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NRG ONCOLOGY PROTOCOL DEVELOPMENT TEMPLATE FOR RADIATION THERAPY

DISEASE SITE: CSI
SUB-COMPONENT: Photon and Proton Therapy

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Underlined highlighted texts are either instructions or suggestions to be deleted or replaced by PIs with regular texts without highlight.

Regular highlighted texts are examples to be selected (remove highlight), deleted or replaced by PIs with regular texts.

5.2 Radiation Therapy

In this section, the modality used to deliver radiation, the method for patient immobilization, and the method to correlate patient geometry and delivery geometry should be clearly described. Requirements for credentialing (including the phantom irradiation credentialing and the IGRT credentialing) should be explicitly specified in the protocol.

[STUDY CHAIRS: Refer to the NRG web site for RTQA Protocol Prescription Guidelines for writing RT prescriptions in NRG protocols [*link to come*].]

For credentialing requirements, please refer to section 8 of the protocol.

Radiation Therapy Schema

Schema at the beginning of the protocol should be followed.

Proton dose shall be reported in Gy (RBE) where the physical proton dose is multiplied by a uniform RBE value equal to 1.1. Proton and photon doses are considered equivalent in terms of biological response for this protocol.

5.2.1 Treatment Technology

List allowed Treatment Modalities (including energy): photons, protons, …..
Required Capabilities: IMRT, IGRT, surface guided radiation therapy (SGRT) etc.

Photon beam therapy will be delivered with nominal x-ray energy of 6 MV or greater. 3D CRT, fixed gantry-IMRT or VMAT using conventional Linac or specialty Linacs (such as Tomotherapy, Halcyon, RefleXion, and MR-Linac) are allowed.

Proton beams can be delivered using pencil beam scanning techniques, uniform scanning, or passive scattering. Both full and partial rotational gantries are permitted for treatment. Additionally, a fixed beam line with an upright patient positioner may be utilized if it has undergone validation approved by the PI and NRG.

5.2.2 Immobilization

Proper immobilization is critical for this protocol. Patient setup reproducibility must be achieved using appropriate clinical devices.

For photon therapy, patients will be treated in a supine position with neck extended and shoulders down, and immobilized with a customized long thermoplastic mask extending to the shoulder and headrest. Knee and legs fixation should be used for lower body positioning and patient comfort. Optionally, the arms can be elevated to allow for more lateralized beams.

In proton therapy, it is crucial to ensure proper validation and accounting of the WET (water equivalent thickness) of any device that in the beam path, including immobilization devices like Vacloc or alpha cradle, as well as the treatment couch, if used. Patients should lie in a straight position on the treatment table, preferably in a supine position for their comfort, while ensuring both shoulders are at an equal height.

Simulation Imaging

This subsection should include information about the extent of CT imaging, field-of-view (FOV), the resolution of the scan information including the slice thickness, and details of the allowed use of contrast agents and the handling of tissue densities when contrast is used.

Both photon and proton treatment plans will be based upon scans obtained with a CT scanner. For photon planning, the institution must have an established relationship between CT number and electron density or mass density. For proton planning, the institution must have an established relationship between CT number and mass density or proton stopping power ratio. Contiguous CT slices of 3mm or less slice thickness should be obtained. The CT scan should cover from the top of the head to the mid-thigh and should include immobilization devices in the beam path. For protons, a non-contrast CT must be acquired for planning.

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

This subsection should also describe additional image modalities, image registration/fusion, and follow-ups. Please indicate "Not applicable" if it does not apply to your protocol. Please do not delete this subsection.

MR imaging is strongly recommended for target delineation in boost planning. Image fusion is recommended to be performed by a qualified medical physicist or by a dosimetrist under the supervision of a qualified medical physicist and reviewed by the attending physician.

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 following the nomenclature standard described in AAPM Task Group report 263. 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 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.

Standard Name	Description	Validation **Required/Required when applicable/Optional**
PTV_3600	PTV to receive 36 Gy (RBE)	**Required when applicable**
PTV_5580	Boost volume to receive total of 55.8 Gy (RBE)	**Required when applicable**

Detailed Specifications

The detailed specifications have to include crucial items such as boundary definitions and margins. GTV, CTV, and PTV should be all defined. If CTV is the same as GTV, then state CTV=GTV. Also state how GTV should be defined. Each specific study should specify that target volumes will be obtained using MRI or using CT if MRI cannot be obtained.

