Essentia Health Community Cancer Research Program
Internal Audit System

Patient Case Review

Study CRA: _____

Study RN: _____

Auditing CRA: _____

Auditing RN: _____

Original 10/2013
Revision 01/24/2019

Informed Consent

(CRA and RN)

Item	Yes	No	N/A	Comments
Consent form document not signed and dated by the patient/study participant (or parent/legally authorized representative, if applicable)				Initial consent revision/version date: _____
Patient/study participant signature cannot be corroborated				
Failure to document the informed consent process with the study participant				
Consent form document missing				
Consent form not signed by patient prior to study registration/enrollment				
Consent form does not contain all required signatures				
Consent form used was not the most current IRB-approved version at the time of patient registration ****SPECIALIST TEAM****				
Re-consent not obtained as required ****SPECIALIST TEAM****				List all reconsent revision/version dates:
Consent of ancillary/advanced imaging studies not executed properly				
Other (explain)				

Audited By _____ **Date** _____

Audited By _____ **Date** _____

Do Changes Need to Be Made?

CRA YES **[ ]** NO **[ ]**

_____

RN YES **[ ]** NO **[ ]**

_____

Have Changes Been Completed?

Original 10/2013
Revision 01/24/2019

Protocol # _____ **Patient Initials** _____ **Patient ID** _____ **Site ID** _____

CRA YES **[ ]** NO **[ ]** **RN** YES **[ ]** NO **[ ]**

Eligibility

(CRA and RN)

Item	Yes	No	N/A	Comments
Review of documentation available at the time of the audit confirms patient/study participant did not meet all eligibility criteria and/or eligibility requirements were not obtained within the timeframe as specified by the protocol				
Pre-study tests/procedures not performed within required timeframe				
Pre-study toxicities not documented				
Protocol treatment given **before** randomization				Date:
All required signatures obtained **after** registration				
Documentation missing; unable to confirm eligibility				
Other (explain)				

Audited By _____ **Date** _____

Audited By _____ **Date** _____

Do Changes Need to Be Made?

CRA YES **[ ]** NO **[ ]**

_____

RN YES **[ ]** NO **[ ]**

_____

Have Changes Been Completed?

CRA YES **[ ]** NO **[ ]** **RN** YES **[ ]** NO **[ ]**

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Treatment

(RN)

Item	Yes	No	N/A	Comments
Incorrect agent/treatment/intervention used				
Additional agent/treatment/intervention used which is not permitted by protocol				
Dose deviations or incorrect calculations (error greater than +/- 10%)				
Dose modification/treatment interventions not per protocol; incorrectly calculated				
Treatment/intervention incorrect, not administered correctly, or not adequately documented				
Timing and sequencing of treatment/ intervention not per protocol				
Unjustified delays in treatment/intervention				
Oral drug compliance not documented (i.e. pill diaries, pill counts)				
Other (explain)				

Audited By _____ **Date** _____

Do Changes Need to Be Made?

CRA YES **[ ]** NO **[ ]**

_____

RN YES **[ ]** NO **[ ]**

_____

Have Changes Been Completed?

CRA YES **[ ]** NO **[ ]** **RN** YES **[ ]** NO **[ ]**

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Revision 01/24/2019

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Disease Outcome / Response

(CRA and RN)

Item	Yes	No	N/A	Comments
Inaccurate documentation of initial sites of involvement				
Tumor measurements/evaluation of status or disease not performed, not reported, or not documented per protocol				
Protocol-directed response criteria not followed				
Claimed response (ie, partial response, complete response, stable) cannot be verified or auditor could not verify the reported response				
Failure to detect cancer (as in a prevention study) or failure to identify cancer progression				
Other (explain)				

Audited By _____ **Date** _____

Audited By _____ **Date** _____

Do Changes Need to Be Made?

CRA YES **[ ]** NO **[ ]**

_____

RN YES **[ ]** NO **[ ]**

_____

Have Changes Been Completed?

CRA YES **[ ]** NO **[ ]** **RN** YES **[ ]** NO **[ ]**

Original 10/2013
Revision 01/24/2019

Protocol # _____ **Patient Initials** _____ **Patient ID** _____ **Site ID** _____

Adverse Events

(RN)

Item	Yes	No	N/A	Comments
Failure to report or delayed reporting of an adverse event that would require filing an expedited Adverse Event (AE) report or reporting to the Group				
Adverse events not assessed by the investigator in a timely manner (per protocol)				
Grades, types, or dates/duration of adverse events inaccurately recorded				
Adverse events cannot be substantiated				
Follow-up studies necessary to assess adverse events not performed				
Recurrent under- or over-reporting of adverse events				
AE assessment sheet does not match EPIC note				
Other (explain)				

Audited By _____ **Date** _____

Do Changes Need to Be Made?

CRA YES **[ ]** NO **[ ]**

_____

RN YES **[ ]** NO **[ ]**

_____

Have Changes Been Completed?

CRA YES **[ ]** NO **[ ]** **RN** YES **[ ]** NO **[ ]**

Original 10/2013
Revision 01/24/2019

Protocol # _____ **Patient Initials** _____ **Patient ID** _____ **Site ID** _____

General Data Management Quality

(CRA)

Item	Yes	No	N/A	Comments
Recurrent missing documentation in the patient/study participant records				
Protocol-specified laboratory tests not done, not reported or not documented including research specimens				
Protocol-specified diagnostic studies including baseline assessments not done, not reported or not documented				
Protocol-specified research/advanced imaging studies not done or submitted appropriately (within timeframe)				
Frequent data inaccuracies				
Errors in submitted data				
Delinquent data submission (> 6 months delinquent is considered a major deficiency; a 3-6 month delinquency is considered a lesser deficiency)				
Demographic sheet completed				**N/A prior to 9/11/2019**
Demographic information is correct in CREDIT (EPIC – optional)				
Other (explain)				

Audited By _____ **Date** _____

Do Changes Need to Be Made?

CRA YES **[ ]** NO **[ ]**

_____

RN YES **[ ]** NO **[ ]**

_____

Have Changes Been Completed?

CRA YES **[ ]** NO **[ ]** **RN** YES **[ ]** NO **[ ]**

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