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NRG ONCOLOGY PROTOCOL DEVELOPMENT TEMPLATE FOR RADIATION THERAPY

DISEASE SITE: Gynecological Cancer
SUB-COMPONENT: Vulva cancer

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Text that is both underlined and highlighted is either an instruction or a suggestion to be deleted or replaced by the Principal Investigators (PIs) using regular text.

Text that is highlighted but not underlined is an example to be selected (by removing the highlighting), deleted or replaced by the PIs using regular text.

5.2 Radiation Therapy

This section should clearly describe the modality used to deliver radiation, the method for patient immobilization, simulation, definition of targets and normal tissues, dose constraints, compliance criteria, daily treatment localization. Requirements for any applicable credentialing (including phantom irradiation credentialing) and pre-treatment review should be explicitly specified in the protocol.

Notes 1,2,...: The note(s) included at this point in the protocol should emphasize special information that the study chair does not want the investigator to overlook. An example is a statement that image-guided radiation therapy (IGRT) is required for the study.

Locally advanced or post-operative vulva cancer will be specified. Describe the fractionation, prescription doses and overall treatment time.

5.2.1 Treatment Technology

List the allowed treatment modalities including the technique and the energy (e.g. photons, protons, electron, brachytherapy, etc.) along with the required capabilities (e.g. intensity modulated radiation therapy (IMRT), IGRT, on-board adaptive IMRT, etc.).

External Beam Radiation Therapy (EBRT)

Photon Therapy

Radiation therapy can be delivered via 3D-conformal radiation therapy (3D-CRT) or IMRT targeting vulva and inguinofemoral and pelvic lymph node regions. 3D-CRT plans can be delivered using photon and electron mixed beams. IMRT plans may include static field arrangements (e.g. 5-9 fields), volumetric modulated arc therapy (VMAT), or TomoTherapy. A pseudo-step-wedge intensity modulation (PSWIM) technique is permitted. MR guided treatment is allowed if a maximum field size can cover the entire target area. The two active MR guided treatment options (Viewray and Elekta) have smaller field sizes than conventional Linacs: 27.4 cm × 24.1 cm for Viewray and 57.4 cm × 22.0 cm for Elekta. Also, the use of on-table adaptive techniques, either CBCT or MRI based is permitted. These adaptive techniques can better account for inter-fraction motion which results in reduced margins and potentially better OAR sparing. 3D-CRT should use 6-18 MV photons or any electron energies, and for IMRT, 6-10 MV photons are recommended.

If MR-guided RT is used in the protocol, guidance should be provided as to when on-board adaptive RT should/could be used (for example during the boost delivery, an isotoxic approach is recommended).

Proton Therapy

A cyclotron or synchrotron-based proton therapy machine must be equipped at least with orthogonal kV x-ray imaging. In-room 3D volumetric imaging capabilities are preferable to monitor anatomical changes. Continuous variable or discrete energies of 70-230 MeV are allowed. The proton energies used for each field should be based on the range and spread-out Bragg peak (SOBP) that is suitable to cover the treatment volume. Double-scattering, uniform scanning, wobbling or intensity-modulated proton therapy (IMPT) using pencil beam scanning is considered an acceptable proton treatment technique. The range shifter is applied when treating shallow target depths.

5.2.2 Immobilization and Simulation

Immobilization

Describe the recommended patient setup and immobilization methods.

Photon/Proton Therapy

Patients are to be immobilized in the supine position in an immobilization device. Immobilization should be performed to ensure the pelvis is positioned consistently throughout treatment. This can be accomplished by immobilizing legs with an alpha cradle, a vac-loc, or a non-custom device. A patient can be in either a “frog- leg” position (to spare the skin in the upper inner thigh) or a straight-leg position in an immobilization device. If an MR-Linac is to be used for treatment the immobilization equipment utilized needs to be MRI-compatible.

Proton Therapy

Immobilization devices for proton therapy patients should also be chosen such that the daily setup errors, both translation and rotational, would cause minimal beam range variations through these devices. All the immobilization devices used in the simulation should be commissioned with appropriate proton-stopping power. An excessive amount of immobilization device should not be in the beam path. Proper customized immobilization and assessment and, if necessary, management of internal motion are essential for effective treatment. The skin fold should be carefully assessed if there is a potential to be in the proton beam path. The variations due to daily differences of patients settling into the immobilization devices should be minimized.

