

ACRIN 6689

RTOG 0837 Substudy

***Assessment of Newly Diagnosed
Glioblastoma with FLT-PET and
DCE-MRI and MRS***

MRI Image Management Plan

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Advanced Imaging Component Time Points

All Advanced-Imaging Eligible Patients Recruited to
RTOG 0837 at Qualified ACRIN 6689 Sites [Until 51 Accrued]

SCHEMA

FLT-PET TIMEPOINTS COINCIDE WITH SHADED TIMEPOINTS.
AN ADDITIONAL BASELINE PET WILL BE PERFORMED ON THE FIRST 25 PARTICIPANTS

DCE-MRI, DSC-MRI, MR Spectroscopy and Blood Sampling

IMAGING TIME POINT 0 - BASELINE #1: WITHIN 7 DAYS PRIOR TO CHEMORADIATION

NOTE: if the Standard-of Care baseline MRI has been completed within 28 days of registration, only the advanced imaging series, (DCE, DSC, MRS) will need to be completed prior to initiation of chemoradiation)
(FIRST 25 SUBJECTS ON STUDY WILL RECEIVE TWO BASELINE FLT-PETs)



IMAGING TIME POINT 1—BETWEEN DOSES: AFTER THE FIRST DOSE OF PLACEBO OR CEDIRANIB BUT BEFORE THE SECOND DOSE

Between 2 to 24 hours after the first dose of placebo or cediranib, but before the second dose of placebo or cediranib/radiation/temozolomide



IMAGING TIME POINT 2—WEEK 4 OF CHEMORADIATION

Advanced imaging MRS, DCE-MRI, and DSC-MRI with blood sampling



IMAGING TIME POINT 3—WEEK 10 (6 Weeks Later - WEEK 4 AFTER CHEMORADIATION)

Advanced imaging MRS, DCE-MRI, DSC-MRI, and dynamic [¹⁸F]FLT PET with blood sampling



IMAGING TIME POINT 4—WEEK 16 (6 Weeks Later - WEEK 10 AFTER CHEMORADIATION)

Advanced imaging MRS, DCE-MRI, and DSC-MRI with blood sampling



IMAGING TIME POINT 5—WEEK 24 (8 Weeks Later - WEEK 18 AFTER CHEMORADIATION)

Advanced imaging MRS, DCE-MRI, and DSC-MRI with blood sampling



IMAGING TIME POINT 6—AT PROGRESSION

Advanced imaging MRS, DCE-MRI, and DSC-MRI with blood sampling

MR and Dynamic PET Imaging
Can Occur on Separate Days
(No More Than 3 Days Between Scans)

Required Sample Size for ACRIN 6689 Advanced Imaging Component: 51 participants from the 177 RTOG-study patients recruited at advanced-imaging sites will undergo the advanced imaging component if they are eligible for imaging. A total of 25 participants will undergo a second [¹⁸F]FLT PET scan (Baseline #2) prior to initiation of chemotherapy; specifically, the first 5 participants from each advanced-imaging site will undergo the second [¹⁸F]FLT PET scan until 25 participants have completed advanced imaging.

Site Eligibility

Pre-qualification of MR and PET imaging scanners and images is required for the advanced imaging component; all imaging-eligible participants recruited at advanced-imaging sites must consent to advanced imaging until all 51 participants are accrued.

MRI Scanner Qualification Procedures

Qualification Requirements Overview

To participate in the ACRIN 6689 trial, a site must perform all of the required MRI series per protocol. Participating sites also must capture and submit both processed and raw MR spectroscopy (MRS) file data. To ensure a site's scanner performs acceptable advanced MRI and MRS sequences, one test MRI scan and one test MRS scan must be completed *on the scanner that will be used consistently throughout the trial*. All MRS test submissions must include raw spectroscopy files (e.g. GE: P-files; Siemens: .rda files; Philips: .spar/.sdat files).

