

RTOG 0837 Substudy
Assessment of Newly Diagnosed Glioblastoma with FLT
PET and DCE MRI and MRS

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Dear PET Imaging Staff,

The PET Image Management Plan contains instructions for all aspects of carrying out the PET imaging component of the ACRIN 6689 trial: *Assessment of Newly Diagnosed Glioblastoma with FLT PET and DCE MRI and MRS*.

For the study objectives to be successfully met, it is critical that you acquire the PET images according to the imaging protocol detailed in this plan. Because the PET imaging protocol required for this study may be new for your site, and perhaps this may be your first time supporting an ACRIN clinical trial, I will be conducting an onsite visit to review the imaging parameters to ensure that you are ready to confidently scan your first study participant.

During the site visit, I will also review the mandatory forms to be completed at the time of each PET scan acquisition as well as the instructions included in the plan for submitting images to the core laboratory at ACRIN headquarters in Philadelphia, PA.

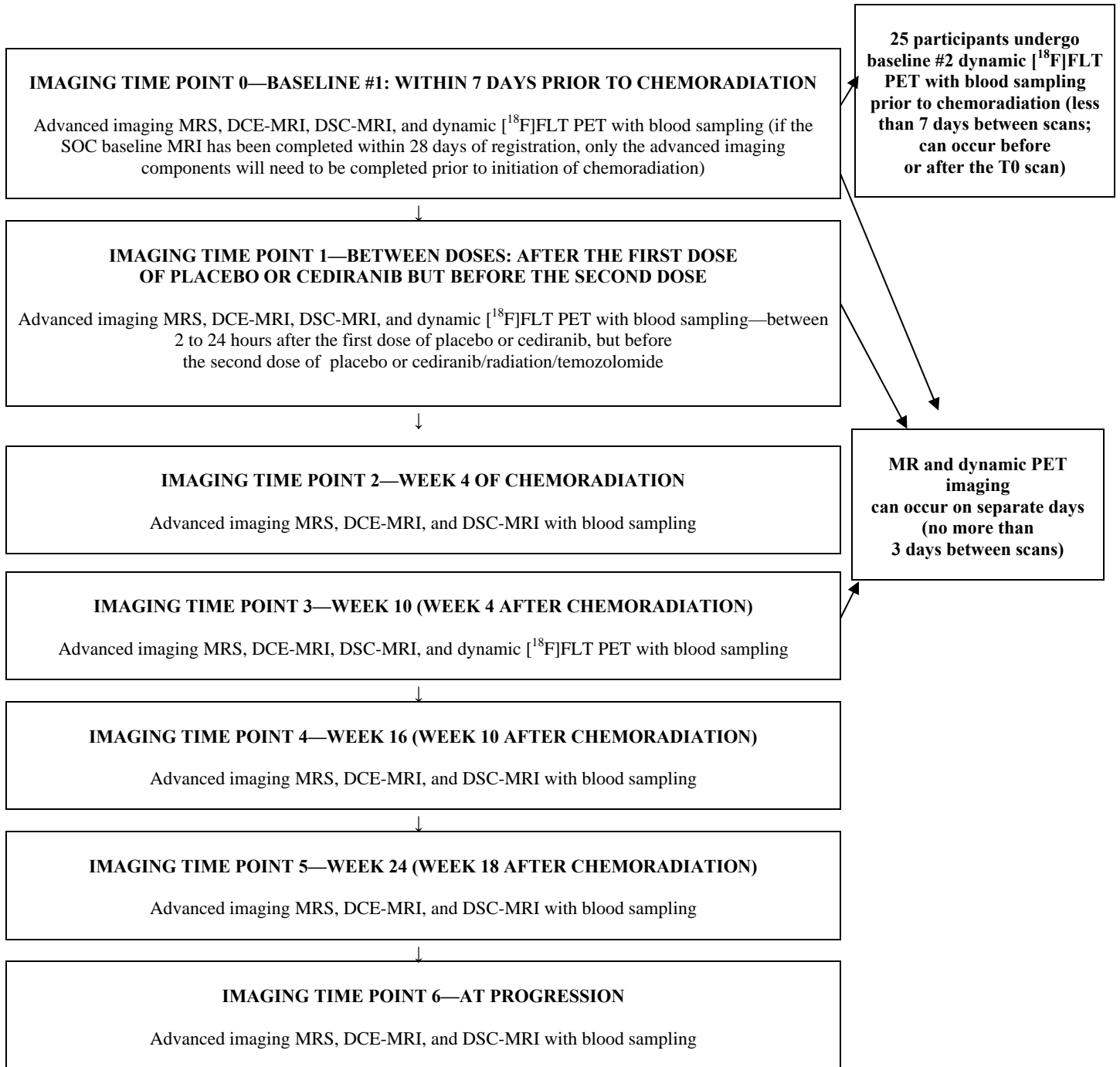
Part of ACRIN standard procedures is a quality control (QC) review of the images sent to the core laboratory. Should a core laboratory technologist performing the QC identify any protocol violations or technical issues, he or she will provide expedient feedback so that you can make the necessary adjustments.