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

CTV: The cranial CTV should include the whole brain, cribriform plate, most inferior part of the temporal lobes, and the pituitary fossa. The spinal CTV should include the entire subarachnoid space, including nerve roots laterally to the lateral edge of vertebral body. The lower limit of the spinal CTV is at the lower limit of the thecal sac.

(Description of CTV delineation to be written by physician PI of the study. Consider defining an irradiation volume that includes or excludes the vertebral body based on the PI's discretion.)

PTV: PTV is generated by adding margins of 3-7mm to cranial and spinal CTVs in all directions (consider margins between 3mm to 20mm). Different margins can be used for different sections of PTV.

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 labeling of structures (ROI Name in DICOM RT Structure Set) does not conform to the standard 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.

Standard Name	Description	Validation **(Required/Required when applicable/Optional)**
Brain	Whole brain parenchyma	Required
BrainStem	Brainstem	Required
Cochlea_L	Left cochlea	Required
Cochlea_R	Right cochlea	Required
Glnd_Submand_L	Left submandibular gland	Required
Glnd_Submand_R	Right submandibular gland	Required
Eye_L	Left eye	Required
Eye_R	Right eye	Required
Lens_L	Left lens	Required
Lens_R	Right lens	Required
Esophagus	Esophagus	Required
Heart	Heart	Required
Larynx	Larynx	Required
Liver	Liver	Required when applicable
Bowel_Small	Small Bowel - bowel bag	Required when applicable
Kidney_L	Left kidney	Required
Kidney_R	Right kidney	Required
Kidneys	Both kidneys	Required
Lung_L	Left lung	Required
Lung_R	Right lung	Required
Lungs	Both lungs	Required
OpticChiasm	Chiasm	Required
OpticNrv_L	Left optic nerve	Required
OpticNrv_R	Right optic nerve	Required
Hippocampus_L	Left hippocampus	Optional
Hippocampus_R	Right hippocampus	Optional
OralCavity	Oral cavity	Required
Ovary_L	Left ovary	Required when applicable
Ovary_R	Right ovary	Required when applicable

Parotid_L	Left parotid	Required
Parotid_R	Right parotid	Required
Pituitary	Pituitary	Required
Skin	Skin contoured as a ring - usually 3-5 mm thick	Required when applicable
SpinalCord	Spinal cord	Required
ThecalSack	Thecal sack	Required
Thyroid	Thyroid	Required

Detailed Specifications

The detailed specifications have to include crucial items such as boundary definitions and margins.

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.

Target Standard Name	**Dose [Gy(RBE)]**	**Fraction Size [Gy(RBE)]**	**# of fractions**	**Dose specification technique**
PTV_3600	36	1.8	20	≥95% of PTV should receive ≥36 Gy
PTV_5580	55.8	1.8	31	≥95% of PTV should receive ≥55.8 Gy in composite plan

For Protons

The dose prescription is defined on CTV on the nominal plan. The CTV coverage must be also evaluated by robust evaluation defined in section 5.2.7

Target Standard Name	**Dose [Gy(RBE)]**	**Fraction Size [Gy(RBE)]**	**# of fractions**	**Dose specification technique**
CTV_3600	36	1.8	20	≥99% of CTV should receive ≥36 Gy
CTV_5580	55.8	1.8	31	≥99% of CTV should receive ≥55.8 Gy in

				composite plan

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 considered to be suboptimal and additional treatment planning optimization is recommended.

