

CPCTR Common Data Elements for Collection of Prostate Cancer Specimens PAPER FORMS version 16 [Data Dictionary Version 22 (09/14/04)]

USER INSTRUCTIONS

Form Completion Guidelines:

- Priorities for completing the form are to fill out all required elements followed by any subset of data that will allow for inclusion in the CPCTR databank. In our recent conference call there were two approaches to this suggested: a) fill out the pathology data (suggested by Jan Orenstein) and fill in the clinical sections later, or b) fill in the basic required elements as well as a core of pathology data (Jules Berman, Mike Becich). In either case, the final goal is to complete as many data elements as possible.
- 2) Any corrections of changes to the forms should be e-mailed to Ashokkumar A. Patel at patelaa@upmc.edu.

<u>STEPS involved in initial screening, inclusion and classification</u> <u>of CPCTR cases</u>

STEP 1 - Pre-screening cases (Research Assistant's Role) - Required Data Elements Pre-Check - these data element searches are recommended before pathologist review. Make sure the case has the following REQUIRED data elements before beginning microscopic examination:

- At least <u>2 blocks</u> are available on case that include prostate tumor *or* <u>1 block</u> for biopsy-only or metastatic cases.
- Date of Birth, Race, Date of Diagnosis and Vital Status must be available to qualify a case and should be collected before microscopic exam and central review by the pathologist is initiated.
- Also # Nodes Examined/Positive must be available.

 NOTE: If these data elements are not found, make a record of this case this for later discussion. We must determine the exclusion rate and if too high we may need modified "required" (asterisked) data elements.

<u>STEP 2</u> - <u>Pathologist Exam</u> - the "pre-screened case" is given to pathologist who begins data recording (Pathologist's Role).

Pathologist determines priorities for entering cases in prostatectomy matrix (Pathologist's Role)

- Priorities for entering cases in prostatectomy neoplastic block matrix
- These should assist the teams in picking the highest value blocks for the CPCTR archives.
- Since the matrix can include up to 5 blocks here are the recommendations for selection criteria:
- 1) The first block should include the largest nodule of tumor (as specified by the CDE)

- 2) The third through fifth blocks should include seminal vesicle invasion, ECE or angiolymphatic invasion (in that order of preference)
- 3) The second block should include the largest amount of PIN and preferred is an area of PIN that is independent of cancer (if that exists). If the blocks with PIN all also contain cancer that does not exclude them. Try then to pick a block that has the largest amount of PIN.
- 4) Try to include at least one block of normal prostate if possible if it is not possible to find a completely normal block then include one with minimal amounts of PIN or carcinoma. Seminal vesicle is not considered a good normal block.
- <u>STEP 3</u> <u>Clinical Information Collection</u> (<u>Research Assistant's</u> <u>Role</u>) If possible, fill out the remaining parts of the form and include the time it took to complete this subsection.
- <u>STEP 4</u> <u>Needle biopsy CDE</u> guidelines (<u>Pathologist's Role</u>). For needle biopsy cases, a matrix similar to the prostatectomy was developed and the criteria are:
- 1) Can include one block or more (up to a maximum of 5).
- 2) Must at least include one block and classify according to the needle biopsy matrix.
- 3) Try to include one block of normal prostate if possible.

<u>STEP 5</u> - <u>Frozen Tissue Prostatectomy archive</u> guidelines (Pathologist's Role)

- Since we have not really started accruing cases it was decided to keep the exclusionary criteria to a minimum until we have a better idea from each site actually reviewing cases.
- Therefore the only criteria we recommend currently are:
 - At least 1 neoplastic block or more need to be able to be entered into the matrix or case is excluded.

<u>STEP 6</u> - <u>Metastasis CDE</u> guidelines (<u>Pathologist's Role</u>).

For metastatic cases, a matrix similar to the prostatectomy was developed and the criteria are:

- 1) Can include one block or more (up to a maximum of 5).
- 2) Must at least include one block and classify according to the metastatic matrix.
- 3) Try to include one block of normal metastatic tissue if possible.

Demographics

Internal Reference Data (This section is not to be supplied to CPCTR only for internal record keeping use only and not to be passed on to IMS)

| 1. Hospi | tal Identifier: | | |
|------------|-----------------|--|--|
| | | | |
| 2. Last N | Name: | | |
| | | | |
| 3. First I | Name: | | |

Demographics

| 4. | Case Identifier (10-digit alphanu | | | MS) | | |
|----|--------------------------------------|---------------|--------------|--------------|---------------|-----|
| 5. | Race*: (circle o | ne): Cau | casian | Pacific Isla | nder | |
| | African American | n Hisp | panic | Asian | Native Americ | an |
| | Unknown | Not Availab | ole | Other (write | in if known): | |
| 6. | Other Race con | nments: | | | | |
| 7. | Hispanic Origin | n: (circle on | e) Yes | No | Unkno | own |
| 8. | Birth date*: | / | | (MM | I/YYYY) | |
| Cl | linical His | tory | | | | |
| 9. | Family History | of Prostate | Cancer | ·: | | |
| | (circle one) | Yes | No | Uni | known | |
| 10 | .Family History | comments | | | | |
| | | | | | | |
| | | | | | | |
| 11 | .Date of Diagno | | | | ncer*: | |
| | | | (IVIIVIZ Y Y | (Y Y) | | |
| 12 | .General Demoç | graphic Con | nment F | ield: | | |
| | | | | | | |

SPECIMEN AVAILABLITY

This section will show the types of specimens available through the Resource.

NOTE: * Case inclusion criteria: Any ONE question #13-20 below must say "YES". (Specific inclusion criteria for each of the bio-specimens below are listed in their respective section)

| 13.Are Prostated | ctomy spe | cimens availat | ole?* | |
|------------------|-------------|-----------------|---------------------|------|
| (circle one) | Yes | No | Unknown | |
| 14.Are Biopsy sp | oecimens a | available?* | | |
| (circle one) | Yes | No | Unknown | |
| 15.Are Regional | Lymph No | ode specimens | available?* | |
| (circle one) | Yes | No | Unknown | |
| 16.Are Metastat | ic specime | ens available?* | : | |
| (circle one) | Yes | No | Unknown | |
| 17.Are Plasma s | amples av | ailable?* | | |
| (circle one) | Yes | No | Unknown | |
| 18.Are Serum sa | imples ava | ailable?* | | |
| (circle one) | Yes | No | Unknown | |
| 19.Are Red Bloo | d Cells (RI | BCs) available | ?* | |
| (circle one) | Yes | No | Unknown | |
| 20.Are Periphera | al Blood M | ononuclear Ce | lls (PBMCs) availab | le?* |
| (circle one) | Yes | No | Unknown | |

PROSTATIC SPECIFIC ANTIGEN (PSA)

| GNUSTIC PSA: |
|--|
| 21.PSA value that prompted Diagnostic Biopsy which showed cancer |
| [>0.0; 9999.0, -1 (unknown)] |
| 22.Date of PSA that Prompted Diagnostic Biopsy which showed cancer |
| / (MM/YYYY) |
| 23.General comments for Diagnostic PSA: |
| |
| |
| |

PSA MATRIX: (Items #24-27 are multiple entry fields)

The PSA matrix section will allow the collection of multiple PSA values that are prior to and after the diagnostic PSA value. We can write scripts to separate the pre-biopsy (for biopsy-only cases)/pre-prostatectomy PSAs from the post-biopsy/pre-prostatectomy PSAs to determine the biochemical recurrence. We can also calculate the diagnostic PSA since we know the biopsy date and all the PSA dates, and will identify the date of the PSA just before the biopsy. Thus, the central database will take the PSA and Date, sort by date, and calculate the needed results. This also allows one to enter in dates in any order (if much later you get an old chart with more values).