Thank you in advance for your diligent efforts in adhering to the procedures described in the image management plan and for helping us ensure the compliance and integrity of the image data collected for the ACRIN 6689 study. I look forward to collaborating with you!

Sincerely,

Adam Opanowski, CNMT, RT (N)
215-940-8890
aopanowski@acr-arrrs.org

ACRIN 6689 Study Schema and Objectives



MRS: magnetic resonance spectroscopy; MRI: magnetic resonance imaging; DCE-MRI: dynamic contrast-enhanced MRI; DSC-MRI: dynamic susceptibility-contrast MRI (perfusion MRI); [¹⁸F]FLT: 3'-deoxy-3'-[¹⁸F] Fluorothymidine; PET: positron emission tomography.

NOTE: For this protocol, "PET" may comprise PET, PET/CT, or MR-PET.

PET Scan Time Points/Visits

ACRIN 6689 MR and Dynamic PET Study Time Table: For All Imaging-Eligible Participants) at Qualified Sites Only (51 Total Are Accrued)

	T0: Baseline (Pre- Chemo/RT)	T1: Between Doses (2 to 24 Hours After 1 st Dose/ Before 2 nd Dose)	T2: Week 4 of Chemo/RT	T3: Week 10	T4: Week 16	T5: Week 24	T6: At Time of Progression
Advanced MR: MRS, DCE-MRI, and DSC- MRI with Blood Collection (Select Sites Only)	X	X	X	X	X	X	X
Dynamic [¹⁸ F]FLT PET with Blood Sampling at 3 Time Points (Select Sites Only)	X [†]	X		X			

† A second baseline (Baseline #2) dynamic [¹⁸F]FLT PET with blood sampling at 3 time points will be conducted on 25 of the 51 ACRIN 6689 advanced imaging-site participants prior to initiation of therapy. See Sections 1.9.2 and 11.6.2 for details.

NOTE: “PET” may refer to PET, PET/CT, or MR-PET depending on the site.

PET Scanner Qualification Procedures

ACRIN qualification of a site's PET or PET/CT scanner is required prior to enrollment of study participants. If the scanner to be used for this trial is already qualified by ACRIN, a site does not need to complete the qualification application, as long as the 2-year PET qualification period has not expired. If the qualification has expired, a site will need to complete a new application. In addition, all sites must complete the "well counter qualification," even if the PET scanner does not need to be qualified or re-qualified.

The application instructions and the application form are available on the ACRIN 6689 protocol-specific Web page (click on the "Imaging Materials" section) at www.acrin.org/6689_protocol.aspx.

Note: If your PET scanner must be qualified, or re-qualified, please submit PET brain images versus the body images specified in the application. In addition, the phantom that is submitted must be acquired with a brain FOV versus a body FOV specified in the application.

Daily Quality Control Requirements

A daily QC check must be performed at the beginning of the day a study participant is to be scanned. The QC check must include the PET scanner, dose calibrator, and well counter, in accordance with the manufacturer recommendations.

