

Introduction

ACRIN Research Associate Tutorial

This training tutorial is designed to provide research associates (RAs) with the basic information necessary to manage ACRIN medical imaging clinical trials. It has been developed collaboratively by the ACRIN Research Associate Executive Committee and ACRIN headquarters staff.

Upon completing the tutorial, RAs will be asked to complete a brief quiz to demonstrate their understanding of the basic concepts related to ACRIN trial management.

Viewing the Educational Modules

The ACRIN RA training comprises five modules:

1. Role of the ACRIN RA and the ACRIN Research Associate Committees
2. ACRIN Organization and Project Management Basics
3. Protocol Development and Regulatory Compliance
4. Data Management
5. Imaging Core Laboratory

Information available on the ACRIN Web site is referenced throughout the tutorial. To enhance this learning opportunity, RAs are encouraged to view the tutorial slides (either printed copy or electronic version) while accessing the Web site references indicated by the → symbol.

ACRIN is fortunate to have many dedicated RAs working on its trials, many of whom have been recognized at the ACRIN Fall Meeting with an "Outstanding Service Award." Their dedication to quality has been, and continues to be, an integral part of ACRIN's success.

We welcome you into the community of ACRIN RAs and hope you find the tutorial instructive as you begin what we hope will be an enjoyable experience working with ACRIN.

Also, we invite you to let us know what you think about the tutorial. Please send your comments to:
RAtutorial@phila.acr.org.

Thank you!

Members of the ACRIN Research Associate Executive Committee take a break during their planning session at the 2008 ACRIN Spring Meeting.
From left to right: Cindy Cobb, Tracy Sitton-Petro, Lynn Werner, Wendy Smith, committee chair, Roslynn Marzan, Tina Taylor, ACRIN HQ committee liaison, Lorna Beccaria, and Pam Harvey, director, ACRIN data management.



Module 1:

Role of the ACRIN RA and the ACRIN RA Committees

Site RA Role in Clinical Trial Success

Research associates (RAs) play an important role in ensuring the safety and welfare of study participants as well as the quality of ACRIN's clinical research. The degree of success achieved by a site in conducting an ACRIN trial is heavily dependent upon the performance of the RA. The RA is responsible for coordinating research activities among the study participants, site principal investigator, and other members of the site research team.

Successfully carrying out a clinical trial also requires the RA to establish positive rapport with patients and develop working relationships with imaging technologists, referring clinicians and their staff, and other hospital departments and services.

ACRIN RA Responsibilities

The general responsibilities of an RA that apply to all ACRIN trials include the following:

- Being knowledgeable about key regulations and policies
 - Those related to the local institution/site
 - Good clinical practices (GCPs) as determined by the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. (Go to www.ich.org/LOB/media/MEDIA482.pdf for the ICH-GCP document.)
- Reading the protocol and sample consent
- Coordinating submission of materials required for study activation
 - Application documents
 - Regulatory documents
 - Imaging documents
- Managing study participant activities
 - Scheduling of protocol-required testing
 - Study procedure compliance
- Maintaining source documents
 - Clinical reports
 - Records and progress notes
- Ensuring submission of timely, complete, and accurate case report forms
 - Respond within the required time frame to any data queries
- Overseeing timely submission of images that adhere to protocol specifications
- Ensuring that study procedures are performed in compliance with:
 - Study protocol
 - GCPs

The Role of the RA Executive Committee

The ACRIN RA Executive Committee was established to support the ACRIN RA in carrying out his or her responsibilities and to provide a variety of forums in which ACRIN RAs can learn and share experiences.

The ACRIN RA Executive Committee contributes to ACRIN in a variety of ways:

- Participates as members of ACRIN's leadership, scientific and support committees
- Coordinates the Annual RA Educational Symposium
- Manages the content for the quarterly ACRIN RA newsletter and the RA Committee section of the Web site
- Mentors new ACRIN RAs through proactive initial contact, basic RA training sessions, and regional support
- Supports quality assurance (QA) activities through data standards and forms testing
- Selects the annual recipient of the Jo-Ann D'Amato RA Award of Excellence for presentation at the ACRIN Fall Meeting
- Providing representation on ACRIN's leadership, scientific, and support committees

Participation in Subcommittees Encouraged

RAs working on ACRIN trials are encouraged to join one of the subcommittees that focus on different aspects of providing ACRIN RA support. Such participation is an excellent way to get to know and learn from others around the country engaged in ACRIN research. The subcommittees include:

- Education
- Mentorship
- Networking and Communication
- Quality Assurance

➔ **Review information about the subcommittees' work at:** www.acrin.org>COMMITTEES>RA COMMITTEE>SUB-COMMITTEES [[LINK](#)]

How to Get Involved

RAs can find information about how to get involved in the ACRIN RA Committee on the ACRIN Web site.

➔ **Review ACRIN RA Committee Materials, including a contact form, at:** www.acrin.org>COMMITTEES>RA COMMITTEE>MATERIALS. [[LINK](#)]



Enjoying a few minutes of nice weather and social time at the ACRIN Spring Meeting are (from left to right) Tracy Sitton-Petro, Pam Harvey, and Lynn Werner.



Tracy Sitton-Petro, second from right, poses with mentoring subcommittee members, from left to right, JoAnn Lorenzo, Ferdnand Osuagwu, and Monene Kamm.

Module 2:

ACRIN Organization and Project Management Basics

What is ACRIN?

The American College of Radiology Imaging Network (ACRIN) is a member of the National Cancer Institute's (NCI) clinical trials cooperative group program. ACRIN is funded largely through a grant from the NCI to conduct multicenter clinical trials related to medical imaging. ACRIN also receives research funding support from industry and corporate partners and from contributors to the ACRIN Fund for Imaging Innovation.

