RTOG 1106 Section 5: Credentialing

5.0 REGISTRATION PROCEDURES

Participating institutions must complete all pre-registration requirements before enrolling patients on study. See the table and text below.

Table 5.0: Summary of Required Credentialing (8/19/13)

ACRIN Credentialing		
Credentialing	**Web Links for Procedures and Instructions**	**Phone Number**
Institution	www.acrin.org/CORELABS/PETCORELABORATORY/PETQUALIFICATION	215-940-8890.
Scanner	http://www.acrin.org/CORELABS/NCICQIEQUALIFICATIONPROGRAM/NCICQIEQUALIFIEdscanner.aspx	

RTOG Credentialing		
Credentialing	**Web Link for Procedures and Instructions**	**Phone Number**
IGRT (Section 5.1) IMRT* (Section 5.2) 3D-CRT** (Section 5.3) Benchmark Case (Sections 5.2, 5.3 and 5.4)	For All: http://atc.wustl.edu/protocols/rtog/1106/1106.html **Note**: Institutions already credentialed for RTOG SBRT lung trials do not need to repeat credentialing for IGRT and IMRT, unless the institution's technique has changed. These sites only need to do Dry Run/Benchmark credentialing (see Section 5.4).	For All: 215-574-3219

* All institutions credentialing for IMRT (or 3D-CRT together with gating or tracking) must irradiate the RPC phantom.

** Institutions intending to use IMRT for some cases are required to complete IMRT credentialing but are not required to complete 3D-CRT credentialing. Institutions using 3D-CRT together with gating or tracking for motion management must irradiate the RPC phantom for credentialing (see IMRT credentialing).

5.1 Pre-Registration Requirements for Image-Guided Radiotherapy (IGRT) Treatment Approach

5.1.1 In order to be eligible to enroll patients on this trial, the center must be credentialed for either 3D-CRT or IMRT and the center must be credentialed for lung image-guided radiotherapy (IGRT). Institutions credentialed for IMRT will be allowed to enter patients using 3D-CRT.

Institutions previously credentialed for these treatment techniques will not be required to repeat this step in many situations. Exceptions to this statement are listed in the various subsections below. Institutions that have not been credentialed by the RTOG to perform 3D-CRT or IMRT MUST apply for 3D-CRT or IMRT credentialing as described below in Sections 5.2 and 5.3. **Note**: Centers credentialed for the use of IGRT for RTOG SBRT lung trials are automatically credentialed for IGRT for this trial but must repeat the process if their IGRT technique has changed. Centers credentialed for RTOG 0617 are automatically credentialed for 3D-CRT for this trial provided that the motion management and dose calculation algorithms are approved as per SBRT trials.

5.1.2 IGRT Credentialing Process

IGRT is mandatory for this study. Each center must be credentialed for lung IGRT. IGRT information is available at the following web site:
http://atc.wustl.edu/credentialing/IGRT_Credentialing_Process.pdf.

- Each institution will be required to undergo credentialing for lung cancer IGRT before registering patients to this protocol. This involves completion of a Facility Questionnaire and a review of at least 1 case from each institution. The first step in the credentialing process is for the institution to complete a new Facility Questionnaire or modify their existing Questionnaire and set up an SFTP account for digital data submission, both of which are available at http://atc.wustl.edu/protocols/rtog/1106/1106.html. In addition to the general information required for completing this questionnaire, the institution must answer all questions pertaining to IGRT in the section relating to this capability.
- Next, the institution must submit a series of 5 consecutive daily pre-treatment images along with a spreadsheet of IGRT data from an anonymized lung cancer patient. This patient should have a lung tumor similar to the patients that are acceptable for inclusion on this protocol.
  See http://atc.wustl.edu/protocols/rtog/1106/1106.html for the spreadsheet that must be completed for this credentialing step. The accepted pre-treatment image types include three-dimensional (3D) volumetric images (either fan- or cone-beam CT using Megavoltage (MV) or kilovoltage (Kv) x-rays or Orthogonal (MV or Kv) 2D images). These images and the spreadsheet will be reviewed by the Principal Investigator, Feng-Ming (Spring) Kong, MD and/or the Medical Physics Co-Chairs, Randall Ten Haken, PhD, Ying Xiao, PhD, or Martha Matuszak, PhD. Once approved, RTOG will notify the institution by e-mail.

