SBRT Credentialing: Understanding the Process from Inquiry to Approval

Andrea Molineu, M.S. and David Followill, Ph.D.
IROC Houston QA Center
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What is credentialing?

- Verification of an appropriate level of competency, typically as a snapshot in time.

- Can apply to all of specific combinations of institutions, radiation oncologists, physicists, TPS or treatment modality.
Purpose of Credentialing

- Educate, educate, educate
- Improve understanding of protocol
- Evaluate ability to deliver dose
- Improve treatment delivery (contouring, IGRT, etc.)

Goal is to reduce deviation rates
Where do you start?

1. Read the protocol.

2. If you did not understand the process the first time you read the protocol, read it again.
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### RT Credentialing Requirements

<table>
<thead>
<tr>
<th>Treatment Modality</th>
<th>Key Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBRT</td>
<td>IMRT</td>
</tr>
<tr>
<td>Facility Questionnaire</td>
<td>X</td>
</tr>
<tr>
<td>The IROC Houston electronic facility questionnaire (FQ) should be completed or updated with the most recent information about your institution. To access this FQ, email <a href="mailto:irochouston@mdanderson.org">irochouston@mdanderson.org</a> to receive your FQ link.</td>
<td></td>
</tr>
<tr>
<td>Credentialing Status Inquiry Form</td>
<td>X</td>
</tr>
<tr>
<td>To determine whether your institution needs to complete any further credentialing requirements, please complete the “Credentialing Status Inquiry Form” found under credentialing on the IROC Houston QA Center website (<a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>)</td>
<td></td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>N/A</td>
</tr>
<tr>
<td>Benchmark Cases</td>
<td>N/A</td>
</tr>
<tr>
<td>Phantom Irradiation</td>
<td>X</td>
</tr>
<tr>
<td>A liver phantom study provided by the IROC Houston QA Center must be successfully completed. Instructions for requesting and irradiating the phantom are found on the IROC Houston website (<a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>). Note that only the most sophisticated technique needs to be credentialed, e.g., if credentialed for IMRT, 3DCRT may be used. VMAT, Tomotherapy, Cyberknife and proton treatment delivery modalities must be credentialed individually.</td>
<td></td>
</tr>
<tr>
<td>IGRT Verification Study</td>
<td>X</td>
</tr>
<tr>
<td>The institution must submit a sample of verification images showing their ability to reproducibly register daily IGRT information with a planning CT dataset (i.e., the GTV falls within the CT simulation defined PTV). The patient (“as if patient”) used for this study must have a target (or mock target) in the liver. The information submitted must include 2 IGRT datasets (from 2 treatment fractions) for a single patient and must employ the method(s) that will be used for respiratory control for patients entered from a particular institution (e.g. abdominal compression, breath hold, etc...). This information with a spreadsheet (the spreadsheet is available on the IROC Houston website, <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>)</td>
<td></td>
</tr>
<tr>
<td>Pre-Treatment Review</td>
<td>X</td>
</tr>
<tr>
<td>The first patient to be enrolled from each institution will be planned per NRG-G1001 specifications and submitted via TRIAD for evaluation by the IROC Houston QA Center and the trial PI or designee. Feedback will be given to the institution within 3 business days regarding any concerns prior to the patient being treated. Any required treatment plan modifications must be resubmitted for evaluation prior to treatment.</td>
<td></td>
</tr>
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</table>

### Credentialing Notification Issued to:

IROC Houston QA Center will notify the institution and NRG Headquarters that all desired credentialing requirements have been met.
Websites to find Credentialing Requirements

- http://irochouston.mdanderson.org
  (http://rpc.mdanderson.org)

- http://www.irocqa.org
Specific Protocol Requirements

**NRG BR001 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 NRG. See [here](#) for information on installing TRIAD.

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

- All participants are asked to complete the [Facility Questionnaire](#).
- All participants are asked to complete and submit a [Specific Benchmark Plan](#). Click [here](#) for the DICOM structure file for CyberKnife.
- Successfully complete the IGRT credentialing study. Details can be found [here](#). (Click [here](#) for IGRT data spreadsheet).
- Irradiate the IROC Houston's SBRT phantom. Please fill in the [request form](#) online.
- Pre-Treatment Review is needed. See section 6.0 of protocol for details.

**Note:**

- Institutions that were previously credentialed to participate in another SBRT protocol or have a question about your status for this protocol, please fill out the [credentialing status inquiry form](#).
- Click [here](#) to access the DVA being used to evaluate all BR001 patients.

- [Frequently Asked Questions](#)
What is the best place to find SBRT credentialing requirements?

Facility Questionnaire

• Trying to get away from multiple questionnaires and hardcopy forms
• FQ is more institutional specific, not protocol specific

This is a web form to gather information about your institution. Please complete the form in its entirety and if encounter any problem please contact the host site, IROC Houston QA Center, at 713-745-8989 or email at IROCHouston@MDanderson.org.

RTF Number
Password

Submit

In order for this questionnaire to work, you must be running Internet Explorer or Firefox with javascript enabled (click here for a pop-up test). Google Chrome and other browsers had not been tested.
Facility Questionnaire

Facility Questionnaire
(Demographics and Technical Survey)

All textboxes are editable. Please review the data below verifying its correctness. If data is missing or changes are required, please make the modifications or additions. Use the appropriate Button to periodically register your changes. Please make sure to click the Submit the Facility Questionnaire button at the end of the form to verify that the information is correct to the best of your knowledge and to close out the form.

*Note: Please fill in as much as you can and submit. You can always fill out the rest or make changes at a later time.