Raw MRS data files can be transmitted to the core laboratory via secure file transfer protocol (SFTP) directly to the image archive. All MRS submissions must include an image demonstrating voxel placement. (See "Image Submission Requirements" for more information.)

Image Qualification Review

Test scans will be reviewed to ensure they are protocol compliant, and the site research associate and lead technologist will receive an e-mail regarding the review results. If the test MRI scans are approved, the site will receive a notification of approval listing the approved scanner's make, model, software version, and station name. If the scans are not approved, a notice explaining the required corrections will be sent via email. Approval of the test images is mandatory prior to a site registering a participant onto the trial.

More Information

Detailed technical parameters are listed below. A PowerPoint presentation on MRS imaging and data submission is available at: www.acrin.org/6689_protocol.aspx (click on "Imaging Materials").

MR Imaging Procedures

All MRI scans must be completed on a 1.5 or 3.0 Tesla scanner. To ensure the reproducibility of images, sites MUST scan study participants on the same ACRIN-approved MRI scanner for which trial qualification scans were performed and using the same protocol-specific parameters consistently at each time point.

Important Note: Please coordinate with your institution's Research Associate, Clinical Coordinator and other persons responsible for scheduling the PET and MRI scans to accommodate study participants' preference for either undergoing the MRI and PET scans on the same day OR for scheduling the scans on separate days, but not longer than 3 days apart per the protocol.

The following is an overview of the MRI and MRS sequences which are mandatory for each study participant enrolled in ACRIN 6689. Parameter specifics are listed on the following pages:

- Scout
- T1 – weighted SE (pre injection)
- T2 3D Axial
- FLAIR
- **T1 maps (2, 10, 15, 20, 30 degrees)** } **DCE-MRI**
- **Dynamic contrast-enhanced images** }
- Diffusion – weighted imaging
- **Dynamic susceptibility contrast imaging - DSC-MRI**
- Post T1 3D – weighted (1 mm isotropic)
- Post T1 – weighted SE (to match pre-contrast scan prescription)
- **3D Volumetric Spectroscopy is preferred. 2D CSI Spectroscopy is accepted***

*See spectroscopy power point presentation located on the ACRIN web site.

Please print the appropriate chart and have it available for review when performing the scan.

ACRIN 6689 MRI PARAMETERS

All MRI scans must be completed on a 1.5 or 3.0 Tesla scanner. To ensure the reproducibility of images, sites MUST scan study participants on the same ACRIN-approved MRI scanner for which trial qualification scans were performed and using the same protocol-specific parameters consistently at each time point.

The following MRI sequences are mandatory across all scanner models for each study participant:

T1 Pre Contrast Spin Echo	Plane	TR	TE		FOV	Phase FOV%	Slice Thickness	Gap	Matrix	Phase	NEX / NSA
	Axial	400-600	min. (<15)		220-240	75%	5mm	1mm	256x192	R-L	1

T2 3D Axial	Plane	TR	TE	Echo Train	FOV	Phase FOV%	Slice Thickness	Gap	Matrix	Phase	NEX / NSA
	Axial	3200	428	944	256	100%	1mm	0mm	256x256	A-P	1

Siemens (SPACE) GE(CUBE)

FLAIR	Plane	TR	TE	TI	FOV	Phase FOV%	Slice Thickness	Gap	Matrix	Phase	NEX / NSA
	Axial	10000	70-130	2500	220-240	75%	5mm	1mm	256x192	R-L	1

T1 Mapping for DCE-MRI (See procedures below)

DCE-MRI **(See procedures below)** ---First Injection---

Diffusion DWI / DTI 2D EPI	Plane	TR	TE	B Value	# of Directions	FOV	Phase FOV%	Slice Thickness	Gap	Matrix	Phase	NEX / NSA
	Axial	7500-8000	80-85	700-1000	6 (min)	220-240	100%	5mm	1mm	128x128 minimum	A-P	1

