Clinical Trial Credentialing: Where to Start and Resources Available
Acknowledgements

• IROC Grant CA180803
• David Followill, Jessica Lowenstein, Ying Xiao for slide support
So your physician tells you that your group will be participating in clinical trials . . .

- Denial
So your physician tells you that your group will be participating in clinical trials . . .

- Anger
So your physician tells you that your group will be participating in clinical trials . . .

- Bargaining
So your physician tells you that your group will be participating in clinical trials . . .

• Depression
Where do I start?

http://irochouston.mdanderson.org
IROC Houston Home Page

http://irochouston.mdanderson.org
http://irochouston.mdanderson.org
### Facility Questionnaire

**Facility Questionnaire (Demographics and Technical Survey) (Read-Only Mode)**

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.

<table>
<thead>
<tr>
<th>General Institution Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Institution Name:</strong> MD Anderson Cancer Center</td>
</tr>
<tr>
<td><strong>Telephone:</strong> 713-563-2500</td>
</tr>
<tr>
<td><strong>Person submitting this form:</strong> <a href="mailto:mglillin@mdanderson.org">mglillin@mdanderson.org</a></td>
</tr>
<tr>
<td><strong>Email:</strong> <a href="mailto:mglillin@mdanderson.org">mglillin@mdanderson.org</a></td>
</tr>
</tbody>
</table>

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>Fax</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you are participating in the IROC Houston QA program, please confirm the TLD/OSLD and billing address form by clicking the OSU BILLING button.
http://irochouston.mdanderson.org
IROC Houston Credentialing Page

http://irochouston.mdanderson.org

Many study groups initiate protocols which use new technologies or treatment techniques. They want to ensure that the participating institutions understand the protocol and can treat patients according to protocol stipulations. Therefore, the IROC Houston has been asked on many occasions to develop and implement credentialing processes. Credentialing is or has been done for RTOG, GOG, NCCTG and NSABP. Credentialing involves proving adequate knowledge of the protocol, treatment planning system, and QA procedures. This is done through the use of questionnaires and one or more test cases. The approval may be for an institution, specific personnel, or both.

- Treatment planning system and algorithm for calculation of dose within heterogeneities approved by the RTOG QA group
- If you have any credentialing questions please contact us at IROC-Credentialing@MDAnderson.org.
IROC Houston Credentialing Page

http://irochouston.mdanderson.org

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 credentialed for this protocol.

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

- All participants are asked to complete the Facility Questionnaire.
- Irradiate the IROC Houston’s 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 the IROC Houston’s head phantom. Please fill in the request form online.
- Complete the BN001 Knowledge Assessment. Please note, the knowledge assessment is only required for PROTON institution.

In order to complete the scanner qualification for Advanced Imaging, the following items must be submitted for qualification prior to each scanner to be used.
IROC Houston Credentialing Page

Many study groups initiate protocols which use new technologies or treatment techniques. They want to ensure that the participating institutions understand the protocol and can treat patients according to protocol stipulations. Therefore, the IROC Houston has been asked on many occasions to develop and implement credentialing processes. Credentialing is or has been done for RTOG, GOG, NCCTG and NSABP. Credentialing involves proving adequate knowledge of the protocol, treatment planning system, and QA procedures. This is done through the use of questionnaires and one or more test cases. The approval may be for an institution, specific personnel, or both.

- Treatment planning system and algorithm for calculation of dose within heterogeneities approved by the RTOG QA group
- If you have any credentialing questions please contact us at IROC-Credentialing@MDAnderson.org.
Credentialing Status Inquiry (CSI) Form

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.
What is credentialing?

- Verifying an appropriate level of competency and ability to provide a basis for confidence

- Applies to
  - Institutions
  - Specific protocols
  - Radiation Oncologists, Med. Physicists
  - Treatment Planning Systems/algorithms
  - Treatment machine
  - Treatment modality
Purpose of Credentialing

- Educate
- Improve understanding of protocol
- Evaluate ability to use new technologies in clinical trials to deliver dose to only the intended treatment site
- Evaluate ability to calculate accurate dose to treatment site
- Evaluate ability to not irradiate critical healthy tissues near tumor
- Improve treatment delivery/patient safety

REDUCE THE NUMBER OF PROTOCOL DEVIATIONS
Credentialing Process
(the big picture)

