A0 ACRIN 6659 Registration/Eligibility

ACRIN Study 6659
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: For potential study participants, Part 2 must be completed before Part 1.

If any of the answers, for **Part 2**, vary from the prompts provided at the start of each question, the patient is **ineligible** and should **not** be enrolled in **ACRIN 6659**. If all answers for **Part 2** correspond with the prompts, and the patient is **eligible**, then proceed with **Part 1**. **Part 1** questions are prompted at the time of on-line case registration.

Part 1: The following questions will be asked at the on-line Case Registration

_____ **1. Name of institutional person registering this case?** *(Initials only, please)*

_____ **(Y) 2. Has the Eligibility Checklist been completed?**

_____ **(Y) 3. Is the participant eligible for this study?**

____ - ____ - _____ **4. Date the study-specific Consent Form was signed** *(Must be prior to study entry)*

_____ **5. Participant Initials** *(Last, First)*

_____ **6. Verifying Physician** *(Site PI)*

_____ **7. Participant's ID Number** *(Do Not utilize a medical record number or radiology assigned number)*

____ - ____ - _____ **8. Date of Birth** *(mm-dd-yyyy)*

_____ **9. Ethnic Category**

1 Hispanic or Latino
2 Not Hispanic or Latino
9 Unknown

_____ **10. Race**

1 American Indian or Alaskan Native
2 Asian
3 Black or African American
4 Native Hawaiian or other Pacific Islander
5 White
6 More than one race
9 Unknown

_____ **(M/F) 11. Gender** *(default to **male**)*

_____ **12. Participant's Country of Residence**

1 USA
2 Canada
3 Other

_____ **13. Zip Code** *(U.S. Residents)*

_____ **14. Participant's Insurance Status**

0 Other
1 Private Insurance
2 Medicare
3 Medicare and Private Insurance
4 Medicaid
5 Medicare and Medicaid
6 Military or Veterans Administration
7 Self Pay
8 No Means of Payment
9 Unknown/Decline to answer

_____ **(N/Y) 15. Will any component of the Participant's care be given at a military or VA facility?**

____ - ____ - _____ **16. Calendar base date** *(mm-dd-yyyy)*

____ - ____ - _____ **17. Registration date** *(mm-dd-yyyy)*

_____ **18. Other country of residence, specify** _____

A0

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part 2: The following questions are to determine patient eligibility:

_____ **(Y) 19. Biopsy proven adenocarinoma of the prostate.**

____ - ____ - _____ **20. Date of prostate biopsy *(mm-dd-yyyy)***

_____ **(Y) 21. Written documentation from the Urologist confirming the scheduled date of the radical prostatectomy at the study site is within 6 months MRI/MRSI.**

____ - ____ - _____ **22. Projected date of surgery (scheduled radical prostatectomy)**

_____ **(Y) 23. The interval between the diagnostic biopsy and the MRI/MRSI is ≥ 6 weeks.**

____ - ____ - _____ **24. Projected date of MRI/MRSI**

_____ **(N) 25. Known contraindications for patient to undergo MRI/MRSI?**
(cardiac pacemakers, non-compatible intracranial vascular clips, metallic hip replacement or other metallic implants in the pelvic area, contraindications to endorectal coil insertion, allergic to latex, etc.)

_____ **(N) 26. Prior cryosurgery, surgery for prostate cancer including TURP, prostatic radiotherapy, rectal surgery, androgen deprivation therapy or complementary alternative medicine?**

_____ **(Y) 27. Patient has agreed to undergo Fleet's enema in preparation for MRSI exam.**

_____ **(Y) 28. Pathologic specimens from radical prostatectomy are available for central pathology analysis**

_____ **(Y/N) 29. Release for medical information consent signed by participant**

For any questions regarding eligibility, contact ACRIN Data Management at 1-800-227-5463.