Dxcc[Gy], Dxcc[%], Dx%[Gy], Dx%[%]: minimum Dose [Gy or %] to the hottest Volume [cc or % of total volume]
DCxcc[Gy], DCxcc[%], DCx%[Gy], DCx%[%]: maximum Dose [Gy or %] to the coolest Complement Volume [cc or % of total volume]
V* dosimetric metrics are to be converted to D* metrics
Minimum dose is defined to D99%[Gy] or D99%[%]
Maximum dose is defined as D0.03cc[Gy] or D0.03cc[%]
Mean[Gy] or Mean[%]: Mean dose [Gy or %]
Dose criteria expressed as % are with respect to the Dose Prescription (see section 5.2.6)

Normalization of Dose: The initial plan is normalized such that at least 95% of the PTV_3600 volume receives prescription dose of 36 Gy, i.e., D95%[Gy] >= 36 Gy. The boost plan is normalized such that more than 95% of the PTV_5580 receives the prescription dose of 55.8Gy in the composite plan.

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

Target Volume Constraints and Compliance Criteria

Name of Structure	Dosimetric parameter*	Per Protocol	Variation Acceptable	Notes (Please remove this column when notes are not needed)
PTV_3600	D95% [Gy(RBE)]	>=36	>=35.28	
	D0.03cc [Gy(RBE)]	<=39.6	<=41.4	

PTV_5580	D95% [Gy(RBE)]	>=55.8	>=54.68	Evaluate in the composite plan
	D0.03cc [Gy(RBE)]	<=61.38	<=64.17	Evaluate in the composite plan

Per Protocol range is excluded from Variation Acceptable range.

Proton dose is specified using a relative biological effectiveness (RBE) value of 1.1

Instead of evaluating PTV coverage, proton plan is required to perform robust evaluation with 3-5 mm patient setup uncertainties (equivalent to CTV to PTV margin in photon therapy) and 2.5-3.5% proton beam range uncertainty. Please refer to Table "Proton robust evaluation on CTV" for robust evaluation compliance criteria. Documents containing the plan robustness evaluation, e.g., screen captures, should be submitted to IROC.

Proton robust evaluation on CTV

Name of Structure	Dosimetric parameter*	Per Protocol	Variation Acceptable	Notes (Please remove this column when notes are not needed)
CTV_3600 nominal	D99% [Gy(RBE)]	>=36	>=35.28	
	D0.03cc [Gy(RBE)]	<=39.6	<=41.4	
CTV_3600 Robust evaluation scenario	D95% [Gy(RBE)]	>=34.2	>=32.4	
	D0.03cc [Gy(RBE)]	<=39.6	<=41.4	
CTV_5580 nominal	D99% [Gy(RBE)]	>=55.8	>=54.68	Evaluate in the composite plan
	D0.03cc [Gy(RBE)]	<=61.38	<=64.17	Evaluate in the composite plan
CTV 5580 Robust evaluation scenario	D95% [Gy(RBE)]	>=19.80	>=19.4	Evaluate on the boost plan only
	D0.03cc [Gy(RBE)]	<=21.78	<=22.77	Evaluate on the boost plan only

Due to the typical pre-defined beam angle selection of CSI, it is acceptable to generate beam specific

PTVs (BsPTVs) for each beam, considering the setup margin perpendicular to the beam direction and the range uncertainty in the proximal and distal directions of the beam. Please refer to Table "Proton evaluation on beam-specific PTV (BsPTV)" for compliance criteria if BsPTV is used.

Proton evaluation on beam-specific PTV (BsPTV)

Name of Structure	Dosimetric parameter*	Per Protocol	Variation Acceptable	Notes (Please remove this column when notes are not needed)
BsPTV_3600	D95% [Gy(RBE)]	>=36	>=35.28	
	D0.03cc [Gy(RBE)]	<=39.6	<=41.4	
BsPTV_5580	D95% [Gy(RBE)]	>=55.8	>=54.68	Evaluate in the composite plan
	D0.03cc [Gy(RBE)]	<=61.38	<=64.17	Evaluate in the composite plan

Required Normal Structure Constraints and Compliance Criteria (all structures should be evaluated in the composite plan)

Name of Structure	Dosimetric parameter	Per Protocol	Variation Acceptable
BrainStem	D0.03cc [Gy(RBE)]	<=57	<=60
OpticNrv_L or OpticNrv_R or OpticChiasm	D0.03cc [Gy(RBE)]	<=54	<=57
SpinalCord	D0.03cc [Gy(RBE)]	<=55	<=57

Per Protocol range is excluded from Variation Acceptable range.

