# Clinical Trial Credentialing: Where to Start and Resources Available







AAPM Andrea Molineu summer 2017

### Acknowledgements

- IROC Grant CA180803
- David Followill, Jessica Lowenstein, Ying Xiao for slide support

Denial



Anger



Bargaining



Depression



#### Where do I start?

http://irochouston.mdanderson.org



## IROC Houston Home Page

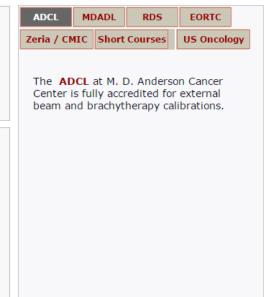
http://irochouston.mdanderson.org



Tel: 713-745-8989

Home Credentialing Participating Institutions New Participant Demographics Form Facility Questionnaire





IROC Announcements

Heterogeneities:

Approved Algorithms

ASTRO Safety Considerations for IMRT

**IMRT** 

ATC Guidelines for the Use ...

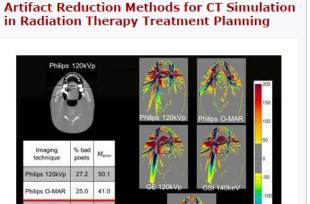
NCI guidelines

**Proton Approval** 

Proton Approval Site Visit Cost-Sharing Structure for NCI-Sponsored Cooperative Group Clinical Trials

**Protons in Clinical Trials** 





An Evaluation of Three Commercial Metal





## http://irochouston.mdanderson.org





#### Facility Qu

The facility questionnaire is a web form used to clinical trials. The username and password should have one yet, please contact the host site, IROC Houston@MDanderson.org. You can also click after verification.

Please complete the form in its entirety and if Houston.

#### 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.

General Institution	n Information	1			
Institution Name:	M D Anderson C	ancer Center		RTF#	1744
Address	Department of R	adiation Physics		Last Accessed:	Jul-18-2017 10:04-AM
	1515 Holcombe			CTEP/NCI Id#:	TX035
City	Houston			Today's Date	26-Jul-2017
State	TX	Country	USA	Zipcode	77030
Telephone:	7135632500	Extension:		Fax:	7135632545
Person submitting this form	- ▼ Mich	ael Gillin		Degree: PhD	
Email	mgillin@mdande		Phone 713 56		
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Physicist	Dr. ▼ Mich	ael Gillin		Degree: Ph.D.	
Email	mgillin@mdande	rson.org	Phone 713-56	3-2507	
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Email	rduerkes@rtsx.co	m	Phone 941302				IN-HOUSE - C.PLA	
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#### IROC Houston Credentialing Page

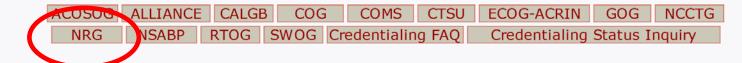
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Home Credentialing Participating Institutions New Participant Demographics Form Facility Questionnaire

#### Credentialing



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.



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#### Credentialing

ACOSOG ALLIANCE CALGB COG COMS CTSU ECOG-ACRIN GOG NCCTG

NRG NSABP RTOG SWOG Credentialing FAQ Credentialing Status Inquiry

#### **NRG Oncology Group**

Activated protocol list Closed protocol list

- BN001 Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Gliobias Sma

  Link to Protoc

  Credentialing Requirements
- BN003 Phase III Trial of Observation Versus Aradiation for a Gross Totally Resected Grade II Meningioma

  Link to Protocol

  Credentialing Requirements
- BN005 A Phase II Trial Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas

  Link to Protocol Credentialing Requirements
- BR001 A Phase 1 Study of Stereotactic Body Radiotherapy (SBRT) for the Treatment of Multiple Metastases

  Link to Protocol Credentialing Requirements Frequently Asked Questions
- BR002 A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy



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Home

Credentialing

**Participating Institutions** 

**New Participant Demographics Form** 

**Facility Questionnaire** 

Previous page Back to credentialing

#### NRG BN001 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 RTOG. See here for information on installing TRIAD.

Please fill out the credentialing status inquiry form to It 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



