clearance, QTc)

◯ Yes
◯ No
◯ N/A

(117) Calculations provided (e.g., creatinine clearance, QTc) are completed appropriately

- Patient's name, DOB, initials of the person completing the calculation, and date calculation performed at the top of each page

◯ Yes
◯ No
◯ N/A

(118) Study specific evaluations/assessment form provided (e.g. ACE-27 Score)

◯ Yes
◯ No
◯ N/A

(119) Study specific evaluations/assessment forms completed appropriately

- As applicable, each page to have patient's name at the top of each page (OR patient's ID number if known) and date of completion
- For ACE-27, to be signed and dated by the MD
- For the ACE-27, utilize the date the MD signed the form for screening tests & evaluations pages and for the registration form

◯ Yes
◯ No
◯ N/A

(120) IVFC was provided

Reminder: Not required for tissue submission only step

◯ Yes
◯ No
◯ N/A

(121) IVFC was completed accurately and completely

Reminders:

- If issues noted with header, section A, or section B, we could note in our findings, but do not ask for them to make any changes unless there is something blatantly incorrect like patient's name, DOB, or study number
- Projected start date does not need to match the planned start date provided by the CRC/RC in email or on cooperative group registration form

◯ Yes
◯ No
◯ N/A

(122) Confirmation of patient acceptance of estimated costs provided

- If multimodality, both Med Onc and Rad Onc included
- For community, documentation that the patient has clinical trial coverage and has been counseled is acceptable
- For Rad Onc, documentation that the patient has clinical trial coverage is acceptable (if treatment plan is not known/confirmed at time of registration)

◯ Yes
◯ No
◯ N/A

(123) If full review/discussion of patient's accepted estimated costs is not required, documentation present regarding patient has clinical trial coverage

◯ Yes
◯ No
◯ N/A

(124) Demographics form provided

- Or other source for demographics

◯ Yes
◯ No
◯ N/A

(125) OnCore calendar screening visits completed

◯ Yes
◯ No
◯ N/A

(126) There are other issues with screening that are not addressed above

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

Eligibility

(127) There are source documents present to support all inclusion/exclusion criteria

Reminder for NYHA Classification

If no caveat to cardiac history noted in the eligibility criteria, MD needs to provide the NYHA classification (i.e. NYHA classification of II or better) If cardiac history language is present in the eligibility criteria (i.e. For patients with known history or current symptoms of cardiac disease, patient must have NYHA class of II or better), NYHA classification only needs to be provided if the patient has a cardiac history. Cardiac history can include: CAD. angina, MI, arrhythmia Cardiac history does not include: HTN or hyperlipidemia

◯ Yes
◯ No
◯ N/A

---

(128) For eligibility criteria without a separate source document, there is a CRC/RC/RA note to document such criteria (e.g., no history of live vaccine)

◯ Yes
◯ No
◯ N/A

---

(129) Clarification regarding eligibility criteria is needed

◯ Yes
◯ No

---

(130) Screening Tests & Evaluations document provided

◯ Yes
◯ No
◯ N/A

---

(131) Screening Tests & Evaluations document completed accurately

Date listed in the date completed column reflects the most recently performed test/evaluation Confirm date listed in the "Randomization/Registration/Treatment must occur on" column is accurate Confirm each test/evaluation is marked with 1st reviewer initials Ensure fields are completed for the consent, insurance, and training verification sections REMINDER: Ensure planned treatment date within protocol allowable window from registration/randomization date (refer to protocol)

STRATIFICATION FACTORS: Please review the protocol for stratification factors. If present, these are to be captured on the Screening Tests & Evaluation pages.