Recommended Normal Structure Constraints (all structures should be evaluated in the composite plan)

Name of Structure	Dosimetric parameter	Per Protocol	Variation Acceptable
Cochlea_L or R	Mean[Gy(RBE)]	<=45	<=50
Bowel_Small	V36Gy[cc]	<=120	NA
Esophagus	V40Gy[%]	<=17	NA
	Mean[Gy(RBE)]	<=30	NA
Eye_L or R	D0.03cc [Gy(RBE)]	<=45	NA
	Mean[Gy(RBE)]	<=35	NA
Glnd_Sumand_L or	Mean[Gy(RBE)]	<=20	NA

R			
Heart	Mean[Gy(RBE)]	<=15	NA
Kidney_L or R	V20Gy[%]	<=30	NA
	Mean[Gy(RBE)]	<=10	NA
Larynx	Mean[Gy(RBE)]	<=25	NA
Lens_L or R	D0.03cc_[Gy(RBE)]	<=15	NA
Liver	Mean[Gy(RBE)]	<=10	NA
Lungs	V20Gy[%]	<=35	NA
	Mean[Gy(RBE)]	<=10	NA
OralCavity	Mean[Gy(RBE)]	<=15	NA
Parotid_L or R	Mean[Gy(RBE)]	<=15	NA
Pituitary	D0.03cc_[Gy(RBE)]	<=60	NA
Thyroid	Mean[Gy(RBE)]	<=20	NA
Ovary_L or R	Mean[Gy(RBE)]	<=5	NA

Delivery Compliance criteria

	Per Protocol	Variation Acceptable	Notes (Please remove this column when notes are not needed)
Start date (X days/weeks after X) (Please remove this row when the start date is not specified in the protocol.)	Within 14 days of simulation		
Overall Treatment time			
Interruptions	<=4 days	5-7 days	

5.2.8 Treatment Planning Priorities and Instructions

- Critical Structure and Target priorities must be listed in order of decreasing importance (We may also use one importance factor for a group of structures).
The following list is given as an example

1. Spinal Cord
2. BrainStem
3. OpticNrv_L or OpticNrv_R or OpticChiasm
3. PTV_3600
4. PTV_5580
5. Cochlea_L or R
6. Heart
7. Lung_L or R
8. Eye_L or R

9. Ovary_L or R
10. Esophagus
11. Kidney_L or R
12. Larynx
13. Parotid_L or R
14. OralCavity
15. Glnd_Submand_L or R
16. Pituitary
17. Thyroid

Treatment plans will be evaluated using dose-volume histograms (DVHs) to ensure adequate coverage of the target and sparing of normal tissues per protocol.

- Required algorithms

Please see the list of acceptable choices of dose calculation algorithms listed on the IROC Houston website at:
http://rpc.mdanderson.org/RPC/home.htm

For Convolution/Superposition type algorithms, 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. These principles hold for Pencil Beam type algorithms and for homogeneous dose calculations when allowed for a clinical trial (e.g., conical collimators in stereotactic radiosurgery).

- Primary dataset for dose calculation
Planning CT image is the primary dataset for dose calculation. For MR-linac treatments, the primary dataset for dose calculation may be the CT or an MRI with an associated electron density map derived via overrides to representative background electron densities or a warped CT to MRI geometry.

-Dose matrix resolution
Dose grid size should be <= 3 mm in all directions.

-List treatment planning recommendations and give link to FAQs

For photon planning, field matching between cranial fields and upper spine field(s) is required. Field matching between upper spine and lower spine fields is required. Junction shifts (feathering) are required after every 5-7 fractions of treatment or an intrafractional feathering technique based on dose gradient at the junctions can be used. For intrafractional feathering using IMRT/VMAT, the minimum overlap between brain and upper spine or upper spine/lower spine fields is recommended to be at least 5cm to produce robust shifts against uncertainties in longitudinal positioning.

For proton treatment planning, it is required to use simulation CT scans without contrast as the primary dataset. The use of MRI and synthetic CT should be avoided for treatment planning.