24.PSA below threshold (<0.1):

25.PSA value (pre/post diagnostic only)

26.Date of PSA

27. General comments for PSA matrix

(PLEASE ENTER DATA IN THE PSA MATRIX TABLE BELOW)

PSA MATRIX TABLE:

| PSA thres | pelow shold 0.1) | PSA value (pre/post diagnostic only) [>0.0; 9999.0, -1 (unknown)] | Date of PSA (Month) | Date of PSA (Year) | General comments for PSA matrix |
|------------|------------------------|---|------------------------|-----------------------|---------------------------------|
| (Circle YI | ES or NO) | [>0.0; 9999.0, -1 (unknown)] | (TATIAT) | (YYYY) | |
| Υ | N | | | | |
| Υ | N | | | | |
| Υ | N | | | | |
| Υ | N | | | | |
| Υ | N | | | | |
| Υ | N | | | | |
| Y | N | | | | |
| Y | N | | | | |
| Y | N | | | | |
| Y | N | | | | |
| Y | N N | | | | |
| Y | N | | | | |
| Y | N | | | | |
| _ | • | | | | |

PSA MATRIX TABLE:

| PSA below threshold (<0.1) (Circle YES or NO) | PSA value (pre/post diagnostic only) [>0.0; 9999.0, -1 (unknown)] | Date of PSA (Month) | Date of PSA (Year) | General comments for PSA matrix |
|--|--|------------------------|-----------------------|---------------------------------|
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |
| Y N | | | | |

ANATOMICAL PATHOLOGY GRADING AND CHARACTERISTICS

PARAFFIN BLOCK MATRIX: (Items #28-40 are multiple entry fields. Up to 5 blocks preferred)

The Paraffin block matrix section will allow the collection of block details on cases that meet the minimum requirements for inclusion (1 paraffin blocks with tumor) into the Resource. NOTE: Priorities for entering cases in prostatectomy neoplastic block matrix

- These should assist the teams in picking the highest value blocks for the CPCTR archives.
- Since the matrix can include <u>up to 5 blocks</u> here are the recommendations for selection criteria:
 - 1) The <u>first block (block a)</u> should include the largest nodule of tumor (as specified by the CDE)
 - 2) The <u>third through fifth blocks (blocks c, d, e)</u> should include seminal vesicle invasion, ECE or angiolymphatic invasion (in that order of preference) NOTE: If SV, ECE, AL do not occur, select the next largest area of tumor for 3 to 5 of the matrix.
 - 3) The <u>second block (block b)</u> should include the largest amount of PIN and preferred is an area of PIN that is independent of cancer (if that exists). If the blocks with PIN all also contain cancer that does not exclude them. Try then to pick a block that has the largest amount of PIN.

NOTE: This section is for the PARAFFIN BLOCK matrix.

It is very possible that some (and occasionally all) of the paraffin blocks in the matrix will also have frozen tissue. When this happens indicate this in items 39a-e. On occasion, there may be some blocks that are only frozen (site dependent) also indicate this in the aforementioned data items.

______ 28a. Paraffin Block Matrix a: Block number ** (Block with largest tumor nodule) Accession and Block # (i.e. SP-91-645-1A): 29a. Paraffin Block Matrix: Most Prominent Histological Type of Invasive Cancer ** (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lvmphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Sarcomatoid carcinoma Small cell anaplastic carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 30a. Paraffin Block Matrix: Primary Gleason Grade** (Circle One) Gleason grade: 1 2 4 5 not primary tumor not adenocarcinoma Unknown PIN only 31a. Paraffin Block Matrix: Secondary Gleason Grade** (Circle One) Gleason grade: 1 2 3 4 not primary tumor PIN only not adenocarcinoma Unknown 32a. Paraffin Block Matrix: Size of Largest Individual Nodule of Invasive Cancer (in cm) __ __ . __ cm (-1=unknown, 0.0 – 99.9 cm) (33a-39a) BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Extracapsular Extension (ECE); Positive Surgical Margin (SM); Perineural Invasion (PN); Seminal Vesicle Invasion (SV); Angiolymphatic Invasion (AL); Type of Block(s) available (circle all that apply) PIN ECE SV ΑL SM DN None Paraffin and frozen Paraffin only Frozen only 40a. Paraffin Block Matrix: block comments

28b. Paraffin Block Matrix b: Block number**: (Block with largest amount of PIN, preferably in area independent of tumor, if possible. If no PIN then sample block with next largest amount of tumor.) Accession and Block # (i.e. SP-91-645-1A): 29b. Paraffin Block Matrix: Most Prominent Histological Type of Invasive Cancer ** (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lymphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Small cell anaplastic carcinoma Sarcomatoid carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 30b. Paraffin Block Matrix: Primary Gleason Grade** (Circle One) 3 Gleason grade: 1 2 4 not adenocarcinoma PIN only not primary tumor Unknown 31b. Paraffin Block Matrix: Secondary Gleason Grade** (Circle One) Gleason grade: 1 2 not adenocarcinoma not primary tumor Unknown PIN only 32b. Paraffin Block Matrix: Size of Largest Individual Nodule of Invasive Cancer (in cm) ___ . __ cm (-1=unknown, 0.0 – 99.9 cm) (33b-39b) BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Extracapsular Extension (ECE); Positive Surgical Margin (SM); Perineural Invasion (PN); Seminal Vesicle Invasion (SV); Angiolymphatic Invasion (AL); Type of Block(s) available (circle all that apply) PINECE SM PNSV AL None Paraffin only Frozen only Paraffin and frozen 40b. Paraffin Block Matrix: block comments _____

28c. Paraffin Block Matrix c: Block number**: (Block with seminal vesicle invasion. If no seminal vesicle invasion, include block with next largest tumor nodule). Accession and Block # (i.e. SP-91-645-1A): 29c. Paraffin Block Matrix: Most Prominent Histological Type of Invasive Cancer ** (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lvmphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Sarcomatoid carcinoma Small cell anaplastic carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 30c. Paraffin Block Matrix: Primary Gleason Grade** (Circle One) Gleason grade: 1 2 4 5 not primary tumor not adenocarcinoma Unknown PIN only 31c. Paraffin Block Matrix: Secondary Gleason Grade** (Circle One) 3 Gleason grade: 1 2 4 PIN only not adenocarcinoma not primary tumor Unknown *32c*. Paraffin Block Matrix: Size of Largest Individual Nodule of Invasive Cancer (in cm) __ __ . __ cm (-1=unknown, 0.0 – 99.9 cm) (33c-39c) BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Extracapsular

28d. Paraffin Block Matrix d: Block number**: (Block with extracapsular extension (ECE) if present. If ECE is not present pick the block with the next largest amount of tumor).

Accession and Block # (i.e. SP-91-645-1A):

| 29d. | Daraffin Bloc | | | | wno of Invacio | 10 |
|--------------------------|--|--|--|----------------------------------|-------------------|------|
| 29a. | Cancer ** (C | ck Matrix: Mos Circle One) | t Prominent i | nistological i | ype or rhvasiv | re |
| Adeno | carcinoma NOS | S (aka acinar) | Undiffer | entiated non-s | mall cell carcino | oma |
| Mucino | ous adenocarci | noma S | Signet ring ade | nocarcinoma | Lymphom | าล |
| Transi | tional (not prin | nary) Ductal | adenocarcinor | na Neuroen | docrine carcino | ma |
| Small | cell anaplastic | carcinoma S | Sarcomatoid ca | rcinoma B | asal cell carcino | oma |
| Squan | nous or adenos | quamous carcin | oma N | lesenchymal tu | ımor (NOS) | |
| PIN or | nly | Unknown | Other (s | specify in comn | nents) | |
| 30d. | Paraffin Bloo | :k Matrix: Prim | nary Gleason | Grade** (Cir | cle One) | |
| Gleaso | on grade: 1 | 2 | 3 | 4 | 5 | |
| not ad | enocarcinoma | not prim | nary tumor | Unknown | PIN only | |
| 31d. | Paraffin Bloo | ck Matrix: Seco | ondary Glease | on Grade** (| Circle One) | |
| Gleaso | on grade: 1 | 2 | 3 | 4 | 5 | |
| not ad | enocarcinoma | not prim | nary tumor | Unknown | PIN only | |
| 32d. | Cancer (in ci | ck Matrix: Size m) cm (-1=unkr | · · | | ule of Invasiv | 'e |
| High (Exten Semir | Grade Prostat sion (ECE); P nal Vesicle In | ATTRIBUTES: ic Intraepithe ositive Surgica vasion (SV); A (circle all that | lial Neoplasia al Margin (SM ngiolymphat | a (PIN); Extra I); Perineural | Invasion (PN |); |
| PIN | ECE | SM | PN | sv | AL N | lone |
| Paraf | fin only | Frozen only | Paraffii | n and frozen | | |
| 40d. | Paraffin Bloo | k Matrix: bloc | k comments | | | |

28e. Paraffin Block Matrix e: Block number**: (Block with angiolymphatic invasion (AI). If AI is not present pick the block with the next largest amount of tumor).