Simulation Imaging

This subsection should include information about the extent of CT or MRI imaging, the resolution of the scan, including the slice thickness, and details of the allowed/suggested use of contrast agents and the handling of tissue densities when contrast is used.

Photon/Proton Therapy

Prior to simulation, wires or other radio-opaque markers may be used on gross disease and surgical scars.

A PET/CT or CT simulation scan is required with a slice thickness ≤ 3.0 mm to define clinical target volume (CTV) and planning target volume (PTV). The scan regions should be extended from L3 or L4 (common iliac bifurcation level) to mid-thigh. The CT scan should be acquired in the same position and immobilization device as for treatment. If the vagina is part of the CTV, two scans with a full and

empty bladder should be considered to generate an internal target volume (ITV). If the rectum is distended at simulation (e.g., >3.5 cm diameter), it is recommended that simulation be repeated after further bowel preparation. If necessary, two scans can be done with bolus over the area of concern (preop: large or superficially located lymph nodes or skin involvement; postop: scars plus a margin of at least 3 cm) and without bolus. Alternatively, a virtual bolus can be added during treatment planning. IV contrast and bowel prep-contrast are allowed for better delineation of the pelvic vessels and small bowel. If contrast material is used, the scans are performed without and with contrast. The scan without contrast is to be used for planning. If only one scan with contrast is obtained, the contrast should be overridden with a density of soft tissues for treatment planning. For patients treated with a MR-Linac system a planning MRI will also be done and the planning CT scan should be performed with the same immobilization and patient positioning to facilitate electron density migration to the MRI planning dataset if necessary. The planning MRI could be done either using a formal planning MRI unit or in the MR-Linac system.

Motion Management Technique

Please remove this subsection if it does not apply to your protocol.

EBRT

The motion due to bladder filling can be taken into consideration in defining the ITV when clinically appropriate. Patients are simulated with a full and empty bladder to evaluate organ motion. If on-table adaptive RT, either MRI or CBCT based, is to be delivered then the use of an ITV may not be necessary and expansions from the CTV don't need to account for inter-fractional motion. Verification imaging or ultrasound to evaluate bladder filling is allowed. Treatment with full bladder will help to reduce the volume of bowel treated and should thus be encouraged. Although on-board adaptive RT provides the opportunity to adapt to the anatomy of the day, it is desirable to maintain bladder filling consistency as much as possible. Creating several different plans that account for different anatomical situations (i.e., empty bladder/full bladder, anteverted/retroverted uterus, etc...) and performing daily imaging to decide which plan from the library of plans is best suited for the day is another valid approach to deal with inter-fraction motion. This efficient approach has the advantage of addressing inter-fraction motion without the need for daily on-board adaptation.

5.2.3 Imaging for Structure Definition, Image Registration/Fusion and Follow-up

Photon/Proton Therapy

A diagnostic pelvic MRI and/or PET-CT fusion with the CT/MRI simulation scan is recommended to aid target delineation. Ideally the diagnostic MRI should be done immediately before or after the planning CT/MRI scan and preferably in the frog-legged position if that is the position to be used for therapy-delivery. Fusion should be optimized to match the MRI/PET-CT scans to the treatment position. Rigid/deformable image registration between PET-CT and CT/MRI simulation scans can be performed and should be reviewed with caution. Deformable image registration between diagnostic MRI and CT/MRI simulation scans is not encouraged to avoid deforming the tumor. For most cases, the diagnostic MRI to CT simulation fusion should focus on the area of interest i.e., the primary tumor and not on pelvic bone. For MR-guided treatment, the diagnostic studies should be fused to the planning MRI.

5.2.4 Definition of Target Volumes and Margins

Note: All structures must be named for digital RT data submission as listed in the table below. The structures marked as “Required” in the table must be contoured and submitted with the treatment plan. Structures marked as “Required when applicable” must be contoured and submitted when applicable. Resubmission of data may be required if the labeling of structures does not conform to the standard DICOM name listed. Capital letters, spacing, and use of underscores must be applied exactly as indicated.

Entries in the first column of the list below will be entered and edited by the QA Staff. The PIs are required to specify the information in the second and third columns. The detailed specifications must include crucial items such as boundary definitions and margins.