DSC - Perfusion-MRI **(See procedures below)** ---2nd Injection---

T1 Post Contrast 3D SPGR (MPRAGE)	Sagittal Plane	TR	TE	TI	Flip Angle	FOV	Phase FOV%	Slice Thick	Gap	Matrix	Phase	NEX / NSA
	(Siemens)	2530	3.44(min)	1100	7°	256	100%	1.3mm	0mm	256x256	A-P	1
	(GE)	~10	~2.8	450	20°	25	100%	1.3mm	0mm	256x256	A-P	1-2

T1 Post Contrast Spin Echo*	Plane	TR	TE		FOV	Phase FOV%	Slice Thickness	Gap	Matrix	Phase	NEX / NSA
	Axial*	400-600	min. (<15)		220-240	75%	5mm	1mm	256x192	R-L	1

*This post-contrast series must be performed in at least the same plane as the pre-contrast spin echo imaging series

-PARAMETERS CONTINUE ON THE FOLLOWING PAGE-

ACRIN 6689 MRI PARAMETERS (cont'd)

3D Volumetric Spectroscopy											
Siemens	Plane	TR	TE	k-space	FOV	Sat Bands	Slice Thick	Flip	Matrix	Phase	NEX / NSA
	Axial	1140	144	Elliptical	>160mm	6 bands	>40mm	Default	12 x 12 x 8	A-P	1
GE	Plane	TR	TE	k-space	FOV	Sat Bands	Slice Thick	Flip	Matrix	Phase	NEX / NSA
	Axial	~10	~2.8	Elliptical	>160mm	6 bands	>40mm	Default	12 x 12 x 8	A-P	.5
See spectroscopy Powerpoint presentation located on the ACRIN web site .											

3D Volumetric Spectroscopy will be performed at all MR Imaging timepoints.

- 3D Volumetric Spectroscopy is preferred. 2D is acceptable if 3D capability is not available.
- The ROI will be placed at the center of the enhancing tumor covering the lesion and the normal brain as much as possible but excluding the subcutaneous fat and sinuses.
- Saturation bands will surround the prescribed volume and elliptical k-space acquisitions will be employed.
- Raw data files must be isolated immediately following the scan and submitted to ACRIN with imaging data.

Choose slice locations for the advanced imaging sequences (DCE, DSC, and MRS) so that the same volume of tissue is imaged for each sequence. For DCE and DSC sequences, be sure as much as possible that the same slice locations are imaged.

Dynamic Contrast - Enhanced (DCE) - MRI Protocol

Description

The DCE-MRI consists of 5 short series used for T1 mapping, followed by the dynamic, contrast-enhanced MRI series. The dynamic series is a “multiphase” technique with images acquired before, during, and after intravenous injection of gadolinium (Gd)-based contrast agent.

Platform / scheduling

Patients must be imaged on the same scanner for all MRI studies.

General technique

- **Prescan calibration** should be performed for the T1 mapping series and should not be repeated until after the dynamic series is completed (if needed).
- The **slice locations** and positioning for the T1 mapping and the dynamic series should be identical.
- For all series, **do not use normalization filters** such as SCIC or PURE.
- If magnets and multichannel head coils are available to perform parallel imaging, speed factors for **ASSET or IPAT of 2** can be used. Do not use higher speed factors.
- If parallel imaging techniques are used, identical parallel imaging techniques must be used on all series.
- If parallel imaging techniques are not available, sites can use zero-filled interpolation in the phase and frequency direction “Zip x 2.”
- Images on the dynamic run should be acquired as **3D SPGR/MPRAGE axial at a 20-35 degree flip**. Do not acquire as oblique.
- 3 to 5mm slice thickness – **yielding a 6cm slab** of effective coverage
- A contrast agent power injector should be used for contrast administration in this study. The power injector should be set up per standard protocol.
- Enough contrast agent should be **loaded for both** the DCE scan and the additional contrast agent used for the DSC-MRI sequence.
- The **rate of injection should be 3 to 5 cc/sec**, followed by a saline flush at the same rate.
- **All phases of the dynamic imaging series must be reconstructed in a single series**. Do not reconstruct dynamic or diffusion imaging in a multi-image or mosaic layout.