Accession and Block # (i.e. SP-91-645-1A):

| 29e. | Paraffin Block M Cancer ** (Circl | | ominent His | stological Type | of Invasive |
|---------------------------|---|--|--|------------------|----------------|
| Adenoc | carcinoma NOS (al | ka acinar) | Undifferen | tiated non-small | cell carcinoma |
| Mucino | us adenocarcinom | na Signe | t ring adeno | carcinoma | Lymphoma |
| Transit | ional (not primary |) Ductal ader | nocarcinoma | Neuroendocri | ne carcinoma |
| Small | cell anaplastic card | cinoma Sarco | matoid carci | noma Basal | cell carcinoma |
| Squam | ous or adenosqua | mous carcinoma | Mes | senchymal tumor | (NOS) |
| PIN on | ly Unk | known | Other (spe | cify in comments | 2) |
| 30e. | Paraffin Block N | latrix: Primary | Gleason Gr | ade** (Circle C | ne) |
| Gleaso | n grade: 1 | 2 | 3 | 4 | 5 |
| not ade | enocarcinoma | not primary | tumor | Unknown | PIN only |
| 31e. | Paraffin Block M | latrix: Seconda | ry Gleason | Grade** (Circle | e One) |
| Gleaso | n grade: 1 | 2 | 3 | 4 | 5 |
| not ade | enocarcinoma | not primary | tumor | Unknown | PIN only |
| <i>32e</i> . | Paraffin Block M Cancer (in cm) cn | latrix: Size of L | | | of Invasive |
| High C Extens Semin | 39e) BLOCK ATT Grade Prostatic I sion (ECE); Posit al Vesicle Invasi (s) available (cir | ntraepithelial I ive Surgical Ma ion (SV); Angio | Neoplasia (argin (SM); olymphatic | Perineural Inva | asion (PN); |
| PIN | ECE | SM | PN | sv | AL None |
| Paraff | in only Fro | zen only | Paraffin a | nd frozen | |
| 40e. | Paraffin Block M | latrix: block co | mments | | |
| | | | | | |

NON-NEOPLASTIC PARAFFIN BLOCK'S:

Try to include at least one block of normal prostate if possible (two blocks are preferred). If it is not possible to find a completely normal block then include one with minimal amounts of PIN or carcinoma. Seminal vesical is not considered a good normal block.

| 41.Paraffin Prostatectomy Non-Neoplastic Block #1: |
|--|
| Accession and Block # (i.e. SP-91-645-1A): |
| |
| |
| |
| 42.Paraffin Prostatectomy Non-Neoplastic Block #2: Accession and Block # (i.e. SP-91-645-1A): |
| |
| |
| |
| 43.General Comments on Paraffin Blocks: |
| |
| |
| |

FROZEN BLOCK MATRIX: (Items #44-56 are multiple entry fields. Up to 5 blocks preferred)

NOTE: This section is for the FROZEN BLOCK matrix.

It is very possible that some (and occasionally all) of the frozen blocks in the matrix will also have paraffin tissue. When this happens indicate this in data element [Type of Block(s) available]. On occasion, there may be some blocks that are only frozen (site dependent) also indicate this in the aforementioned data items.

The Frozen block matrix section will allow the collection of block details on cases that meet the minimum requirements for inclusion into the Resource.

NOTE: Priorities for entering cases in prostatectomy neoplastic block matrix

- These should assist the teams in picking the highest value blocks for the CPCTR archives.
- Since the matrix can include <u>up to 5 blocks</u> here are the recommendations for selection criteria:
 - 1) The <u>first block (block a)</u> should include the largest nodule of tumor (as specified by the CDE)
 - 2) The <u>third through fifth blocks (blocks c, d, e)</u> should include seminal vesicle invasion, ECE or angiolymphatic invasion (in that order of preference) NOTE: If SV, ECE, AL do not occur, select the next largest area of tumor for 3 to 5 of the matrix.
 - 3) The <u>second block (block b)</u> should include the largest amount of PIN and preferred is an area of PIN that is independent of cancer (if that exists). If the blocks with PIN all also contain cancer that does not exclude them. Try then to pick a block that has the largest amount of PIN.

NOTE: This section is for the FROZEN BLOCK matrix.

It is very possible that some (and occasionally all) of the frozen blocks in the matrix will also have paraffin tissue. When this happens indicate this in items 55a-e). On occasion, there may be some blocks that are only frozen (site dependent) also indicate this in the aforementioned data items.

______ 44a. Frozen Block Matrix a: Block number ** (Block with largest tumor nodule) Accession and Block # (i.e. SP-91-645-1A): 45a. Frozen Block Matrix: Most Prominent Histological Type of Invasive Cancer ** (Circle One) Undifferentiated non-small cell carcinoma Adenocarcinoma NOS (aka acinar) Mucinous adenocarcinoma Signet ring adenocarcinoma Lvmphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Sarcomatoid carcinoma Small cell anaplastic carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 46a. Frozen Block Matrix: Primary Gleason Grade** (Circle One) Gleason grade: 1 2 4 not adenocarcinoma not primary tumor Unknown PIN only 47a. Frozen Block Matrix: Secondary Gleason Grade** (Circle One) Gleason grade: 1 2 3 4 PIN only not adenocarcinoma not primary tumor Unknown 48a. Frozen Block Matrix: Size of Largest Individual Nodule of Invasive Cancer (in cm) __ __ . __ cm (-1=unknown, 0.0 – 99.9 cm) (49a-55a) BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Extracapsular Extension (ECE); Positive Surgical Margin (SM); Perineural Invasion (PN); Seminal Vesicle Invasion (SV); Angiolymphatic Invasion (AL); Type of Block(s) available (circle all that apply) PIN ECE ΡN SV ΑL SM None Paraffin and frozen Paraffin only Frozen only 56a. Frozen Block Matrix: block comments ______

44b. Frozen Block Matrix b: Block number**: (Block with largest amount of PIN, preferably in area independent of tumor, if possible. If no PIN then sample block with next largest amount of tumor.)

