Imaging and Radiation Oncology Core Group

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Sr. Director, Radiation Oncology Services
IROC Administrator
## NCI Cooperative Group Restructuring

<table>
<thead>
<tr>
<th>NRG</th>
<th>ECOG-ACRIN</th>
<th>The Alliance</th>
<th>Existing Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTOG: Radiation Therapy Oncology Group</td>
<td>ACRIN: American College of Radiology Imaging Network</td>
<td>NCCTG: North Central Cancer Treatment Group</td>
<td>SWOG: Southwest Oncology Group</td>
</tr>
<tr>
<td>NSABP: National Surgical Adjuvant Breast and Bowel Project</td>
<td>ECOG: Eastern Cooperative Oncology Group</td>
<td>CALGB: Cancer and Leukemia Group B</td>
<td>COG: Children’s Oncology Group</td>
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<tr>
<td>GOG</td>
<td>Gynecologic Oncology Group</td>
<td>ACOSOG: American College of Surgeons Oncology Group</td>
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IROC’s Definition
Who Are WE?

The Imaging and Radiation Oncology Core Group better known as IROC:

- Is A New Clinical Trial Quality Assurance Organization comprised of 6 QA Centers with multiple PIs.

- IROC RT and Imaging Centers have an extensive and impressive amount of experience, knowledge and infrastructure to aid in the improvement of clinical outcomes for cancer patents.
IROC Grant Process

- Grant submitted 1/15/2013 to NCI through the ACR (398 page document)
  - Proposes 6 QA centers with multiple PIs
  - Budget of $ 7M for first year (6 QA centers)
  - Followill – Contact PI and IROC Co-Director (therapy)
- Review on July 16, 2013
- Start date of no earlier than 3/1/2014
- Award notice received 5/26/14
IROC’s Mission

Provide integrated radiation oncology and diagnostic imaging quality control programs in support of the NCI’s NCTN Network thereby assuring high quality data for clinical trials designed to improve the clinical outcomes for cancer patients worldwide.
IROC Principal Investigators

David S. Followill, PhD, IROC Co-director
and principal investigator for radiation oncology
and chief of outreach physics in the Department of
Radiation Physics at the University of Texas MD
Anderson Cancer Center in Houston

Michael V. Knopp, MD, PhD, IROC Co-director
and principal investigator for imaging
and the director of the Wright Center of Innovation in
Biomedical Imaging at Ohio State University in
Columbus, Ohio
IROC
IMAGING AND RADIATION ONCOLOGY CORE
Global Leaders in Clinical Trial Quality Assurance

IROC Philadelphia Imaging
IROC Philadelphia RT
IROC Ohio
IROC St. Louis
IROC Houston
IROC Rhode Island
ACR IROC Grant
Co-Directors: D. Followill, Houston (RT) and M.V. Knopp, Ohio (Imaging)
Sub-awards to:

- IROC Ohio
  PI: M.V. Knopp

- IROC Houston
  PI: D. Followill

- IROC Rhode Island
  PI: T.J. FitzGerald

- IROC Philadelphia (RT)
  PI: J. Galvin

- IROC Philadelphia (Imaging)
  PI: M. Rosen

- IROC St. Louis
  PI: J. Michalski
IROC Leadership Structure

IROC Executive Committee
Co-Directors: Followill/Knopp
IROC Admin: King/O’Meara/Laurie
IROC’s NCTN RT Core Services

Principal supervisors of a core service

NCTN RT Core Service Operations

Site Qualification
Followill/Galvin

Trial Design Support
Galvin/Fitzgerald

Credentialing
Molineu/Xiao

Data (Pre-rev.) Mgmt
Straube/Ulin

Case Review
Leif/O'Meara/Laurie

Data (Post-rev.) Mgmt
Laurie/O'Meara

Houston QA Center

All IROC QA Centers

Houston-Phil. (RT)
QA Centers

Phil (RT), Rhode Is.,
St Louis QA Centers

Phil (RT), Rhode Is.,
Houston QA Centers

Phil (RT), Rhode Is.
QA Centers

NCTN Participating Sites

Responsible QA Centers for core service

Global Leaders in Clinical Trial Quality Assurance
IROC’s 5 General NCTN Core Services

