

MrOS Prostate Cancer Adjudication Form

Draft

MrOS ID#	Acrostic	Staff ID#	Form completed by:
P1ID	P1ACROST	P1STAFF	<input type="radio"/> Clinical Center <input type="radio"/> Coordinating Center

1 Was prostate cancer diagnosed? Yes No → Go to question #13, page 2.

2 Date of prostate cancer diagnosis: / /
Month Day Year

3 Why was prostate cancer suspected? (Mark only one)

Symptoms Rising PSA No documentation
 Abnormal (high) PSA Low free PSA % Abnormal tests -- other. Please specify:
 Abnormal prostate exam Not suspected

4 Primary Method for confirmation of prostate cancer: (Mark all that apply)

Biopsy of the prostate TRUS of the prostate
 Biopsy of distant site Other method, please specify:

5 Diagnostic Confirmation:

Microscopically confirmed:

Positive histology (pathology)
 Positive exfoliative cytology (no positive histology)
 Positive histology (pathology), (distant metastatic site only)
 Positive microscopic confirmation, method not specific

Not microscopically confirmed:

Positive laboratory test/marker study (e.g. elevated PSA or acid phosphatase)
 Direct visualization w/out microscopic confirmation
 Radiography and other imaging techniques without microscopic confirmation
 Clinical diagnosis only

Confirmation unknown:

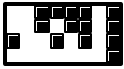
Unknown if microscopically confirmed

6 Were Gleason Scores available? Yes No

Record Gleason Scores:			Date Gleason Scores determined:		
P1GLEA1	+	P1GLEA2	=	P1GLEAS	P1GLEADT /
Histologic Gleason Score 1 (1-5)		Histologic Gleason Score 2 (1-5)		Gleason Sum	Month Day Year
					Source:

7 Was histologic stage available?

Yes → Record Histologic stage: Well differentiated Poorly differentiated/Undifferentiated
 No Moderately differentiated Unknown tumor histology



MrOS Prostate Cancer Adjudication Form



Draft

MrOS ID#	Acrostic	Form completed by:
<input type="text"/> <i>P2ID</i>	<input type="text"/> <i>P2ACROST</i>	<input checked="" type="radio"/> Clinical Center
		<input checked="" type="radio"/> Coordinating Center

P2AC

8 Staging of Tumor. Yes → *P2NSTAGE*
 Is staging known? No *P2STGA*
 T = *P2TSTAGE* N = M = *P2MSTAGE*

9 Type of cancer diagnosed: Adenocarcinoma Other →
P2CATYPE

10 Were any of the following imaging/laboratory studies used to evaluate prostate cancer diagnosis? (Mark all that apply)

- P2PAP* PAP (prostatic acid phosphates)
- P2TRUS* TRUS (transrectal ultrasound)
- P2CT* CT
- P2MRI* MRI
- Bone scan *P2BSCAN*
- No Imaging Study done *P2NOIMG*
- Other, please specify: *P2IMGOTH*
- No documentation *P2IMGND*

11 What was the initial treatment of the tumor (within 6 months of diagnosis)? (Mark all that apply)

- P2RADPCT* Radical prostatectomy
- P2EBRT* External beam radiation therapy
- P2BRAC* Brachytherapy
- P2HORM* Hormone therapy
- Observation *P2OBS*
- No documentation *P2TRTND*
- Other. Please specify: *P2TXOTH*

12 Is a PSA level taken in the six months prior to diagnosis available?

Yes No *P2PSAA*

a. PSA (ng/ml) at time most closely preceding procedure that confirmed prostate cancer diagnosis: *P2PSA* . ng/ml

b. Is free fraction of PSA available for the PSA level above? Yes No *P2PSAFFA*

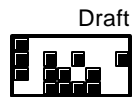
Free fraction: *P2PSAFF.* ng/ml OR *P2PSAFFP.* %

c. Date PSA level taken: *P2PSADT* /

Month Day Year

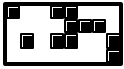
13 Signature of Physician Adjudicator:

DATE



Draft





MrOS Prostate Cancer Adjudication Form

Draft

MrOS ID#	Acrostic	Staff ID#	Form completed by:
P1ID	P1ACROST	P1STAFF	<input type="radio"/> Clinical Center <input type="radio"/> Coordinating Center

1 Was prostate cancer diagnosed? Yes No → **Go to question #13, page 2.**

2 Date of prostate cancer diagnosis: / /
Month Day Year

3 Why was prostate cancer suspected? (Mark only one)

Symptoms Rising PSA No documentation
 Abnormal (high) PSA Low free PSA % Abnormal tests -- other. Please specify:
 Abnormal prostate exam Not suspected

4 Primary Method for confirmation of prostate cancer: (Mark all that apply)

Biopsy of the prostate TRUS of the prostate
 Biopsy of distant site Other method, please specify:

5 Diagnostic Confirmation:

Microscopically confirmed:	Not microscopically confirmed:
<input type="radio"/> Positive histology (pathology) <input type="radio"/> Positive exfoliative cytology (no positive histology) <input type="radio"/> Positive histology (pathology), (distant metastatic site only) <input type="radio"/> Positive microscopic confirmation, method not specific	<input type="radio"/> Positive laboratory test/marker study (e.g. elevated PSA or acid phosphatase) <input type="radio"/> Direct visualization w/out microscopic confirmation <input type="radio"/> Radiography and other imaging techniques without microscopic confirmation <input type="radio"/> Clinical diagnosis only