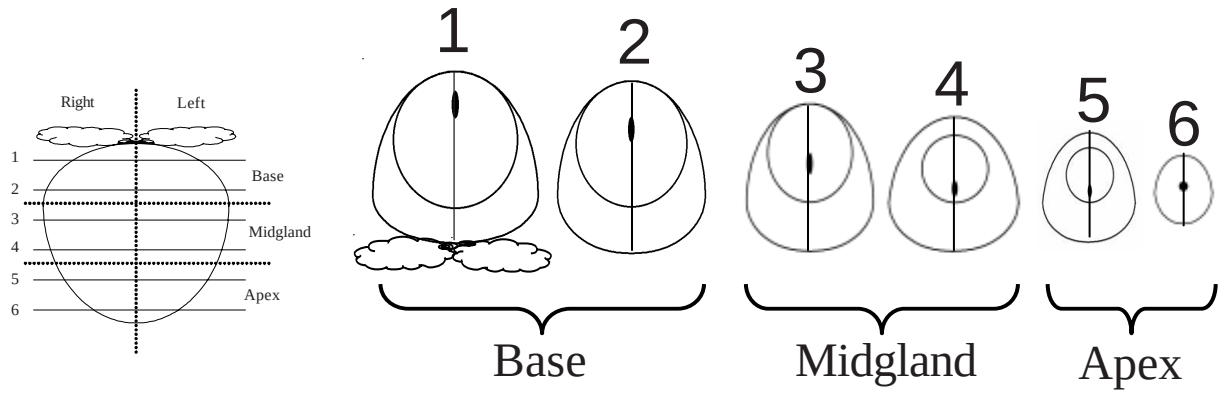
_____ _____-_____-_____

Signature of person responsible for the data [1] Date form completed (mm-dd-yyyy)

_____

Signature of person entering data onto the web [2]

APPENDIX V DIAGRAM OF THE PROSTATE



A C R I N

American College of Radiology Imaging Network

MR Imaging and MR Spectroscopic Imaging of Prostate Cancer Prior to Radical Prostatectomy

Contact Information

ACRIN Study 6659

Protocol Manager:

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ACRIN 6659
American College of Radiology
1101 Market Street, 14th Floor
Philadelphia, PA, 19107

Data Management: Jo-Ann D'Amato

I1

ACRIN 6659
Initial Clinical Evaluation Form

ACRIN Study **6659**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Complete this form for all **6659** participants within **1 week** of registration. All dates are recorded mm/dd/yyyy. This form is to be completed by the RA and submitted via the ACRIN website.

For revised or corrected form: check box and fax to 215-717-0936. ☐

General Information

1. Date of MRI/MRSI _____-_____-_____ (mm-dd-yyyy)

2. Most recent PSA value before biopsy ____

3. Date of PSA: _____-_____-_____ (mm-dd-yyyy)

4. Is the patient currently taking Complementary Alternative Medicine (CAM)?

____

1 No
2 Yes*
99 Unknown

***If yes, specify:** _____

4a. Start date of CAM therapy _____-_____-_____ (mm-dd-yyyy)

4b. End date of CAM therapy (if continuing leave blank) _____-_____-_____ (mm-dd-yyyy)

4c. Dosage _____

5. Has the patient had a prior history of hormone therapy?

____

1 No
2 Yes*
99 Unknown

***If yes, specify:** _____

5a. Prior hormonal therapy end date _____-_____-_____ (mm-dd-yyyy)

6. Has the patient had prior surgery for bladder cancer, prostate cancer, including TURP, prostatic radiotherapy, radiotherapy for rectal cancer, or Androgen deprivation therapy?

____

1 No
2 Yes*

***If yes, specify:** _____

7. Is the patient allergic to latex?

____

1 No
2 Yes
99 Unknown

I1 Revision ☐

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Histopathologic Information

8. Date of biopsy which confirmed malignancy: ____-____-____ (mm-dd-yyyy)

9. Indicate the method of malignancy confirmation:

☐

1 Needle biopsy
2 TURP
3 Other
99 Unknown

If other, specify: _____

10. Indicate histologic type:

☐

1 Adenocarcinoma
2 Other
99 Unknown

If other, specify: _____

11. Indicate histologic grade:

☐

1 GX Grade cannot be assessed
2 G1 Well differentiated (slight anaplasia) (Gleason 2-4)
3 G2 Moderately differentiated (moderate anaplasia) (Gleason 5-6)
4 G3-4 Poorly differentiated/undifferentiated (marked anaplasia) (Gleason 7-10)