Accession and Block # (i.e. SP-91-645-1A):

| ı aı aı | iii oiny | 1102611 Offing | Falailli | Tana nozen | | |
|--------------------------------|---|---|---|-------------------------------|---------------|---------|
| PIN Paraf | ECE fin only | SM Frozen only | | Sv n and frozen | AL | wone |
| High Exter Semi Block | Grade Prostansion (ECE); nal Vesicle II (s) available | ATTRIBUTES: latic Intraepitheli Positive Surgical nvasion (SV); Are (circle all that | ial Neoplasia I Margin (SN ngiolymphati | (PIN); Extra); Perineural | Invasion | |
| 48b. | Cancer (in | ck Matrix: Size o cm) _ cm (-1=unkno | _ | | le of Invas | sive |
| not ac | denocarcinoma | a not prima | ary tumor | Unknown | PIN o | nly |
| Gleas | on grade: 1 | 2 | 3 | 4 | 5 | |
| 47b. | Frozen Bloo | ck Matrix: Secon | dary Gleasoi | n Grade** (Ci | rcle One) | |
| not ac | denocarcinoma | a not prima | ary tumor | Unknown | PIN o | nly |
| Gleas | on grade: 1 | 2 | 3 | 4 | 5 | |
| 46b. | Frozen Bloo | ck Matrix: Prima | ry Gleason G | rade** (Circl | e One) | |
| PIN o | nly | Unknown | Other (s | pecify in comm | nents) | |
| Squar | mous or adenc | osquamous carcino | oma N | lesenchymal tu | ımor (NOS) | |
| Small | cell anaplastic | c carcinoma Sa | arcomatoid ca | rcinoma B | asal cell ca | rcinoma |
| Trans | itional (not pri | imary) Ductal a | adenocarcinor | na Neuroen | docrine car | cinoma |
| Mucin | ous adenocard | cinoma Si | gnet ring ade | nocarcinoma | Lymp | homa |
| Adenc | ocarcinoma NC | OS (aka acinar) | Undiffer | entiated non-si | mall cell car | rcinoma |
| 45b. | | ck Matrix: Most F (Circle One) | Prominent Hi | stological Ty | pe of Inva | sive |

44c. Frozen Block Matrix c: Block number**: (Block with seminal vesicle invasion. If no seminal vesicle invasion, include block with next largest tumor nodule). Accession and Block # (i.e. SP-91-645-1A):

45c. Frozen Block Matrix: Most Prominent Histological Type of Invasive Cancer ** (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lvmphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Sarcomatoid carcinoma Small cell anaplastic carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 46c. Frozen Block Matrix: Primary Gleason Grade** (Circle One) Gleason grade: 1 2 3 4 5 not adenocarcinoma not primary tumor Unknown PIN only 47c. Frozen Block Matrix: Secondary Gleason Grade** (Circle One) Gleason grade: 1 2 3 4 PIN only not adenocarcinoma not primary tumor Unknown Frozen Block Matrix: Size of Largest Individual Nodule of Invasive 48c. Cancer (in cm) __ __ . __ cm (-1=unknown, 0.0 – 99.9 cm) (49c-55c) BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Extracapsular Extension (ECE); Positive Surgical Margin (SM); Perineural Invasion (PN); Seminal Vesicle Invasion (SV); Angiolymphatic Invasion (AL); Type of Block(s) available (circle all that apply) PIN ECE ΡN SV ΑL SM None Paraffin and frozen Paraffin only Frozen only Frozen Block Matrix: block comments

44d. Frozen Block Matrix d: Block number**: (Block with extracapsular extension (ECE) if present. If ECE is not present pick the block with the next largest amount of tumor).

Accession and Block # (i.e. SP-91-645-1A):

| Paraf [.] | IIII OIIIY | I I UZEII UIIIY | Paraiiii | | | |
|--------------------------|---|--|--|----------------------------------|-------------------|----------|
| | fin only | Frozen only | Doroffi | n and frozen | | |
| PIN | ECE | SM | PN | sv | AL N | one |
| High (Exten Semir | Grade Prosta sion (ECE); F nal Vesicle In | ATTRIBUTES: tic Intraepithel Positive Surgica tvasion (SV); At (circle all tha | ial Neoplasia I Margin (SM ngiolymphat | a (PIN); Extra 1); Perineural | Invasion (PN |); |
| 48d. | Cancer (in c | k Matrix: Size o :m) _ cm (-1=unkn | | | le of Invasive | : |
| not ad | lenocarcinoma | not prim | ary tumor | Unknown | PIN only | |
| Gleaso | on grade: 1 | 2 | 3 | 4 | 5 | |
| 47d. | Frozen Bloc | k Matrix: Secon | dary Gleaso | n Grade** (Ci | rcle One) | |
| not ad | lenocarcinoma | not prim | ary tumor | Unknown | PIN only | |
| Gleaso | on grade: 1 | 2 | 3 | 4 | 5 | |
| 46d. | Frozen Bloc | k Matrix: Prima | ry Gleason G | Grade** (Circ | e One) | |
| PIN or | nly | Unknown | Other (s | specify in comm | nents) | |
| Squan | nous or adenos | squamous carcino | oma N | lesenchymal tu | ımor (NOS) | |
| Small | cell anaplastic | carcinoma S | arcomatoid ca | ircinoma B | asal cell carcino | oma |
| Transi | tional (not prir | mary) Ductal | adenocarcinor | na Neuroen | docrine carcino | ma |
| Mucino | ous adenocarc | inoma S | ignet ring ade | nocarcinoma | Lymphom | na |
| Adeno | carcinoma NO | S (aka acinar) | Undiffer | entiated non-si | mall cell carcino | oma |
| 45d. | Frozen Bloc Cancer ** (| k Matrix: Most I Circle One) | Prominent H | istological Ty | pe of Invasive | . |

44e. Frozen Block Matrix e: Block number**: (Block with angiolymphatic invasion (AI). If AI is not present pick the block with the next largest amount of tumor).

Accession and Block # (i.e. SP-91-645-1A):

| - | -55e) BLOCK AT Grade Prostatic | TRIBUTES: | Presence of: | · | acapsular | |
|-------|-----------------------------------|----------------|----------------|----------------|--------------------|----|
| 48e. | Frozen Block N Cancer (in cm) |) | | | ıle of Invasive | |
| not a | denocarcinoma | not prim | ary tumor | Unknown | PIN only | |
| Gleas | on grade: 1 | 2 | 3 | 4 | 5 | |
| 47e. | Frozen Block N | /latrix: Secon | dary Gleasor | n Grade** (C | ircle One) | |
| not a | denocarcinoma | not prim | ary tumor | Unknown | PIN only | |
| Gleas | on grade: 1 | 2 | 3 | 4 | 5 | |
| 46e. | Frozen Block N | /latrix: Prima | ry Gleason G | rade** (Circ | le One) | |
| PIN o | nly U | nknown | Other (s | pecify in comr | ments) | |
| • | mous or adenosqu | | | | | |
| | cell anaplastic ca | | | | Basal cell carcino | ma |
| Trans | itional (not prima | ry) Ductal | adenocarcinon | na Neuroer | ndocrine carcinor | ma |
| Mucir | nous adenocarcino | ma S | ignet ring ade | nocarcinoma | Lymphom | а |
| | ocarcinoma NOS (| • | | | | |
| | Cancer ** (Cir | cle One) | | | | |

NON-NEOPLASTIC FROZEN BLOCK'S:

Try to include at least one block of normal prostate if possible (two blocks are preferred). If it is not possible to find a completely normal block then include one with minimal amounts of PIN or carcinoma. Seminal vesical is not considered a good normal block.

| 57.Frozen Prostatectomy Non-Neoplastic Block #1: Accession and Block # (i.e. SP-91-645-1A): |
|--|
| |
| 58.Frozen Prostatectomy Non-Neoplastic Block #2: Accession and Block # (i.e. SP-91-645-1A): |
| |
| 59.Frozen Tissue: Warm Ischemic Time (in minutes) ** |
| minutes (0 to 99; use -1 for unknown) |
| 60.General Comments on Frozen Blocks: |
| |
| |

Enter the overall characteristics of the prostatectomy. 61.Date of Prostatectomy** __ _ / __ _ (MM/YYYY) 62.1s Residual Carcinoma Present at Prostatectomy?** (circle one) Yes No **HGPIN** only Donor Unknown 63.Lobe Laterality One - unspecified (laterality unknown) (circle one) One – right lobe only One – left lobe only Two – bilateral involvement 64. Most Prominent Histological Type of Invasive Cancer** (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lymphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Small cell anaplastic carcinoma Sarcomatoid carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 65.2nd Most Prominent Histological Type of Invasive Cancer (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lymphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Sarcomatoid carcinoma Small cell anaplastic carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) Comments:

HISTOLOGICAL CHARACTERISTICS OF PROSTATECTOMY

66. Prostatectomy: Primary Gleason Grade * * (Circle One) Gleason grade: 2 3 4 5 1 not adenocarcinoma not primary tumor Unknown PIN only 67. Prostatectomy: Secondary Gleason Grade * * (Circle One) 2 Gleason grade: 1 3 5 not adenocarcinoma not primary tumor Unknown PIN only 68. Prostatectomy: Gleason Sum Score ** (Circle One) Gleason score 2 Gleason score 3 Gleason score 4 Gleason score 5 Gleason score 6 Gleason score 7 Gleason score 8 Gleason score 9 Gleason score 10 not adenocarcinoma not primary tumor unknown 69. Percentage of Gleason 4/5 grade (in all of 6's and 7's): __ __ % (0.x – 100 %, -1 = unknown) 70. Size of Largest Individual Nodule of Invasive Cancer (in cm): __ __ . __ . __ cm (0.x – 999, -1 = unknown) 71. Percentage of Gland Occupied by Tumor: (Circle One) <5% 5 to 25% >25% Unknown 72. Multifocal Disease: (Circle One) Definition: Multifocal tumors MUST be separated by a certain distance (1-2 cm) so that the chance of artifactual sectioning is eliminated. The INDEX tumor is the primary case and the size is determined from that tumor. Yes No Unknown 73. Presence of High Grade Prostatic Intraepithelial Neoplasia: (Circle One) Yes - # of foci unknown Yes – 1 or 2 foci in region of tumor Yes – 1 or 2 foci away from tumor Yes - multifocal No Unknown

Focal Multifocal Established Unknown None 75. Surgical Margin Involvement: (Circle One) All surgical margins free of tumor Tumor focal at margin Tumor widespread at margin Unknown 76.Presence of Perineural Invasion: (Circle One) Yes No Unknown 77. Presence of Seminal Vesicle Invasion: (Circle One) Yes No Unknown 78. Presence of Angiolymphatic Invasion: (Circle One) Yes No Unknown 79. General Comments Section for Prostatectomy:

74.Extraprostatic Extension/Extracapsular Invasion: (Circle One)

Definition: Extraprostatic or Extracapsular extension seen in prostatectomy. Focal Extracapsular extension is defined as less than 0.8mm of ECE and established is >0.8mm. Multifocal is greater than 2 different foci of ECE.

REGIONAL LYMPH NODE STATUS AT THE TIME OF PROSTATECTOMY

Include the lymph node status at the time of the prostatectomy.

- -If there is regional lymph node exploration prior or equal to the prostatectomy date, but after the initial diagnostic biopsy, then enter values here (in the Lymph Node section).
- -Regional lymph nodes removed <u>after the prostatectomy</u> or Distant lymph nodes should be enter in the *METASTASIS MATRIX* section.

 NOTE:

<u>Regional lymph nodes</u> are of the true pelvis. They are pelvic nodes below the bifurcation of the common iliac arteries and include: Pelvic (NOS), Hypogastric, Obturator, Iliac (internal, external, NOS), and Sacral (lateral, presacral, promontory, NOS) nodes.

<u>Distant lymph nodes</u> are outside the confines of the true pelvis and their involvement constitutes distant metastasis. They can be imaged using ultrasound, computed tomography, magnetic resonance imaging, or lymphangiography, and include: aortic (para-aortic, periaortic, lumbar), common iliac, inguinal, superficial inguinal (femoral), supraclavicular, cervical, scalene, and retroperitoneal (NOS) nodes.

| 80.Date of Regional Lymph Node resection |
|---|
| / (MM/YYYY) |
| 81.Nodes Examined** |
| Comments: 1) NOTE: -1 = "nodes examined, but number unknown" 2) If no nodes are examined or do not know if any were examined, then enter "0". |
| # of examined nodes: (> 0; 99, -1 = "nodes examined, number unknown") |
| 82.Nodes Positive** Comments: 1) NOTE: -1 = "some nodes are positive, but number unknown" 2) If no nodes are positive or do not know if any were positive, then enter "0". |
| # of positive nodes: (> 0; 99, -1 = "nodes examined, number unknown") |
| 83.Lymph Node Non-Neoplastic Block #1: Accession and Block # (i.e. SP-91-645-1A): |
| 84.General Comments Section for Lymph Nodes: |
| |
| |

REGIONAL LYMPH NODE BLOCK MATRIX: [Items #85-87 are multiple entry fields. Up to 3 blocks preferred (blocks a-c)]

NOTE: This section is for the LYMPH NODE BLOCK matrix. Only positive lymph nodes found at the time of the prostatectomy should be entered into the matrix. Lymph nodes removed at later dates should be entered in the METASTASIS BLOCK MATRIX.

| Accession and | Block # (i.e. SP | rix #1: Neoplastic Block number: -91-645-1A): | |
|------------------------------|------------------------------------|--|-----------------|
| | lode Block Mat | rix #1: Size of Largest Individual No | - odule of |
| | cm (0.x – | 999, -1 = unknown) | |
| 87a.Lymph N (Circle On | | rix #1: Presence of Extracapsular Ex | tension (ECE): |
| Yes | No | Unknown | |
| 85b.Lymph N Accession and | lode Block Mat Block # (i.e. SP | rix #2: Neoplastic Block number: -91-645-1A): | |
| | lode Block Mat | rix #2: Size of Largest Individual No | |
| | cm (0.x – | 999, -1 = unknown) | |
| 87b.Lymph N (Circle On | | rix #2: Presence of Extracapsular Ex | ctension (ECE): |
| Yes | No | Unknown | |
| 85c.Lymph N Accession and | ode Block Mat Block # (i.e. SP | | ====== |
| | ode Block Mat | rix #3: Size of Largest Individual No | - dule of |
| | cm (0.x – | 999, -1 = unknown) | |
| 87c.Lymph N (Circle On | | rix #3: Presence of Extracapsular Ex | tension (ECE): |
| Yes | No | Unknown | |

RECURRENCE/METASTATSIS STATUS:

The Recurrence/Metastasis Status data elements are separated into three categories:

- 1) <u>Biochemical recurrence</u> calls using the PSA recurrence algorithm developed by the CPCTR.
- 2) <u>Clinically verified Tissue recurrence/metastasis</u> for cases, which do not have blocks available for the Resource.
- 3) <u>Metastatic Tissue block matrix</u> for cases that have tissue available through the Resource from anatomical sites that show recurrence/metastasis of prostate cancer.

BIOCHEMICAL RECURRENCE: (calculated values)

The biochemical recurrence calls are made using the PSA recurrence algorithm developed by the CPCTR. Further details on the algorithm used can be received by contacting the Resource.

NOTE: <u>Data for #88-90</u> can be filled in manually from the IMS file for Institutional record. <u>These fields DO NOT need to be captured locally.</u>

88. Biochemical Recurrence Status:

| Value | Value Description |
|--------------------|--|
| Never Disease Free | Residual tumor present |
| No recurrence | No recurrence |
| PSA recurrence | Recurred based on CPCTR PSA recurrence algorithm |
| Unknown | Call cannot be determined using the algorithm |

| 89.Recurrence PSA value: | |
|-----------------------------|-------------------|
| [>0.0; 999 | 9.0, -1 (unknown) |
| 90.Date of Biochemical Recu | ırrence Status: |
| / | (MM/YYYY) |

CLINICALLY VERIFIED TISSUE RECURRENCE/METASTASIS:

These cases are those that do not have tissue blocks available, but are known clinically to have a recurrence/metastasis.