Dynamic Contrast - Enhanced (DCE) - MRI Protocol (cont'd)

T1 Mapping Series Technique (run prior to injection):

- Five (5) **3D SPGR/MPRAGE** series, total (with same prescription as dynamic series). One each, performed at 30, 20, 15, 10, and 2 degrees prior to the dynamic series. Tune to the first series and do not run pre-scan again for any subsequent T1 map, nor the dynamic DCE series.
- The repetition time (TR) must be identical for all flip angles.
- The lowest flip angle should be 2 degrees. ACRIN can provide source code to compile to run this sequence, if needed.
- **For the baseline study**
 - If prior studies are available, center the slice locations (in the z-direction) for T1 mapping series on the area with the largest enhancing abnormality.
 - If no prior studies are available, center slice locations on the area with largest abnormality on T2-weighted images.
 - Note that if the largest abnormality is near the top or bottom of the brain, it is acceptable for the highest or lowest slice locations (respectively) to be outside of the brain or outside of coil coverage.
- **For subsequent studies**
 - Center the slice locations for mapping sequence to match those of the baseline study.

DCE-MRI Dynamic Series Technique

- Allowable contrast agents: Magnevist, Omniscan, Dotarem, ProHance, and Gadovist.

Do not use MultiHance.

- The contrast agent should be administered using a power injector. Patients will require a heparin lock or other similar device for the administration of contrast agent during the dynamic sequence with the patient in the scanner.
- The frame rate (time per phase) of the multiphase acquisition should be acquired in **6 seconds or less** such that each volume should be completely sampled every six seconds or more frequently, if possible.
- Injection takes place **after 10 baseline frames** (phases) are obtained.
- **The total imaging time should be 5.5 minutes.** This amounts to 55 to 95 frames (phases), depending upon the acquisition time. The total number of slices acquired should be 660 to 1,900, depending on the number of slices in each frame.
 - For example: *If your time per phase works out to 5 seconds per phase, then:*
 - 5 seconds x 66 phases = 330 seconds (5.5 minutes)**
 - 66 phases x 10 slices per phase = 660 slices**
 - Inject at 50 seconds (5 seconds x 10 frames)**
- Contrast agent administration is 0.1 mmol/kg via power injector (3 to 5 cc/sec), followed by a flush with 20 cc of normal saline at the same rate.

Dynamic Susceptibility Contrast (DSC) - MRI Protocol

Description

The DSC-MRI protocol consists of administering a preload of a Gd (the Gd used for the DCE exam), followed by the collection of echo planar imaging (EPI) data before, during, and after administration of an additional bolus of Gd contrast agent. The DSC acquisition is started 5 to 10 min after the DCE acquisition.

General technique

- The EPI sequence should be set up to collect at least 120 points with a TR between 1.0 and 1.5 seconds. A GRE-EPI, SE-EPI, or a simultaneous GRE/SE-EPI sequence can be used:
 - For GRE-EPI, echo time (TE) should equal 30 to 40 milliseconds.
 - For SE-EPI, TE should equal 70 to 105 milliseconds.
 - If using a combined GRE/SE-EPI sequence, use the minimum TE for SE, which will likely be slightly longer than the 70 to 105 milliseconds range listed above.

Specific DSC-MRI acquisition

Start the DSC-MRI sequence. After collecting at least 30 baseline phases / measurement points, inject the bolus of contrast agent (0.1 mmol/kg). Continue collecting the data so that at least 120 phases / measurement points are collected per slice.

Examples of the DSC-MR images collected and time course from a single voxel are shown below in Figure 1. Note the transient darkening of the image and the decrease in signal as the contrast agent passes through the tissue.