12. Gleason Score - Primary Pattern

☐

Grade 1-5 99 = Unknown

13. Gleason Score - Secondary Pattern

☐

Grade 1-5 99 = Unknown

14. Gleason Score, Combined (sum of the primary and secondary, unless unknown)

☐

99 = Unknown

I1 Revision ☐

ACRIN Study **6659**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

15. Location of Positive Biopsy (check all that apply)

☐ Right Base ☐ Left Base
☐ Right Midgland ☐ Left Midgland
☐ Right Apex ☐ Left Apex

16. T ☐ **Indicate the Clinical T Staging:**

Primary Tumor (T)

1 TX
2 TO
3 T1
4 T1a
5 T1b
6 T1c
7 T2
8 T2a
9 T2b
10 T3
11 T3a
12 T3b
13 T4

17. Projected date of the Radical Prostatectomy _____-_____-_____ (mm-dd-yyyy)
(within **6** months of MRI/MRSI)

COMMENTS: _____

_____

_____

_____ Date form completed ____-____-_____ (mm-dd-yyyy)

Signature of person responsible for the data [1]

_____

Signature of person entering data onto the web [2]

A C R I N

American College of Radiology Imaging Network

MR Imaging and MR Spectroscopic Imaging of Prostate Cancer Prior to Radical Prostatectomy

Forms Package index

ACRIN Study 6659

Form		Version Date
AO	Registration Form	02-26-03
I1	Initial Evaluation Form	03-21-03
M3	MRI/MRSI Imaging Technical Form	02-05-04
PC	Pathology Slide Submission Form	12-11-02
P4	Central Pathology Form	08-19-04
QA	Quality Assurance MRSI Form	06-17-04
PR	Protocol Variation Form	07-24-03

M3 **ACRIN 6659**
MRI/MRSI Imaging Technical Form

ACRIN Study 6659
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: The study designated Radiologist is to complete this form for all study participants within 1 **week** of the **MR/MRSI** exam.
Note: **Part 1 MUST** be completed prior to **Part 2**. Record all dates in mm-dd-yyyy format. Submit completed form to **ACRIN** HQ, Data Management.

Part 1: MRI *ONLY*

1a. Date of MRI: |__|__|-|__|__|-|__|__|__|__| (mm-dd-yyyy)

2. Was MRI completed?
1 No*
2 Yes

2b. *If no MRI, indicate the reason:
1 Technical problems with MRI system
2 Claustrophobia
3 Other, specify:_____

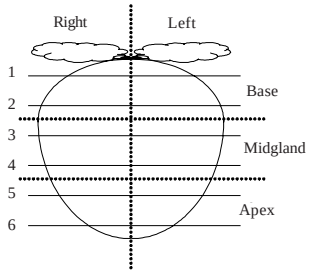
2c. Did MRI parameters follow the protocol?
1 No
2 Yes

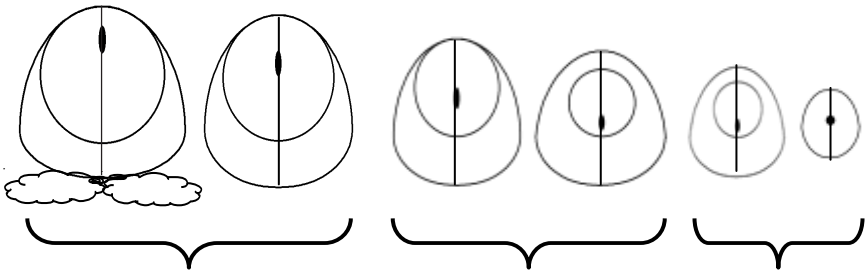
2d. MR image quality:
1 excellent
2 good
3 poor, reason_____
9 non-diagnostic

3. Which sextants, contain post-biopsy hemorrhage (irregular areas of increased signal on T1 images):
(Check **all** that apply)

- ☐ No sexants contain hemorrhage
- ☐ Left Apex (LA)
- ☐ Left Midgland (LM)
- ☐ Left Base (LB)
- ☐ Right Apex (RA)
- ☐ Right Midgland (RM)
- ☐ Right Base (RB)
- ☐ All sexants contain hemorrhage
- ☐ Unable to determine

4. Based on MRI, draw, number (to a maximum of 4) and label all suspected peripheral zone malignant foci on the schematic diagram of the prostate shown below. These pictures are to be used as reference only, and in conjunction with the diagram. Please note that use of the diagram allows for foci to cross sextants.