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Home

Credentialing

Participating Institutions

**New Participant Demographics Form** 

**Facility Questionnaire** 

#### IROC Houston Credentialing Page

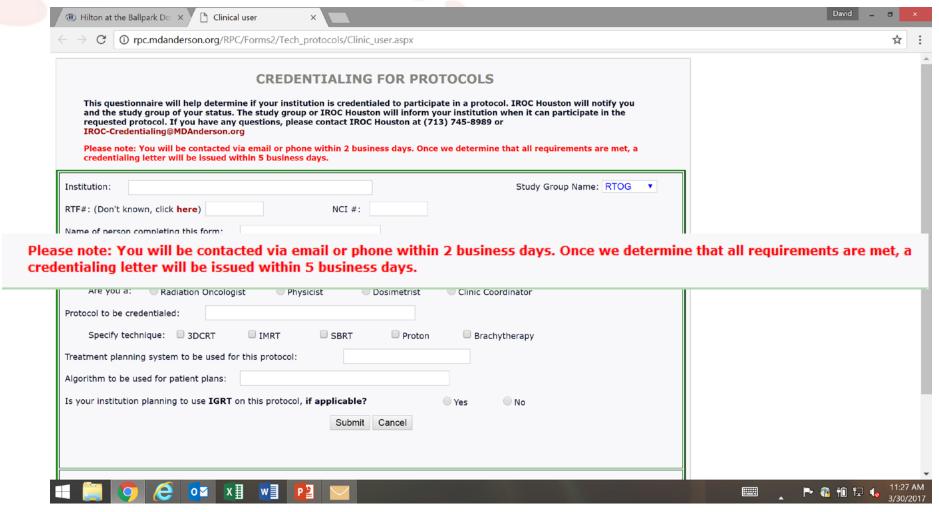
#### Credentialing



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**





### 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

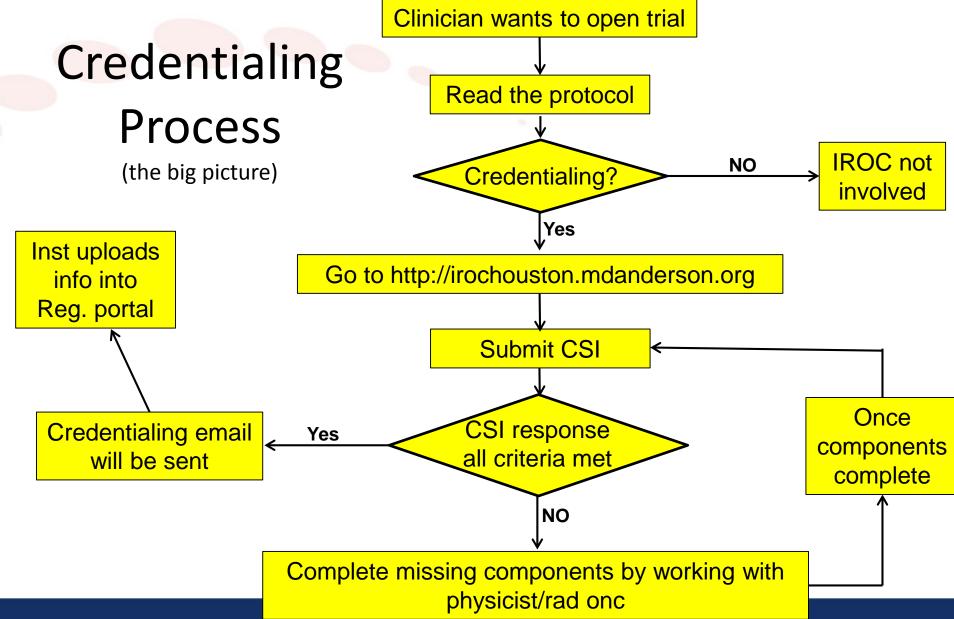


## **Purpose of Credentialing**

- 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







	Web Li	ink for I	Procedi	ures and Instructions: <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>
RT Credentialing	Treatn	nent Mo	odality	
Requirements	SBRT	IMRT	Proton	Key Information
Facility Questionnaire	Х	Х	Х	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.
Credentialing Status Inquiry Form	X	X	Х	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> )
Knowledge Assessment	N/A	N/A	N/A	
Benchmark Cases	N/A	N/A	N/A	
Phantom Irradiation	X	X	X	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). 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.
IGRT Verification Study	X	Х	Х	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, <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>
Pre-Treatment Review	X	X	X	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:
Institution				IROC Houston QA Center will notify the institution and NRG Headquarters that all desired credentialing requirements have been met