Please refer to the NRG Gynecological contouring atlases: *Vulvar Cancer Atlas - MIM and Full Access interactive viewer packages with the final consensus contours are available on the NRG website at: <https://www.nrgoncology.org/ciro-gynecologic>*

Standard name	Description	Validation Required/Required when applicable/Optional
GTV	GTV to receive dose cGy (e.g., GTV to receive 5040cGy indicated as GTV_5040)	Required
CTV	CTV to receive dose cGy	Required
ITV	ITV to receive dose cGy	Required when applicable
PTV	PTV to receive dose cGy	Required (Photon only)
PTV_dose-xx	PTV receiving dose cGy minus xx mm from skin surface. e.g., PTV_4500-03: PTV receiving 4500 cGy is cropped by 3 mm from the external contour	Required when applicable (Photon only)

Detailed Specification

Target volumes: The definitions of volumes will be in accordance with the 1999 ICRU Report 62.

GTV_: The GTV is defined as all gross disease and involved lymph nodes determined from clinical information and biopsy results.

CTV_: The CTV includes the primary vulva and nodal regions. The CTV covers the entire post op surgical bed in adjuvant cases.

ITV : If appropriate for the study, patients can be simulated with both a full and empty bladder (i.e., 2 simulation scans). Two scans are to be fused to generate ITV. If on-board adaptive RT is to be utilized, then the use of a bladder ITV may not be necessary, but one should still account for intra-fraction bladder motion in their margin strategy.

PTV : The PTV is defined as the CTV, or ITV plus an appropriate margin. When using on-board adaptive RT approaches the appropriate margins utilized may be reduced but need to be fully evaluated as each approach has different efficacies in dealing with inter and intra-fraction motion (Plan Library, CBCT Guided, real-time tracking and MRI Guided). (Photon only)

For proton therapy, only CTV is defined as the treatment target, and robustness optimization shall be applied to the CTV to ensure coverage. Much like the PTV is a surrogate to ensure proper CTV coverage in photon therapy, a robustness analysis must be used to verify appropriate CTV coverage for proton treatments.

5.2.5 Definition of Critical Structures and Margins

Note: All structures must be named for digital RT data submission as listed in the table below. The structures marked as “Required” in the table must be contoured and submitted with the treatment plan. Structures marked as “Required when applicable” must be contoured and submitted when applicable. Resubmission of data may be required if the labeling of structures does not conform to the standard DICOM name listed. Capital letters, spacing, and use of underscores must be applied exactly as indicated.

Entries in the first column of the list below will be entered and edited by the QA Staff. The PIs are required to specify the information in the second and third columns. The detailed specifications must include crucial items such as boundary definitions and margins.

Please refer to the **NRG Gynecological contouring atlases: *Female RTOG normal pelvis*** in website at: <https://www.nrgoncology.org/ciro-gynecologic>

Photon Therapy

Standard name	Description	Validation Required/Required when applicable/Optional
External	External patient contour encompassing all patient anatomy with a single contour on each slice.	Required
External-PTV	All tissue excluding the PTV generated by subtracting the PTV receiving dose cGy from the external contour.	Required

Spc_Bowel	The space that the bowel may occupy	Required
Rectum	Rectum	Required
Bladder	Bladder	Required
Femur_L	Left femur	Required
Femur_R	Right femur	Required
BoneMarrow	Bone Marrow	Required when applicable
Anus	Anus	Required when applicable
Bolus_xxmm	Bolus that is xx millimeters thick e.g., Bolus_03mm: 3 mm bolus	Required when applicable

Proton Therapy

Standard name	Description	Validation Required/Required when applicable/Optional
External	External patient contour	Required when applicable
External-CTV	All tissues excluding the CTV	Required when applicable
Spc_Bowel	The space that the bowel may occupy	Required when applicable
Rectum	Rectum	Required
Bladder	Bladder	Required
Femur_L	Left femur	Required
Femur_R	Right femur	Required
BoneMarrow	Bone Marrow	Optional
Anus	Anus	Required when applicable

Detailed Specification

Photon/Proton Therapy

Spc_Bowel: Small bowel will be contoured in each slice in which it appears including at least 2 cm but no more than 3-4 cm above the PTV (photon) or CTV (proton). The small bowel will be contoured in its entirety within these parameters, including adipose and mesentery.

Rectum: The outer rectal wall will be contoured and filled in, treating the organ as a solid continuous structure, and will be defined from the inferior margin 2 cm above the anal verge and superior margin where the rectum turns to become the sigmoid colon.

Bladder: The outer bladder wall will be contoured and filled in, treating the organ as a solid continuous structure.