Base Midgland Apex

Table Positions: _____ **Table Positions:** _____ **Table Positions:** _____

Imaging site to enter slice locations for anatomical slices viewed in each area.

Comments: _____

_____

5. Based on MRI Images alone, indicate below your "confidence in the presence of malignant foci", "the probability of malignant foci presence" and the size of malignant foci. A response is required for each sextant.

The probability of malignant foci presence is meant to be a subjective reader-specific measure, representing the reader's belief or confidence that foci are present.

If no foci are seen, please enter 1 for the "confidence rating" and 0 for the "probability of foci presence".

Note: It is important for each reader to be consistent across patients, i.e., rather than trying to determine a probability scale that produces similar results across readers (for the same patient), the main objective is to obtain a probability scale with strong validity at the reader level. Hence, readers should use their previous values as reference when determining the "probability of malignant foci presence" for each sextant.

	Confidence In presence of Malignant Foci		Probability of Malignant Foci Presence (100% = highest probability)	Maximum Axial diameter of Malignant Foci (mm)
Left Apex (LA)	___	**Confidence Scale** 1 Definitely not present 2 Probably not present 3 Indeterminate 4 Probably present 5 Definitely present	___ ___ ___ %	___ ___ ___
Left Midgland (LM)	___		___ ___ ___ %	___ ___ ___
Left Base (LB)	___		___ ___ ___ %	___ ___ ___
Right Apex (RA)	___		___ ___ ___ %	___ ___ ___
Right Midgland (RM)	___		___ ___ ___ %	___ ___ ___
Right Base (RB)	___		___ ___ ___ %	___ ___ ___

6. Date of MR Interpretation: ___ ___-___ ___-___ ___ ___ ___ (mm-dd-yyyy)

7. Reader ID: ___ ___ ___ ___ ___ ___ ___

Part 2: MRI/MRSI Imaging

8. Date of MRI/MRSI: |__|__|-|__|__|-|__|__|__|__| **(mm-dd-yyyy)**

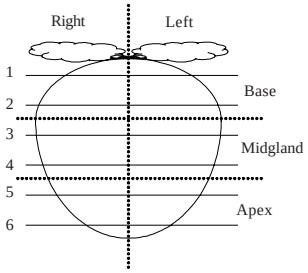
9a. |__| **Was MRSI completed?**
1 No *
2 Yes

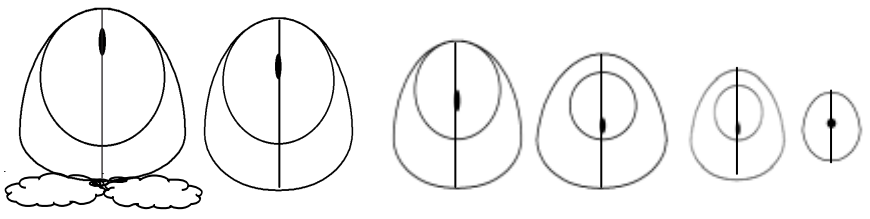
9b. |__| ***If no MRSI, indicate the reason:**
1 Technical problems with PRESS/PROSE package
2 Claustrophobia
3 Other, specify: _____

9c. |__| **Did MRSI parameters follow protocol?**
1 No
2 Yes

9d. |__| **MRSI image quality:**
1 excellent
2 good
3 poor, reason _____
9 non-diagnostic

10. Based on combined MRI/MRSI, a maximum of four (4) foci must be drawn in the diagrams presented to the left of the pictures labeled Base, Midgland, and Apex. These pictures are to be used as reference only, and in conjunction with the diagram. Please note that use of the diagram allows for foci to cross sextants.





Base | Midgland | Apex

Table Positions: _____ **Table Positions:** _____ **Table Positions:** _____

Imaging site to enter slice locations for anatomical slices viewed in each area.

11. Based on the review of combined MRI/MRSI images combined, fill in the appropriate values within each sextant. A response is required for each sextant. Ratio values must be entered for all sextants, even if a sextant is considered tumor free, please be sure to provide the maximum ratio that could possibly represent abnormal tissue in that sextant.