## Phantom family



**Spine** 

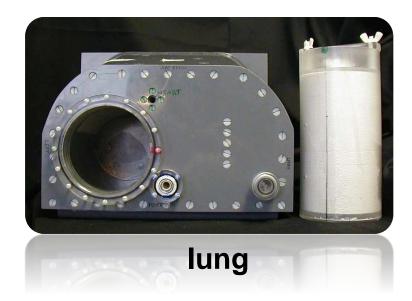








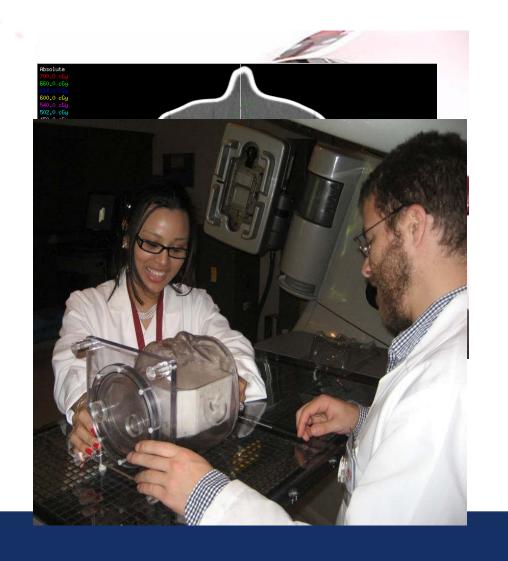
SRS



	Phantom Request Fori	m For F	Protocol	
Institution:				
RTF No:	RTF Number?			
Physicist first name:				
Physicist last name:				
Physicist phone number:				
Physicist email:				
Physician email to receive the r	eport:			
Shipping to:				
Address1:				
Address2:				
City:				
State/Province:				
Zip Code:				
Country				
Country  Is the machine physically locate	ad at the address above?		○ Yes	○ No
Is the machine physically locate	ed at the address above?		● Yes	○ No
	ed at the address above?		© Yes	○ No
Is the machine physically locate f "NO", Address:	ed at the address above?		© Yes	○ No
Is the machine physically locate	ed at the address above?		⊚ Yes	● No
Is the machine physically locate f "NO", Address:		● Yes	• Yes	○ No
Is the machine physically locate f "NO", Address: Name of Facility:		● Yes		○ No
Is the machine physically located f "NO", Address: Name of Facility:  Is this repeat phantom? Phantom requested (Please selection)	ct one):	● Yes		○ No
Is the machine physically locate f "NO", Address: Name of Facility: Is this repeat phantom?		● Yes		○ No
Is the machine physically located if "NO", Address: Name of Facility: Is this repeat phantom? Phantom requested (Please selection)	ct one): • Proton Brain	● Yes		○ No
Is the machine physically located f "NO", Address: Name of Facility: Is this repeat phantom? Phantom requested (Please selection of the select	ct one):  Oproton Brain Proton H&N Proton Thorax Proton Liver	● Yes		◎ No
Is the machine physically located f "NO", Address: Name of Facility: Is this repeat phantom? Phantom requested (Please selection of the select	ct one):  Proton Brain Proton H&N Proton Thorax	● Yes		○ No

### **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



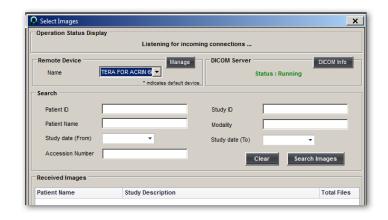
#### **TRIAD**

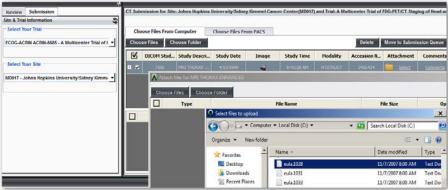
#### What is TRIAD

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

https://www.ctsu.org/public/default\_login.aspx

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.



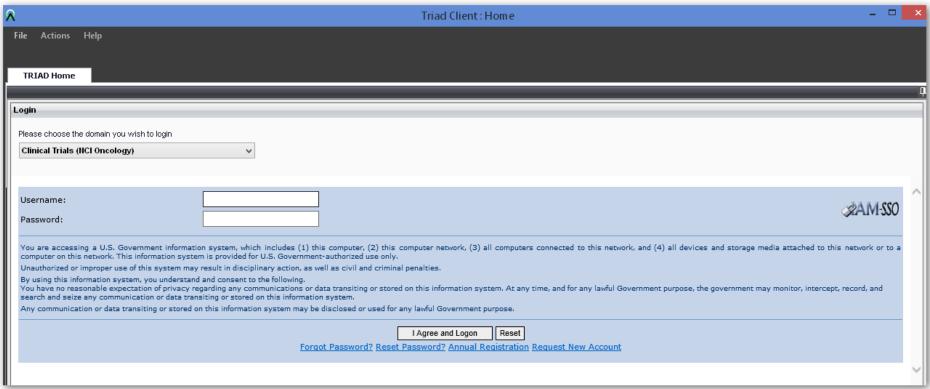
### **Accessing TRIAD**

- ➤ 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 1<sup>st</sup> RT data for all NSABP, GOG and RTOG (NRG) trials will be submitted via TRIAD