BoneMarrow: The pelvic bone will be contoured as a surrogate for the bone marrow. The pelvic bone from the superior to the inferior aspect of the PTV or CTV (proton) can be auto-contoured. This can be accomplished with the use of a CT-density-based auto-contouring algorithm. The femoral heads but

not the femoral necks should be included in the bone marrow contour. Please see below for an example of contoured pelvic bone.

5.2.6 Dose Prescription

Note: The information provided in this section can be used for adjusting the dose constraints for treatment planning purposes. This table, together with the planning priority table, should be used during dose optimization. It is important to remember that ideal plans might not be achievable in all cases. Thus, the Compliance Criteria table could be different than the information given here. Cases will be scored using the Compliance Criteria table.

Photon Therapy

For locally advanced vulva cancer, the prescription dose is 45-50.4 Gy in 25-28 fractions at 1.8-2.0 Gy per fraction with a sequential boost of 6-16 Gy in 2.0 Gy per fraction. For simultaneous integrated boost (SIB) cases, the primary target PTV will receive 45-50 Gy and the gross disease in lymph nodes will receive 2.2-2.3 Gy per fraction with a total dose of 55-57.5 Gy, depending on location and size of lymph nodes. For post-operative vulva cancer, 45-50 Gy in 25 fractions will be delivered to the operative bed. A sequential boost of 6-10 Gy in 2.0 Gy per fraction may be delivered.

Target standard name	Dose (Gy)	Fraction size (Gy)	# of fractions	Frequency	Dose specification technique
PTV_4500	45	1.8	25	Daily	Covering 95% of PTV
PTV_5000	50	2	25	Daily	Covering 95% of PTV
PTV_5040	50.4	1.8	28	Daily	Covering 95% of PTV
PTV_5500 (SIB only)	55	2.2	25	Daily	Covering 95% of PTV
PTV_5750 (SIB only)	57.5	2.3	25	Daily	Covering 95% of PTV

Sequential Boost

Target standard name	Dose (Gy)	Fraction size (Gy)	# of fractions	Frequency	Dose specification technique
PTV_	6-16	2.0	3-8	Daily	Covering 95% of PTV

Sequential boost dose may be different depending on the case (locally advanced or post-operative case), and either IMRT or 3D-CRT and/or electron fields can be used depending on lymph nodes location and body habitus.

Proton Therapy

Robustness optimization to the CTV is recommended for proton therapy, with setup uncertainties (the same as the PTV margin) in all directions. Range uncertainties should be used according to their institutions' protocol.

5.2.7 Compliance criteria

The compliance criteria listed here will be used to score each case. Given the limitations inherent in the treatment planning process, the numbers given in this section can be different than the prescription table. The Per Protocol and Variation Acceptable categories are both considered to be acceptable. The Per Protocol cases can be viewed as ideal plans, and the Variation Acceptable category can include more challenging plans that do not fall at or near the ideal results. A final category, called Deviation Unacceptable, results when cases do not meet the requirements for either Per Protocol or Variation Acceptable. Plans falling in this category are suboptimal and additional treatment planning optimization is recommended.

VxGy[cc], VxGy[%], Vx%[cc], Vx%[%]: Volume [cc or %] receiving Dose [Gy or %]
Dxcc[Gy], Dxcc[%], Dx%[Gy], Dx%[%]: Dose [Gy or %] to Volume [cc or % of total volume]
Minimum dose is defined to D98%[Gy] or D98%[%]
Maximum dose is defined as D0.03cc[Gy] or D0.03cc[%]
Mean[Gy] or Mean[%]: Mean dose in Gy or %

Normalization of Dose: The plan is normalized such that 95% of the PTV₁ volume receives 95% of prescription dose or higher.

Note: Deviation Unacceptable occurs when dose limits for Variation Acceptable are not met

Target Volume Constraints and Compliance Criteria

The SIB and/or sequential boost constraints will be evaluated from the composite plan and may be changed depending on variations in the protocol.