It is recommended to apply robust optimization for the CTV whenever possible. A setup uncertainty ranging from 3mm to 5mm (equivalent to the CTV to PTV margin in photon therapy) should be applied in six orthogonal directions (±x, ±y, ±z). Additionally, it's essential to include a range uncertainty of 2.5% to 3.5% to address range uncertainties.

Give the well pre-defined beam angle arrangement, it is acceptable to generate beam-specific PTVs (BsPTVs) for each beam, considering the setup margin in the perpendicular directions and the range uncertainty in the proximal and distal directions of the beam.

For brain fields, either a single posterior-anterior (PA) beam or two posterior oblique beams or the combination of both can be utilized. Posterior oblique beams, for example, angled 15 degrees from the horizontal plane might be helpful to reduce dose to the lens and improve dosimetric coverage of the cribriform plate. Single PA beams are typically used for spine fields.

If PBS is used, it's essential to establish a minimum dose gradient of 6 cm (preferably 8-10 cm) in the field junction regions. This gradient should be smooth and not take a step-like form. For RayStation users, independent isocenters robust optimization in the superior-inferior directions can create a smooth dose gradient. Additionally, implementing robust optimization with independent isocenters in the left-right directions can enhance the robustness at the junction, which proves especially useful when a patient has difficulty aligning their spine straight. Other TPS, like Eclipse, have introduced an auto feathering function to achieve the same purpose. Other approaches, such as using the background dose method and/or additional supplemental volumes to guide robust planning to achieve the slow dose gradient can be used.

If passive scattering or uniform scanning is used, apertures and compensators should be used for conformal dose distribution. The spine/ spine and spine/cranial junctions shift must be applied, preferably once a week, to feather out the hot and cold spots in the junction region.

5.2.9 Patient specific QA

- Describe technique and give Gamma test parameters in mm and percentage and Gamma pass rate recommendation.

Any patient-specific QA that needs to be acquired should follow institutional guidelines and AAPM task group report recommendations.

For IMRT/VMAT plans, patient specific QA is required. Any patient-specific QA performed should follow your institutional guidelines. It is important that the QA measurements capture the junction area of each field. The recommended patient specific QA criteria is for 90% of the comparison points to pass a ±3%/2mm Gamma Index analysis.

For proton patient-specific QA, it is recommended to measure at least one plane depths within the target region. In cases where the fields' length exceeds the measuring region of the QA device, it is

necessary to conduct two separate measurements at the superior and inferior portions of the field to cover the entire field.

A log-based QA approach is also acceptable, provided that the institution has implemented a comprehensive and robust QA program for log-based procedures.

5.2.10 Treatment Localization/IGRT

Image-guided radiation therapy (IGRT) is radiation therapy using imaging to facilitate accuracy and precision throughout its entire process. 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, with computer assisted process, i.e. image handling together with calculation of shift and rotations (if available) must be determined with computer assistance.

The following information should be provided for localization guidance

- What kind of isocenter localization techniques will be used (simple/advanced/combined), and with what frequency?
- Will imaging to assess 'straightness' be used?
- Is IGRT tied to margin reduction?
- The time points of imaging (e.g. before, mid, after treatment)? This should be decided based on immobilization, treatment margin, etc.
- Allowed image guidance methods: 2D x-ray, 3D-xray, 3D-MRI (for MR-Linac), electromagnetic localization, optical surface imaging, 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

Daily image guidance is required for photon and proton therapy. Acceptable IGRT methods may include orthogonal kV imaging, cone beam CT, in room diagnostic CT with referenced geometry to treatment machine, or 3D-MRI (in MR-Linac). Image registration is performed based on bony structures. Use of 3-5 mm PTV margin expansion is based on utilization of IGRT for daily setup and localization. Setup errors identified on IGRT images of >1mm or >1 degree should be corrected.

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 or robustness analysis margins. The imaging dose to the patient may become significant if repeated studies are done for patients with severe set up problems (e.g. requiring frequent corrections that are larger than the PTV/robustness analysis margins). It is recommended that patients demonstrating significant set up problems during the first week of treatment be moved to a revised treatment plan with larger margins.

5.2.11 Case Review

The Principal Investigators, XXX, MD will perform ongoing remote RT Quality Assurance Review after cases enrolled have been received at IROC Philadelphia-RT.