The Imaging and Radiation Oncology Core (IROC) Group: A Proposed New Clinical Trial Quality Assurance Organization

David Followill, Ph.D.
Director
Radiological Physics Center
NCI Clinical Trial Reorganization

CTAC Clinical Trials Strategic Planning Subcommittee

NCI Disease/Imaging Steering Committees: Evaluation/Prioritization of Trials

Network Research Support Services

- Network RT & Imaging Core Services Centers
- Network Group Integrated Translational Science Centers
- Tumor Banks

NCI Division of Extramural Activities Review

4 Adult and 1 Pediatric U.S. Network Groups

- Adult Group #1 Ops & Stats
- Adult Group #2 Ops & Stats
- Adult Group #3 Ops & Stats
- Adult Group #4 Ops & Stats
- Pediatric Ops & Stats

NCI National Clinical Trials Network

Administrative Support Services

- NCI Central IRB
- CTSU

Network Lead Academic Participating Sites

- CCOPS & MB-CCOPs
- Other Academic Centers
- Community Practices
- International Members
Clinical Trial Groups

Current
RTOG
NSABP
GOG
NCCTG
CALGB
ACOSOG
ECOG
ACRIN
SWOG
COG

March 1, 2014
NRG Oncology
Alliance
ECOG/ACRIN
SWOG
COG
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 $15M for first year (6 QA centers)
  - Followill – Contact PI and IROC Co-Director (therapy)

- Review on July 16, 2013
- Award notice by 11/2013
- Start date of no earlier than 3/1/2014
- RPC grant ends 12/31/2013 (administrative extension until new grant begins)
Members of IROC

ACR IROC Grant
Contact PI, Co-Director RT:
D. Followill, Houston;
Co-Director Imaging:
M.V. Knopp, Ohio

IROC Ohio
PI: M. V Knopp

IROC Houston
PI: D. Followill

IROC Rhode Island
PI: TJ FitzGerald

IROC St Louis
PI: J Michalski

IROC Philadelphia (RT)
PI: J. Galvin

IROC Philadelphia (Imaging)
PI: M. Rosen
IROC 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 Leadership Structure

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

Principal supervisors of a core service

- Site Qualification: Followill/Galvin
  - Houston QA Center
- Trial Design Support: Galvin/Fitzgerald
  - All IROC QA Centers
- Credentialing: Molineu/Xiao
  - Houston-Phil. (RT) QA Centers
  - St Louis QA Centers
- Data (Pre-rev.) Mgmt: Straube/Ulin
  - Phil (RT), Rhode Is., Houston QA Centers
- Case Review: Leif/O’Meara/Laurie
  - Phil (RT), Rhode Is. QA Centers
- Data (Post-rev.) Mgmt: Laurie/O’Meara

NCTN RT Core Service Operations

NCTN Participating Sites

Responsible QA Centers for core service
# Trial Concept and Protocol Consultation

## Key Contact QA Centers

<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>ECOG/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>
<td>Rhode Island</td>
<td>Ohio</td>
</tr>
</tbody>
</table>

[IROC - Imaging and Radiation Oncology CORE](http://www.iroc.org) | [MD Anderson Radiological Physics Center](http://www.mdanderson.org)
IROC Services

Patient Case Clinical and Technical Reviews

Pre-Treatment

On-Treatment

Post-Treatment

IROC facilitates the logistics and data organization for the clinical reviews.

Study Groups will supply clinicians.
The ACR/IROC Cloud

- Clinical Data/CRF
  - Site
  - RT/Image DICOM Data
  - Data Submission with Automatic Validation
  - TRIAD
    - Workflow Manager; Data Archive
  - Remote Application Environment
    - Mimvista Velocity Matlab RTP...
  - ACR/IROC Cloud

- OPEN/RSS/Other RAVE
- NCTN Statistics & DM Centers
  - NCTN Network Groups

- IROC QA Offices
Summary

• 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.
Thank You

Questions?