

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 credentialed 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 credentialed or to inquire about their missing requirements for a specific protocol.

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 credentialed for a randomized proton vs. photon trial.

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

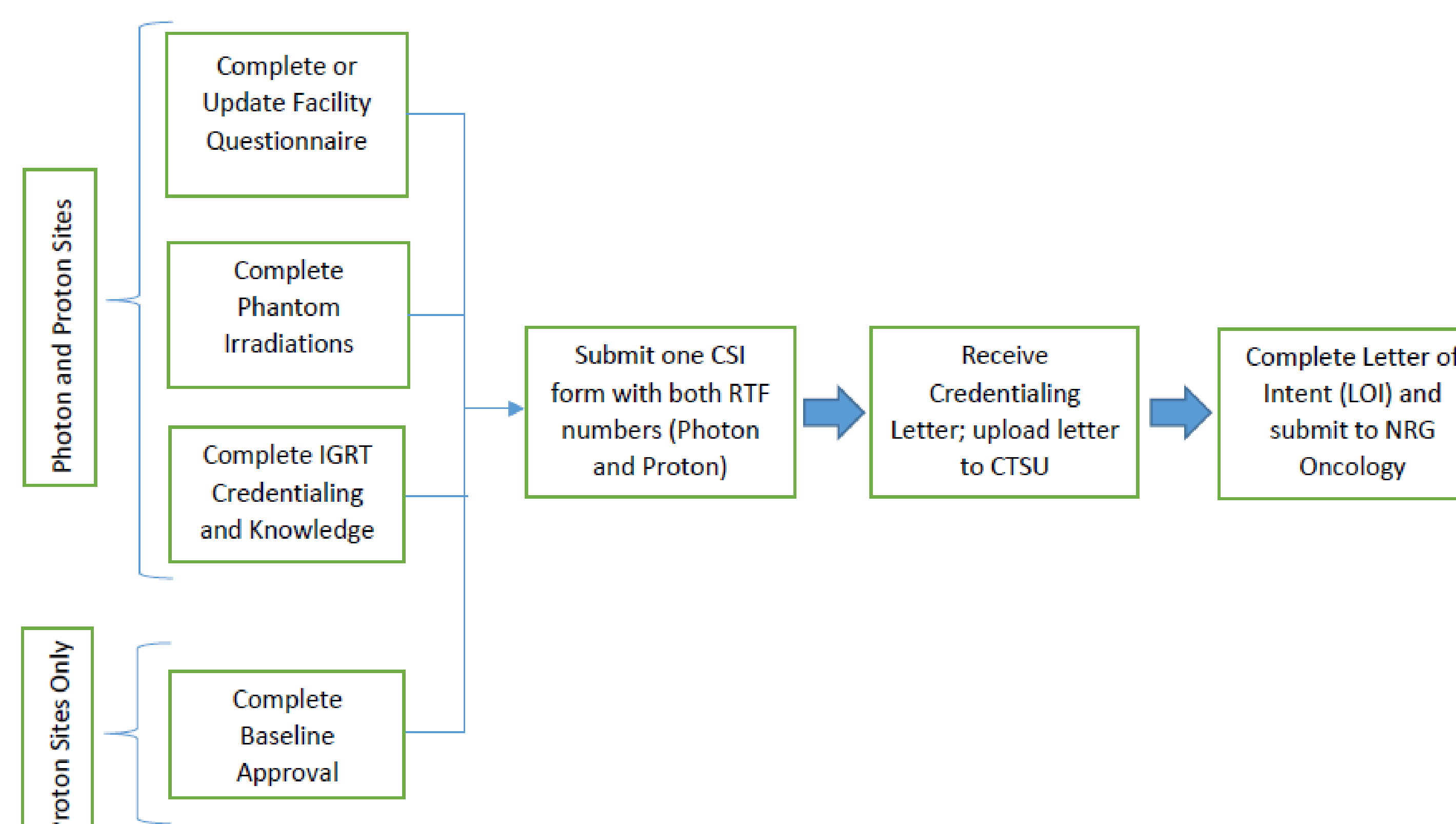


Fig. 3: Flowchart for completing credentialing for randomized photon vs. proton trials.

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 credentialed; however, the photon site may be credentialed 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 credentialed 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.

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

Support:

IROC grant CA180803 awarded by the NCI