ACRIN conducts medical imaging clinical trials and disseminates corresponding research results toward the overarching goal of lengthening and improving the quality of life of cancer patients.

→ **Review information about ACRIN's mission and research agenda for its NCI 2008-2012 grant period at:** www.acrin.org/RESEARCHERS>CONDUCTING RESEARCH/SCIENTIFIC PLAN 2008- 2012 [\[LINK\]](#)

ACRIN's Research Support

ACRIN's research is supported by **ACRIN headquarters** located in Philadelphia, PA; the **ACRIN Biostatistics Center** located at Brown University in Providence, RI, and the **American College of Radiology (ACR)**, a professional society with a membership of over 30,000 radiologists, nuclear medicine physicians, and radiation oncologists located in Reston, VA.

The research support functions carried out at **ACRIN headquarters** include project management, data management, protocol development and regulatory compliance, imaging core laboratory support, and publications and data sharing coordination.

The **ACRIN Biostatistics Center** provides statistical support that includes statistical design of imaging research, data monitoring and reporting, and data analysis.

As the ACRIN grant business official, **ACR** provides computing, meeting planning, human resource, finance, and other infrastructure support for ACRIN.

→ **Review contact information for ACRIN personnel at:** www.acrin.org [\[LINK\]](#) OR www.acrin.org/ADMINISTRATION>CONTACT US [\[LINK\]](#)

ACRIN's Committee Structure

ACRIN carries out its research through a committee structure that includes:

- Six **scientific** committees
- Four **scientific support** committees
- Six **support** committees (including the Research Associate Executive Committee)

The activity of the committees is overseen by the ACRIN Steering Committee, which is made up of ACRIN leadership, NCI representatives, and committee chairs.

→ **Review information about ACRIN's leadership and committees at:** www.acrin.org/COMMITTEES>INTRODUCTION OR www.acrin.org/ADMINISTRATION>ORGANIZATIONAL CHART [\[LINK\]](#)

Types of ACRIN Trials

ACRIN conducts the following types of cancer-related studies:

- **Screening** (e.g., ACRIN 6652: Digital vs. Standard Film Mammography)
- **Staging** (e.g., ACRIN 6659: Prostate Cancer Staging with MRI and MRSI)
- **Treatment** (e.g., ACRIN 6673: RFA of the Liver)
- **Treatment response** (e.g., ACRIN 6678: Treatment Response with PET)

ACRIN is expanding its research portfolio to include imaging of other diseases as strategic opportunities arise.

➔ **Review more ACRIN trials at:** www.acrin.org/PROTOCOL_SUMMARY_TABLE [\[LINK\]](#)

Research Collaborations

ACRIN frequently collaborates with other **NCI clinical trial cooperative groups** to conduct research. Its role in such “intergroup” trials is determined according to the following guidelines:

- **When a study’s primary aim relates to imaging**, ACRIN is often the only group, or the lead group, managing the trial.
 - **ACRIN-managed trial** (e.g. ACRIN 6664: The National CT Colonography Trial)
 - **ACRIN-led intergroup trial** (e.g. ACRIN 6668/RTOG 0235: Predicting Lung Cancer Treatment with PET)
- **When a study’s primary aim relates to some aspect of treatment**, ACRIN participates in a variety of ways including:
 - **Supporting the primary aim of an intergroup treatment trial** (e.g., RTOG 0625/ACRIN 6677: Brain Tumors: Staging with MR Perfusion Imaging and MR Spectroscopy)
 - **Carrying out an imaging substudy** (e.g., ECOG 2804/ACRIN 6676: Renal Cell Carcinoma: Predicting Treatment Response)
 - **Managing the image archive for another group** when the research aim has little or no relationship to imaging) (e.g., ACOSOG Z0433: Radiofrequency Ablation of Lung Cancer)

➔ **Review a summary of ACRIN trials at:** www.acrin.org/PROTOCOL_SUMMARY_TABLE [\[LINK\]](#)

Site Application Process for ACRIN Clinical Trial Participation

There are two types of ACRIN trial applications: a **general qualifying application (GQA)** and a **protocol-specific application (PSA)**. In the case of a trial led by ACRIN, both applications are required. In a trial led by another cooperative group, the GQA is often waived, but the PSA is still required.

➔ **Review more information about ACRIN applications and access the GQA at:** www.acrin.org/RESEARCHERS>CONDUCTING_RESEARCH>SITE_APPLICATION [\[LINK\]](#)



ACRIN Staff and members of the RA Committee enjoy a lunch break together at ACRIN headquarters. **Left photo**, from left to right: Wanda Marfori, Jamie Downs, Tracy Sitton-Petro, Maria Oh, Monene Kamm, and Lynn Werner; **Right photo**, from left to right: Mary Klaus Clark, Tina Taylor and Lisa Camacho.

➔ Review a **PSA** by going to the **Protocol Summary Table** and clicking on the trial of interest. That will take you to the **Protocol-Specific Page** on which you'll find all application and activation materials. Below are screen shots of the Protocol Summary Table, a protocol-specific page, and the location of that trial's application materials.