Note: If any of the QC results are outside of the manufacturer's guidelines, the study must be rescheduled and the problem resolved prior to scanning a study participant.

For the ACRIN-qualified PET scanner:

- Keep calibrated in accordance with the manufacturer's recommendations.
- Routinely assess the scanner for quantitative integrity and stability by scanning a standard quality control phantom with the same acquisition and reconstruction protocols as those used for study participants.
- Perform standard uptake value (SUV) verification measurements to include the dose calibrator used to measure the doses of study participants, to ensure that the dose calibrator and PET scanner are properly cross-calibrated (i.e., the dose measured in the dose calibrator and injected into the phantom matches the results obtained from analysis of the phantom images).
- Perform a QC (empty port transmission) scan at the beginning of the day a study scan is to be completed. The QC sinogram should be visually inspected for abnormalities.

For the dose calibrator:

- Perform QC of the dose calibrator throughout the course of the study. This typically will include daily constancy, quarterly linearity, and annual accuracy tests, all of which should be documented.

Well Counter Calibration Procedures

NOTE: As a pre-qualification measure, sites will need to demonstrate appropriate well counter cross calibration.

1. The time of all measurements should be documented in reference to a single clock. If possible, the clocks on the PET scanner, well counter, and dose calibrator (if it has a clock) should be synchronized to this reference clock.
2. Fill a uniform cylindrical phantom (18-22 cm diameter) with water and eliminate as many air bubbles as possible.
3. Fill a syringe with a sufficient activity of ^{18}F to achieve a concentration in the phantom of approximately 0.2 $\mu\text{Ci/mL}$. Make sure the syringe is properly placed inside the dose calibrator. Assay the syringe activity in the dose calibrator and record the assay result in mCi and the assay time.
4. Withdraw approximately 60 mL of water from the phantom using a large syringe and an 18-gauge needle.
5. Add the ^{18}F into the phantom and thoroughly rinse the syringe contents into the phantom. Assay the residual activity in the syringe in the dose calibrator and record the assay result and assay time, seal the phantom and repeatedly invert to mix the solutions. Enter the measured full syringe activity (mCi), measured full syringe activity assay time, residual syringe activity (mCi), residual syringe activity assay time, and volume of the completely filled phantom (mL) in the EXCEL spreadsheet. [Note: The phantom volume should be obtained from the manufacturer of the phantom.]
6. Add water to the phantom to fill it completely. Re-seal and thoroughly mix the contents of the phantom, to make sure that the ^{18}F is uniformly distributed.
7. Using a calibrated balance (with at least 1 mg precision), weigh each of three (labeled 1,2,3) gamma counting tubes with their respective caps, and enter the weight of each gamma counting tube (including cap) separately in the EXCEL spreadsheet.
8. Withdraw three 1.0 mL samples from the phantom with a syringe or pipette and place into the weighed gamma counting tubes from Step 7. Replace the cap on each gamma counting tube.
9. Re-seal the phantom and position in the center of the PET scanner gantry using the phantom holder supplied with the scanner.

10. Perform a 20-minute static scan of the phantom using standard acquisition and reconstruction parameters.
11. Using the same calibrated balance as in step 7, weigh each of the gamma counting tubes containing the samples and enter the results in the EXCEL spreadsheet.
12. With a pipette or syringe, place 1.0 mL of tap water into a gamma counting tube labeled 'BKG' for measuring background radiation.
13. Count each of the samples and the BKG tube in the well counter for 60 seconds using a counting window set for 511 keV photons, or close equivalent. Enter the counting results and start times of the counting of each sample into the Excel spreadsheet.
14. The formulas in the spreadsheet will combine the weight of the samples and the number of counts per minute and display the well counter rate concentration, $R_{(wc)}$ (cpm/mL), decay corrected back to the start time of the PET scan. The cpm/mL is calculated by dividing by the net volume of the sample in the gamma counting tube, assuming a density of 1 g/mL.
15. Upon completion of the image reconstruction, measure the mean SUV (based on weight) by drawing a large circular ROI, on one plane and then copying that ROI, to all planes (EXCEPT THE FIRST AND THE LAST PLANE). Average the mean SUVs for all the ROI's throughout the phantom as measured by the PET scanner.
16. Using the Excel spreadsheet provided, enter the data from the procedure above to compute the cross-calibration factor.
17. The calibration factor (CF) between the well counter and the PET scanner is calculated as follows:

$$CF = PET/R_{(wc)}$$

Note: The units of CF are SUV/(cpm/mL), which is used by multiplying the sample cpm/mL to convert the units to sample SUV.

