

Purpose:

To describe the credentialing process for randomized photon vs. proton NCI sponsored trials.

Methods:

IROC-Houston issues credentialing letters for approximately 75 different NCI NCTN clinical trials and this number is ever growing. The complexity of qualifying requirements for sites of newer trials is also growing. To more effectively and efficiently deal with these growths, we utilize an in-house program written in MATLAB that pulls all relevant information from several databases and organizes them into a credentialing letter that our staff can issue via email (Fig. 4).

Specifically, these randomized photon vs. proton NCI sponsored trials incur a large amount of complexity due to requiring two sites, a photon and proton site, to be independently verified by our in-house program but credentialled simultaneously via one credentialing letter issued to both sites. The process for receiving credentialing begins with a Credentialing Status Inquiry (CSI) Form as seen in Fig. 1, which is completed by a site that would like to be credentialled or to inquire about their missing requirements for a specific protocol.

CREDENTIALING FOR PROTOCOLS

This questionnaire will help determine if your institution is credentialled to participate in a protocol. IROC Houston will notify you and the study group of your status. The study group or IROC Houston will inform your institution when it can participate in the requested protocol. If you have any questions, please contact IROC Houston at (713) 745-8989 or IROC-Credentialing@MDAnderson.org

Please note: You will be contacted via email or phone within 2 business days. Once we determine that all requirements are met, a credentialing email (PDF letter for a few protocols) will be issued within 5 business days.

Institution: <input type="text"/>	Study Group Name: <input type="text" value="RTOG"/>
RTF#: (Don't know, click here) <input type="text"/>	NCI #: <input type="text"/>
Name of person completing this form: <input type="text"/>	
Phone #: <input type="text"/>	Email address: <input type="text"/>
Are you a: <input checked="" type="radio"/> Radiation Oncologist <input type="radio"/> Physicist <input type="radio"/> Dosimetrist <input type="radio"/> Clinic Coordinator	
Protocol to be credentialled: <input type="text"/>	
Specify technique: <input type="checkbox"/> 3DCRT <input type="checkbox"/> IMRT <input type="checkbox"/> SBRT <input type="checkbox"/> Proton <input type="checkbox"/> Brachytherapy	
Treatment planning system to be used for this protocol: <input type="text"/>	
Algorithm to be used for patient plans: <input type="text"/>	
Is your institution planning to use IGRT on this protocol, if applicable? <input type="radio"/> Yes <input type="radio"/> No	
For randomized photon vs. proton protocols, please list the RTF# of your partner proton center: (Don't know, click here) <input type="text"/>	

Fig. 1: A CSI form from IROC-Houston's webpage.

Methods (cont.):

Individually, sites must meet the protocol's requirements which range from having an updated Facility Questionnaire and phantom irradiation for both proton and photon to receiving baseline approval for proton sites. The baseline proton approval consists of a site visit, proton Facility Questionnaire, TLD output check, and successful completion of the baseline phantoms (prostate and spine for all modalities, plus the lung phantom for pencil beam scanning). Distinctively new for credentialing of these protocols is the submission of a Letter of Intent (LOI) by both sites to NRG Oncology Regulatory to participate as partners in the given trial. An example of these requirements can be seen in Fig. 2 with a flowchart in Fig. 3 that describes the general procedure for being credentialled for a randomized proton vs. photon trial.

NRG BN005 Requirements

This trial will utilize TRIAD for dosimetry digital treatment data submission. TRIAD is the American College of Radiology's (ACR) image exchange application and it is used by the RTOG. See [here](#) for information on installing TRIAD.

Please fill out the [credentialing status inquiry](#) form to let us know that you would like to be credentialled for this protocol.

Proton centers must have a partner photon center to be credentialled and vice versa. All sites must submit a Letter of Intent (LOI) to NRG Oncology Regulatory to receive approval to participate in this trial. For more details see [NRG Oncology website](#).

In order to complete the **IMRT credentialing** process the following items must be completed:

- Complete or update the [Facility Questionnaire](#).
- Irradiate the IROC Houston's IMRT H&N phantom. Please fill in the [request form](#) online.

In order to complete the **Proton credentialing** process, the following items must be completed:

- All participants must have completed [baseline approval](#) for proton therapy.
- All participants are asked to complete the [Facility Questionnaire](#).
- Irradiate IROC Houston's proton brain phantom. Please fill in the [request form](#) online.

Fig. 2: An example of the credentialing page for a randomized photon vs proton trial from IROC-Houston's webpage.