6674	Breast Cancer: Treatment Evaluation with Focused Ultrasound Ablation under MRI guidance (MRgFUS) Mitchell Schnall, MD, PhD Christopher Comstock, MD	Magnetic Resonance Imaging	In Development	
GYNECOLOGICAL PROTOCOLS				
6651 GOG	Cervical Cancer: Staging with CT and MRI David Hricak, MD, PhD	Magnetic Resonance Imaging	Results Published	208 208
6671	Cervical Cancer: Treatment Planning with PET/CT and USPIO MRI Mostafa Atri, MD, ACRIN Principal Investigator Michael Gold, MD, GOG Study Chair	Magnetic Resonance Imaging	Open	5 325
HEAD/NECK/NEUR PROTOCOLS				
6658	Supraglottic Cancer: Volume Measurement Reliability with CT Suresh Mukherji, MD	Computed Tomography	Results Published	24 24
6662 NABTT	Malignant Glioma: Volume Measurement Reliability with MRI Birgit B. Ertl-Wagner, MD	Magnetic Resonance Imaging	Publications in Process	48 48

HOME | PATIENTS | RESEARCHERS | COMMITTEES | CORE LABS | **PROTOCOL SUMMARY**

PROTOCOL SUMMARY TABLE > PROTOCOL 6671

PROTOCOL SPECIFIC MATERIALS

- [Data Forms](#)
- [Site Memos](#)
- [Protocol Application and Site Activation Materials](#)
- [Imaging Materials](#)
- [Recruitment and Educational Materials](#)
- [6671 Contact Personnel](#)
- [Participating Sites](#)
- [General Resources](#)

PROTOCOL ACRIN 6671/GOG 0233

Utility of Preoperative PET-CT & USPIO MRI Prior to Primary Chemoradiotherapy for Locoregional Cervical Cancer

Protocol Documents

- [Protocol-GOG-0233/ACRIN 6671 Amendment 2, 8.16.07](#) [PDF]
- [SOC-GOG-0233/ACRIN 6671 Amendment 2, 8.16.07](#) [PDF]
- [Informed Consent-GOG 0233/ACRIN 6671](#) [DOC]

Principal Investigator: Mostafa Atri, MD, ACRIN Principal Investigator
Michael Gold, MD, GOG Study Chair

Status: Open

Primary Objectives:

PROTOCOL SPECIFIC MATERIALS

- [Data Forms](#)
- [Site Memos](#)
- [Protocol Application and Site Activation Materials](#)
- [Imaging Materials](#)
- [Recruitment and Educational Materials](#)
- [6671 Contact Personnel](#)
- [Participating Sites](#)
- [General Resources](#)

6671/GOG 0233 Protocol Application and Site Activation Materials

For an overview of ACRIN application process, [click here](#).

Protocol Specific Application (PSA)
Each site interested in participating must complete the PSA. [ACRIN 6671 PSA Form](#) [DOC]

Modality-specific Quality Assurance (QA) Questionnaire
Sites that do not have ACR accreditation for the PET/CT scanner or the MRI scanner to be used for scanning trial participants must submit a QA questionnaires for both imaging modalities with the PSA. A site's application will not be reviewed unless either ACR accreditation is documented in the PSA or the required PET/CT and MRI QA questionnaires are submitted.

- [PET QA Questionnaire](#) [DOC]
- [MRI QA Questionnaire](#) [DOC]

Other Forms

Forms Required Prior to Site Activation or Data Center Login Access

- [FDA 1572 Form](#) [DOC]
- [Case Reimbursement Schedule](#) [DOC]
- [Username and Password Request Form](#) [DOC]

Protocol Activation Checklist

This checklist is intended to inform site research personnel about all of the requirements necessary (applications, imaging requirements, training etc.) for a site to activate the ACRIN 6671 protocol. [check list](#) [DOC]

The Protocol Activation Checklist

In addition to the variation in applications required, processes and materials required to activate a trial also vary slightly from trial to trial. A **Protocol Activation Checklist** that describes all activation requirements is posted to the **Protocol Application and Site Activation Materials** page (see above screenshot example).

Items that are generally required prior to the activation of a trial site include:

- An ACRIN Participating Institution Agreement between ACRIN and the facility
- A signed case reimbursement schedule (an addendum to the institution agreement)
- Human subject research training certification
- Investigator form and curriculum vitae

Username and Password Request Form and Reader IDs

Each person who will enter data into the Web forms located on the ACRIN Data Center Web site must complete a **Username and Password Request** form to obtain a **login ID** (see Module 4: Data Management for more information about the data center login functions).

In addition, this same form is used to request a **reader ID** for each radiologist working on ACRIN trial(s). The reader ID is a 7-digit alpha-numeric code that identifies the radiologist reading the images or performing an image-related procedure for an ACRIN trial and is required on case report forms associated with these research activities.

Once a completed Protocol Specific Application has been submitted, ACRIN administration will process a site's Username and Password Request forms and issue ACRIN Data Center login IDs and reader IDs.

Review the Username and Password Request form available on any of the open, protocol-specific Web site pages: [www.acrin.org/PROTOCOL SUMMARY TABLE>PROTOCOL 6678>PROTOCOL ACTIVATION AND SITE APPLICATION MATERIALS](http://www.acrin.org/PROTOCOL_SUMMARY_TABLE>PROTOCOL_6678>PROTOCOL_ACTIVATION_AND_SITE_APPLICATION_MATERIALS) [\[LINK\]](#)

Additional Site Support

ACRIN is eager to support site research personnel however possible with the conduct of its clinical trials. This support includes:

- **Coordinating regularly scheduled calls** so that site RAs participating in a specific trial can obtain updates, ask questions, and learn important information from each other
- **Providing participant recruitment materials**, including brochures, consent flip charts, and eligibility cards
- **Providing supportive problem solving assistance** for sites facing barriers to accrual through the Participant Enrollment Support Committee

→ **Review recruitment materials for ACRIN 6678 at:** [www.acrin.org/PROTOCOL SUMMARY TABLE>PROTOCOL 6678>RECRUITMENT AND EDUCATIONAL MATERIALS](http://www.acrin.org/PROTOCOL_SUMMARY_TABLE>PROTOCOL_6678>RECRUITMENT_AND_EDUCATIONAL_MATERIALS) [\[LINK\]](#)



ACRIN staff members celebrate with the 2006 Jo-Ann D'Amato award recipient (from left to right) Diane Evans (awardee) and ACRIN staff Maria Oh, Irene Mahon and Donna Hartfeil.