Well Counter Cross-Calibration Spreadsheet

Note: Print out spreadsheet prior to scanning.

ACRIN 6689 FLT Cross Calibration Worksheet

F-18 Phantom Information:		Dose Calibrator Device: _____	
Measured Dose:	Activity: _____ mCi	Measurement Time:	_____ hh:mm:ss
Residual Dose:	_____ mCi		_____ hh:mm:ss
Net Phantom Activity: _____ mCi			
Phantom:	Volume: _____ ml	Radioactive Concentration:	_____ uCi/mL
		@ Scan Start Time:	NAN

Well Counter Information:			Well Counter Device: _____		
Gamma Counting Tube 1:	Empty Weight: _____ g	With Liquid Weight: _____ g	Net Weight:	0.000 g	
Gamma Counting Tube 2:	_____ g	_____ g		0.000 g	
Gamma Counting Tube 3:	_____ g	_____ g		0.000 g	
Background (water):	Sample Counts: _____ CPM	Sample Start Time:	_____ hh:mm:ss	Count Duration:	_____ hh:mm:ss
Gamma Counting Tube 1:	_____ CPM	_____ hh:mm:ss	_____ hh:mm:ss	_____ hh:mm:ss	
Gamma Counting Tube 2:	_____ CPM	_____ hh:mm:ss	_____ hh:mm:ss	_____ hh:mm:ss	
Gamma Counting Tube 3:	_____ CPM	_____ hh:mm:ss	_____ hh:mm:ss	_____ hh:mm:ss	
Gamma Counting Tube 1:	Corrected CPM/g: _____				
Gamma Counting Tube 2:	_____				
Gamma Counting Tube 3:	_____				
Average Gamma Tube Counts: _____ CPM/mL *			@ Scan Start Time: NAN		
* Assumes density of 1g/mL					

Phantom Scan Image Analysis:		PET Imaging Device: _____	
Phantom Weight for Scanner:	_____ kg *		
* Use same significant digits as accepted by scanner			
Scan Start Time:	_____ hh:mm:ss	Scan Duration:	_____
Average ROI Activity of Phantom SUV Scan:		SUV: _____	@ Scan Start Time: NAN

Cross Calibration Results			
Measured Phantom Concentration:	_____ uCi/ml	@	NAN (From Dose Calibrator)
Average Phantom Activity:	0.000 SUV	@	NAN (From Image Analysis)
Average Gamma Tube Counts:	_____ CPM/mL	@	NAN (From Well Counter)
Well Counter To PET Scanner Conversion Factor: _____ SUV / (CPM/mL)			
Well Counter To Dose Calibrator Conversion Factor: _____ uCi / CPM			

Blood Sampling Procedures

Note: Prior to study site activation, demonstration of appropriate cross-calibration of the PET scanner is required. Use of a dose calibrator, rather than a NaI-detector well counter, for counting of blood samples is strictly prohibited, because the dose calibrator is not sensitive enough for the required activity measurements. Prior to performing the study, print out the Blood Sampling (BS) Form for completion during the procedure. Data recorded on the form will need to be entered into ACRIN's Web-based form. Step-by-step instructions regarding blood sampling procedures follow:

1. The time of each blood draw and of all measurements should be documented in reference to a single clock. If possible, the clocks on the PET scanner, well counter, and dose calibrator (if it has a clock) should be synchronized to this reference clock.
2. The well counter being used should have a CF determination within 1 week prior to the study (see Appendix III). The value and the date of calibration must be entered on the FLT PET BS Form.
3. Three venous blood samples should be drawn at 15, 30, and 60 minutes (± 2 minutes) from the IV placed in the arm opposite the one used for the FLT injection. The exact time of the blood draws must be recorded.
4. To avoid dilution, 3-5 mL of blood must be drawn for "waste" prior to withdrawing each of the blood samples.
5. Withdraw 3-5 mL of blood for each sample.
6. Use a calibrated balance (with at least 1 mg precision) to weigh each of 3 gamma counting tubes with their respective caps. Enter the weight of each gamma counting tube (including cap) on the BS Form.
7. After weighing the empty gamma counting tube with cap, expel from the sample syringe approximately 1.0 mL of blood and transfer the sample into the gamma counting tube with another syringe or pipette and cap the tube.
8. Using the same calibrated balance as in step 7, weigh each of the sample gamma counting tubes and enter the results on the BS Form.
9. Background counts must be measured in the well counter prior to counting each of the blood samples. The background count must be performed with nothing in the well counter for an interval of 2 minutes. Results must be recorded on the BS Form.
10. Following the background measurement, count the gamma counting tube containing the blood sample for 2 minutes. Results must be recorded on the BS Form.
11. It is preferable to count the blood samples after all three have been collected.
12. Provide the form to the research associate for entering data in the Web-based form.

ACRIN 6689 Blood Sampling Form

Note: Print out BS form prior to scanning.

<div style="border: 1px solid black; padding: 5px; display: inline-block;"> BS </div>	ACRIN 6689/ RTOG 0837 Chemoradiation and Adjuvant Temozolomide Plus Cediranib Versus Conventional Chemoradiation and Adjuvant Temozolomide... Advanced Imaging FLT PET Blood Sampling Form If this is a revised or corrected form, please <input checked="" type="checkbox"/> box. <input type="checkbox"/>	ACRIN Study 6689 PLACE LABEL HERE Institution _____ Institution No. _____ Participant Initials _____ Case No. _____	
1. Timepoint ^[1] <input type="radio"/> T0 Baseline 1 (within 7 days prior to chemoradiation) <input type="radio"/> T0 Baseline 2 (<i>1st 5 patients at each site</i>) <input type="radio"/> T1 Between doses (within 2 to 24 hours after 1st dose) <input type="radio"/> T3 Week 10 2. Was blood sampling completed? ^[2] <input type="radio"/> 1 No (complete Q2a, initial and date form) <input type="radio"/> 2 Yes (continue to Q3) 2a. Reason not done ^[3] <input type="radio"/> 1 Scan not done <input type="radio"/> 88 Other, specify _____ ^[4] 3. Date of imaging / blood sampling ^[5] _____ (mm-dd-yyyy)	Part I. Preparation for Blood Sampling <input type="checkbox"/> 1. Check box to confirm that clocks were synchronized to the PET scanner prior to performing procedures ^[6] Well Counter calibration factor 2. CF Value _____ • _____ uCi/cpm ^[7] 3. Date of calibration _____ ^[8] (mm-dd-yyyy) <input type="checkbox"/> 4. Check box to confirm that blood sampling was done with the IV catheter NOT used for the [¹⁸ F] FLT injection ^[9]		
Part II. Blood Sampling All elements of this table are required. If any are checked unknown, complete a PR form.			
	15 minutes after start of emission scan (± 2 minutes)	30 minutes after start of emission scan (± 2 minutes)	60 minutes after start of emission scan (± 2 minutes)
Exact Time of Blood Draw <i>Military time</i>	_____ : _____ <i>hh:mm</i> ^[10] <input type="checkbox"/> Unknown ^[11]	_____ : _____ <i>hh:mm</i> ^[25] <input type="checkbox"/> Unknown ^[26]	_____ : _____ <i>hh:mm</i> ^[40] <input type="checkbox"/> Unknown ^[41]
Exact Start Time of Counting <i>Military time</i>	_____ : _____ . _____ <i>hh:mm:ss</i> ^[12] ^[13] <input type="checkbox"/> Check if seconds not recorded (leave seconds field blank) ^[14]	_____ : _____ . _____ <i>hh:mm:ss</i> ^[27] ^[28] <input type="checkbox"/> Check if seconds not recorded (leave seconds field blank) ^[29]	_____ : _____ . _____ <i>hh:mm:ss</i> ^[42] ^[43] <input type="checkbox"/> Check if seconds not recorded (leave seconds field blank) ^[44]
Weight of empty gamma tube	_____ . _____ <i>mg</i> ^[15] <input type="checkbox"/> Unknown ^[16]	_____ . _____ <i>mg</i> ^[30] <input type="checkbox"/> Unknown ^[31]	_____ . _____ <i>mg</i> ^[45] <input type="checkbox"/> Unknown ^[46]
Weight of filled gamma tube	_____ . _____ <i>mg</i> ^[17] <input type="checkbox"/> Unknown ^[18]	_____ . _____ <i>mg</i> ^[32] <input type="checkbox"/> Unknown ^[33]	_____ . _____ <i>mg</i> ^[47] <input type="checkbox"/> Unknown ^[48]
Background counts (empty well counter)	_____ . _____ <i>cpm</i> ^[19] <input type="checkbox"/> Unknown ^[20]	_____ . _____ <i>cpm</i> ^[34] <input type="checkbox"/> Unknown ^[35]	_____ . _____ <i>cpm</i> ^[49] <input type="checkbox"/> Unknown ^[50]
Gamma tube count (with blood sample)	_____ . _____ <i>cpm</i> ^[21] <input type="checkbox"/> Unknown ^[22]	_____ . _____ <i>cpm</i> ^[36] <input type="checkbox"/> Unknown ^[37]	_____ . _____ <i>cpm</i> ^[51] <input type="checkbox"/> Unknown ^[52]
Length of Counting	_____ . _____ <i>mm:ss</i> ^[23] <input type="checkbox"/> Unknown ^[24]	_____ . _____ <i>mm:ss</i> ^[38] <input type="checkbox"/> Unknown ^[39]	_____ . _____ <i>mm:ss</i> ^[53] <input type="checkbox"/> Unknown ^[54]
_____ ^[55] Initials of person(s) completing this form	_____ ^[56] Date form completed (mm-dd-yyyy)		