	Total Number of Probably/Definitely Abnormal Voxels	Maximum Choline to Creatine Ratio (C:C)	Maximum Choline+Creatine to Citrate Ratio (C+C:C)	Maximum Axial diameter of Malignant Foci (mm)
Left Apex (LA)	___	___ . ___	___ . ___	___
Left Midgland (LM)	___	___ . ___	___ . ___	___
Left Base (LB)	___	___ . ___	___ . ___	___
Right Apex (RA)	___	___ . ___	___ . ___	___
Right Midgland (RM)	___	___ . ___	___ . ___	___
Right Base (RB)	___	___ . ___	___ . ___	___

12. Based on the review of combined MRI/MRSI images combined, fill in the appropriate values within each sextant. A response is required for each sextant.

The probability of malignant foci presence is meant to be a subjective reader-specific measure, representing the reader's belief or confidence that foci are present.

If no foci are seen, please <u>enter</u> 1 for the "confidence rating" and 0 for the "probability of foci presence".

Note: It is important for each reader to be consistent across patients, i.e., rather than trying to determine a probability scale that produces similar results across readers (for the same patient), the main objective is to obtain a probability scale with strong validity at the reader level. Hence, readers should use their previous values as reference when determining the "probability of malignant foci presence" for each sextant.

	Confidence In presence of Malignant Foci	Probability of Malignant Foci Presence (100% = highest probability)
Left Apex (LA)	___	___ %
Left Midgland (LM)	___	___ %
Left Base (LB)	___	___ %
Right Apex (RA)	___	___ %
Right Midgland (RM)	___	___ %
Right Base (RB)	___	___ %

<u>Confidence Scale</u>
1 Definitely not present
2 Probably not present
3 Indeterminate
4 Probably present
5 Definitely present

13. Date of MRI/MRSI Interpretation: __-__-____ (mm-dd-yyyy)

14. Reader ID: _____

Comments: _____

_____

_____

_____

Signature of person responsible for the data [1]

_____-_____-_____

Date Form Completed (mm-dd-yyyy)

_____

Signature of person entering data onto the web [2]

MX

ACRIN 6659
Consensus Review Form

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Form is completed by consensus reviewers.

MR Diagram	*Pathologic cancer present*	*Pathologic sextants*	*Pathologic tumor size- long axis mm*	*Pathologic tumor size- short axis mm*	*Pathologic long axis (u)*	*Pathologic short axis (u)*	*Scale mm*	*Scale (u)*	
Left Apex (LA)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	☐☐	☐☐					
Left Midgland (LM)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	☐☐	☐☐					
Left Base (LB)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	☐☐	☐☐					
Right Apex (RA)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	☐☐	☐☐					
Right Midgland (RM)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	☐☐	☐☐					
Right Base (RB)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	☐☐	☐☐					

1. Spectral Quality:

- o 1
- o 2
- o 3
- o 4
- o 5

2. Consensus Hemorrhage:

- o No
- o Yes

3. TZ Cancer:

- o No
- o Yes
  - o Not Dominant
  - o Dominant

MX

ACRIN 6659
Consensus Review Form

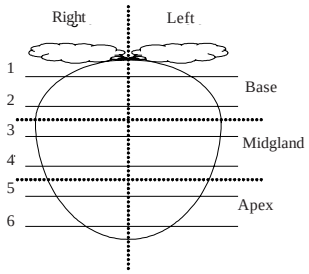
ACRIN Study **6659**

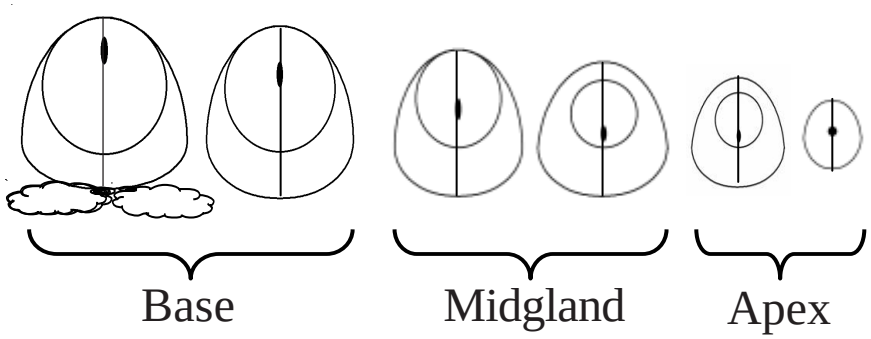
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