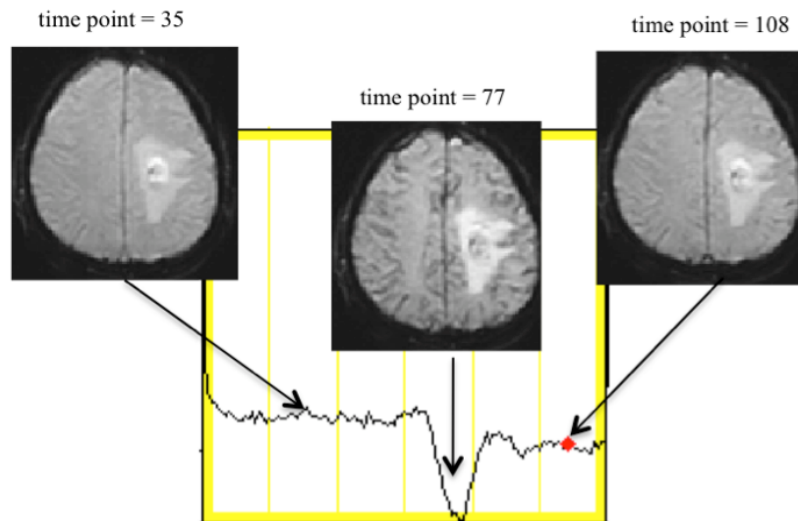


Figure 1. Example images and signal time course collected during a DSC study.

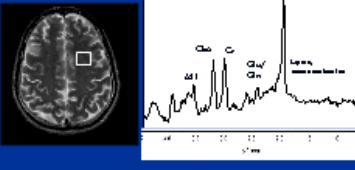
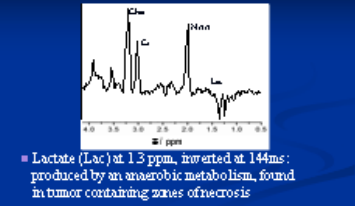
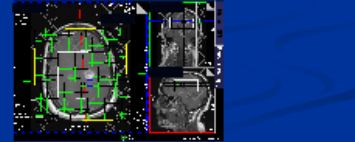
Shown are GRE-EPI images collected at three different time points, before, during and after the bolus injection of contrast agent, along with an example signal time course from one voxel. Notice that the image and voxel signal intensity transiently decrease as the bolus of contrast passes through the tissue (ideally after approximately 30 baselines).

MR Spectroscopy Protocol

3D Volumetric Spectroscopy will be performed at all MR Imaging timepoints.

- 3D Volumetric Spectroscopy is preferred. 2D is acceptable if 3D capability is not available.
- The ROI will be placed at the center of the enhancing tumor covering the lesion and the normal brain as much as possible but excluding the subcutaneous fat and sinuses.
- Saturation bands will surround the prescribed volume and elliptical k-space acquisitions will be employed.
- Raw data files must be isolated immediately following the scan and submitted to ACRIN with imaging data.

Vendor-specific instructions regarding acquisition, raw-data procurement and data submission are available via the [ACRIN 6689 web site](#).

<p style="text-align: center;">ACRIN-6689 - MRS data acquisition and Raw Data Handling Instructions - For Siemens Data</p>	<p style="text-align: center;">In vivo MR Spectroscopy</p> <p style="text-align: center;">Representative fMRS of a normal human brain @3T</p> 
1	2
<p>■ Proton MRS is able to detect the following metabolites:</p> <ul style="list-style-type: none"> ■ N-Acetyl Aspartate (NAA) at 2 ppm: Marker of neuronal density and viability ■ Creatine (Cr) at 3 ppm: Energy metabolism, generation of ATP ■ Choline (Cho) at 3.2 ppm: Pathological alterations in membrane turnover, increased in tumors ■ Lipids (Lip) between 0.8 - 1.5 ppm: Breakdown of tissue, elevated in brain tumors - lipids indicate necrosis 	 <p>■ Lactate (Lac) at 1.3 ppm, inverted at 144ms: produced by an anaerobic metabolism, found in tumor containing zones of necrosis</p>
3	4
<p style="text-align: center;">The Sequence</p> <ul style="list-style-type: none"> ■ 3D chemical shift imaging using a Point-resolved spectroscopy (PRESS) excitation pulse sequence. ■ 3D Volumetric Spectroscopy preferred 2D CSI Spectroscopy is acceptable 	<p style="text-align: center;">Optimal Voxel Placement</p> <ul style="list-style-type: none"> ■ The ROI will be placed at the center of the enhancing tumor covering the lesion and the normal brain as much as possible but excluding the subcutaneous fat and sinuses. 
5	6