Module 3:

Protocol Development and Regulatory Compliance

Required Regulatory Materials

Regulatory requirements that must be met before a trial can open at a site include the following:

- Regulatory materials must be submitted, including proof of **Federalwide Assurance (FWA)** approval by the **Office for Human Research Protections (OHRP)** and an **FDA Form 1572** or **ACRIN Statement of Investigator**.
- All personnel working on a protocol must provide proof of **human research subject protection training** (either institutional or NIH training is acceptable) prior to logging into the ACRIN Data Center.
- A site must provide ACRIN with proof of its **local IRB approval of the protocol, the site-specific consent form**, and, if applicable, **recruitment materials**.

→ **Review materials about regulatory requirements at:** [www.acrin.org/ ADMINISTRATION>ADMINISTRATIVE RESOURCES>REGULATORY](http://www.acrin.org/ADMINISTRATION>ADMINISTRATIVE RESOURCES>REGULATORY) [[LINK](#)]

Remote Monitoring

Remote monitoring helps ACRIN ensure sites are carrying out the study in compliance with all protocol and regulatory requirements early in the accrual phase.

- **After a site has registered a few cases**, ACRIN regulatory staff initiates the monitoring process according to the **protocol-specific monitoring plan**.
- **The Site RA** submits requested documents for review by ACRIN staff.
- **Instructions and materials are provided to each site for monitoring preparations.**

On-Site Audits

On-site audits are an integral part of ACRIN's quality assurance and regulatory compliance programs:

- Audits are scheduled **per protocol-specific guidelines**, usually 18 months after a site's first enrollment of a participant.
- If a site participates in multiple ACRIN trials, several trials may be audited at one time.
- Several weeks before an audit, the principal investigator is provided with a list of cases to be reviewed. At least one unannounced case is also reviewed.
- In certain circumstances, a mail-in audit may be conducted in lieu of an on-site audit.

→ **Review the ACRIN Audit Manual at:** www.acrin.org/ADMINISTRATION>ADMINISTRATIVE RESOURCES>REGULATORY >AUDIT MANUAL [[LINK](#)]

Adverse Event Reporting

An adverse event (AE) is any untoward medical occurrence in a participant that does not necessarily have a causal relationship to the study intervention.

- Assessment of grade and attribution of an AE must be assigned by the site principal investigator.
- **Prompt reporting of AEs** is the responsibility of every investigator and RA involved in ACRIN research.
- Protocol-specific AE reporting information can be found in each ACRIN protocol.
- General AE reporting information can be found in the ACRIN AE Manual.

→ **Review the ACRIN Adverse Event Manual at:** www.acrin.org/ADMINISTRATION>ADMINISTRATIVE RESOURCES>REGULATORY >ADVERSE EVENT MANUAL [[LINK](#)]

Module 4: Data Management

The Role of Data Management

The primary role of the ACRIN data managers and other data management support staff is to ensure the accuracy, completeness, and timeliness of research data submitted by participating institutions.

This role is critical for the analysis of data that leads to the publication of research results, which ultimately supports ACRIN's mission of improving the lives of cancer patients.

Specific Role of the ACRIN Data Manager

Data managers work with other participants of the protocol team to:

- Develop the case report forms (CRFs) that record important research data
- Ensure timely submission of forms and adherence to protocol
- Ensure data consistency and integrity through quality control measures
- Respond to questions from site research personnel about eligibility and form completion
- Report when study data are ready for analysis

Key Data Management Resources on the ACRIN Web Site

The ACRIN Web site provides information and materials required to manage an ACRIN study. It also serves as the point of entry to the ACRIN Data Center, where site RAs are able to enter case-specific data and run calendar reports. In addition, the Web site provides research personnel with access to up-to-date accrual reports for active studies.

→ **Log on to the ACRIN home page to find the Data Center Login and Accrual Tracker Report features at: www.acrin.org.**

The screenshot shows the ACRIN website home page. At the top left, there is a section titled "Clinical Trial Reader Study Opportunity" with a "read more ..." link. To the right is a colorful medical image. Below this is a navigation bar with links: HOME, PATIENTS, RESEARCHERS, COMMITTEES, CORE LABS, PROTOCOL SUMMARY TABLE, and ADMINISTRATION. The main content area is divided into two columns. The left column contains four sections: "DATA CENTER LOGIN" (with a description and a link), "ACCRUAL TRACKING REPORT" (with a description and a link), "SITE OPERATIONS TOOL" (with a description and a link), and "LINKS" (with a "Contact Us" link). The right column contains a "NETWORK CHAIR WELCOME" section with a welcome message and a paragraph about ACRIN's research. Two orange arrows point from the text above to the "DATA CENTER LOGIN" and "ACCRUAL TRACKING REPORT" links on the website.