MRI





Base
Image slice range

		–					

From **To**

Slice Position

O S
O I _____ **to** O S
O I _____

Midgland
Image slice range

		–					

From **To**

Slice Position

O S
O I _____ **to** O S
O I _____

Apex
Image slice range

		–					

From **To**

Slice Position

S
I _____ **to** O S
O I _____

Comments:

_____

_____

_____

_____

MX

ACRIN 6659
Consensus Review Form

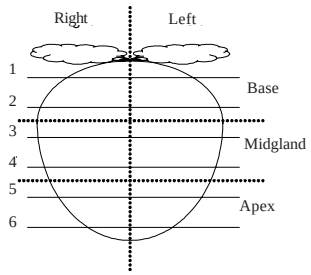
ACRIN Study 6659

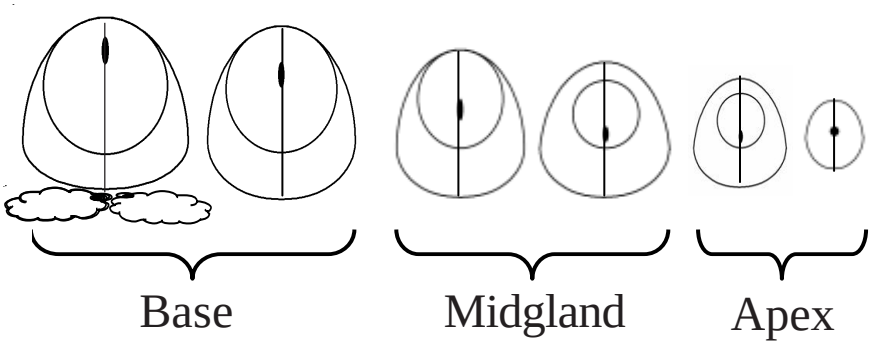
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

MRS





Base
Image slice range

__ __ – __ __

From **To**

Slice Position

OS OI _____ **to** OS OI _____

Midgland
Image slice range

__ __ – __ __

From **To**

Slice Position

OS OI _____ **to** OS OI _____

Apex
Image slice range

__ __ – __ __

From **To**

Slice Position

S I _____ **to** OS OI _____

Comments:

_____

_____

_____

_____

Pathologist signature: _____

Radiologist signature: _____

Radiologist signature: _____

Radiologist signature: _____

Statistician signature: _____

Date of Consensus Review: _____ / _____ / _____
mm dd yyyy

_____ _____-_____-_____
Form Entered By *Date Form Entered (mm-dd-yyyy)*

MX ACRIN 6659 Consensus Review Form

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Form is completed by consensus reviewers.

MR Diagram	Pathologic cancer present	Pathologic sextants	Pathologic tumor size- long axis mm	Pathologic tumor size- short axis mm	Pathologic long axis (u)	Pathologic short axis (u)	Scale mm	Scale (u)	
Left Apex (LA)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	___	___					
Left Midgland (LM)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	___	___					
Left Base (LB)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	___	___					
Right Apex (RA)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	___	___					
Right Midgland (RM)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	___	___					
Right Base (RB)	☐ No ☐ Yes	☐ LA ☐ RA ☐ LM ☐ RM ☐ LB ☐ RB	___	___					

Pathologist signature:	**Comments:**
Radiologist signature:	**Comments:**
Radiologist signature:	**Comments:**
Radiologist signature:	**Comments:**
Statistician signature:	**Comments:**

Date of Consensus Review: _____ / _____ / _____
mm dd yyyy

_____ _____-_____-_____

Form entered by [1] Date form entered (mm-dd-yyyy)