Clinician wants to open trial

- Read the protocol

Credentialing? (NO)

- IROC not involved

Credentialing? (YES)

- Go to http://irochouston.mdanderson.org
  - Submit CSI
  - CSI response: all criteria met
    - YES: Credentialing email will be sent
    - NO: Complete missing components by working with physicist/rad onc

Inst uploads info into Reg. portal

Once components complete
<table>
<thead>
<tr>
<th>RT Credentialing Requirements</th>
<th>Web Link for Procedures and Instructions: <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Modality</strong></td>
<td><strong>Key Information</strong></td>
</tr>
<tr>
<td>Treatment Modality</td>
<td></td>
</tr>
<tr>
<td>SBRT</td>
<td></td>
</tr>
<tr>
<td>IMRT</td>
<td></td>
</tr>
<tr>
<td>Proton</td>
<td></td>
</tr>
<tr>
<td><strong>Facility Questionnaire</strong></td>
<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>
</tr>
<tr>
<td><strong>Credentialing Status Inquiry Form</strong></td>
<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>
</tr>
<tr>
<td><strong>Knowledge Assessment</strong></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<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 web site (<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>
</tr>
<tr>
<td><strong>Benchmark Cases</strong></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Phantom Irradiation</strong></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>IGRT Verification Study</strong></td>
<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 (&quot;as if patient&quot;) 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, <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>).</td>
</tr>
<tr>
<td><strong>Pre-Treatment Review</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**Credentialing Notification Issued to:**

IROC Houston QA Center will notify the institution and NRG Headquarters that all desired credentialing requirements have been met.
Phantom family

IMRT H&N

Spine

SRS

liver

lung
Phantom Request Form For Protocol

Institution: 
RTF No: 
Physician first name: 
Physician last name: 
Physician phone number: 
Physician email: 
Physician email to receive the report: 

Shipping to:
Address1: 
Address2: 
City: 
State/Province: 
Zip Code: 
Country: 

Is the machine physically located at the address above? 
Yes No

If "NO","Address:" 
Name of Facility: 

Is this repeat phantom? 
Yes No

Phantom requested (Please select one):
- SRS Head
- IMRT H&N
- IMRT Thorax
- 3D CRT Thorax
- IMRT Spine
- Photon Liver
- Proton Brain
- Proton H&N
- Proton Thorax
- Proton Liver
- Proton Prostate
- Proton Spine

Method to account for respiratory motion (if applicable):
Phantom Credentialing Process

- Request phantom
- Phantom is shipped
- Phantom is imaged
- Treatment plan developed
- Treatment is delivered
- Phantom is returned
- Plan is submitted electronically
Other things to know:

- IRB approval at institution required
- CTEP-IAM account required
- TRIAD for submitting data
- CIRO resources
IRB Approval

• Your site must have IRB approval for the trial to submit cases. If your IRB has expired you will not be able to submit to TRIAD.

• CTSU will need an updated IRB
Rostering and Roles

• What the site user should do
  1. Get a CTEP-IAM account
  2. Set permanent password for CTEP-IAM
  3. Contact their affiliated group to be added to the roster
  4. Contact their CTSU Site Administrator to be assigned the appropriate role
  5. Any staff who will be submitting data MUST be listed on the site roster as TRIAD SITE USER
TRIAD

What is TRIAD

TRIAD™ is the American College of Radiology’s (ACR’s) image and data exchange platform. TRIAD is a standards based open architecture platform that supports HIPAA security rules relevant to Clinical Trials. It automatically de-identifies the DICOM headers and cleans the PHI from the DICOM images before submission via the internet. Access to the application is role-based and controlled by username and password.
How does TRIAD fit into my workflow

- Upload files, search folders from network, local system or CD
- DICOM query/retrieve from local PACS system, workstations, or modalities
- Accept DICOM storage requests from local PACS system, workstations, or modalities
- Attach non-DICOM objects to submissions, such as pdf, jpeg, bitmap, etc.
Never submitted using TRIAD
Basic First Steps