Key Web Site Resources: Protocol Documents

The following materials related to each ACRIN trial are available on the product-specific page:

- The current protocol document
- The informed consent template for the more recently activated trials
- Any protocol amendments (explanation of changes to the original document)

The screenshot shows the ACRIN website navigation bar with links for HOME, PATIENTS, RESEARCHERS, COMMITTEES, CORE LABS, **PROTOCOL SUMMARY TABLE**, and ADMINISTRATION. Below the navigation bar is a breadcrumb trail: > PROTOCOL SUMMARY TABLE > PROTOCOL 6673. The ACRIN logo (AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK) is in the top right corner. The main content area is split into two columns. The left column, titled "PROTOCOL SPECIFIC MATERIALS", contains links for Data Forms, Site Memos, Recruitment and Educational Materials, 6673 Contact Personnel, Participating Sites, General Resources, PI Manual [PDF], and Regulatory Resources (Audit Manual [PDF], Adverse Event Reporting [PDF]). The right column, titled "ACRIN PROTOCOL 6673", contains the title "Multicenter Feasibility Study of Percutaneous Radiofrequency Ablation of Hepatocellular Carcinoma in Cirrhotic Patients", a "Protocol Documents" section with links for "Protocol-ACRIN 6673 Amendment 3, 2.26.08 [PDF]", "SOC-ACRIN 6673 Amendment 3, 2.26.08 [PDF]" (highlighted with an orange arrow), and "Informed Consent-ACRIN 6673 [DOC]", a "Principal Investigator" section for Gerald Dodd, III, MD, a "Status" section for "Accrual Complete", a "Main Objective" section, and a "Participants" section.

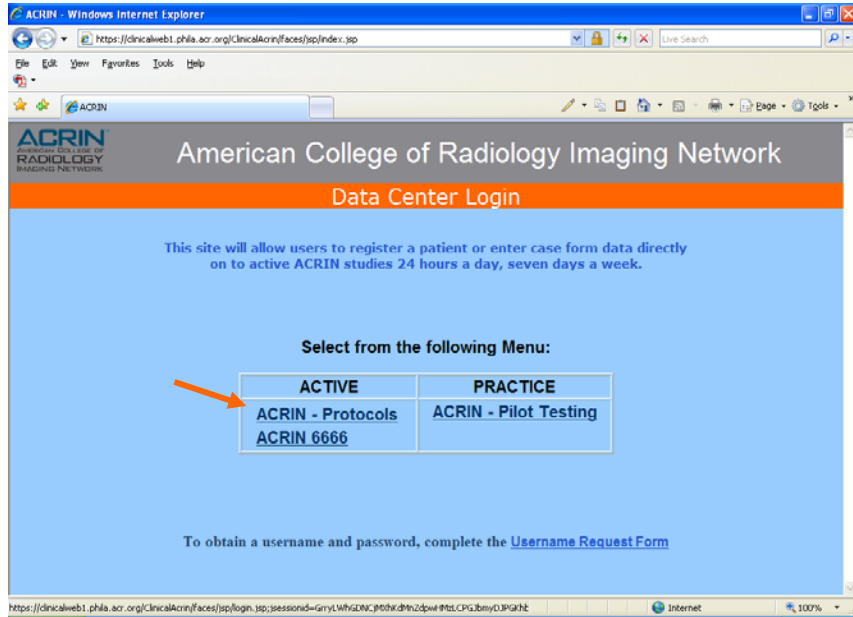
Key Web Site Resources: Data Forms

- Data forms for a study are posted on the Web site shortly before a trial activates. The forms are accessed by clicking on the “Data Forms” link in the protocol-specific materials section of the protocol-specific page.
- An index of all forms is provided, along with a listing of any form revisions.

The screenshot shows the ACRIN website navigation bar with links for HOME, PATIENTS, RESEARCHERS, COMMITTEES, CORE LABS, and **PROTOCOL S**. Below the navigation bar is a breadcrumb trail: > PROTOCOL SUMMARY TABLE > PROTOCOL 6671 > 6671 Data Forms. The main content area is split into two columns. The left column, titled "PROTOCOL SPECIFIC MATERIALS", contains links for Data Forms (highlighted with an orange arrow), Site Memos, Protocol Application and Site Activation Materials, Imaging Materials, Recruitment and Educational Materials, 6671 Contact Personnel, and Participating Sites. The right column, titled "PROTOCOL 6671 Data Forms", contains a "Forms Revisions" section with links for "Form revisions 6671", "Form revisions 2-6-08", and "Form revisions 2-18-08", a "Forms Index" section with a link for "6671 Index" (highlighted with an orange arrow), a "Forms Sets" section with links for "6671 CRF Set", "6671 Pet/CT Forms Set", and "6671 MRI Forms Set", and a "DATA FORMS" section with a "Visit 1: PET/CT - Within 7 days from Registration Visit:" and links for "TA PET Technical Assessment Form", "C1 PET/CT Lymph Node Evaluation page 1", and "C2 PET/CT Bladder Lymph Node Evaluation".

Navigating the Data Center: An Overview

- Clicking on the Data Center Login link on the home page of the ACRIN Web site takes you to the Data Center.
- From the Data Center page, clicking on “ACRIN - Protocols” takes you to the actual login page.



Navigating the Data Center: Logging On

- Enter your login ID and password, which are required to enter the Data Center. These are provided when your site has completed all other activation requirements to participate in a specific trial.
- On the Institution Information page, click on your institution # to access the main menu. Your login ID and password are linked to the institution #.

Please enter your Logon ID and Password. Then click the Logon button.

Login

Password

[Forgot your Login ID or Password?](#)