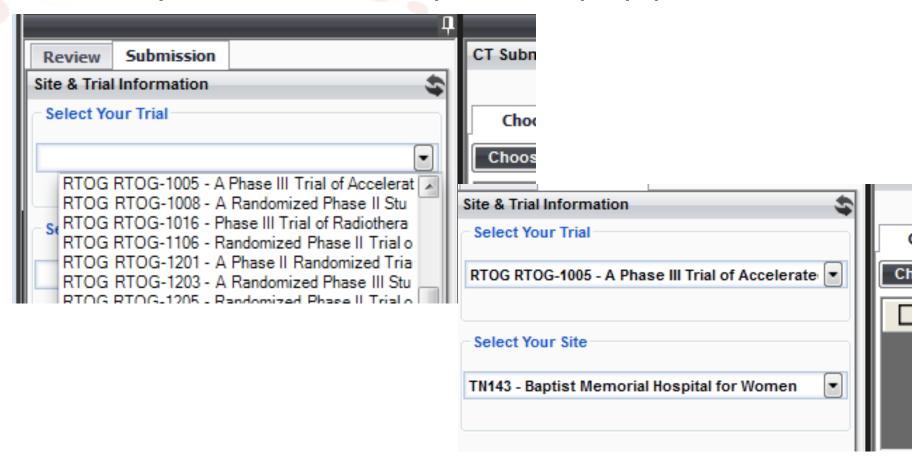


## Logon page using the CTEP –IAM interface



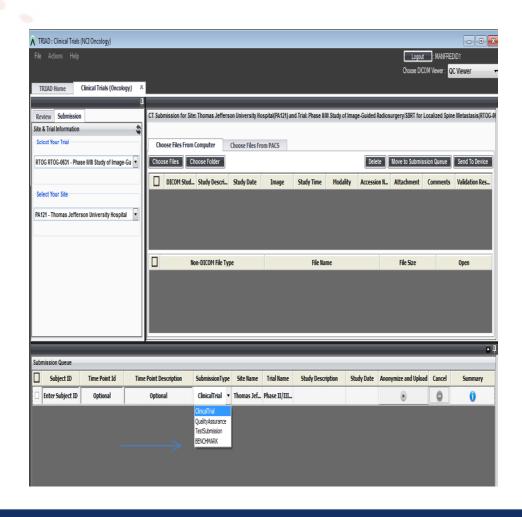


#### Select the Trial you want to submit, and your site will pre-populate in the next box

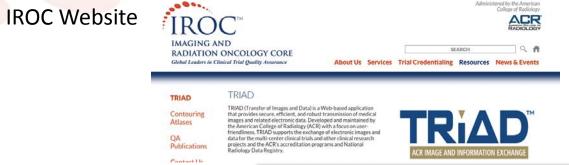


## Trials that have RT credentialing

- 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



**TRIAD** Website



**RTOG Website** 





#### 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

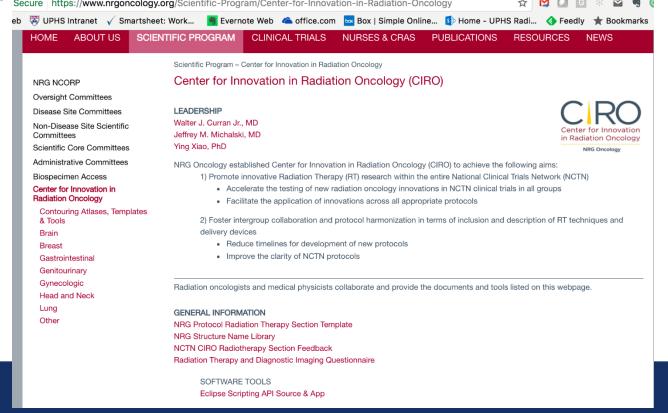


#### WEBPAGE

https://www.nrgoncology.org/Scientific-Program/Center-for-Innovation-in-Radiation-Oncology

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.