Photon Therapy

Name of structure	Dosimetric parameter	Per Protocol	Variation Acceptable	Deviation Unacceptable
PTV_4500	D95% [% of PD]	≥ 95	≥ 90	< 90
	D0.03cc [% of PD]	≤ 110	≤ 115	> 115
PTV_5000	D95% [% of PD]	≥ 95	≥ 90	< 90
	D0.03cc [% of PD]	≤ 110	≤ 115	> 115
PTV_5040	D95% [% of PD]	≥ 95	≥ 90	< 90
	D0.03cc [% of PD]	≤ 110	≤ 115	> 115
PTV_5500 (SIB only)	D95% [% of PD]	≥ 95	≥ 90	< 90
	D0.03cc [% of PD]	≤ 110	≤ 115	> 115
PTV_5750 (SIB only)	D95% [% of PD]	≥ 95	≥ 90	< 90
	D0.03cc [% of PD]	≤ 110	≤ 115	> 115
PTV_6600 (Sequential boost)	D95% [% of PD]	≥ 95	≥ 90	< 90
	D0.03cc [% of PD]	≤ 110	≤ 115	> 115

Per Protocol range is excluded from Variation Acceptable range. PD = prescribed dose
 Sequential boost dose may vary (See section 5.2.6)

Proton Therapy

Robustness analysis of any proton treatment plan should account for, at a minimum, eight positional offset scenarios (plus/minus in each direction) and range independently. The value for the position should be similar to the photon's PTV margin (e.g., 3-5 mm), and the range should be the standard value for the institution (e.g., 3-5%). The margin defined here is as water equivalent distance (WED), not the geometric expansion from the CTV. The beam-specific proximal or distal margins are calculated from the CTV based on the range and the SOBP of the specific beam. The lateral margin considers a setup error of 3-5 mm plus the additional margin required to cover the CTV (e.g., penumbra (passive scattering) or one spot sigma (pencil beam scanning). For target coverage dose constraints of proton plans, the values reported must be obtained from the worst-case scenario of the robustness analysis.

Normal Structure Constraints and Compliance Criteria

Constraints will be evaluated from the composite plan with SIB and/or sequential boost and may be changed depending on overlapped volumes with targets and variations in the protocol.

Photon Therapy

Name of Structure	Dosimetric parameter	Per Protocol	Variation Acceptable	Deviation Unacceptable
Rectum	D60% [Gy]	<=45	<=50	>50
	D0.03cc [Gy]	<=60	<=65	>65
Bladder	D35% [Gy]	<=45	<=50	>50
	D0.03cc [Gy]	<=60	<=65	>65
Femurs	D15% [Gy]	<=30	<=35	>35
	D5% [Gy]	<=40	<=44	>44
	D0.03cc [Gy]	<=50	<=55	>55
Anus	D50% [Gy]	<=40	<=45	>45
	D0.03cc [Gy] [†]	<=50	<=55	>55
Spc_Bowel	D30% [Gy]	<=40	<=45	>45
	D0.03cc [Gy]	<=55	<=60	>60
	V45Gy [cc]	<=190	<=300	>300
Bowel Loop* (On-board adaptive)	D30% [Gy]	<=40	<=45	>45
	D0.03cc [Gy]	<=55	<=60	>60
BoneMarrow	Mean [Gy]	<=30	<=35	>35
	V10Gy [%]	<=85	<=90	>90
	V20Gy [%]	<=70	<=75	>75

Per Protocol range is excluded from Variation Acceptable range. [†]If the vulvar cancer extends posteriorly, this constraint may not be met without compromising the target coverage.

*When on-board RT is being used the bowel loops should be contoured instead of the SPC_Bowel approach.

Proton Therapy

For OAR dose parameters (excluding _PRV structures) of proton plans, the dose parameters should be reported from the nominal plan only. For OAR that are defined with a _PRV of proton plans, the dose parameters should be obtained for the worst-case scenario of the robustness evaluation on the nominal structure contour (not the expanded _PRV structure).

Delivery Compliance criteria

	Per Protocol	Variation Acceptable	Deviation Unacceptable
Start date (X days/weeks after X) (Please remove this row when the start date is not specified in the protocol.)	Within 6 weeks after surgery (if post-operative)	Within 8 weeks after surgery	>8 weeks after surgery
Treatment delays	Interruption of 0 days	Interruption of 1-7 consecutive days	>7 days
Overall treatment time	<=50 days	<=60 days	>60 days

5.2.8 Treatment Planning Priorities and Instructions

- Critical Structure and Target priorities must be listed in order of decreasing importance

The following list is an example

1. PTV (photon)/CTV (proton)
2. Femurs
3. Rectum
4. Bladder
5. Spc_Bowel
6. Anus
7. Bone marrow

- Required algorithms

Convolution/Superposition, Monte Carlo, etc...

For Convolution/Superposition-type algorithms, the dose should be reported as computed inherently by the given algorithm. For Monte Carlo or Grid Based Boltzmann Solver algorithms, conversion of Dm (dose-to-medium) to Dw (dose-to-water) should be avoided. Dm, computed inherently by these algorithms, should be reported. Pencil Beam algorithm is strongly discouraged.