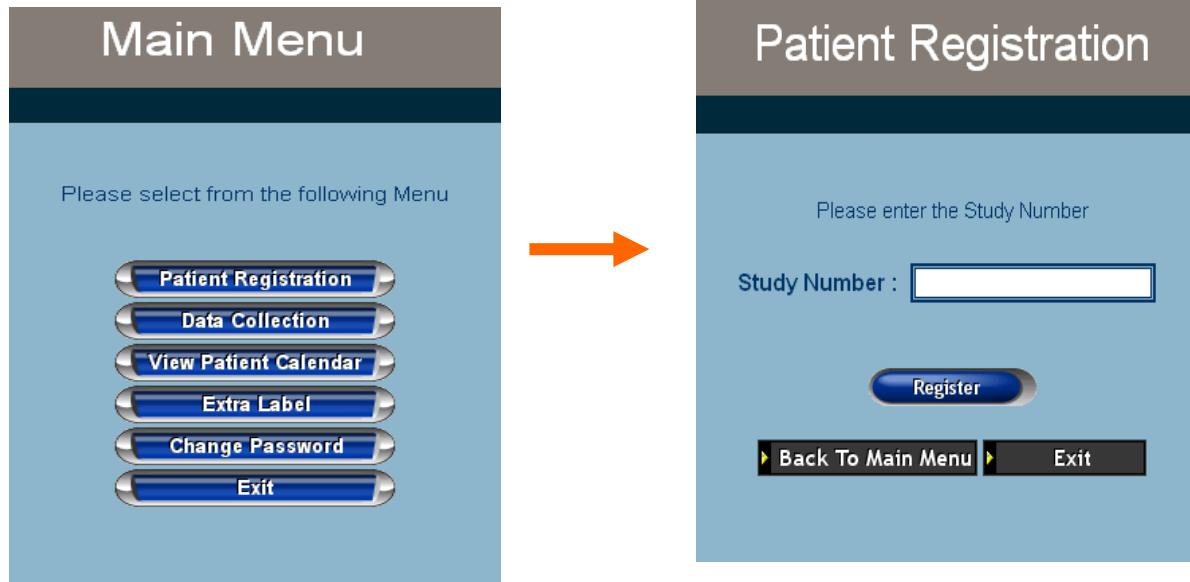
Institution Information

Please Select your Institution and Group from the List Displayed

Group	Inst No	Institution
ACRIN	9999	Test Institution

Navigating the Data Center: Patient Registration

- From the Main Menu page, select “Patient Registration” to begin.
- Then enter the specific study number.



Navigating the Data Center: Patient Registration

- Clicking on the “Register” button brings you to the “Eligibility Checklist” page.
- Patient data should be entered directly onto the Eligibility Checklist also referred to as the A0 form.
- Notification of successful registration is sent via e-mail to the site research staff entering the registration/eligibility information.

The screenshot shows the "Eligibility Checklist" form. It includes the following fields and options:

- 1. INSTITUTIONAL PERSON REGISTERING CASE: [Text Input]
- 2. HAS THE ELIGIBILITY CHECKLIST BEEN COMPLETED?
1. No
2. Yes
- 3. PATIENT ELIGIBLE FOR THIS STUDY?
1. No
2. Yes
- 4. DATE THE STUDY-SPECIFIC CONSENT FORM WAS SIGNED. (MMDD/YYYY): [MM] [DD] [YYYY]
- 5. PARTICIPANT INITIALS (LAST, FIRST) (L, F): [Text Input]
- 6. VERIFYING PHYSICIAN: [Text Input]
- 7. PARTICIPANT ID#: [Text Input]
- 8. DATE OF BIRTH: [MM] [DD] [YYYY]
- 9. ETHNIC CATEGORY
1. Hispanic or Latino
2. Not Hispanic or Latino
9. Unknown



Navigating the Data Center: The Case Calendar

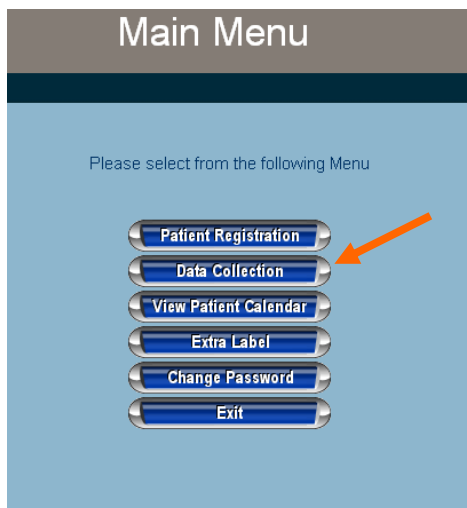
- A **participant-specific calendar** is generated for each registered case to ensure timely submission of data.
- For each case, the calendar identifies all data forms, images, and reports due for submission and, if applicable, the randomization group.

Calendar Example

PATIENT CONFIRMATION/CALENDAR				
STUDY	6678 - FDG-PET/CT AS A PREDICTIVE MARKER: PROSPECTIVE VALIDATION IN NSCLC			
INSTITUTION	9999 - Test Institution			
CASE NO 13	PATIENT LH	ID# 14546854	PHYSICIAN dr house	
TREATMENT OPTION	1 - GROUP A		STEP NO - 1	
CALENDAR BASE DATE 02/13/2007	CASE ENTRY DATE 02/13/2007			
FORM DESCRIPTION	KEY	DUE	ASSD	RECVD
FDG PET/CT ELIGIBILITY CHECKLIST	A0	02/13/2007	02/13/2007	02/13/2007
INITIAL EVALUATION/ON-STUDY	II	02/27/2007	00/00/0000	00/00/0000
CT VOLUMETRIC IMAGES VISIT A1	CA	03/13/2007	00/00/0000	00/00/0000
PET/CT LOCAL INTERPRETATION FORM VISIT A1	P1	03/13/2007	00/00/0000	00/00/0000
TECHNICAL ASSESSMENT FORM VISIT A1	T1	03/13/2007	00/00/0000	00/00/0000
CT VOLUMETRIC IMAGES VISIT A2 & B1	CB	03/20/2007	00/00/0000	00/00/0000
CT RECIST IMAGES PRE-CHEMO CYCLE 1	CM	03/20/2007	00/00/0000	00/00/0000
PET/CT LOCAL INTERPRETATION FORM VISIT A2 & B1	P2	03/20/2007	00/00/0000	00/00/0000
TECHNICAL ASSESSMENT FORM VISIT A2 & B1	T2	03/20/2007	00/00/0000	00/00/0000
CHEMOTHERAPY ASSESSMENT FORM CYCLE 1	C1	04/03/2007	00/00/0000	00/00/0000
CT VOLUMETRIC IMAGES VISIT A3 & B2	CC	04/17/2007	00/00/0000	00/00/0000
PET/CT LOCAL INTERPRETATION FORM VISIT A3 & B2	P3	04/17/2007	00/00/0000	00/00/0000
TECHNICAL ASSESSMENT FORM VISIT A3 7 B2	T3	04/17/2007	00/00/0000	00/00/0000
CT RECIST IMAGES POST-CHEMO CYCLE 2	CN	05/08/2007	00/00/0000	00/00/0000
CT RECIST IMAGES POST-CHEMO CYCLE 4	CP	06/19/2007	00/00/0000	00/00/0000
CT RECIST IMAGES POST-CHEMO CYCLE 6	CS	07/31/2007	00/00/0000	00/00/0000
END OF STUDY DISPOSITION FORM - STATN	DS	04/08/2008	00/00/0000	00/00/0000