Blood Sample Collection

All subjects enrolled in ACRIN 6689 shall have 10ml of blood withdrawn at the time of MR imaging.

This blood is to be forwarded to the ACRIN 6689 Central Pathology Laboratory for blood collection. *Blood samples are **NOT** to be submitted with imaging.*

For more information on blood collection and sample submission for ACRIN 6689, please contact the ACRIN core laboratory.

MR Data Submission Instructions

MRI Collection Time Points/Visits

- 0 – Baseline - WITHIN 7 DAYS PRIOR TO CHEMORADIATION
- 1 – BETWEEN DOSES: AFTER THE 1st DOSE OF PLACEBO OR CEDIRANIB BUT BEFORE THE 2nd DOSE
- 2 – WEEK 4 OF CHEMORADIATION
- 3 – WEEK 10 (WEEK 4 AFTER CHEMORADIATION)
- 4 – WEEK 16 (WEEK 10 AFTER CHEMORADIATION)
- 5 – WEEK 24 (WEEK 18 AFTER CHEMORADIATION)
- 6 – Progression

Following are instructions for submitting the two types of MR scans required at each time point in this protocol.

Raw MRS Data File Submission Instructions

Raw spectra data and screen capture showing voxel placement can be submitted to ACRIN on media or via SFTP client: <ftp://xray.acrin.org>.

Raw spectra data files submitted in this manner must be named according to the labeling convention:

Subject ID_Timepoint

Contact the ACRIN core laboratory at 215-574-3238 to obtain a login and password for submitting these data via sftp.

Please refer to the vendor-specific PowerPoint presentations for locating the .rda file (Siemens), .spar/.sdat file (Philips), and .P-file (GE) located at: www.acrin.org/6689_protocol.aspx (“Imaging Materials”).

Upon submitting spectra and screen capture, submit the Imaging Transmittal Worksheet (see “Imaging Transmittal Worksheet Instructions”) according to the directions on the worksheet.

Note: TRIAD v3.0 (for future release as of May, 2010) will also allow for the submission of MRS raw files, jpegs and other non-DICOM data.

Please contact TRIAD-support@phila.acr.org or call 215-940-8820 for more information.

MR Image Submission Instructions

Sites have two options for submitting MR images to ACRIN's image archive

- Using ACRIN's image transfer application (TRIAD)
- Express mailing images on a CD-ROM

Important Note: All MR images for this protocol must be provided in DICOM format.

TRIAD software for secure submission and anonymization

The preferred image transfer method for active sites is via TRIAD, a software application that ACRIN provides for installation on PC. TRIAD collects image sets from a scanner's computer or from the picture archiving communications system (PACS). The TRIAD software anonymizes, encrypts, and utilizes lossless compression of the images as they are transferred to the ACRIN image archive in Philadelphia. Once equipment-readiness has been determined, imaging personnel from ACRIN can coordinate installation and training for the software. For more information, contact:

TRIAD-support@phila.acr.org or call 215-940-8820.

Upon electronically submitting the MR images, sites should then immediately submit the **Image Transmittal Worksheet** (see "Image Transmittal Worksheet Instructions") to the ACRIN core laboratory at 215-923-1737 or e-mail it to jqimpel@phila.acr.org

Media delivery instructions

For exams submitted via a CD-ROM, please affix a label to the CD jacket that includes: study name, site name, site number, subject number, date of scan(s), image time point, and type of imaging. Do not apply adhesive labels directly to the CD.