- Primary dataset for dose calculation

Photon Therapy

The primary data set for dose calculations is CT. In the case in which contrast is present during the treatment planning CT, the density of the contrast should be overridden to a representative background electron density. Heterogeneity corrections must be applied. For MRI-guided EBRT treatments the primary dataset will often be a planning MRI, but to utilize planning MRI datasets for treatment

planning the imaging system and workflows must be properly commissioned. Additionally, MRI simulators now exist that can create electron density maps so that a planning MRI can be utilized for dose calculations. Again these imaging systems and workflows need to be properly commissioned prior to use.

Proton Therapy

The Monte Carlo algorithm for optimization is highly recommended. If the Monte Carlo optimization is not used, at least the Monte Carlo calculation dose should be calculated as a reference.

- Dose matrix resolution

Dose grid size should be ≤ 3 mm (preferably ≤ 2 mm to minimize effects of partial volume averaging) in all directions.

- List treatment planning recommendations and give link to FAQs

5.2.9 Patient-specific QA

- Describe the technique and give the Gamma Index Analysis pass rate recommendation

For photon IMRT/VMAT plans or proton IMPT plans, patient-specific QA is highly recommended. Any patient-specific QA performed should follow respective institutional guidelines. If on-table adaptive RT is to be performed, then patient-specific QA is also recommended. The recommended patient-specific QA criterion is that 90% of the comparison points pass gamma criteria of dose difference/distance-to-agreement of $\pm 3\%/2$ mm with a 10% dose threshold (AAPM TG 218 report).

5.2.10 Daily Treatment Localization/IGRT

Image-guided radiation therapy (IGRT) is radiation therapy using imaging to facilitate accuracy and precision throughout its entire process, from target and normal tissue delineation, to radiation delivery, to adaptation of therapy to anatomic and biological changes over time in individual patients. In this section we use the terminology IGRT to focus on image-guidance at the time of radiation delivery to ensure its adherence to the planned treatment.

If the protocol requires IGRT, the following information should be provided for localization guidance

- Will simple isocenter localization technique be used at the beginning of treatment and daily thereafter?
- Will more advanced IGRT techniques be used?
- Is IGRT tied to margin reduction?
- Allowed image guidance methods: 2D x-ray, 3D x-ray, MRI, electromagnetic localization, optical surface imaging, MRI-guidance, other
- Image registration techniques: fiducial markers, bone as surrogate, soft tissue, other
- State the frequency for localization checks
- Give recommendations for correcting (e.g. correcting for linear shifts less than 1 mm is not recommended)
- Recording of shift information must be provided for the IGRT credentialing process
- Other

Photon/Proton Therapy

Daily IGRT is required for this protocol when the IMRT or IMPT treatment technique is used. Any form of online imaging is acceptable, such as MV or kV planar imaging, MVCT or MV CBCT, kV CBCT, CT on rails, on board MRI, etc. The AAPM recommendations for verifying the coincidence of the imaging and treatment reference points must be adhered to the daily use of IGRT. In general, image registration will be used for setup verification using bone landmarks only and not for soft tissue alignment, while the CT or CBCT/on board MRI will be used to ensure proper inclusion of the soft tissue CTV in the fields in addition. Small soft tissue shifts may be acceptable. Otherwise, the treating physician may elect to postpone treatment or re-simulate.

Management of Radiation Dose to the Patient from IGRT

NRG Oncology is concerned about the estimated doses given from IGRT and is committed to limiting the imaging dose when IGRT is used in any of its protocols. This can be accomplished by avoiding the use of this technology to make small changes in patient positioning that are within the stated PTV margins. The imaging dose to the patient may become significant if repeated CBCT studies are performed for patients with severe set up problems (e.g., requiring frequent corrections that are larger than the PTV margins). It is recommended that patients demonstrating severe set-up problems during the first week of treatment be moved to a treatment with larger margins or be re-simulated. MRI guidance strategies are beneficial in the management of radiation dose from IGRT due to the fact that no-ionizing radiation is used to generate these high-quality on-board images.

5.2.11 Case Review

A pre-treatment review will be performed by the study PI. See section (XX) for case submission and process via TRIAD and IROC Philadelphia. Also, RT-Specific pre-registration requirements and IMRT credentialing in this protocol are described in section (YY).