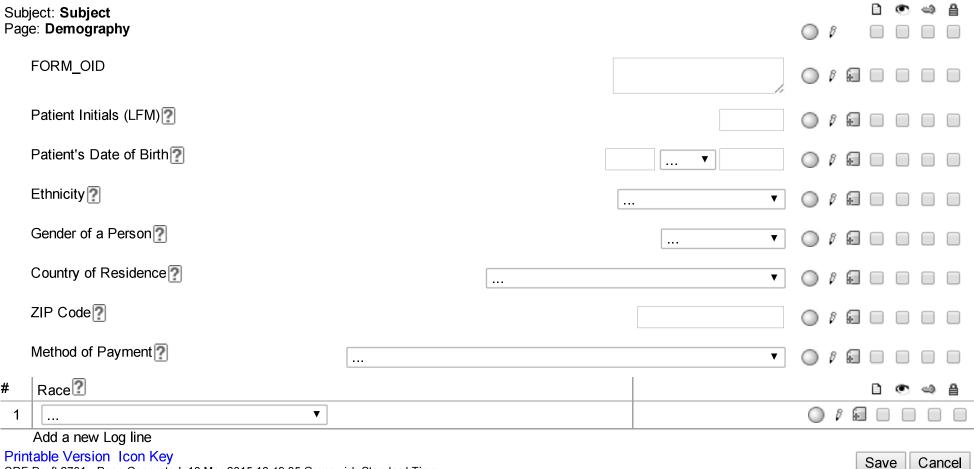
ACRIN 6702

Diffusion Weighted Imaging for Detection and Diagnosis of Breast Cancer

CRF Set

Subject: Subject Page: CT Image Transmittal Worksheet?				O 8	□ •	
Date of imaging	[🔻		O 8 🗊		
Date of imaging submission		🔻		O 8 🗊		
Mode of image submission			TRIAD sFTP Disk Hard Drive	O 8 6		
# PET data sets submitted	Select all that apply	Comments			₿€	⇔ 🔒
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	t: Subje DCE-MR	ct I Assess	ment																		O 8		• • • • • • • • • • • • • • • • • • •
IM	PORTA	NT REQU	JIREMENT	Γ:This for	n mus	t be s	igned	by th	e Radiolo	gist to co	onfirm that DCE	-MRI was revi	iewed before	DWI									
Da	ite of MF	RI scan																	🔻		0 8 6		
Re	ader Na	me?																			0 8 6		
Total number of BI-RADS 3,4 and 5 MRI-detected lesions that were not previously biopsied.																							
# Lesic	n Breast	: Quadran	Clock tposition	Distance from the nipple from nipple:	MRI finding type	ML Size	SI Size	AP Size	Shape ?	Margin <table-cell></table-cell>	Internal enhancement ?	NME Distribution	Internal enhancemen patterns ?	t T2 Signal	Initial kinetics ?	Delayed kinetics	Was Computer Added Detection (CAD) software used to assess kinetics?		Recommendation	Type of		D	● ⇔ 音
1 Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	O 8		
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Subject: Subject Page: DWI Central Assessment			O 8	•	
Date of MRI scan	v		000		
Total number of MRI-detected lesions that are BI-RADS 3, 4, or 5 based on DCE-MRI:			000		
DWI quality score:			000		
In which breast was normal fibroglandular tissue measured?		Right Left None	000		
Reason normal fibroglandular tissue was not measured?	Patient has fatty breasts; not sufficient fibroglandular tissue Suspicious enhancement throughout; no ritissue identified Patient has had prior mastectomy Image artifact in normal tissue regions Other	normal	O 8 6		
Provide the normal tissue ADC values					
Normal ADC b=0,100,600,800:			O 8 €		
Normal ADC b=0,800:			O 8 €		
Normal ADC b=0,600:			O 8 @		
Normal ADC b=0,100:			00		
Normal ADC b=100,600,800:			000		
Normal ADC b=100, 600:			000		
Normal ADC b=100, 800:			0 8 6		