Complete the **Image Transmittal Worksheet** (see "Image Transmittal Worksheet Instructions") and include with the media shipment.

Mail the images and worksheet to:

**American College of Radiology Imaging Network
Imaging Core Laboratory
Attn: ACRIN 6689
1818 Market Street, 16th floor
Philadelphia, PA 19103**

Image Transmittal Worksheet Instructions

The Image Transmittal Worksheet (ITW) on the following page can also be found on the protocol-specific page of the ACRIN Web site: www.acrin.org/6689_protocol.aspx (click on "Imaging Materials").

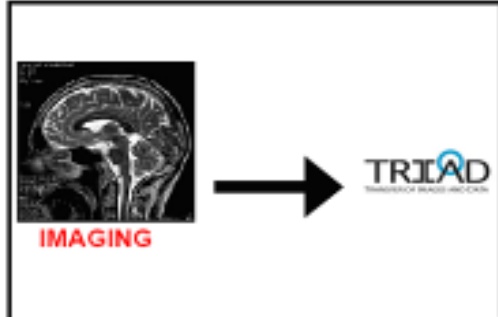
MRI images and MRS data are required to be submitted to ACRIN after each time point (or visit), as recorded on the ITW.

The ITW must include the site number/subject number, as well as the name of the technologist performing the scan. Other information required on this form includes the time point, date of study, participant date of birth (for quality control purposes), and mode of image submission (submission via TRIAD is preferred).

Sites must also provide the e-mail address of the person who should receive feedback regarding image quality. An ACRIN core laboratory imaging specialist reviews the ITW in order to confirm the number of series, number of images, and the appropriate identifying/de-identified information for the imaging study.

Important Note: This form **MUST** be completed in its entirety. No image submissions will be credited as being received without a fully completed ITW.

SEND ITW VIA FAX OR EMAIL. THEN...



OR



THEN



↓ ↓
ftp://xray.acrin.org

**ACRIN 6689 RTOG 0837
Imaging Transmittal Worksheet**



Instructions: This worksheet is to be completed for all RTOG 0837 subjects who have been enrolled in ACRIN 6689. Email completed worksheet to imagearchive@phila.acr.org or fax to 215.923.1737.

For exams submitted on media, include this worksheet with the media shipment. Please affix a label to the jacket of the media to include: study name, site name, NCI institution code, case no, date of exam(s), time point, and type of imaging. For further information contact the Image Management Center at ACRIN. http://www.acrin.org/6689_protocol.aspx

This worksheet **MUST** accompany all submissions immediately after each timepoint/visit.
NO EXAMS WILL BE CREDITED WITHOUT A COMPLETED WORKSHEET.

ALL ADVANCED IMAGING PARAMETERS AND PROCEDURAL INSTRUCTIONS ARE LISTED IN THE ACRIN 6689 IMAGING MANUAL. ALL SERIES ARE REQUIRED TO BE PERFORMED ACCORDING TO PROTOCOL.

The following required series have been performed and submitted according to protocol (check all that apply):

- | | |
|---|---|
| 1. <input type="checkbox"/> T1 Pre Contrast Spin Echo | 5. <input type="checkbox"/> DCE-MRI Dynamic Series |
| 2. <input type="checkbox"/> T2 FSE | 6. <input type="checkbox"/> Diffusion / DTI 2D EPI |
| 3. <input type="checkbox"/> FLAIR | 7. <input type="checkbox"/> DSC - Perfusion |
| 4. T1 Mapping for DCE-MRI | 8. <input type="checkbox"/> T1 Post Contrast Spin Echo |
| <input type="checkbox"/> 2 degrees <input type="checkbox"/> 20 degrees | 9. <input type="checkbox"/> T1 Post Contrast 3D SPGR |
| <input type="checkbox"/> 10 degrees <input type="checkbox"/> 30 degrees | 10. <input type="checkbox"/> MR Spectroscopy Raw Data file |
| <input type="checkbox"/> 15 degrees | 11. <input type="checkbox"/> Screen capture of MRS voxel Rx |