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Study Participant Preparation and Positioning

Please be aware of the following for the study participants:

- No deliberate fasting is required prior to injection.
- Encourage participants to be well hydrated prior to the scan.
- Blood glucose measurement is not required.
- Participant's height and weight must be measured using calibrated and medically approved devices (not verbally relayed by the participant).

Note: Serial scans of the same participant must be done on the same scanner for this study.

18F-FLT PET Imaging Protocol

Following are the steps for conducting the PET scan for the ACRIN 6689 study. To aid data entry, print out the TA, BS, EX and ITW forms along with the Well Counter Cross-Calibration spreadsheet prior to scanning. Enter data on paper forms for later entry in the respective Web form or spreadsheet.

Note: Exact time collection is key to the success of this protocol. A global time piece (e.g., a portable stop watch) should be used consistently as a standardized measuring tool throughout the trial for all time collection. The time piece will need to accurately record minutes, at the least, and preferably seconds as well. It will be used to collect time at dose counting, injection time, imaging start time, blood sampling time, and blood counting time.

1. Injection of ^{18}F -FLT

- Two IV catheter access lines (18 or 20 gauge is preferred) are placed, one in each arm – one for the FLT injection and the other for blood sampling during the scan.
- Intravenous injection of ^{18}F -FLT (0.07 mCi/kg = 2.59 MBq/kg and the maximum allowable radioactive dose 5.0 mCi = 185 MBq) into one arm infused over 1 minute with 90 minute dynamic PET imaging starting at the initiation of infusion.
- A saline flush should follow the ^{18}F -FLT injection.
- The exact time of calibration of the dose should be recorded using the study-designated standardized global time piece; the exact time of injection should be noted and recorded to permit correction of the administered dose for radioactive decay. In addition, any of the dose remaining in the tubing or syringe, or that was spilled during injection, should be recorded.
- Adverse events (AEs) should be solicited in an open-ended fashion (i.e., “How are you feeling?”) at this time.