General Institution Information

Institution Name: M D Anderson Cancer Center
Address: Department of Radiation Physics
1515 Holcombe
City: Houston
State: TX
Zipcode: 77030
Telephone: 7135632500
Fax: 7135632545

Last Accessed: Mar-09-2015 03:32:PM
CTEP/NCI Id#: TX035
Today's Date: 27 May 2015
RTF#: 1744

Person submitting this form:
- Michael Gillin
Degree: PhD

Email: mgillin@mdanderson.org
Phone: 713 563 2507

If you are participating in the IROC Houston QA program, please confirm the TLD/OSLD and billing address form by clicking the OSL/BILLING button.

List the primary individuals responsible for general questions regarding clinical trials and dosimetry compliance (OSLD/ILD monitoring) for NCI sponsored clinical trials.

Physicist
First Name: Dr.
Last Name: Michael Gillin
Degree: PhD

Email: mgillin@mdanderson.org
Phone: 713-563-2507
Credentialing Status Inquiry (CSI) Form

**CREDENTIALING FOR PROTOCOLS**

This questionnaire will help determine if your institution is credentialed 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 IROCHouston@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 letter will be issued within 5 business days.

<table>
<thead>
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<td>2013</td>
<td>379</td>
</tr>
<tr>
<td>2014</td>
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Knowledge Assessment

Simply a test to verify that key details of the protocol are understood.
Benchmark Cases

- CT datasets requiring contouring (sometimes) and treatment planning according to the protocol.
- Most often these cases are required by study PI.
- Trying to not use these since everyone submits a case to be evaluated but never puts patients onto the trial.
- Trying to transition to using the first patient submitted from each institution having a pre-treatment review.
Lung SBRT - Heterogeneity Correction Algorithms

- Must use the acceptable algorithms

**Acceptable**
- Brain Lab / Monte Carlo Eclipse / AAA
- Eclipse / ACUROS
- Pinnacle / Collapsed Cone Convolution – Adaptive Convolve XiO / Superposition – Fast Superposition
- Monaco / Monte Carlo
- Helax / Collapsed Cone
- TomoTherapy / Convolution Superposition
- Corvus / Monte Carlo Multiplan / Monte Carlo
- In House TPS / Monte Carlo

**Unacceptable**
- Brain Lab / Pencil Beam Eclipse / Pencil Beam
- Pinnacle / Fast Convolve
- XiO / Modified Clarkson – Convolution Helax / Pencil Beam
- Corvus / Pencil Beam Multiplan / Ray Tracing
- In House TPS / Pencil Beam or Clarkson base
Which of the following classes of heterogeneity correction algorithm is not acceptable for lung SBRT in NCI funded clinical trials?

20% 1. AAA

20% 2. Convolution Superposition

20% 3. Monte Carlo

20% 4. Pencil Beam

20% 5. ACUROS
4. Pencil Beam

Phantom Irradiation

Is this repeat phantom?  ○ Yes  ○ No

Phantom requested (Please select one):

○ SRS Head
○ IMRT H&N
○ Proton Head
○ Proton Prostate
○ IMRT Thorax
○ 3D CRT Thorax
○ Proton Thorax
○ IMRT Spine
○ Proton Spine
○ Photon Liver
○ Proton Liver

Method to account for respiratory motion (if applicable):

Protocol to be credentialed for:

Has your IRB granted approval for this protocol?  ○ Yes  ○ No

Machine:

Make:
Phantoms

- 3 prostate phantoms
- 25 lung phantoms
- 8 Spine phantoms
- 15 H&N phantoms
- 12 SRS phantoms
- 10 liver inserts
Phantoms Shipped

- SRS head
- Spine
- Liver
- Prostate
- Lung
- H&N

Phantom shipping is based on a Prioritization score

- Date of request
- IRB approval
- Completion of other credentialing requirements
- Request by study PI
- Large accruing center
- Logistical performance in the past
IGRT

- Subdivided into anatomic regions (H&N, thorax and abdomen)
- Current method is to
  - describe technique used,
  - provide image files displaying the registration from 2 consecutive treatment fractions
  - complete a spreadsheet of shifts performed
- IGRT credentialing is currently under review and may be modified in the future.
Grandfathering

• We love it!!
• Goal to minimize your work and ours!
• Let the IROC Houston staff tell you if you need to do anything via the CSI form.
Proton Therapy

• Two processes to using proton in NCI clinical trials
  – Approval process – institution must complete several requirements (FQ, annual beam monitoring, baseline phantoms, on site visit, electronic data transmission)
  – Protocol specific credentialing as outlined above (phantoms, IGRT, KA, etc)
The proton center approval process includes the following except:

<table>
<thead>
<tr>
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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. Baseline phantom irradiations</td>
</tr>
<tr>
<td>20%</td>
<td>2. Knowledge Assessment</td>
</tr>
<tr>
<td>20%</td>
<td>3. On site Dosimetry visit</td>
</tr>
<tr>
<td>20%</td>
<td>4. Annual Beam monitoring</td>
</tr>
<tr>
<td>20%</td>
<td>5. Facility Questionnaire</td>
</tr>
</tbody>
</table>
2. Knowledge Assessment

- Guidelines for the Use of Proton Radiation Therapy in NCI-Sponsored Cooperative Group Clinical Trials, rrp.cancer.gov/content/docs/proton.doc, 2012
Approval

• Once all of the requirements have been met, IROC Houston will notify all pertinent parties that the institution is credentialed via email.

• CTSU adds attribute to RSS to allow institution to enroll patients
Summary

• There can be just a few steps or many depending on the specifics of the protocol.
  – Oligometastaseses protocols – complex
  – Brain protocol – simple

• Do not start the process at the last minute. Be Proactive. It takes time and effort.

• Let the team at IROC Houston help you
Thank you

Questions?