Navigating the Data Center: Data Collection

- Once a case is registered, all relevant forms can be obtained through the “Data Collection” link on the Main Menu page.



Study No 6678 Institution 9999 - Test Institution
Case No 6 Patient Name ss

FormCd	Description	Due Date	Recvd Date
6678I1	Initial Evaluation / On-study	0.50 Months - 02/19/2007	00.00.0000
6678T2	PET/CT Technical Assessment Form - Visit A2 & B1	1.25 Months - 03/12/2007	00.00.0000
6678T3	PET/CT Technical Assessment Form - Visit A3 and B2	2.00 Months - 04/09/2007	00.00.0000
6678T4	PET/CT Technical Assessment Form - Visit B3	2.75 Months - 04/30/2007	00.00.0000
6678T1	PET/CT Technical Assessment - Visit A1	14.00 Months - 04.02.2008	00.00.0000

Back To Main Menu Exit

Data Quality Assurance

Data quality assurance is an important component of overall data management. ACRIN employs a tiered approach to quality control processes.

1. The first line process is executed through ACRIN's Web-based registration/data collection system, which includes online logic/range checks designed to prevent data entry errors.
2. The second line process is an automated validation check review of data after it has been received into the clinical trial database.
3. The third line process of monitoring data quality is performed by ACRIN's Biostatistics Center, which includes monthly reports.
4. In addition, a manual review of data is performed by the Data Management and Imaging departments.

Monitoring and on-site audits are another key aspect of data quality control integrity review performed at ACRIN. These activities are described in Module 3 Protocol Development and Regulatory Compliance.

The following data quality reports, queries, and alerts are incorporated to ensure that quality data are submitted on a timely basis for analyzing ACRIN trial results:

- Sending "**forms due reports**" to sites identifying forms, images, and supporting documents that (according to the case calendar) should have been submitted
- Sending **data queries** to sites about data flagged for follow-up because of incorrect, incomplete, or missing entries
 - The Z1 query form relates to data, and the Z5 query form relates to images
- Building **online Web entry validation logic spontaneously alerts site research** personnel entering the data of potential problems prior to submitting the form



Research associates who have supported patient accrual into the ACRIN 6668 trial at the Florida Radiation Oncology Group Baptist Medical Center gather for a group photo.



Cindy Cobb, right, talks with new members of the RA subcommittees about her committee experience. With Cindy from left to right are Suzanne Lenz, Lisa Camacho, and Mary Klaus Clark.

Module 5: Imaging Core Laboratory

Role of the Imaging Core Laboratory

The ACRIN Imaging Core Laboratory is designed to support imaging studies in producing reliable quantitative, semi-quantitative, and qualitative end points (overall study outcomes) that can be used to assess disease status.

→ **Find out more about Imaging Core Laboratory services at:**

[HTTP://WWW.ACRIN.ORG/CORELABS/TABID/92/DEFAULT.ASPX](http://www.acrin.org/corelabs/tabid/92/default.aspx).

Imaging Qualification for Trial Participation

Qualification requirements vary from study to study and may include the following:

- Qualifying a scanner or other piece of equipment required to carry out the protocol
- Qualifying images to ensure that they meet the parameters established in the protocol

Sites may have to obtain formal approval for scanner and/or image qualification. Information about these requirements is described in the protocol.

→ **Review typical imaging qualification materials for the ACRIN 6678 trial at:** [www.acrin.org/PROTOCOLSUMMARYTABLE>PROTOCOL 6678 >IMAGING MATERIALS](http://www.acrin.org/PROTOCOLSUMMARYTABLE>PROTOCOL6678>IMAGINGMATERIALS) [\[LINK\]](#)

PROTOCOL SUMMARY TABLE > PROTOCOL 6678 > 6678 IMAGING MATERIALS

PROTOCOL SPECIFIC MATERIALS Data Forms Site Memos Protocol Application and Site Activation Materials Imaging Materials Recruitment and Educational Materials 6678 Contact Personnel Participating Sites General Resources PI Manual [PDF] Regulatory Resources Audit Manual [PDF] Adverse Event Reporting [PDF]	6678 IMAGING MATERIALS Imaging Qualification Requirements and Instructions PET Qualification Instructions [DOC] PET Qualification Application [DOC] ACRIN Qualification Instructions for CT [DOC] CT Technique Charts and Procedures GE Scanners [DOC] Philips Scanners [DOC] Siemens Scanners [DOC] Toshiba Scanners [DOC] Image Submission Image Transmittal Worksheet
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Image Acquisition Overview

Each trial presents unique imaging requirements, which are described in the protocol. An important role of the research site investigator, assisted by the site RA, is to ensure that the technologists performing the study scans are aware of and adhere to the required imaging specifications.