5.2 Pre-Registration Requirements for IMRT Treatment Approach (8/19/13)
Only Required for Institutions Intending to Use IMRT Planning and Delivery

Institutions not intending to use IMRT for any patients entered on this study can go directly to Section 5.3. However, it is important to point out that some of the requirements in Section 5.3 overlap with requirements in this section. When this is the case, Section 5.3 refers the reader back to the relevant sub-section below.

5.2.1 In order to utilize IMRT on this study, the institution must have met specific technology requirements and have provided baseline physics information. Instructions for completing these requirements or determining if they already have been met are available at http://rpc.mdanderson.org/rpc; select “Credentialing” and “Credentialing Status Inquiry”.

5.2.2 The institution must complete the following steps to be credentialed for IMRT:

- First, if the institution has not previously met the credentialing requirement for IMRT lung irradiation, the institution must complete relevant sections in the Facility Questionnaire mentioned in Section 5.1.2 above, paying special attention to the sections on 3D-CRT (if the institution will use this treatment modality for some patients) and IMRT. Additionally, the section describing the motion management technique the institution will use for entering patients on this study must be completed. This information must be sent to RTOG via ATC (see the web site at http://atc.wustl.edu).
- Second, an IMRT phantom study must be successfully completed through the RPC. Instructions for requesting and irradiating the phantom are available on the RPC web site at http://rpc.mdanderson.org/rpc/; select “Credentialing” and “RTOG”. Upon review and successful completion of the phantom irradiation, the RPC will notify both the registering institution and RTOG Headquarters that the institution has completed this requirement.
- Third, the institution must generate target and critical structure contours, plus a treatment plan for a Benchmark case. The details for Benchmark testing are provided in Section 5.4. The Benchmark case also serves to verify and credential the institution’s ability to register required PET/CT imaging studies with planning CT information. The details of this procedure are provided in Section 5.4. Upon review and successful completion of the Benchmark credentialing, RTOG will notify the institution that the institution has successfully completed this requirement. Fourth, the institution must complete credentialing for motion management. Motion management credentialing is incorporated into the phantom irradiation process. No added credentialing steps are required for most

motion management techniques. However, when tracking or gating are employed, the phantom irradiation of IMRT credentialing described in Section 5.2.2 must be completed using a moving phantom supplied by RPC to simulate respiratory motion. Institutions must inform the RPC about their motion management technique at the time they request a phantom for the credentialing irradiation. All institutions intending to use IMRT for any of the patients they register to this study must irradiate the RPC phantom for credentialing. As detailed in the next section, institutions using only 3D-CRT for patients registered to this study also must irradiate a phantom under certain circumstances. As outlined in the next section, this exception applies for 3D-CRT as it does for IMRT when institutions use either tumor tracking or beam gating for motion management. Institutions can contact the RPC (713-745-8989) for information regarding credentialing associated with motion management.

- Institutions are required to send planning and contouring information for the initial patients they register for treatment on this study for rapid review before the start of RT. This step is similar to the Benchmark requirement with one important difference. The Pre-treatment Review cases have to be completed under the restrictions of the short timelines that are necessary to enter patients on this study (see Section 5.4.3).

5.3 Pre-Registration Requirements for 3D-CRT Treatment Approach (8/22/12)

Institutions using 3D-CRT and not intending to use IMRT are required to irradiate a phantom only when the motion management approaches of target tracking or beam gating are used during treatment delivery and an acceptable dose calculation heterogeneity correction algorithm is used. Other institutions treating with 3D-CRT will not be required to perform a phantom irradiation. Please contact the RPC to obtain a phantom at http://rpc.mdanderson.org/rpc.

5.3.1 Only institutions that have met the technology requirements and that have provided the baseline physics information my enter patients onto this study.

5.3.2 The institution must complete the following steps to become credentialed for 3D-CRT:

- First, the Facility Questionnaire discussed above must be completed with special attention to the section for 3D-CRT and the section describing the institution's motion management techniques. The questionnaire is available at http://atc.wustl.edu and must be approved by RTOG prior to registering any patients.
- Second, as stated above, when the motion management techniques of target tracking or beam gating are used, a phantom irradiation that includes a moving table to simulate respiratory movement must be used for credentialing. This step fulfills the requirement for motion management. For institutions not using either gating or tracking, completing the Facility Questionnaire by describing the motion management technique completes this requirement.
- Third, institutions intending to use 3D-CRT only as their as their planning and delivery technique when entering patients on this protocol also will have to complete the Benchmark credentialing test discussed in the IMRT section 5.2.2, above, using 3D-CRT. The details of the Benchmark credentialing are described in Section 5.4. The Benchmark case is available online at: http://atc.wustl.edu/protocols/rtog/1106/1106/html. RTOG Headquarters will notify the institution when all requirements have been met and the institution is eligible to enter patients onto this study.
- Fourth, institutions are required to send planning contouring information for the initial patients they register for treatment on this study for rapid review before the start of RT. This Pre-treatment Review process is described further in Sections 5.2.2 and 5.4.