**If the CRS Screening Tests/Evaluations Document needs to be updated for any reason (i.e. addition of stratification factors, updates due to newer version), make the updates and send to Program Manager and Reg Specialist to post in eREG

◯ Yes
◯ No
◯ N/A

(132) Screening Tests & Evaluations document signed and dated by 1st reviewer

- Date is on or after the last assessment/procedure/test was performed and/or reviewed

◯ Yes
◯ No
◯ Known pending at time of review

(133) Screening Tests & Evaluations document signed and dated by physician

- Date is on or after the last assessment/procedure/test was performed and/or reviewed

◯ Yes
◯ No
◯ Known pending at time of review

(134) A screening test/procedure/evaluation will time out prior to registration/randomization/treatment

◯ Yes
◯ No
◯ N/A

(135) Sponsor specific checklist/form provided

◯ Yes
◯ No
◯ N/A

(136) Sponsor specific checklist/form was completed accurately

◯ Yes
◯ No
◯ N/A

(137) For cooperative group studies, appropriate registration form(s) and/or CRS Cooperative Group Enrollment form provided

◯ Yes
◯ No
◯ N/A

(138) For cooperative group studies, appropriate registration form(s) and/or CRS Cooperative Group Enrollment form completed accurately

Reminders

- Registrar does not need to be completed
- If we are prompted in OPEN to round or add decimals to a lab value, we do not ask the staff to update the form
- If OPEN requires a different lab unit than what is listed on the form, staff need to correct this on the form
- ECHOs: Utilize the lower number in the range unless it is an NRG study. For NRG studies, utilize the average and round up (60-65% becomes 63%)
- "Date of Authorization" is the date the patient signed the HIPAA consent NOTE: The CRS Cooperative Group Enrollment Form should be a part of the Screening Tests & Evaluations pages. If not, please update to include. Remember to remove any information that is already being captured on the registration form.

◯ Yes
◯ No
◯ N/A

(139) For cooperative group studies, there is source present for questions on the registration form that were not otherwise specified/captured in eligibility criteria

◯ Yes
◯ No
◯ N/A

(140) Eligibility pages printed from most recent, IRB approved version of the protocol

◯ Yes
◯ No

(141) Protocol specific eligibility pages completed accurately

- Patient's name is on each page
- Each eligibility criteria has first reviewer initials
- For lab assessments, the lab result and relevant range value, if applicable, are included
- For contraception, it is written in what the patient agreed to or why not applicable (e.g. hysterectomy)
- Applicable notes are included such as: Dates of scans, dates of applicable prior treatment and washouts, other notes as relevant for the 2nd reviewer
- Confirm all dates are appropriately calculated for prior treatment washouts, as applicable

◯ Yes
◯ No

(142) Eligibility pages signed and dated by 1st reviewer

- Date is on or after the last assessment/procedure/test was performed and/or reviewed

◯ Yes
◯ No
◯ Known pending at time of review

(143) Eligibility pages signed and dated by physician

- Date is on or after the last assessment/procedure/test was performed and/or reviewed

◯ Yes
◯ No
◯ Known pending at time of review

Deviation noted with eligibility criteria and/or screening test/procedure/evaluation

◯ Yes
◯ No

(144) Clear documentation of discussion with the sponsor and the PI/treating MD present regarding the deviation(s) with eligibility criteria and/or screening test/procedure/evaluation

◯ Yes
◯ No
◯ N/A

(145) If there is a planned deviation, an Exception Request was submitted and approved by the IRB prior to registration/randomization

◯ Yes
◯ No
◯ N/A

(146) Patient met all eligibility criteria

◯ Yes
◯ No

(147) Eligibility criteria not met

☐ Baseline adverse event
☐ ECOG
☐ Histology/Pathology
☐ Imaging result (i.e. metastatic disease, no measurable disease)
☐ Lab
☐ Medical history
☐ Staging
☐ Surgical history
☐ Test/evaluation out of window
☐ Test result (i.e. ECG, Echo, PFT)
☐ Treatment history
☐ Other

Further explanation to "Other" for eligibility criteria that was not met

(148) There are other issues with eligibility that are not addressed above

◯ Yes
◯ No

Notes/Comments for Internal Use ONLY

QA Section

Email sent to CRC/RC/RA with list of findings. Copy Manager and Supervisor (as applicable).

Email must be organized into two sections (as noted below) and have a clear description of issues. Provide timeframes of when the corrections need to be completed.