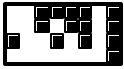
Confirmation unknown:
 Unknown if microscopically confirmed

6 Were Gleason Scores available? Yes No

Record Gleason Scores:			Date Gleason Scores determined:		
<input type="text"/>	+	<input type="text"/>	=	<input type="text"/>	<input type="text"/>
<small>Histologic Gleason Score 1 (1-5)</small>		<small>Histologic Gleason Score 2 (1-5)</small>		<small>Month</small>	<small>Day</small>
		<small>Gleason Sum</small>		<small>Year</small>	
			Source: _____		

7 Was histologic stage available?

Yes → Record Histologic stage:
 Well differentiated Poorly differentiated/Undifferentiated
 Moderately differentiated Unknown tumor histology



MrOS Prostate Cancer Adjudication Form

Draft



MrOS ID#	Acrostic	Form completed by:
<input type="text"/> <i>P2ID</i>	<input type="text"/> <i>P2ACROST</i>	<input checked="" type="radio"/> Clinical Center
		<input checked="" type="radio"/> Coordinating Center

P2AC

8 Staging of Tumor. Yes → *P2NSTAGE*
 Is staging known? No *P2STGA*
 T = *P2TSTAGE* N = M = *P2MSTAGE*

9 Type of cancer diagnosed: Adenocarcinoma Other →
P2CATYPE

10 Were any of the following imaging/laboratory studies used to evaluate prostate cancer diagnosis? (Mark all that apply)

- P2PAP* PAP (prostatic acid phosphates)
- P2TRUS* TRUS (transrectal ultrasound)
- P2CT* CT
- P2MRI* MRI
- Bone scan *P2BSCAN*
- No Imaging Study done *P2NOIMG*
- Other, please specify: *P2IMGOTH*

11 What was the initial treatment of the tumor (within 6 months of diagnosis)? (Mark all that apply)

- P2RADPCT* Radical prostatectomy
- P2EBRT* External beam radiation therapy
- P2BRAC* Brachytherapy
- P2HORM* Hormone therapy
- Observation *P2OBS*
- No documentation *P2TRTND*
- Other. Please specify: *P2TXOTH*

12 Is a PSA level taken in the six months prior to diagnosis available?

Yes No *P2PSAA*

a. PSA (ng/ml) at time most closely preceding procedure that confirmed prostate cancer diagnosis: *P2PSA* . ng/ml

b. Is free fraction of PSA available for the PSA level above? Yes No *P2PSAFFA*

Free fraction: *P2PSAFF.* ng/ml OR *P2PSAFFP* %

c. Date PSA level taken: *P2PSADT* /

Month Day Year

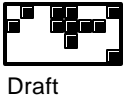
13 Signature of Physician Adjudicator:

DATE



Draft





MrOS Prostate Cancer Initial Notification

MrOS ID#	Acrostic	Staff ID#
PXID	PXACROST	PXSTAFF

Submit form to data system within 10 working days of clinic notification of prostate cancer.

1 Did the prostate cancer occur after the participant's enrollment date?

Yes No Participant refused to provide information/access to records



PXCANCER

2 Date of cancer diagnosis:

PXDATEBC		/			
Month	Day		Year		

3 Date clinic notified of cancer:

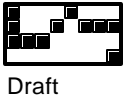
PXDATEBP		/			
Month	Day		Year		

4 Source of prostate cancer report:

- | | |
|---|---|
| <input type="radio"/> Participant calls clinic | <input type="radio"/> Health care provider |
| <input type="radio"/> Surrogate calls clinic | <input type="radio"/> Hospital discharge record |
| <input type="radio"/> Returned tri-annual questionnaire | <input type="radio"/> Death certificate |
| <input type="radio"/> Follow-up telephone call for tri-annual questionnaire | <input type="radio"/> Other, please specify: |
| <input type="radio"/> MrOS Clinic Visit (not baseline) | |

PXSOURCE

5 Complete Contact Information Worksheet. Ensure source of report, and physician/medical records contact information is included.



MrOS Prostate Biopsy Initial Notification



MrOS ID#	Acrostic	Staff ID#	Initial Report Date:
PZID	PZACROST	PZSTAFF	PZDATE /
			Month Day Year

Submit form to data system within 10 working days of clinic notification of prostate biopsy.

- 1 Did the prostate biopsy occur after the participant's enrollment date?
 Yes No Participant refused to provide information/access to records
PZEFDATE

2 Date of biopsy: *PZDATEBC* / / /
 Month Day Year

3 Date clinic notified of biopsy: *PZDATEBP* / / /
 Month Day Year

4 Source of prostate cancer/biopsy report:

- Participant calls clinic
- Surrogate calls clinic
- Returned tri-annual questionnaire
- Follow-up telephone call for tri-annual questionnaire
- MrOS Clinic Visit (not baseline)
- Health care provider
- Hospital discharge record *PZSOURCE*
- Death certificate
- Other, please specify:

5 Did prostate biopsy occur \geq 6 months AFTER a biopsy confirmed prostate cancer diagnosis? (Cancer report may be at baseline visit.)
 Yes No *PZAFTER*

No further documentation is required. Send this form to the data system and a copy to the Coordinating Center.

Complete Contact Information Worksheet. Ensure source of report, and physician/medical records contact information is included. Collect pathology report and send appropriate documents to Coordinating Center.