In addition, studies may employ imaging parameters and/or technique charts that provide detailed specifications about how an imaging exam is to be performed.

→ Find the MRI imaging parameters for ACRIN 6671 at: [www.acrin.org/PROTOCOL SUMMARY TABLE>PROTOCOL /PROTOCOL 6671>IMAGING MATERIALS](http://www.acrin.org/PROTOCOL_SUMMARY_TABLE>PROTOCOL/PROTOCOL_6671>IMAGING_MATERIALS) [LINK]

Image Submission Process: TRIAD

Transfer of Images and Data (TRIAD) is the Web-based software developed by the American College of Radiology (ACR) to enable the transmission of images to and from sites participating in ACRIN research and to and from the ACRIN image archive database located at ACRIN headquarters in Philadelphia.

The TRIAD software that can be downloaded from the TRIAD Web site and installed on a site server (computer) with site support provided as needed.

→ Find out more about TRIAD by visiting the TRIAD Web site at <http://triad.acr.org>.

Images required for a research study are transferred from a scanner console or picture archiving and communications system (PACS) to a computer with TRIAD software (referred to as the TRIAD server).

Images are transferred daily from the TRIAD server to the ACRIN image archive. Images can also be sent from the image archive to the site server. Investigators can then “pull” the images from the server to a workstation for interpretation.

A flow diagram of how images are transferred follows.

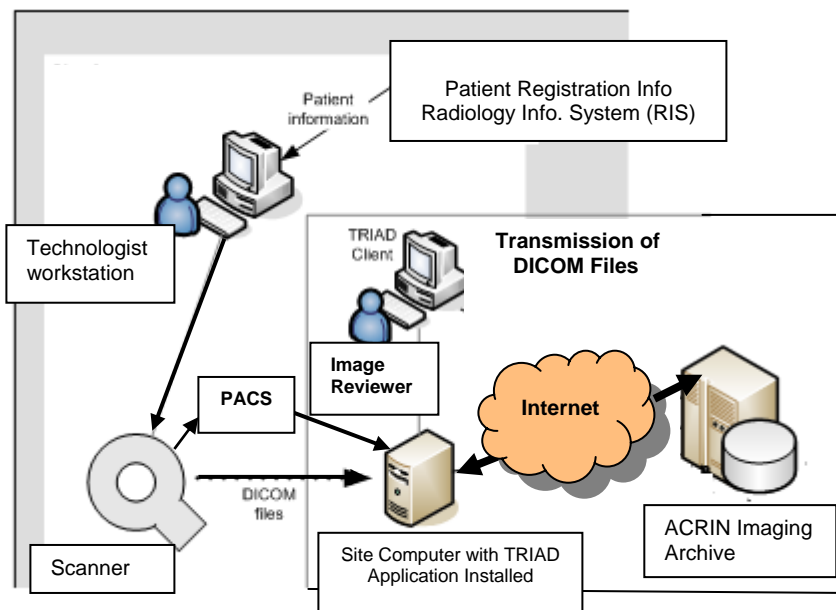


Image Submission Process: De-identifying the DICOM Header Information

The DICOM header on images contains information identifying the participant that must be replaced. This must be done prior to submitting the images, either with software provided by the institution or by the TRIAD software.

Participant information is replaced with:

- ACRIN institution number
- ACRIN study number
- ACRIN case number

Image Submission Process: The Image Transmittal Worksheet

The image transmittal worksheet (ITW) allows ACRIN imaging support staff to confirm whether all images a site intended to submit have been received.

A completed ITW must accompany each set of images submitted to ACRIN for any imaging exam. For images submitted via TRIAD, e-mail the ITW to imagearchive@phila.acr.org or fax to 215-923-1737.

→ Find the ITW for protocol ACRIN 6677 at: [www.acrin.org/PROTOCOL SUMMARY TABLE>PROTOCOL ACRIN 6677>IMAGING MATERIALS](http://www.acrin.org/PROTOCOL_SUMMARY_TABLE>PROTOCOL_ACRIN_6677>IMAGING_MATERIALS) [\[LINK\]](#)

Image Review Process

All images received at ACRIN headquarters undergo a manual quality review by a certified technologist to ensure that all the required images were received and that the imaging parameters meet study requirements.

- Images that meet study requirements are credited to the study calendar.
- A confirmation e-mail is sent to the site when the images are credited.
- Notification of any image discrepancies is sent to the site via a Z5 form.

Image Submission Follow up

Sites receive an image query when image submission is overdue:

- Reminder letters are generated once a week for 3 weeks or until the site resolves the query.
- Any Z5 form received by a site should be completed and returned to the Imaging Core Laboratory.
- The form should be e-mailed to imagearchive@phila.acr.org or faxed to 215-923-1737.
- A protocol deviation (PR) form should be submitted if requested by the image query.



ACRIN Core Laboratory staff Anthony Levering (standing) and Jim Gimpel (middle) review new software with Mark Rosen, MD, PhD, the ACRIN MR/CT Core Laboratory director.

CONGRATULATIONS!

You have finished the ACRIN RA Tutorial and can now take the tutorial quiz to test your knowledge about ACRIN. To complete the quiz, go to the RA Committee section of the ACRIN Web site to access the quiz link.

REMEMBER: Demonstrating a basic understanding of ACRIN and ACRIN clinical trials is required prior to obtaining a user name and password.

→ Find the tutorial quiz at: www.acrin.org>COMMITTEES>RA COMMITTEE>MATERIALS [[LINK](#)]



Research associates attending the day-long RA educational session at the ACRIN Fall Meeting network during the evening reception.



Wendy Smith, RA committee chair, presents the Jo-Ann D'Amato Award of Excellence to UCLA RA Ferdinand Osuagwu.