NOTE: Verification for clinical recurrence can be via radiology imaging, biopsy/resection, or surgery. However, a clinician's note indicating recurrence in a specific distant site would be sufficient. However this does not include notes of recurrence because of PSA (Biochemical), note must say "bone, liver, etc. mets".

| 91 | Tissue | Recurrence | /Metastasis: | Distant | site 1 | Circle On | e) |
|----|----------|-----------------|---------------|---------|----------|-----------|--------------------|
| | . 1133UC | IXCCGI I CI ICC | IVICTUSTUSIS. | Distant | 3110 1 1 | | \sim $^{\prime}$ |

| Bla | adder | Blood | | Bone | Bone Marrow | | | |
|-----------------------------------|---|-------------------------------------|--|---------------------|---|--|--|--|
| Bra | ain | Carcinomatosis | | CNS | Generalized | | | |
| Liv | ver | Local extens | ion | Lung | Peritoneum | | | |
| Re | ctum | Lymph Node | s (Distant) | Lymph Nodes (Regio | | | | |
| Ski | in | None | Other (NOS) |) | Unknown | | | |
| | 92.Date of Tissue Recurrence/Metastasis: Distant site 1/(MM/YYYY) | | | | | | | |
| | | rence/Metas | | | ======= le One) | | | |
| | | | | | | | | |
| Bla | adder | Blood | | Bone | Bone Marrow | | | |
| | | Blood Carcinomato | sis | Bone CNS | Bone Marrow Generalized | | | |
| Bra | ain | | | | | | | |
| Bra Liv | ain ver | Carcinomato | ion | CNS Lung | Generalized | | | |
| Bra Liv | ain ⁄er ctum | Carcinomato Local extens | ion s (Distant) | CNS Lung Lymp | Generalized Peritoneum | | | |
| Bra Liv Red Ski 94.Da | ain ver ctum in te of Tissu | Carcinomato Local extens Lymph Node | ion s (Distant) Other (NOS) e/Metastasis | CNS Lung Lymp | Generalized Peritoneum h Nodes (Regional) Unknown | | | |

95. Tissue Recurrence/Metastasis: Distant site 3 (Circle One)

| | Bladder | Blood | | Bone | Bone Marrow |
|-----|----------------|------------------------------|------------------|-----------------|--------------------|
| | Brain | Carcinomat | Carcinomatosis | | Generalized |
| | Liver | Local exten | sion | Lung | Peritoneum |
| | Rectum | Lymph Nod | les (Distant) | Lymp | h Nodes (Regional) |
| | Skin | None | Other (NOS |) | Unknown |
| | | | | | |
| 96 | 6.Date of Tiss | ue Recurren | ce/Metastasi | s: Distant site | e 3 |
| | /_ | | (MM/YYYY) | | |
| === | ====== | ====== | ====== | ====== | ======= |
| 97 | | nments for 0 /Metastasis: | Clinically Verif | fied Tissue | |
| | | | | | |
| | | | | | |
| | | | | | |

METASTATIC TISSUE BLOCK MATRIX: (Items #98-108 are multiple entry fields):

- -Enter as many blocks available (Three blocks are preferred).
- -If multiple metastatic sites are present, then enter at least 1 block from each site.
- -Try to include at least one block of normal tissue from the same site if possible. If it is not possible to find a completely normal block then include one with minimal amounts of carcinoma.
- -The first 3 metastatic blocks matrix are included as *Blocks a, b, c.* (Print additional forms if necessary)

| 98a.Metastatio | Block | Matrix | #1: | Block | number |
|----------------|-------|--------|-----|--------------|--------|
|----------------|-------|--------|-----|--------------|--------|

Accession and Block # (i.e. SP-91-645-1A):

___._.______

99a.Metastatic Block Matrix #1: Specimen source (Circle One)

Biopsy Resection Fine Needle Aspirate

Other Unknown

100a.Metastatic Block Matrix #1: Tissue Type (Circle One)

| Bladder | Blood | | Blood Bone | | Bone Marrow | | |
|---------|-----------------|------------|----------------|--------------------|-------------|--|-------------|
| Brain | Carcinomatosis | | Carcinomatosis | | CNS | | Generalized |
| Liver | Local extension | | Lung | | Peritoneum | | |
| Rectum | Lymph Node | | Lymp | h Nodes (Regional) | | | |
| Skin | None | Other (NOS |) | | Unknown | | |

101a.Metastatic Block Matrix #1: Most Prominent Histological Type of Invasive Cancer (Circle One)

| Adenocarcinoma NO | 5 (aka acınar) |) Undiff | rerentia | ted non- | -small c | eli carcino | ma |
|--|----------------|----------------------------|----------|----------|----------|-------------|----|
| Mucinous adenocarci | Signet ring a | Signet ring adenocarcinoma | | | Lymphom | na | |
| Transitional (not prir | mary) Duc | tal adenocarcir | noma | Neuro | endocrir | ne carcino | ma |
| Small cell anaplastic carcinoma Sarcomatoid carcinoma Basal cell carcino | | | | | oma | | |
| Squamous or adenos | squamous car | cinoma | Mesen | nchymal | tumor | (NOS) | |
| PIN only | Unknown | Other | (specify | y in con | nments) | | |
| Comments: | | | | | | | _ |
| | | | | | | | |

| 99b.Metastat | | ix #2: Specim | | • | e) |
|---------------------|----------------|------------------|---------------|--------------|----------------|
| Biopsy | Resection | Fine | Needle As | pirate | |
| Other | Unknown | | | | |
| 100b.Metasta | atic Block Ma | trix #2: Tissue | Type (Cir | cle One) | |
| Bladder | Blo | od | Bone | Bone Marrow | |
| Brain | Carcinoma | atosis | CNS | Gener | alized |
| Liver | Local exte | ension | Lung | Perito | neum |
| Rectum | Lymph No | des (Distant) | Ly | mph Node | es (Regional) |
| Skin | None | Other (NOS | S) | Unkno | own |
| | cer (Circle Or | • | | | |
| Mucinous adenoca | ircinoma | Signet ring a | adenocarcin | oma | Lymphoma |
| Transitional (not p | orimary) Du | ıctal adenocarci | noma Ne | euroendocrii | ne carcinoma |
| Small cell anaplas | tic carcinoma | Sarcomatoid | l carcinoma | Basal | cell carcinoma |
| Squamous or ade | nosquamous ca | arcinoma | Mesenchy | ymal tumor | (NOS) |
| PIN only | Unknown | Other | r (specify in | comments |) |
| Comments: | | | | | |
| | | | | | |
| | | | | | |

| | etastatic Bloc (Circle One) | k Matrix #2: | Percentage of Tissu | e Occupied by |
|--------------|--------------------------------|-----------------|---------------------------------------|----------------------|
| | <5% | 5 to 25% | >25% | Unknown |
| 104b.N | etastatic Bloc (Circle One) | | Presence of Therap | y effects |
| | Yes | No | Unknown | |
| 105b.W | Accession an | d Block # (i.e. | Non-Neoplastic Bloc SP-91-645-1A): | |
| | | | | |
| 106b.N | etastatic Bloc | k Matrix #2: | Type of Block(s) av | ailable (Circle One) |
| Para | affin only Froz | zen only | Paraffin and froze | n |
| 107b.D | ate of Metasta | ntic Block Mat | trix #2: | |
| | /_ | | (MM/YYYY) | |
| 108b.G —— | eneral Comme | ents Section f | for Metastatic Block | Matrix #2: |
| | | | | |

| 99c.Metastat | ic Block Matrix | #3: Specim | en source | (Circle One) | |
|---------------------|------------------|----------------------|---------------|-----------------------|-----------|
| Biopsy | Resection | Fine Needle Aspirate | | | |
| Other | Unknown | | | | |
| 100c.Metasta | atic Block Matri | x #3: Tissue | e Type (Circ | cle One) | |
| Bladder | ladder Blood | | Bone | Bone Marrow | ne Marrow |
| Brain | Carcinomato | osis | CNS | Generalized | |
| Liver | Local extens | sion | Lung | Peritoneum | |
| Rectum | Lymph Node | es (Distant) | Ly | mph Nodes (Regio | nal) |
| Skin | None | Other (NO | S) | Unknown | |
| Invasive Can | cer (Circle One |) | | Histological Type o | |
| Mucinous adenoca | arcinoma | Signet ring a | adenocarcin | oma Lymphon | าล |
| Transitional (not p | orimary) Duct | al adenocarci | noma Ne | euroendocrine carcino | ma |
| Small cell anaplas | tic carcinoma | Sarcomatoio | d carcinoma | Basal cell carcin | oma |
| Squamous or ade | nosquamous card | cinoma | Mesenchy | mal tumor (NOS) | |
| PIN only | Unknown | Othe | r (specify in | comments) | |
| Camanaanta | | | | | |

| 103c.Metastatic Block Matrix #3: Percentage of Tissue Occupied by Tumor (Circle One) | | | | | | |
|--|--|------------------|---|---------|--|--|
| | <5% | 5 to 25% | >25% | Unknown | | |
| 104c.M | etastatic Bloc (Circle One | | Presence of Therapy | effects | | |
| | Yes | No | Unknown | | | |
| 105c.M | Accession an | nd Block # (i.e. | Non-Neoplastic Blo c SP-91-645-1A): | | | |
| | | - — - | | | | |
| 106c.M | 106c.Metastatic Block Matrix #3: Type of Block(s) available (Circle One) | | | | | |
| Para | Paraffin only Frozen only Paraffin and frozen | | | | | |
| 10 7 c.D | 107c.Date of Metastatic Block Matrix #3: | | | | | |
| | /_ | · | (MM/YYYY) | | | |
| 108c.General Comments Section for Metastatic Block Matrix #3: | | | | | | |
| | | | | | | |

STAGING

Pathological and Clinical Staging will be based on using the <u>AJCC Manual for Staging of Cancer</u>, 5th Ed.

