CARDIAC-SPARING WHOLE LUNG IMRT IN CHILDREN AND YOUNG ADULTS WITH LUNG METASTASES: A FEASIBILITY STUDY

Forms Packet includes:

- Cardiac Sparing Whole Lung IMRT Baseline Data Submission Checklist
- Cardiac Sparing Whole Lung IMRT Follow-Up Data Submission Checklist
- Cardiac Sparing Whole Lung IMRT Study Response Form
- Cardiac Sparing Whole Lung Adverse Event Transmittal Form
- Cardiac Sparing Whole Lung IMRT Off-Study Form

Notes regarding data to be submitted:

Patients enrolled on this study have pulmonary metastatic disease from several different eligible tumors. The possible treatment regimens will vary from case to case. Without one standard treatment it is impossible to reduce the data capture to standard elements. Therefore, submission of your institutional medical record documents which provide the details of the chemotherapy and non-pulmonary radiation delivered during lung radiation treatment and for two years follow-up will be required. The baseline data and follow-up data checklists are provided to help organize the documents that are needed. It is not necessary to submit all the documents on the checklist at the same time, but please include a checklist with each submission.

Cardiac Sparing Whole Lung IMRT Baseline Data Submission Checklist

2/13/2012

Patient Initials (F, L): _____ Registration #: _____

_____ **History and Physical (done by medical oncologist)**
If current chemotherapy and/or other treatment information is not included in the H & P, the information should be provided in another document

_____ **History and Physical (done by radiation oncologist)**
If information about prior radiation therapy treatment is not included in the H & P, the information should be provided in another document

_____ **Pre-treatment test results**
(CBC, differential, platelets, liver enzymes)

_____ **EKG (report only)**

_____ **ECHO (report only)**

_____ **Chest CT (report only)**

Name and email of person submitting the data: _____

_____

Date the data was submitted to QARC: _____

The form and data should be submitted to: CardiacSparingIMRT@QARC.org

Questions about the data to be submitted should be directed to the email above.

Cardiac Sparing Whole Lung IMRT Follow-Up Data Submission Checklist
2/13/2012

Patient Initials (F, L): _____ Registration #: _____

Studies to Be Obtained	Frequency	Date of Scan/Evaluation
History and Physical (done by medical oncologist)	**q 4 mo x 6**	_____
History and Physical (done by radiation oncologist)	**q 4 mo x 6**	_____
Follow-up Test Results:		
- **CBC, differential, platelets**	**q 6 mo x 4**	_____
- **liver enzymes**	**q 4 mo x 6**	_____
EKG (*report only*)	**q 6 mo x 4**	_____
ECHO (*report only*)	**q 6 mo x 4**	_____
Chest CT (*report only*) (this does not need to be submitted again with this form if included with the Response form)	**q 6 mo x 4**	_____

Name and email address of the person submitting the data: _____

_____

Date the data was submitted to QARC: _____

The data should be submitted to: CardiacSparingIMRT@QARC.org

Question about the form or data to be submitted should be directed to the email above.

Cardiac Sparing Whole Lung IMRT Study Response Form

2/13/2012

Patient Initials (F L): _____ Registration#: _____

Evaluation time point:

[ ] – 6 months after completion of Radiation Therapy
[ ] – 12 months after completion of Radiation Therapy
[ ] – 18 months after completion of Radiation Therapy
[ ] – 24 months after completion of Radiation Therapy
[ ] – Recurrence/Progression
[ ] – Other (please specify below)

Reference time point:

[ ] – Baseline/pre-chemotherapy
[ ] – 6 months after completion of Radiation Therapy
[ ] – 12 months after completion of Radiation Therapy
[ ] – 18 months after completion of Radiation Therapy
[ ] – 24 months after completion of Radiation Therapy
[ ] – Other (please specify below)

Other:

		Measurements (using RECIST 1.0 criteria – longest dimension only in cm):	
	Site:	Evaluation Time Point	Reference Time Point
Target Lesion 1	_____	_____	_____
Target Lesion 2	_____	_____	_____
Target Lesion 3	_____	_____	_____
Target Lesion 4	_____	_____	_____
Target Lesion 5	_____	_____	_____
Target Lesion 6	_____	_____	_____
Target Lesion 7	_____	_____	_____
Target Lesion 8	_____	_____	_____
Target Lesion 9	_____	_____	_____
Target Lesion 10	_____	_____	_____
Sum of the Target Lesions		_____	_____

Cardiac Sparing Whole Lung IMRT Study Response Form

2/13/2012

Patient Initials (F L): _____ Registration#: _____

Response at Selected Evaluation Time Point:

_____ CR (disappearance of all target lesions).

_____ PR (at least a 30% decrease of disease measurement done to confirm measureable disease at study entry).

_____ PD (at least a 20% increase in the disease measurement, taking as reference the smallest disease measurement recorded since the start of treatment, or the appearance of one or more new lesions).

_____ SD (neither sufficient shrinkage to qualify as PR nor sufficient increase to qualify as PD taking as reference the smallest disease measurement since the treatment started).

Date of scan for Evaluation Time Point: _____

Date of scan for Reference Time Point: _____

Name and email address of the person completing this form: _____

_____

Date the response assessment was completed: _____

Copies of radiology reports should be included with each Study Response Form (the report for the reference time point does not need to be included if previously submitted).

All forms and reports should be submitted to: CardiacSparingIMRT@QARC.org.

Questions about the form or the data to be submitted can be submitted to the same email.

Cardiac Sparing Whole Lung Adverse Event Transmittal Form

2/13/2012

Patient Initials (F, L): _____ Registration #: _____

Number of forms included in this submission: _____

Please attach a completed MedWatch 3500 form for each expected or unexpected Adverse Event per sections 16.1 and 16.2 of the protocol.

Name and email address of person submitting the form: _____

_____

Date the form and data were submitted to QARC: _____

The data should be submitted to: CardiacSparingIMRT@QARC.org

Questions about the form or data to be submitted should be directed to the email above.

Cardiac Sparing Whole Lung IMRT Off-Study Form

2/13/2012

Patient Initials (F L): _____ Registration#: _____

Please indicate the reason the patient has been removed from study:

_____ Death

_____ Lost to follow-up

_____ Withdrawal of consent for any further data submission.

The date of the event should be included in the comments section below.

Comments:

Please include any additional supportive information/documentation that are relevant with the submission of this form.

Name and email address of the person completing this form: _____

_____

Date the form was completed: _____

The form and additional data should be submitted to: CardiacSparingIMRT@QARC.org

Questions about the form should be submitted to the same email