1) Eligibility/Screening Findings (All findings MUST be addressed prior to registration)

- Eligibility criteria: There must be documentation to support that all eligibility criteria were met

- Screening tests: All screening tests must have been performed and documented per protocol

- eSource logs have been requested and populated

- Consent: The ICF was completed correctly. All topics that are required to be addressed during the consent visit were discussed and patient's responses are documented in a consent note
- Items that may affect the patient's willingness to participate:

Example 1 (email confirming that financial counselling was performed and the patient agreed to the cost assessment)

Example 2 (pharmacy reviewed for prohibited meds

If patient is taking a prohibited med, there is documentation that the MD has decided what action to take with the med and patient has agreed to the plan

)
- The Eligibility Checklist, the Screening Tests/Evaluations Form, and the OPEN Registration Form must be completed without error

2) Clerical/Administrative Findings (should be addressed as soon as possible but will not hold up registration)

- Examples - patient's identifier is missing from the baseline QOLs; additional protocol number is missing from the consent process form; a checkbox is missed on the IVFC form; the wrong type of subject history is selected on the BAF; mis-spelled words NOTE: In general, QA can register if the MD has not approved the BMPF. However, if an eligibility criteria states that any AEs/BMPs related to prior cancer therapy must have resolved to grade 1 or better (or something similar), the MD must provide attributions on the BMPF and approve before the subject can be registered.

(9/29/2025)

NOTE: If a patient is evaluated for eligibility and does not meet every criteria, alert the CRC/RC/RA as soon as possible and list the specific inclusion/exclusion criteria in question

EMAIL FOR COMMUNITY CHECKS:

- Initiate a brand new email to the requestor with the findings. Include the patient's name in the body of the email. Include the Community Network Second Check Team email address (CRSNetworkcheckteam@upmc.edu).
- SUBJECT LINE: 2nd Check Findings - HCC XX-XXX - XX (patient initials) (i.e., 2nd Check Findings - HCC 18-195 - RN)

◯ Yes
◯ No

Comments regarding email to CRC/RA

Upload 2nd check findings email

All findings fully addressed by CRC/RA

• Subjects must not to be registered in OPEN unless the first, second, and investigator signatures have been reviewed and confirmed, and all outstanding issues identified during the check have been resolved

If you were working from home whenever you confirmed eligibility:

- A new email was sent utilizing the template saved on the working drive: DeptShare > WorkingDrive > Quality & Education > Eligibility Reviews > 2nd Reviewer Eligibility Confirmation
- Reminder: the most updated eligibility pages and Screening Tests & Evaluations pages are attached to the email

◯ Yes
◯ No

Comment regarding all findings being fully addressed

Subject registered in OPEN

• REMINDER: After demographics, if they ask for patient number, use either XXX or 000

NOTE: Save the OPEN forms in the patient's eChart (Eligibility Checklist - Registration)

◯ Yes
◯ No
◯ N/A

Registration email sent

Utilize the New Patient Registration email template located on CRS Central SharePoint site: CRS Central > Clinical > Clinical Documents > NEW STUDY TEMPLATES COPY THIS FOLDER > Checklists

- For HCC and Magee registrations, Send the Registration Confirmation and Full Enrollment Form to: PharmPCIInvestigationalDrugServ@UPMC.EDU (not required for tissue submission registrations or for radiation treatment only trials); the treating physician (include Med Onc MD and Rad Onc MD if applicable); the disease center service account; QA/QC team.
- For community registrations, Send the Registration Confirmation and Full Enrollment Form to: PharmPCIInvestigationalDrugServ@UPMC.EDU (not required for tissue submission registrations or for radiation treatment only trials); the treating physician (include Med Onc MD and Rad Onc MD if applicable); CRC; RC; RA (listed on CRS Cooperative Group enrollment form and/or Oncore); CRSNetworkcheckteam@upmc.edu ; local pharmacist(s) if Pinnacle, Williamsport, or Western Maryland (see below table); the disease center service account for whichever is the first center listed under the Management Group in OnCore.; QA/QC team. If trial includes radiation information which needs items uploaded to IROQ/TRIAD include: CCRadOncResearchTeam@upmc.edu on email

Eligibility tab in OnCore: If the Eligibility tab is not completed, please add this to your registration email as a reminder for the CRC/RC to update. You do not need to go back into OnCore to confirm this was updated.