PATHOLOGICAL STAGING:

109. pT Stage** (Circle One)

pT0 pT1 pT1a pT1b pT1c

pT2 pT2a pT2b pT3 pT3a pT3b

pT4 pTX

| Value | Value Description |
|-------|--|
| рТ0 | No evidence of primary tumor |
| pT1 | Clinically inapparent tumor not palpable nor visible by imaging |
| pT1a | Tumor incidental histologic finding in 5% or less of tissue resected |
| pT1b | Tumor incidental histologic finding in more than 5% of tissue |
| ртто | resected |
| pT1c | Tumor identified by needle biopsy (e.g., because of elevated PSA) |
| pT2 | Tumor confined within prostate* |
| pT2a | Tumor involves 1 lobe |
| pT2b | Tumor involves both lobes |
| pT3 | Tumor extends through the prostatic capsule** |
| рТ3а | Extracapsular extension (unilateral or bilateral) |
| pT3b | Tumor invades seminal vesicle(s) |
| pT4 | Tumor is fixed or invades adjacent structures other than seminal |
| P14 | vesicles |
| рТХ | Primary tumor cannot be assessed |

110. pN Stage** (Circle One)

pNO pN1 pNX

| Value | Value Description | | |
|-------|--|--|--|
| pN0 | No regional lymph node metastasis | | |
| pN1 | Metastasis in regional lymph node or nodes | | |
| pNX | Regional lymph nodes cannot be assessed | | |

111. pM Stage** (Circle One)

pMO pM1 pM1a pM1b pM1c pMX

| Value | Value Description |
|-------|---------------------------------------|
| pM0 | No distant metastasis |
| pM1 | Distant metastasis |
| рМ1а | Non-regional lymph node(s) |
| pM1b | Bone(s) |
| рМ1с | Other site(s)* |
| pMX | Distant metastasis cannot be assessed |

CLINICAL STAGING:

112. cT Stage (Circle One)

| ТО | T1 | T1a | T1b | T1c | |
|----|-----|-----|-----|-----|-----|
| T2 | T2a | T2b | Т3 | Т3а | T3b |
| T4 | TX | | | | |

| Value | Value Description | | |
|-------|--|--|--|
| T0 | No evidence of primary tumor | | |
| T1 | Clinically inapparent tumor not palpable nor visible by imaging | | |
| T1a | Tumor incidental histologic finding in 5% or less of tissue resected | | |
| T1b | Tumor incidental histologic finding in more than 5% of tissue | | |
| TID | resected | | |
| T1c | Tumor identified by needle biopsy (e.g., because of elevated PSA) | | |
| T2 | Tumor confined within prostate* | | |
| T2a | Tumor involves 1 lobe | | |
| T2b | Tumor involves both lobes | | |
| Т3 | Tumor extends through the prostatic capsule** | | |
| T3a | Extracapsular extension (unilateral or bilateral) | | |
| T3b | Tumor invades seminal vesicle(s) | | |
| T4 | Tumor is fixed or invades adjacent structures other than seminal | | |
| 1 4 | vesicles | | |
| TX | Primary tumor cannot be assessed | | |

113. cN Stage (Circle One)

NO N1 NX

| Value | Value Description | | |
|-------|--|--|--|
| NO | No regional lymph node metastasis | | |
| N1 | Metastasis in regional lymph node or nodes | | |
| NX | Regional lymph nodes cannot be assessed | | |

114. cM Stage (Circle One)

MO M1 M1a M1b M1c MX

| Value | Value Description |
|-------|---------------------------------------|
| MO | No distant metastasis |
| M1 | Distant metastasis |
| M1a | Non-regional lymph node(s) |
| M1b | Bone(s) |
| M1c | Other site(s)* |
| MX | Distant metastasis cannot be assessed |

| General Staging Comments: | |
|----------------------------------|----------------------------------|
| | General Staging Comments: |

VITAL STATUS/FOLLOW UP DATE

Record the patient's vital status and most recent follow up date.

NOTE: If an attempt was made to follow up the patient history but no new data was collected since the last follow up, <u>make a note in the *final comments*</u> that an attempt was made on a specific date, and that the case may be "lost to follow up".

| | atus/Follow Up: Date Last Known Alive* | : |
|-------|---|-------------------|
| | / | (MM/YYYY) |
| 117. | Date of Death: | |
| | / | (MM/YYYY) |
| 118. | Vital Status*: (Circle Or | ne) |
| Alive | Dead | Lost to follow up |
| Dead | with Warm Autopsy | |
| 119. | Final Comments: | |
| | | |
| | | |
| | | |

THERAPY MATRIX (Items #120-123 are multiple entry

fields): Record the patient's treatment history.

- -Enter as many treatment information available.
- -If therapy event was part of initial planned treatment, please mark appropriate data field.
- -The data fields for the first 3 therapy events are included as *Therapy matrix a, b, c.* (Print additional forms if necessary)
- -"Per Initial Treatment Plan" is defined as: If there is no treatment plan, established protocol, or management guidelines, and consultation with a physician advisor is not possible, use the principle: 'initial treatment must begin within four months of the date of initial diagnosis.

120a. Therapy matrix: Type of Therapy: (Circle One) Chemotherapy Cryotherapy Watchful waiting Brachytherapy External Beam Radiation Radiation Therapy, NOS Immunotherapy Hormone Therapy, NOS Medical hormone suppression Alternative Therapy (specify in comments) Surgical orchiectomy **Experimental (specify in comments)** 121a. Therapy matrix: Therapy Start Date __ __/__ __ (MM/YYYY) 122a. Therapy matrix: Per Initial Treatment Plan? ** (Circle One) Yes No Unknown 123a. Therapy Matrix Comments: ______ 120b. Therapy matrix: Type of Therapy: (Circle One) Brachytherapy Chemotherapy Cryotherapy Watchful waiting External Beam Radiation Radiation Therapy, NOS **Immunotherapy** Hormone Therapy, NOS Medical hormone suppression Alternative Therapy (specify in comments) Surgical orchiectomy **Experimental (specify in comments)**

| 121b. T | 121b. Therapy matrix: Therapy Start Date | | | | | |
|--|--|-------------------------|-------------------|-----------------------|------------------|--|
| _ | / | (MN | M/YYYY) | | | |
| 122b. Therapy matrix: Per Initial Treatment Plan? ** (Circle One) (If there is no treatment plan, established protocol, or management guidelines, and consultation with a physician advisor is not possible, use the principle: 'initial treatment must begin within four months of the date of initial diagnosis.) | | | | | | |
| Y | es | No | Unknov | wn | | |
| 123b. T | herapy Matrix | Comments: | | | | |
| | | | | | | |
| ===== 120c. T | ====== herapy matrix | ====== : Type of The | ===== erapy: (| ====== Circle One) | ========= | |
| Brachyt | herapy | Chemothera | ару (| Cryotherapy | Watchful waiting | |
| Externa | l Beam Radiat | ion Radia | ation The | erapy, NOS | Immunotherapy | |
| Hormon | e Therapy, NC | OS Medic | cal horm | one suppres | ssion | |
| Alternat | ive Therapy (| specify in co | mments |) Surgic | cal orchiectomy | |
| Experim | ental (specify | in comment | :s) | | | |
| | herapy matrix | | | | | |
| | / | (MN | M/YYYY) | | | |
| 122c. T | herapy matrix | : Per Initial | Treatme | nt Plan? ** | (Circle One) | |
| Y | es | No | Unknov | wn | | |
| 123c. T | herapy Matrix | Comments: | | | | |
| | onal overall omments on T | | | ts: | | |
| 125. G | eneral Overal | Comments of | on Thera | ру: | | |

NEEDLE BIOPSY BLOCK MATRIX: [Items #126-134 are multiple entry fields. <u>Up to 5 blocks preferred (blocks a-e)</u>]

- Here are the recommended criteria for needle biopsy:
- 1) Can include one block or more (up to 5)
- 2) Must at least include one neoplastic block and classify according to the needle biopsy matrix.