RTOG SITE NUMBER: [] RTOG SUBJECT ID: [] Subject DOB: [] [] 19 [] (dd/month/19yy)

ACRIN SITE NUMBER: [] ACRIN SUBJECT ID: []

SITE NAME: [] Date of Study: [] [] 20 [] (dd/month/20yy)

Timepoint Being Submitted:

- 0 - Baseline WITHIN 7 DAYS PRIOR TO CHEMORADIATION
- 1 - BETWEEN DOSES: AFTER THE FIRST DOSE OF PLACEBO OR CEDIRANIB BUT BEFORE THE SECOND DOSE
- 2 - WEEK 4 OF CHEMORADIATION
- 3 - WEEK 10 (WEEK 4 AFTER CHEMORADIATION)
- 4 - WEEK 16 (WEEK 10 AFTER CHEMORADIATION)
- 5 - WEEK 24 (WEEK 18 AFTER CHEMORADIATION)
- 6 - PROGRESSION

Technologist completing scan: [] _____

Form Completed By: [] _____ Date: [] [] 20 []

Email: [] _____ Phone: [] _____

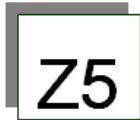
ACRIN
1818 Market Street • Suite 1600
Philadelphia, PA 19103
Attn: 6686 Imaging Core Laboratory

S
A
M
P
L
E

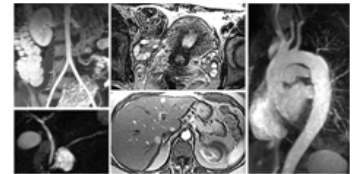
Quality Control Procedures

ACRIN imaging specialists review all ITWs and images submitted to ensure images comply with the protocol parameters. Should the specialist discover that images or image-related data are missing, inaccurate, or inconsistent with the imaging protocol, sites are notified through the following process:

1. An **imaging query** describing the problem is e-mailed to the study coordinator. Such a query is also referred to as a Z5 form (see example below).
2. The site should resolve the problem as quickly as possible and must maintain a hard copy of the completed and signed query at the site.
3. A site receives up to three reminders to resolve a query. After that time, an outstanding query is reported to the trial leadership for assistance with resolution.



Imaging Query



Request for Additional Imaging Information

DATE of this request:

TO:

Case#:

Inst. Name:

FROM: Core Lab

Subject: Imaging Query

Study No./Name: ACRIN 6684

The above mentioned case from your institution is incomplete or requires a clarification. Kindly supply the missing images and/or subject information described in the Site Response section, to make the case available for final review. **Please print and sign this form and return to Adam Opanowski, CNMT, RT (N) via FAX to (215) 923-1737 as soon as possible.**

****Queries requiring the submission of incomplete image data will not be resolved until the missing image data is received by ACRIN.****



×	Image Type	Study Date	Explanation	Site Response
[]			Missing Images/Views - Study incomplete. (**See Comments)	
[]			Date of Birth (DOB) on Images does not match DOB in Clinical DB . Please Confirm correct DOB. (See Comments)	
[]			Anatomy Not Covered (ANC) (**See Comments)	
[]			Poor Quality Images (**See Comments)	
[]			Incorrect Case # assigned to images (**See Comments)	
[]			Incorrect technical factors utilized (**See Comments)	
[]			OTHER (**See Comments)	

ACRIN Comments:

SITE Comments:

Institution Representative:

Phone No.:

Email:

Signature: _____

Date: _____

ACRIN Core Lab Contact Information:

Jim Gimpel RT (R)(MR)
Imaging Analyst
Lead Technologist – ACRIN 6686
jgimpel@acr-arrs.org
1818 Market Street – Suite 1600
Philadelphia, PA 19103
Attn: Imaging – 0825
(215) 574-3238

Sandy Toland-Cary RT (R)(MR)
Imaging Technolgist
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