Pharmacy contacts:

· Central PA (Pinnacle sites: PA041, PA045, PA486, PA498, PA504): laytont2@upmc.edu (Tyler Layton); bogdanr@upmc.edu (Renee Bogdan) ; finneym2@upmc.edu (Maria Finney)

· Williamsport (PA050): penfieldcm@upmc.edu

· Western Maryland (MD031): shernss@upmc.edu (Susan Shern) and hughesje@upmc.edu (Jennessa Morgan)

◯ Yes
◯ No
◯ N/A

Data submission protocol specific email reminder sent to RA, CRC, and RC as applicable

Templates located on the working drive: DeptShare > WorkingDrive > Quality & Education > Eligibility Reviews > Registration > email registration templates
• If a template does not exist, one should be created using the consent and protocol documents
• If the protocol version on the footer does not match the current protocol version, one should update the document as needed

◯ Yes
◯ No
◯ N/A

Registration log updated - located on QA SharePoint site

◯ Yes
◯ No

OnCore Updated

For cooperative group studies:
• On Study with the Sequence No. (patient ID), on study date (if applicable), disease site, histology, diagnosis date, and Subject Staff - Registering Coordinator and 2nd Check of Eligibility or 3rd Check of Eligibility

For non-cooperative group studies:
• Update OnCore: On Study with Subject Staff - 2nd Check of Eligibility

◯ Yes
◯ No

Working Drive Updated

DeptShare > WorkingDrive > Quality & Education > Eligibility Reviews

Patient specific folder created under study

- Email(s) regarding findings
- Registration email
- Data Submission Reminder email

◯ Yes
◯ No

Signed 2nd checks (Eligibility pages & Screening Tests & Evaluations pages)

- Signed 2nd check uploaded to patient's eChart ---- Reminder: delete the unsigned forms from the patient's eChart
- For community checks: Wet ink signed eligibility checklist filed in community site folder If you were working from home whenever eligibility was confirmed

- Email confirming eligibility uploaded to the patient's eChart (Eligibility Checklist - Registration)

◯ Yes
◯ No
◯ N/A

Comments

Follow Up

Follow up required

◯ 2 or less emails/communication
◯ 3 or more emails/communication

Were there additional findings not reported by QA?

◯ Yes
◯ No
◯ N/A

Additional findings not reported by QA

Any other comment(s) regarding FU

Upload final follow-up document

Scoring

COMPLETION OF FORMS

Completion of Forms - Total number of tasks completed correctly/accurately

_____

Completion of Forms - Total number of tasks reviewed

_____

Completion of Forms - Overall Evaluation (%)

_____

SOURCE PROVIDED

Source Provided - Total number of tasks completed correctly/accurately

_____

Source Provided - Total number of tasks reviewed

_____

Source Provided - Overall Evaluation (%)

_____

SIGNATURES OBTAINED

Signatures Obtained - Total number of tasks completed correctly/accurately

_____

Signatures Obtained - Total number of tasks reviewed

_____

Signatures Obtained - Overall Evaluation (%)

_____

INFORMED CONSENT PROCESS

Informed Consent Process - Total number of tasks completed correctly/accurately

_____

Informed Consent Process - Total number of tasks reviewed

_____

Informed Consent Process - Overall Evaluation (%)

_____

SCREENING & ELIGIBILITY

Screening & Eligibility - Total number of tasks completed correctly/accurately

_____

Screening & Eligibility - Total number of tasks reviewed

_____

Screening & Eligibility - Overall Evaluation (%)

_____

ELIGIBILITY OUTCOME

Patient meets eligibility criteria

[eligibility_met]

If eligibility criteria not met, reason not met

[eligibility_reason]

Further explanation to "Other" for eligibility criteria that was not met

- [eligibility_other_reason]