2. FLT PET Imaging

- A single field-of-view 90 minute dynamic imaging sequence must begin with initiation of the ^{18}F -FLT infusion (see table in Excel spreadsheet).
- The participant should empty his/her bladder immediately before the acquisition of images.
- Participants should be imaged in the supine position with head immobilization. Head immobilization procedures for PET imaging are site-specific.
- An attenuation scan should be performed after emission scanning. The transmission scan should be a low-dose CT scan for the PET/CT or a transmission scan for the PET-only devices. The transmission scan type, length, etc. should exactly match that used in the calibration and qualification procedure.
- **Note:** “PET” may refer to PET, PET/CT, or MR-PET depending on the site.
- During the dynamic emission scan, three (3) venous blood samples are obtained at 15, 30, and 60 minutes. Blood must be drawn from the IV that was **not** used for the FLT injection. The exact time of the blood draws should be recorded using the standard global time piece for the study.

- Whole blood samples of 1mL each are counted in a multichannel gamma well counter that is calibrated in units of cpm/uCi (refer to Well Counter Cross-Calibration Instructions and Blood Sampling Procedures).
- The exact time that each blood sample is counted should be recorded using the global time piece.
- Blood activity is averaged and then expressed as uCi/mL, decay-corrected to the time of injection.

3. FLT PET Imaging Reconstruction Protocol

- The PET data are corrected for dead time, scatter, random, and attenuation using standard algorithms provided by the scanner manufacturer.

Image reconstruction is performed as specified in the ACRIN certification of the PET scanner.

Dynamic 6689 Sequence Excel Spreadsheet

	Frame Number	Start (Sec)	Duration (Sec)	End (sec)	Frame Duration (sec)	Number of Frames (sec)	Total Frame Duration (sec)	Blood Samples (min after Inj)
9								
10	1	0	5	5	5	15	75	15
11	2	5	5	10	15	5	75	30
12	3	10	5	15	30	5	150	60
13	4	15	5	20	60	4	240	
14	5	20	5	25	180	2	360	
15	6	25	5	30	300	15	4500	
16	7	30	5	35		46	5400	
17	8	35	5	40				
18	9	40	5	45				
19	10	45	5	50				
20	11	50	5	55				
21	12	55	5	60				
22	13	60	5	65				
23	14	65	5	70				
24	15	70	5	75				
25	16	75	15	90				
26	17	90	15	105				
27	18	105	15	120				
28	19	120	15	135				
29	20	135	15	150				
30	21	150	30	180				
31	22	180	30	210				
32	23	210	30	240				
33	24	240	30	270				
34	25	270	30	300				
35	26	300	60	360				
36	27	360	60	420				
37	28	420	60	480				
38	29	480	60	540				
39	30	540	180	720				
40	31	720	180	900				
41	32	900	300	1200				
42	33	1200	300	1500				
43	34	1500	300	1800				
44	35	1800	300	2100				
45	36	2100	300	2400				
46	37	2400	300	2700				
47	38	2700	300	3000				
48	39	3000	300	3300				
49	40	3300	300	3600				
50	41	3600	300	3900				
51	42	3900	300	4200				
	43	4200	300	4500				
	44	4500	300	4800				
	45	4800	300	5100				
	46	5100	300	5400				

PET Image Submission Requirements and Options

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

- Using ACRIN's image transfer application (TRIAD) (this is the preferred method)
- Express mailing images on a CD-ROM

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

TRIAD software for SFTP submission

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

Upon electronically submitting the PET images, sites should fax the Image Transmittal Worksheet (see "Image Transmittal Worksheet Instructions") to the ACRIN core laboratory at 215-923-1737 or e-mail it to aeg-7335@acr-arrrs.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 it with the media shipment.