MX

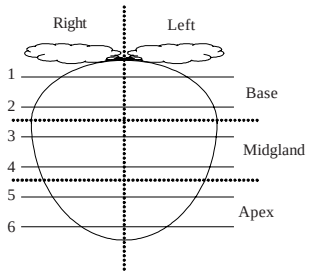
ACRIN 6659
Consensus Review Form

ACRIN Study **6659**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____



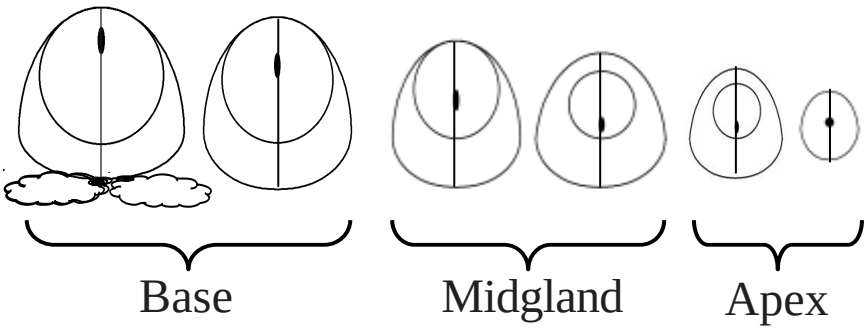


Image slice range

|_|_| – |_|_|

Slice Position

O S
O I _____

Image slice range

|_|_| – |_|_|

Slice Position

O S
O I _____

Image slice range

|_|_| – |_|_|

Slice Position

O S
O I _____

Comments:

_____

_____

_____

_____

P4 ACRIN 6659
Central Pathology Evaluation Form

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Complete this form for all **6659** participants within **4 weeks** of recipient of specimens. All dates are recorded mm-dd-yyyy.

For revised or corrected form, check box and fax to 215-717-0936. ☐

1. Date of Radical Prostatectomy: _____-_____-_____ (mm-dd-yyyy)

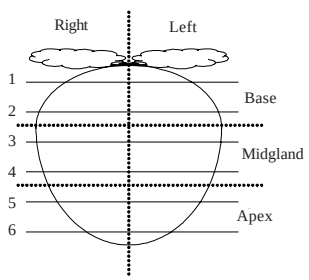
2. Indicate combined Gleason Score (e.g., 3+3=6) for each anatomic area, also level of PCI, Tumor Location, and Surgical Margins.

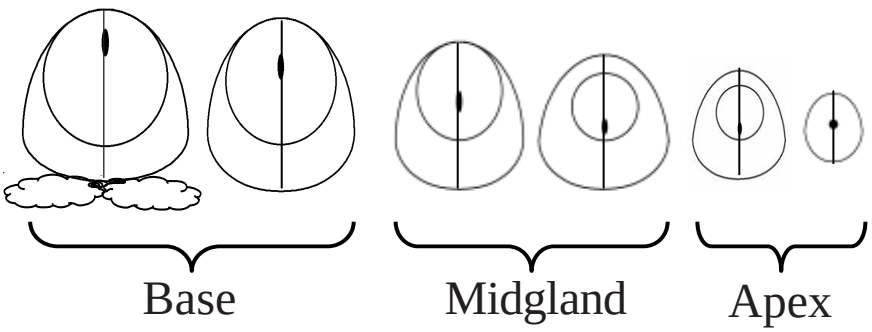
	Gleason Score	Level of PCI (Extra Capsular Extension)	Tumor Location	Surgical Margin
Left Apex (LA)	____	____	____	____
Left Midgland (LM)	____	____	____	____
Left Base (LB)	____	____	____	____
Right Apex (RA)	____	____	____	____
Right Midgland (RM)	____	____	____	____
Right Base (RB)	____	____	____	____

Table Code Instructions

*A response of **"0"** is required for **No** cancer or tumor.

Gleason Score	Level of PCI	Tumor Location	Surgical Margin
0 No Cancer (2-10) 98 Cannot be assessed 99 Unknown	0 No Tumor 1 Level 0 or 1 2 Level 2 3 Level 3 Focal 4 Level 3 Established	0 No Tumor 1 Anterior 2 Posterior 3 Both	0 No Tumor 1 Negative Margin 2 Positive Margin





P4 Revision ☐

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Prostate Tumor

3. ___ Seminal vesicle invasion?