Enter one log line for each study lesion with suspicion level of BI-RADS 3, 4 or 5 based on DCE-MRI

#	Lesion number ?	Breast	Quadrant		Is the lesion visible on DWI?	ADC b=0,100,600,800:	ADC b=0,800:	ADC b=0,600:	ADC b=0,100:	ADC b=100,600,800:	ADC b=100, 600:	ADC b=100, 800:		B ●	⇔ ≜
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	O 8		

Add a new Log line

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	e: DWI Loc		essment								0	₿				
	Was ADC	тар са	lculated w	ith all b-	values?]				O No O Yes	0	8 🖅				
	Provide the b-value combination used to calculate ADC map? ADC b=0,600 ADC b=0,800 ADC b=100,600,800 Other Enter one log line for each previously unbiopsied lesion with suspicion level of BI-RADS 3, 4 or 5 based on DCE-N							0	8 🖅							
	Lesion Number?			Clock	Is the	ADC 2	Did reviewing DWI	What is the	What is the post DWI recommendation?	Post DWI type of additional	RI		₿	•	۹	₽
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	0	₿				
rin	Add a new table Version	•										ſ	Sav	<u></u>	Car	ncel

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Subject: Subject

Page: Eligibility Checklist

FORM_OID

Date the informed consent was signed

Was the informed consent obtained from the patient?

Has the participant received chemotherapy in the last 6 months?

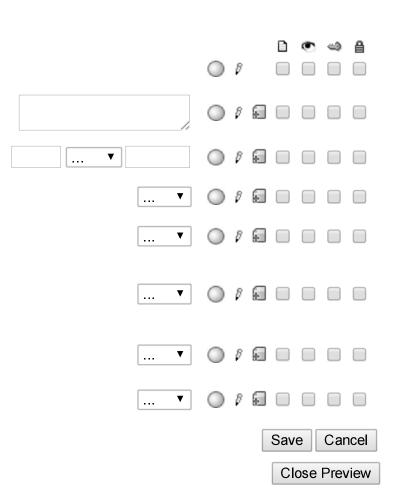
Does the patient have at least one MRI-detected lesion, which has not been previously biopsied, categorized as either BI-RADS 3, 4, or 5 based on DCE-MRI only (without reference to DWI)?

Did the participant complete a breast MRI examination with DWI that meets protocol criteria?

Is the participant scheduled to begin neoadjuvant chemotherapy before pathologic confirmation of lesion outcome?

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Subject: Subject Page: End of Study		O 8	,]
Date of disposition	▼	O 8)
Provide reason for study disposition by selecting one of the following	Protocol defined follow up completed Participant lost to follow up Participant refused follow up/withdrew Death Adverse Event/Side Effects/Complications Disease progression Study terminated by sponsor Protocol violation-did not meet eligibility Protocol violation-technical problems Protocol violation-related to study visits Protocol violation-related to imaging Protocol violation-related to randomization Other, specify	O 8)
Date of Death		O 8)
Cause of Death	Disease progressionOther, specify	0 8)
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	oject: Subje je: Follow		ging								0	₿				=	
	Was imagi follow-up t			oerformed	since last	study visit or				○ No ○ Yes	0	₿	•				
	Select the reason imaging was not done Not indicated							ant missed appointment ant unable to be located ant refused g physician's choice	0	₿	•						
	1 1	log lin	e for eac	I	I		- · 			I .							
#	Lesion number	Breast	Quadrant	1	Date of imaging	imaging	BI-RADS Assessment		vup mendation					•	٩	₽	
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	Add a new 27 Days 33 Days	v Log lir	ne							V	0		=				
	155 Days									Y	0		 				
	211 Days									v	0	₽	£				
	338 Days									▼	0	₽	•				
	394 Days									V	0	β	•				
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	ject: Sul e: Follo v		esion Dia	gnosis								0	₿				
						r each lesion reported , repeating the lesion i		E-MRI for	rm. For le	sions that u	nderwent p	atho	logic	al sa	mpl	ing,	
#	Lesion number	Breast	Quadrant	Clock position ?	from the nipple	Was a biopsy or surgery performed on this lesion that has not previously been reported to ACRIN?	Reason tissue sampling was not done?		Type of procedure	Type of image guidance used for tissue sampling	Procedure findings	,			•	4	≜
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	0	₿				
	Add a n	_	line														
	27 Days	•							1	7			8 🗊				
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Form Preview