Secure https://www.nrgoncology.org/Scientific-Program/Center-for-Innovation-in-Radiation-Oncology





## **Radiation Therapy Section Templates**

- Templates for each disease site
  - https://www.nrgoncology.org/ciro-contouring-atlasestemplates-and-tools
- 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**

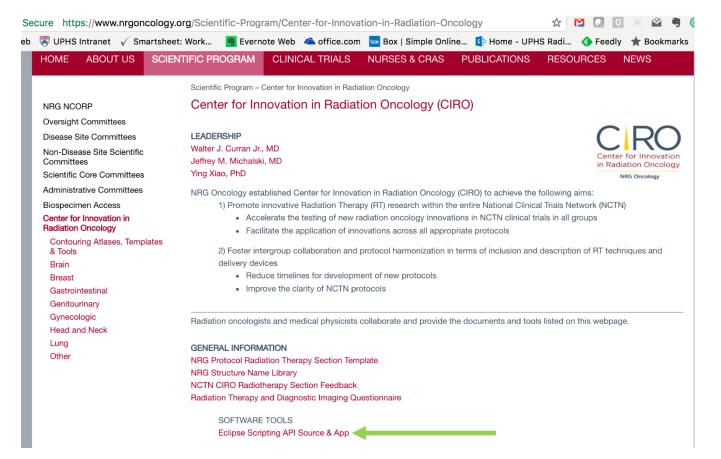
- Head and Neck Atlas Link
- NRG Protocol Radiation Therapy Section Template (includes Proton and Photon)
- HN001: DVA Spreadsheet; Eclipse Templates; MiMsoftware Scripts/Templates
- HN003: DVH Evaluation spreadsheet; Eclipse Templates; MiMsoftware Scripts/Templates





#### Plan evaluation

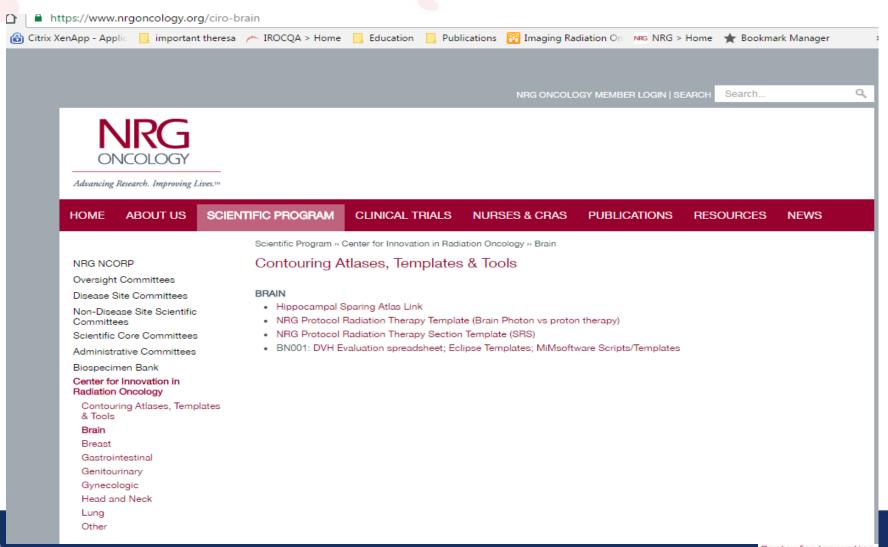
#### **Eclipse Plan Evaluation Scripts**





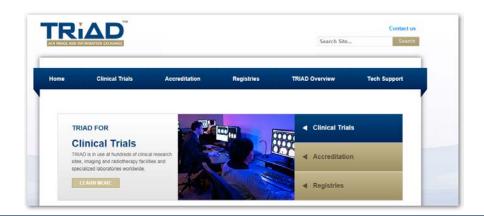


## **Brain Site Example**



#### **TRIAD** Resources

- Resources
  - TRIAD Support help desk hotline: 215-940-8820 / 703-390-9858
  - TRIAD Support email: <u>TRIAD-Support@acr.org</u>
  - TRIAD Website: <a href="http://triadhelp.acr.org/">http://triadhelp.acr.org/</a>
  - TRIAD FAQs: <a href="https://cr-ctsut4-">https://cr-ctsut4-</a>
     web.acr.org/TriadWeb/Common/Support.aspx





#### **CTSU** Resources

#### Resources

- CTSU Help Desk: <a href="mailto:ctsucontact@westat.com">ctsucontact@westat.com</a> or 1-888-691-8039
- CTEP Registration: <a href="mailto:ctepreghelp@ctep.nci.nih.gov">ctepreghelp@ctep.nci.nih.gov</a> or 703-738-9171
- CTEP-IAM website: <a href="https://eapps-ctep.nci.nih.gov/iam/index.jsp">https://eapps-ctep.nci.nih.gov/iam/index.jsp</a>
- CTSU website: <u>www.ctsu.org</u>
  - 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