1 No
2 Yes, unilateral
3 Yes, bilateral
99 Unknown

4. ___ Indicate histologic type:

1 Adenocarcinoma
2 Other, specify: _____
99 Unknown

5. pT ___ Indicate Primary Pathologic Stage:

1	pT2	Organ confined
2	pT2a	Unilateral, involving one-half of one lobe or less
3	pT2b	Unilateral involving more than one-half of one lobe but not both lobes
4	pT2c	Bilateral disease
5	pT3	Extraprostatic extension
6	pT3a	Extraprostatic extension Positive surgical margin should be indicated by an R1 descriptor (residual microscopic disease)
7	pT3b	Seminal vesicle invasion
8	pT4	Invasion of bladder, rectum
99		Unknown

6. ___ Disagreement Impacting Clinical Care

1 No
2 Yes*

* Please fax letter of notification to **Protocol 6659** (include Case No. and Institution Site No.) ACRIN Data Management @ 215-717-0936

COMMENTS: _____

_____

_____

_____ Date form completed ____-____-_____ (mm-dd-yyyy)

Signature of person responsible for the data [1]

PC ACRIN 6659
Pathology Submission Form

Study # 6659 | **Case#_____**

If this is a revised or corrected form, please ✓ box. ☐

Institution | **Institution #**

Patient | **Patient I.D.**

INSTRUCTIONS: This form must be completed and mailed with the Pathology Specimens whenever slides are sent. All **slides** must be sent with the **Pathology Transmittal Form (PC)**. At the time of shipment, a copy of the **PC** form and the **PI** (pathology report) should also be **faxed** to **ACRIN Data Management at 215-717-0936**.
*Specimens need to be labeled with the **ACRIN Study and Case Number**.

☐ **DE**

Lesion Type*	Procedure Date	Number of Slides	Slide ID	Pathology Specimen#
	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			

***Type**
1 Index Lesion
2 Lesion 2
3 Lesion 3
4 Lesion 4

REQUIRED ENCLOSURES:

_____**Pathology Report(s) (to ACR)**

_____**Slides (see Protocol Sec. 11.5)**

*** Fax to ACR copy of this form and Pathology reports.**

SEND TO:
Thomas Wheeler, M.D.
ACRIN Study 6659
The Methodist Hospital
Deputy Chief / Pathology Service
6565 Fannin, MS 205
Houston, TX 77030

SUBMITTED BY:_____

TELEPHONE NO:(_____)_____

PR

ACRIN 6659
MR Imaging and MR Spectroscopic Imaging of Prostate Cancer Prior to Radical Prostatectomy
Protocol Variation Form

ACRIN Study **6659**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Patient Initials _____ **Case No.** _____

Instructions: In the instance a protocol requirement is not met please record the necessary information below. Complete a separate form for each case and for each instance. Retain the form in the case study file. Fax a copy to ACRIN Headquarters at (215) 717-0936. Data Management will note this information in the database to prevent multiple queries.

1. Check The Protocol Event Being Reported: (report only one per form)

- ☐ Participant completed study activity before signing consent
- ☐ Participant withdrew study consent, provide documentation
- ☐ Patient did not follow enema administration prior to Imaging
- ☐ Radical Prostatectomy not able to be scheduled within 6 months of Imaging
- ☐ Participant not able to tolerate endorectal coil insertion for imaging
- ☐ Participant not able to complete Imaging portion of study
- ☐ Other, specify _____

2. Describe The Protocol Event Reported Above _____

Research Associate

Date form completed ___-___-200 **(mm-dd-yyyy)**

HQ Code

HQ Research Associate

QA **ACRIN 6659**
Quality Assurance Form

ACRIN Study 6659

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Phantom QA Spectroscopy

I. Record the following, after the Auto Prescan:

Water linewidth-FWHM: (phantoms =2 Hz):

A) Flip Ang (water suppression flip angle): _____

B) SuppLvl (percent of residual water) _____

C) R1 _____, R2 _____, TG _____, AX_____

II. Record the following shims located in Spectro Prescan page:

X _____, Y _____, Z _____ Shim Values

III. Go to Browser menu, view spectral dataset and record the following:

	S/N (calculated by scanner)	**RATIO**
NA		
Cr		<**REF** ** >
Ch		
H_2O		

**** The signal to noise ratio of creatine should be ≥90 to 1. If not, check with your service engineer.**

_____

Signature of person responsible for the data [1]

Date form completed ____-____-_____
(mm-dd-yyyy)