5.4 The Benchmark, Rapid Review, and Image Registration Credentialing Process (8/19/13)

5.4.1 Benchmark Credentialing

The credentialing process consists of a Benchmark test case provided by the Study Chairs of this protocol, as described in Section 5.2.2 for IMRT and in Section 5.3.2 for 3D-CRT. The Benchmark case is available at http://atc.wustl.edu/protocols/rtog/1106/1106.html. The purpose of the Benchmark credentialing case is to:

1) verify the institution's ability to submit treatment planning and imaging data using an appropriate digital format;
2) demonstrate the institution's understanding and implementation of details of this protocol;
3) verify the institution's ability to correctly contour structures and targets;
4) confirm the institution's ability to produce treatment plans that meet the requirements of the protocol, which include accurate image registration.

Case, imaging, and procedural instructions related to the Benchmark credentialing can be directly downloaded from http://atc.wustl.edu/protocols/rtog/1106/1106.html, This protocol should be used as the instruction for target delineation and RT adaptive planning. **The Benchmark should be submitted for review according to Section 12.** The credentialing criteria of the Benchmark are the same as specified in this protocol for actual cases with minor deviation, as specified in Section 6.0.

5.4.2 Image Registration Credentialing

Image Registration credentialing is in addition to the requirement for daily IGRT for patient positioning on the RT treatment couch. This requirement addresses the registration of the pre- and during-RT PET/CT with the CT-simulation study performed at the start of treatment. The credentialing of the imaging registration will be performed as part of the credentialing Benchmark case. Detailed instructions are available online. The institution must submit the screen captures of the registrations of CT1/PET1, CT2/PET2, CT1/CT2 with axial, sagittal, and coronal views through the center of the target volume as specified in Section 12.2. Imaging registrations will be further reviewed by the Study Chairs during the real time rapid review for the initial cases from each center.

5.4.3 Pre-Treatment Reviews

Pre-treatment review credentialing of the initial patients is designed to further verify an institution's ability to correctly contour structures and create protocol compliant treatment plans. Like the Benchmark credentialing procedure, pre-treatment reviews can further verify the institution's ability to adhere to the protocol instructions. The idea of the pre-treatment review process is to require institutions to send their radiation treatment plan for the first patient that is randomized to the "adaptive" arm (Arm 2) for rapid review by the Study Chairs. This patient cannot start treatment until the pre-treatment review is completed and approval received. Subsequent patients may not be enrolled until the pre-treatment review is approved and the site is notified by RTQA

5.5 Pre-Registration Requirements for FDG-PET and CT Guided Adaptive Radiation Therapy (8/19/13)

5.5.1 Only institutions that have met the following requirements may enter patients onto this study.

- The institution must have an ACRIN qualified PET/CT scanner and must follow ACRIN scanning protocols (see Section 6.14). This scanner must be used on all patients entered onto this trial. The credentialing process and application forms, as well as the FDG-PET standard operating procedures (SOPs) are available on the PET Core Lab web site (browse at http://www.acrin.org/CORELABS/PETCORELABORATORY.aspx). Facilities that have a qualified scanner are listed at http://www.acrin.org/CORELABS/NCICQIEQUALIFICATIONPROGRAM/NCICQIEQUALIFIEDSITES.aspx.

- For this study, the institution must use a flat palette imaging couch for scanning for imaging registration match with simulating CT for both the FDG-PET/CT and FMISO-PET/CT. Accurate imaging registration is essential before enrolling any patient for this protocol.

- Adequate image registration between FDG-PET and the CT from the PET/CT scanner and the CT of the PET/CT with a simulating CT is required. Deformable registration is not permitted.

5.5.2 Scanners qualified within the last 2 years for other ACRIN studies involving quantitative FDG-PET/CT will be automatically credentialed for this study (after verification of the above requirements by the ACRIN PET Core Laboratory and confirmation of a flat palette imaging couch).

