SBRT Credentialing: Understanding the Process from Inquiry to Approval

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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
<table>
<thead>
<tr>
<th>RT Credentialing Requirements</th>
<th>Treatment Modality</th>
<th>Key Information</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>SBRT</td>
<td>IMRT</td>
</tr>
<tr>
<td>Facility Questionnaire</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Credentialing Status Inquiry Form</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Benchmark Cases</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Phantom Irradiation</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>IGRT Verification Study</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Pre-Treatment Review</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Web Link for Procedures and Instructions: <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a></td>
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</tbody>
</table>

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 irochouston@mdanderson.org to receive your FQ link.

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 ([http://irochouston.mdanderson.org](http://irochouston.mdanderson.org)).

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 web site ([http://irochouston.mdanderson.org](http://irochouston.mdanderson.org)). Note that only the most sophisticated technique needs to be credentialled, e.g., if credentialled for IMRT, 3DCRT may be used. VMAT, Tomotherapy, Cyberknife and proton treatment delivery modalities must be credentialled individually.

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 web site, [http://irochouston.mdanderson.org](http://irochouston.mdanderson.org)).

The first patient to be enrolled from each institution will be planned per NRG-GI001 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.

**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://irochouston.mdanderson.org)
  ([http://rpc.mdanderson.org](http://rpc.mdanderson.org))

- [http://www.irocqa.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?

| 20% 3. | http://irochouston.mdanderson.org |
| 20% 4. | https://www.nrgoncology.org |
| 20% 5. | http://atc.wustl.edu |
http://irochouston.mdanderson.org

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

<table>
<thead>
<tr>
<th>Institution Name:</th>
<th>M D Anderson Cancer Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Department of Radiation Physics</td>
</tr>
<tr>
<td></td>
<td>1515 Holcombe</td>
</tr>
<tr>
<td>City</td>
<td>Houston</td>
</tr>
<tr>
<td>State</td>
<td>TX</td>
</tr>
<tr>
<td>Zipcode</td>
<td>77030</td>
</tr>
<tr>
<td>Telephone:</td>
<td>7135632500</td>
</tr>
<tr>
<td>Person submitting this form:</td>
<td>Michael Gillin</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:mgillin@mdanderson.org">mgillin@mdanderson.org</a></td>
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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 question regarding clinical trials and dosimetry compliance (OSLD/TLD monitoring) for NCI sponsored clinical trials.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr.</td>
<td>Michael</td>
<td>Ph.D.</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:mgillin@mdanderson.org">mgillin@mdanderson.org</a></td>
<td></td>
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<tr>
<td>Fax</td>
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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>
<tr>
<th>Time Period</th>
<th>Number of CSI Forms</th>
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<tbody>
<tr>
<td>2013</td>
<td>379</td>
</tr>
<tr>
<td>2014</td>
<td>927</td>
</tr>
<tr>
<td>Jan to March 2014</td>
<td>97</td>
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<tr>
<td>Jan to March 2015</td>
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<td>3/1/13 – 3/1/14</td>
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<tr>
<td>3/1/14 – 3/1/15</td>
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Knowledge Assessment

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

CREDENTIALING FOR NRG BN001 KNOWLEDGE ASSESSMENT QUESTIONNAIRE

This questionnaire is intended to evaluate your understanding of the protocol. If there are any questions please contact the IROC Houston at (713) 745-8989 or IROCHouston@mdanderson.org

1. Patients in the proton arm will be treated to a dose of _______ Gy(RBE) in _______ fractions with a simultaneous integrated boost to _______ Gy(RBE) in _______ fractions.

2. A diagnostic contrast-enhanced MRI of the brain must be performed postoperatively within _______ hours of resection. The enhancing tumor must have a maximal diameter of _______ cm.

3. All proton centers must be able to deliver proton therapy or partner with a proton therapy site for patients randomized.
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?

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<tbody>
<tr>
<td>20%</td>
<td>1. AAA</td>
</tr>
<tr>
<td>20%</td>
<td>2. Convolution Superposition</td>
</tr>
<tr>
<td>20%</td>
<td>3. Monte Carlo</td>
</tr>
<tr>
<td>20%</td>
<td>4. Pencil Beam</td>
</tr>
<tr>
<td>20%</td>
<td>5. ACUROS</td>
</tr>
</tbody>
</table>
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
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:

| 20% | 1. Baseline phantom irradiations |
| 20% | 2. Knowledge Assessment          |
| 20% | 3. On site Dosimetry visit       |
| 20% | 4. Annual Beam monitoring        |
| 20% | 5. Facility Questionnaire        |
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.
  – Oligometastases 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?