1. Have the Enrolling Site Lead RA and be added to the enrolling site roster as a TRIAD SITE USER
2. For RT submissions the Medical Physicist or Dosimetrist should have this role. For DI the RA or technologist per site protocol
3. If the staff responsible for submitting does NOT have a CTEP IAM log in they need to request one through CTSU
4. Go to the IROC Website for TRIAD installation and software requirements. Staff with Administrative Rights may be needed
   https://www.irocqa.org/Resources/TRIAD
5. For RT submissions -TRIAD should be installed where the RT Treatment Plan data can be uploaded from.
6. Once installed Select Data to be uploaded. Do NOT submit as a zipped file.
Accessing TRIAD

- Integrated with CTSU log in using CTEP-IAM username and password
- Any staff who will be submitting RT digital data MUST be listed on the site roster as TRIAD SITE USER
- The Lead RA must update their roster with the staff members that need to submit via TRIAD on the CTSU website
- NON- RTOG sites need to update their rosters directly through the CTSU helpdesk
- After March 1st RT data for all NSABP, GOG and RTOG (NRG) trials will be submitted via TRIAD
Logon page using the CTEP –IAM interface
Select the Trial you want to submit, and your site will pre-populate in the next box.
Trials that have RT credentialing

• To submit IGRT and Benchmarks for trials
• Once you select data to import and send submission you can select “Benchmark” to submit.
• Note: the term benchmark will be changing to **RT credentialing**
Where to find information on TRIAD

IROC Website

TRIAD Website

RTOG Website

Global Leaders in Clinical Trial Quality Assurance
Center for Innovation in Radiation Oncology (CIRO)

• Aim 1: Promote innovative Radiation Therapy research within the entire National Clinical Trials Network

• Aim 2: Foster intergroup collaboration and protocol harmonization in terms of inclusion and description of RT techniques and delivery devices
The CIRO webpage provides several resources for the network such as atlases, protocol templates for RT sections, and applications to facilitate RT data preparation and submission.
Radiation Therapy Section Templates

• Templates for each disease site

• Example links: Templates for Head and Neck
  – Including H&N Atlas Link
  – Including NRG Protocol Radiation Therapy Template (including Proton and Photon)
    • Contouring Atlases, Templates & Tools

HEAD & NECK
• Head and Neck Atlas Link
• NRG Protocol Radiation Therapy Section Template (includes Proton and Photon)
• HN001: DVA Spreadsheet; Eclipse Templates; MIMsoftware Scripts/Templates
• HN003: DVH Evaluation spreadsheet; Eclipse Templates; MIMsoftware Scripts/Templates
Plan evaluation
Eclipse Plan Evaluation Scripts
Brain Site Example

NRG Oncology

Contouring Atlases, Templates & Tools

BRAIN
- Hippocampal Sparing Atlas Link
- NRG Protocol Radiation Therapy Template (Brain Photon vs proton therapy)
- NRG Protocol Radiation Therapy Section Template (SRS)
- BN301: DVH Evaluation spreadsheet; Eclipse Templates; MimSoftware Scripts/Templates
TRIAD Resources

• Resources
  – TRIAD Support email: TRIAD-Support@acr.org
  – TRIAD Website: http://triadhelp.acr.org/
  – TRIAD FAQs: https://cr-ctsut4-web.acr.org/TriadWeb/Common/Support.aspx
CTSU Resources

- CTSU Help Desk: ctsucontact@westat.com or 1-888-691-8039
- CTEP Registration: ctepreghelp@ctep.nci.nih.gov or 703-738-9171
- CTEP-IAM website: https://eapps-ctep.nci.nih.gov/iam/index.jsp
- CTSU website: www.ctsu.org
  - TRIAD Help Sheet
  - CTEP-IAM Fact Sheet
IROC Resources

Resources

• IROC Houston
  713-745-8989 / fax 713-745-1364
  irochouston@mdanderson.org

• IROC Ohio
  614-293-2929 / fax 614-293-9275
  help@irocohio.org

• IROC Philadelphia-Diagnostic Imaging (DI)
  215-940-8820 / fax 215-923-1737
  irocphila-di@acr.org

• IROC Philadelphia-Radiation Therapy (RT)
  215-574-3219 / fax 215-923-1737
  irocphila-rt@acr.org

• IROC Rhode Island
  401-753-7600 / fax 401-753-7601
  irocri@qarc.org

• IROC St. Louis
  314-747-5415 / fax 314-747-5423
  irocstl@radonc.wustl.edu
I can do this all day!

- Acceptance