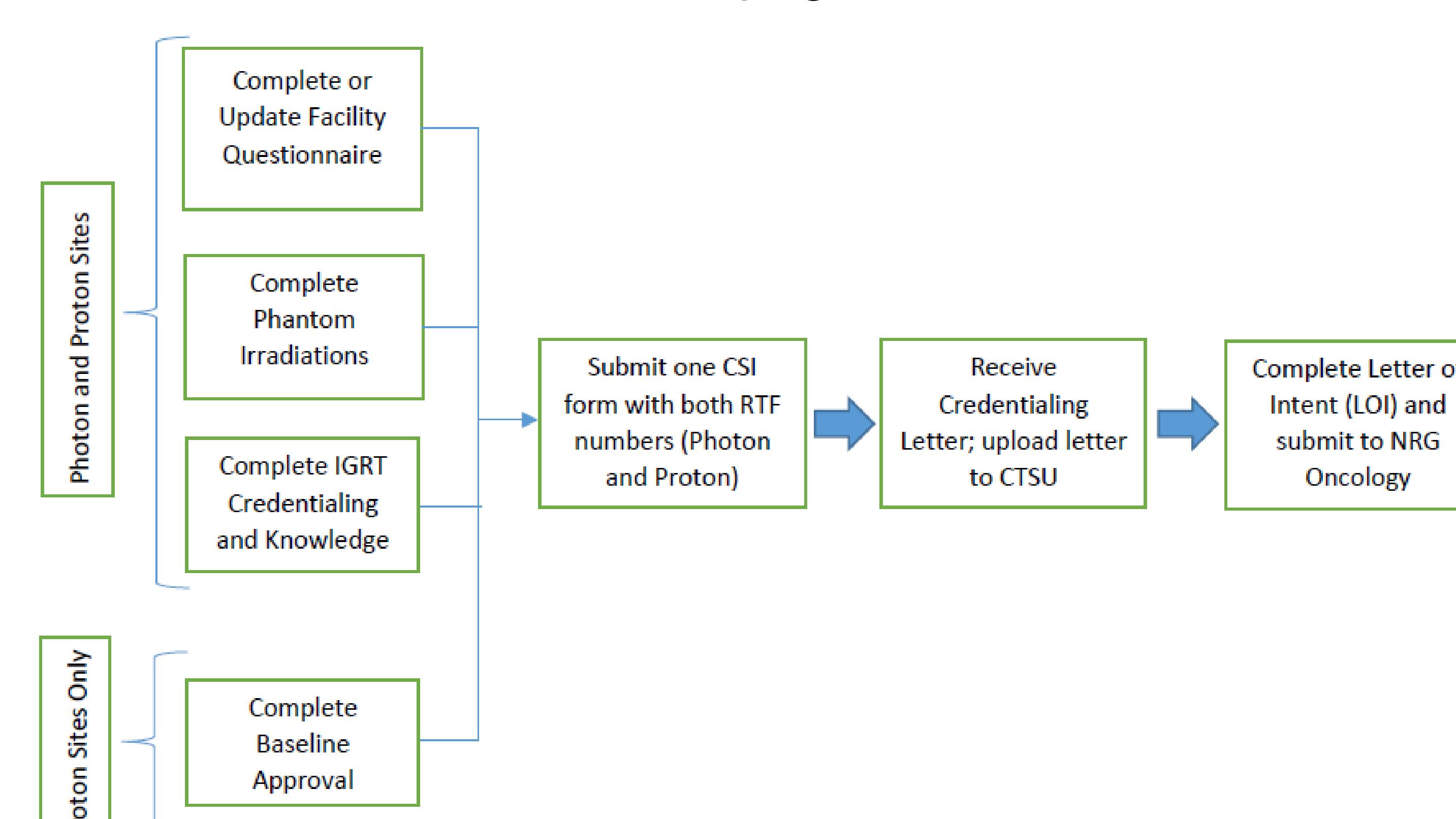


Fig. 3: Flowchart for completing credentialing for randomized photon vs. proton trials.

Results:

Currently, three NCI sponsored trials exist that require this new simultaneous credentialing of photon and proton sites: NRG-BN005, RTOG-1308 and NRG-GI003. In addition, NRG-BN001 requires dual credentialing if a proton site wishes to be credentialled; however, the photon site may be credentialled on its own. As of June 2018, NRG-BN005 has accumulated 7 proton sites with 21 partner photon sites. 10 and 6 proton/photon sites have been credentialled for RTOG-1308 and NRG-GI003, respectively.

Conclusion:

Trials randomizing between protons and photons require for sites with these modalities to partner in their credentialing activities. This task can be accomplished efficiently when both sites know the requirements.

Dear,

[Proton Site Name] (RTF#, NCI#) and [Photon Site Name] (RTF# NCI#) have completed the following credentialing requirements for NRG BN005.

[Proton Site Name] (RTF#, NCI#, proton)

-Modality Approved for Proton: PBS
-Proton Facility Questionnaire was updated on 2017-12-21
-Proton Brain Phantom was approved with Pencil Beam Scanning on 2013-10-24

[Photon Site Name] (RTF#, NCI#, photon)

-Facility Questionnaire was updated on 2017-12-21
-H&N phantom was approved with Raystation on 2014-10-30

[Proton Site Name] (RTF#, NCI#, proton) has passed the RT credentialing requirements for NRG BN005 utilizing Proton (Pencil Beam Scan) technique. This notification acts as your credentialing letter.

[Photon Site Name] (RTF# NCI#, photon) has passed the RT credentialing requirements for NRG BN005 utilizing IMRT technique for standard photon beams. This notification acts as your credentialing letter.

Effective February 9, 2017, use of the Regulatory Submission Portal will become mandatory per CTSU. Institutions will need to upload this notification to the Regulatory Submission Portal. CTSU will then update RSS. If you have an urgent situation and need to register a patient please contact the Regulatory Help Desk immediately at 1-866-651-CTSU for further instruction and guidance.

Fig. 4: An example of a credentialing letter for a randomized photon vs. proton trial.

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