3/16/2015

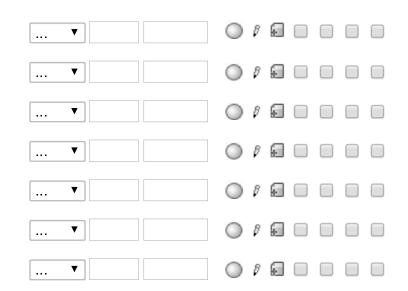
Subject: Subject Page: Follow up-Participant Status		O 8	
Was follow-up information obtained for this time-point?	○ No ○ Yes	000	
Reason follow-up information was not obtained:			
Unable to contact participant's treating physician		000	
Unable to contact participant's family member or participant proxy		000	
Unable to review participant's medical record		000	
Unable to contact the participant		000	
Source of information used to obtain participant data for this form: $oxed{?}$			
Site physician		O 8 @	
Outside physician/hospital		O 8 @	
Family		000	
Medical record		000	
Cancer registry		000	
Participant		000	
What was the method of contact?	○ Office visit ○ Telephone ○ Mail	000	
Date the data was obtained	▼	000	
Participant vital status	○ Alive ○ Dead ○ Unknown ○ Unspecified	000	
Date participant last known to be alive ?	 ▼	O 8 9	

Date of death ? 27 Days 33 Days 155 Days 211 Days 228 Days

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394 Days

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Save Cancel

Subject: Subject Page: Lost to Follow-Up										• •	
	FORM_OID						O 8	•			
	Patient Lost to Follow-Up										
	Was the study participant unable to be oper defined criteria?	ontacted for follow-up				O No Yes	08				
	Date of last contact			•			O 8				
#	Methods of Contact	Date of most recent attempt								.	∌ ≜
1	Data	Data					0 8	3			
	Add a new Log line										
	Study Participant Found										
	Was a study participant previously deem to be contacted?	ned lost to follow-up able				O No Yes	O 8	•			
	Date most recent contact			▼			O 8	•			
	Lost to Follow-Up Internal Review										
	Study participant lost to follow-up approve	ved?				No Yes	() B				
	Date of Approval			•			O 8	•			
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Sub	oject: Subject			[•) 4	a			
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	Add a new Log line									
	COMMENTS				0	8 9				
	Name of Technologist			//	0	0 9				
	Technologist phone number			0	0 6					
	Technologist email		0	8 8						
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Subject: Subject Page: MRI Clinical Indication		O 8			
Clinical indication for MRI (Check all that apply):					
Evaluate extent of disease for known breast cancer		0 8 🗊			
Further evaluation of lesion detected on other imaging		0 8 1			
Further evaluation of palpable lesion		O 8 🗊			
Short interval follow-up MRI		08			
Screening due to personal history of breast cancer		08			
Screening due to genetic risk or family history of breast cancer		08			
Evaluate implant integrity		08			
Known malignant axillary adenopathy, unknown primary		08			
Other		08			
Specify Indication	/ı	08			
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Subject: Subject Page: Other Image Transmittal Worksheet ?						0	8				
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	Date of imaging submission		[▼		0	8 🗊			
	Mode of image submission					TRIAD sFTP Disk Hard Drive	0	8 🖬			
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	Name of Technologist					h	0	8 🗐			
	Technologist phone number						0	8 🗊			
	Technologist email						0	8 🗊			
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	COMMENTS			//	0	8 🗊				
	Name of Technologist			//	0	8 🗊				
	Technologist phone number				0	8 🗊				
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