1. Site Qualification
   (FQs, ongoing QA, proton approval, resources)

2. Trial Design Support/Assistance
   (protocol review, templates, help desk, key contact QA centers)

3. Credentialing
   (tiered system to minimize institution effort)

4. Data Management
   (pre-review, use of TRIAD, post-review for analysis)

5. Case Review
   (Pre-, On-, Post-Treatment, facilitate review logistics for clinical reviews)
IROC Management Committee

Six IROC PIs

IROC Subcommittee co-chairs

IROC Administrators

IROC Key Staff (RT and Imaging)

Purpose: manage IROC QA services/operations to ensure the uniform implementation of IROC core services, prioritization of core services and establish, in collaboration with the NCTN groups, future directions of IROC
# IROC QA Centers Key Support
*(IROC Support Contacts for NCTN Groups)*

<table>
<thead>
<tr>
<th>NCTN GROUP</th>
<th>RADIATION ONCOLOGY</th>
<th>IMAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alliance</td>
<td>Houston</td>
<td>Ohio</td>
</tr>
<tr>
<td>COG</td>
<td>Rhode Island</td>
<td>Rhode Island</td>
</tr>
<tr>
<td>ECON-ACRIN</td>
<td>Rhode Island</td>
<td>Philadelphia (I)</td>
</tr>
<tr>
<td>NRG Oncology</td>
<td>Philadelphia (RT)</td>
<td>Philadelphia (I)</td>
</tr>
<tr>
<td>SWOG</td>
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<td>Ohio</td>
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The ACR/IROC Cloud
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.
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
Where to find information on TRIAD
TRIAD (Transfer of Images and Data) is a Web-based application that provides secure, efficient, and robust transmission of medical images and related electronic data. Developed and maintained by the American College of Radiology (ACR) with a focus on user-friendliness, TRIAD supports the exchange of electronic images and data for the multi-center clinical trials and other clinical research projects and the ACR’s accreditation programs and National Radiology Data Registry.

A new TRIAD website will be launched soon, so please check back!
What does TRIAD look like

Select Clinical trials (NCI oncology) note: this title will be changing soon to be more clear
Log in page using the CTEP –IAM interface
Select the Trial you want to submit, and your site will pre-populate in the next box.
What if I do not see the trial I want to submit for?
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
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**
Once imported select **Move to submission**
Data moved to submission section

- Place a Check mark next to the case to submit
- Enter the Case number under subject ID
- Submission Type. Select *Clinical* for cases
  *Benchmark* for credentialing data
- Click Anonymize and upload
Anonymization and Validation Summary

- To see how the data was anonymized click on the word **Summary**
- To see how the validation either passed or failed click on the word **Success or Failed**
Anonymization Summary
You can compare how it was originally identified and how TRIAD de-identified it
Structure Validation (Success)

If your validation status is a success then all of the structures that were required in the protocol were submitted and labeled correctly.
Structure Validation (Failure)

If your Validation Status is labeled as failure then all of the Structures that were required in the protocol were NOT submitted and/or labeled correctly.
Validation Failure

• Currently even if the structure validation failed. The import to TRIAD is still completed.

• You may be requested to resubmit the case correctly once it is QA’d.

• Please note that it did not comply and submit your next case correctly.
Structure Validation

• In the near future however, structure names that do not match the list in the protocol or are missing required structures will not be imported into TRIAD

• The issues will need to be resolved at the site before it can be submitted to TRIAD
Structure Validation

• Ensure the physics and dosimetry staff always have the most up-to-date IRB approved version of the protocol

• 2 weeks prior to this implementation a broadcast will go out indicating the effective date as each trial is rolled out

• Ensure the dosimetry staff know when this will be enforced
Summary

• The NCI NCTN Reorganization is how IROC started.
• IROC has 2 Co-PIs, with ACR as the Grantee
• IROC RT QA centers have decades of experience, knowledge and infrastructure.
• Protocol review as early as possible is critical to establishing appropriate QA procedures.
• Patient case reviews require IROC and Groups to work together.
• RT and Imaging are working closely together.
• Collaboration and feedback from NCTN Groups is required.
• Groups to have complete accessibility to data.
• Explanation of TRIAD and where to find TRIAD
• IROC Website is Active and continues to receive content update
Thank You

Questions