5.5.3 Credentialing for imaging registration and target delineation can be accomplished through completion of the credentialing Benchmark study, available at http://atc.wustl.edu/protocols/rtog/1106/1106.html.

5.6 Regulatory Pre-Registration Requirements

5.6.1 U.S. and Canadian institutions must fax copies of the documentation below to the CTSU Regulatory Office (215-569-0206), along with the completed CTSU-IRB/REB Certification Form, https://www.ctsu.org/public/CTSU-IRBcertif_Final.pdf, prior to registration of the institution's first case:

- IRB/REB approval letter;
- IRB/REB approved consent (English and native language versions*****);

***Note**: Institutions must provide certification/verification of IRB/REB consent translation to RTOG Headquarters (described below)

- IRB/REB assurance number

Non-English Speaking Canadian and Non-North American Institutions:

Translation of documents is critical. The institution is responsible for all translation costs. All regulatory documents, including the IRB/REB approved consent, must be provided in English and in the native language. Certification of the translation is optimal but due to the prohibitive costs involved RTOG will accept, at a minimum, a verified translation. A verified translation consists of the actual REB approved consent document in English and in the native language, along with a cover letter on organizational/letterhead stationery that includes the professional title, credentials, and signature of the translator as well as signed documentation of the review and verification of the translation by a neutral third party. The professional title and credentials of the neutral third party translator must be specified as well.

5.6.2 Pre-Registration Requirements FOR CANADIAN INSTITUTIONS

Prior to clinical trial commencement, Canadian institutions must complete and fax to the CTSU Regulatory Office (215-569-0206) Health Canada's Therapeutic Products Directorates' Clinical Trial Site Information Form, Qualified Investigator Undertaking Form, and Research Ethics Board Attestation Form.

5.6.3 Pre-Registration Requirements FOR NON-CANADIAN INTERNATIONAL INSTITUTIONS

***For institutions that do not have an approved LOI for this protocol*:**

International sites must receive written approval of submitted LOI forms from RTOG Headquarters prior to submitting documents to their local ethics committee for approval. See http://www.rtog.org/Researchers/InternationalMembers.aspx .

***For institutions that have an approved LOI for this protocol*:**

All requirements indicated in your LOI Approval Notification must be fulfilled prior to enrolling patients to this study.

5.7 Patient Registration

5.7.1 Online Registration

Patients can be registered only after eligibility criteria are met.

Each individual user must have an RTOG user name and password to register patients on the RTOG web site. To get a user name and password:

- The investigator and research staff must have completed Human Subjects Training and been issued a certificate (Training is available via http://phrp.nihtraining.com/users/login.php).
- A representative from the institution must complete the Password Authorization Form (http://www.rtog.org/LinkClick.aspx?fileticket=-BXerpBu5AQ%3d&tabid=219) and fax it to 215-923-1737. RTOG Headquarters requires 3-4 days to process requests and issue user names/passwords to institutions.

An institution can register the patient by logging onto the RTOG web site (http://www.rtog.org), going to "Data Center Logon" and selecting the link for new patient registrations. The system triggers a program to verify that all regulatory requirements (OHRP assurance, IRB approval) have been met by the institution. The registration screens begin by asking for the date on which the eligibility checklist was completed, the identification of the person who completed the checklist, whether the patient was found to be eligible on the basis of the checklist, and the date the study-specific informed consent form was signed.

Once the system has verified that the patient is eligible and that the institution has met regulatory requirements, it assigns a patient-specific case number. The system then moves to a screen that confirms that the patient has been successfully enrolled. This screen can be printed so that the registering site will have a copy of the registration for the patient's record. Two e-mails are generated and sent to the registering site: the Confirmation of Eligibility and the patient-specific calendar. The system creates a case file in the study's database at the

DMC (Data Management Center) and generates a data submission calendar listing all data forms, images, and reports and the dates on which they are due.

If the patient is ineligible or the institution has not met regulatory requirements, the system switches to a screen that includes a brief explanation for the failure to register the patient. This screen can be printed.

Institutions can contact RTOG web support for assistance with web registration: websupport@acr.org.

In the event that the RTOG web registration site is not accessible, participating sites can register a patient by calling RTOG Headquarters, at (215) 574-3191, Monday through Friday, 8:30 a.m. to 5:00 p.m. ET. The registrar will ask for the site's user name and password. This information is required to assure that mechanisms usually triggered by web registration (e.g., drug shipment, confirmation of registration, and patient-specific calendar) will occur.