Mail the images and worksheet to:

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

Image Transmittal Worksheet Instructions

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

PET images are required to be submitted to ACRIN after each time point (or visit) that must be 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.

Note: Print out ITW prior to scanning



ACRIN 6689 Imaging Transmittal Worksheet
 RANDOMIZED, PHASE II, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF
 CONVENTIONAL CHEMORADIATION AND ADJUVANT TEMOZOLOMIDE PLUS CEDIRANIB
 VERSUS CONVENTIONAL CHEMORADIATION AND ADJUVANT TEMOZOLOMIDE PLUS
 PLACEBO IN PATIENTS WITH NEWLY DIAGNOSED GLIOBLASTOMA

Instructions: Imaging exams should be submitted to the ACRIN-Image Management Center after each time-point/visit. A completed, signed Image Transmittal Worksheet MUST accompany all imaging exams submitted to ACRIN for each time-point. For exams submitted via the internet, complete this worksheet and e-mail to aopanowski@acr-arrs.org or fax to 215-923-1737. For exams submitted via media, complete this worksheet and include with the media shipment. Please affix a label to the jacket of the media to include: study name, site name, and case no., date of exam, time point, and type of imaging.

***Reminder for PET/CT imaging:** All PET exams should contain three trans-axial whole body series, attenuated and non-attenuated corrected PET and the CT images.
 For further information or questions contact the Image Management Center at ACRIN.

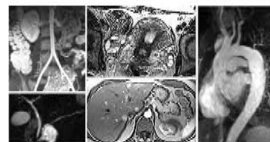
Section I: Image Data Demographics			
ACRIN Site Number: <input type="text"/>		ACRIN Case Number: <input type="text"/>	
Patient DOB: <input type="text"/> - <input type="text"/> -19 <input type="text"/>	Study Date <input type="text"/> - <input type="text"/> -20 <input type="text"/>	Patient Initials <input type="text"/> First M Last	
Image Submission: <input type="checkbox"/> FLT PET Scan <input type="checkbox"/> PET Technical Assessment Form (TA) <input type="checkbox"/> (EX) FLT Administration Form <input type="checkbox"/> Blood Sampling Form <input type="checkbox"/> Cross-Calibration Spreadsheet <input type="checkbox"/> Other _____			
Section II: Time point being submitted			
<input type="checkbox"/> Imaging Time Point 0 FLT PET Scan <input type="checkbox"/> Imaging Time Point 1 FLT PET Scan <input type="checkbox"/> Imaging Time Point 3 FLT PET Scan			
Section III: PET Scanner			
Image from an ACRIN Approved Scanner? <input type="checkbox"/> Yes <input type="checkbox"/> No Record Scanner Model and Station:			
Type of Scanner: <input type="checkbox"/> PET/CT <input type="checkbox"/> PET only <input type="checkbox"/> PET/MRI			
Institution Comments: 			
Form Completed By:	Phone:	Email:	Date:

ACRIN Image Management Center
 ACRIN 6689
 American College of Radiology
 1818 Market Street, Suite 1600
 Philadelphia, PA 19103

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.



Request for Additional Imaging Information

DATE of this request: _____

TO: _____ Inst.#: _____ Inst. Name: _____

FROM: _____ Subject: **ACRIN IMAGING QUERY RESPONSE REQUEST**
 Study No./Name.: **ACRIN 6689**

The above mentioned case from your institution is incomplete or requires a clarification. Kindly supply the missing images and/or subject information described, to make the case evaluable for final review. Please print this form and return to ACRIN via FAX to Adam Opanowski, CNMT, RT (N) FAX No. 215.923-1737

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

X	Case	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)	
[]				Digital Image files damaged. (**See Comments)	
[]				Poor Quality Films (**See Comments)	
[]				Incorrect Case # assigned to images (**See Comments)	
[]				Incorrect technical factors utilized (**See Comments)	
[]				Anatomy Not Covered (ANC) (**See Comments)	
[]				OTHER (**See Comments)	

ACRIN Comments:

SITE Comments:

Institution Representative: _____ Phone No.: _____ Email: _____