NOTE: for biopsy-only cases, it is a requirement to enter the "subsequent prostatectomy" field in the biopsy attribute section.

"Biopsy-Only" cases are cases due to advance disease or other reasons that did NOT lead to a prostatectomy.

| 126a. Biopsy Matrix: Block number Accession and Block # (i.e. SP-91-645-1A): | | | | | |
|--|-------------|-----------------|-----------------|---------------------|--|
| | | | | — — | |
| 127a. Biopsy Matrix: M (Circle One) | ost Prom | inent Histoloç | gical Type of I | nvasive Cancer: | |
| Adenocarcinoma NOS (ak | a acinar) | Undiffer | entiated non-sr | mall cell carcinoma | |
| Mucinous adenocarcinoma | a | Signet ring ade | enocarcinoma | Lymphoma | |
| Transitional (not primary) | Ducta | l adenocarcino | ma Neuroend | docrine carcinoma | |
| Small cell anaplastic carci | noma | Sarcomatoid ca | arcinoma Ba | asal cell carcinoma | |
| Squamous or adenosquar | nous carcii | noma M | Mesenchymal tu | mor (NOS) | |
| PIN only Unk | nown | Other (s | specify in comm | ents) | |
| | | | | | |
| 128a. Biopsy Matrix: P | rimary Gl | eason Grade: | (Circle One) | | |
| Gleason grade: 1 | 2 | 3 | 4 | 5 | |
| not adenocarcinoma | not prir | mary tumor | Unknown | PIN only | |
| | | | | | |
| 129a. Biopsy Matrix: So | econdary | Gleason Grac | le: (Circle One |) | |
| Gleason grade: 1 | 2 | 3 | 4 | 5 | |
| not adenocarcinoma | not prir | mary tumor | Unknown | PIN only | |
| | | | | | |
| 130a. Biopsy Matrix: S | ize of Lar | gest Individu | al Nodule of Ir | nvasive Cancer | |
| (in cm) · · | cm (- | 1=unknown, (| 0.0 – 99.9 cm) |) | |

(131a-133a) BIOPSY BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Perineural Invasion (PN); Angiolymphatic Invasion (AL). (circle all that apply) PIN PNΑL None 134a. Biopsy Matrix: block comments _____ 126b. Biopsy Matrix: Block number Accession and Block # (i.e. SP-91-645-1A): 127b. Biopsy Matrix: Most Prominent Histological Type of Invasive Cancer: (Circle One) Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lymphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Small cell anaplastic carcinoma Sarcomatoid carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Unknown Other (specify in comments) 128b. Biopsy Matrix: Primary Gleason Grade: (Circle One) Gleason grade: 1 2 3 4 5 not adenocarcinoma not primary tumor Unknown PIN only 129b. Biopsy Matrix: Secondary Gleason Grade: (Circle One) 3 Gleason grade: 1 2 5

not primary tumor

not adenocarcinoma

PIN only

Unknown

| 130b. Biopsy Matrix: Size of Largest Individual Nodule of Invasive Cancer (in cm) | | | | | | | |
|---|-------------------------------------|--------------|----------------|------------------|--------------------|--|--|
| (III CIII | • | cm (-1 | =unknown, (| 0.0 – 99.9 cm) | | | |
| (131b-133b) BIOPSY BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Perineural Invasion (PN); Angiolymphatic Invasion (AL). (circle all that apply) | | | | | | | |
| PIN | PN | AL | None | | | | |
| 134b. Bio | 134b. Biopsy Matrix: block comments | | | | | | |
| | | | | | | | |
| 126c. Biopsy Matrix: Block number Accession and Block # (i.e. SP-91-645-1A): ——————————————————————————————————— | | | | | | | |
| | • | | | | all cell carcinoma | | |
| | adenocarcinor | | | nocarcinoma | · . | | |
| Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma | | | | | | | |
| Small cell | anaplastic car | cinoma S | Sarcomatoid ca | ircinoma Ba | sal cell carcinoma | | |
| Squamous | or adenosqua | amous carcin | oma N | Mesenchymal tur | nor (NOS) | | |
| PIN only | | known | | specify in comme | ents) | | |
| 128c. Bio | psy Matrix: | Primary Gle | ason Grade: | (Circle One) | | | |
| Gleason gr | ade: 1 | 2 | 3 | 4 | 5 | | |
| not adeno | carcinoma | not prim | nary tumor | Unknown | PIN only | | |

| 129c. Biops | y Matrix: Sec | ondary G | leason Grad | le: (Circle O | ne) | |
|---|--|-------------------|--|----------------|-----------------------|--|
| Gleason grad | e: 1 | 2 | 3 | 4 | 5 | |
| not adenocar | cinoma | not prima | ary tumor | Unknowr | n PIN only | |
| 130c. Biops (in cm) | 130c. Biopsy Matrix: Size of Largest Individual Nodule of Invasive Cancer (in cm) cm (-1=unknown, 0.0 - 99.9 cm) | | | | | |
| (131c-133c) BIOPSY BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Perineural Invasion (PN); Angiolymphatic Invasion (AL). (circle all that apply) | | | | | | |
| PIN | PN | AL | None | | | |
| ====================================== | y Matrix: bloo | ===== ck numbe | ====================================== | | | |
| 127d. Biopsy Matrix: Most Prominent Histological Type of Invasive Cancer: (Circle One) | | | | | | |
| Adenocarcino | ma NOS (aka a | acinar) | Undiffer | entiated non- | -small cell carcinoma | |
| Mucinous ade | enocarcinoma | Sig | gnet ring ade | enocarcinoma | Lymphoma | |
| Transitional (| not primary) | Ductal a | idenocarcino | ma Neuro | endocrine carcinoma | |
| Small cell and | aplastic carcino | oma Sa | arcomatoid ca | arcinoma | Basal cell carcinoma | |
| Squamous or | adenosquamo | us carcino | ma M | Mesenchymal | tumor (NOS) | |
| PIN only | Unkno | wn | Other (s | specify in con | nments) | |

| 128d. Biopsy Matrix: Primary Gleason Grade: (Circle One) | | | | | | |
|---|----------------|----------------|--------------|-----------------|------------|--|
| Gleason grade | e: 1 | 2 | 3 | 4 | 5 | |
| not adenocard | cinoma | not primary to | umor | Unknown | PIN only | |
| | | | | | | |
| 129d. Biops | y Matrix: Sec | ondary Gleas | on Grade: (| Circle One) | | |
| Gleason grade | e: 1 | 2 | 3 | 4 | 5 | |
| not adenocard | cinoma | not primary to | umor | Unknown | PIN only | |
| | | | | | | |
| 130d. Biopsy | y Matrix: Size | of Largest I | ndividual No | odule of Invasi | ive Cancer | |
| (| | cm (-1=unk | known, 0.0 - | - 99.9 cm) | | |
| (131d-133d) BIOPSY BLOCK ATTRIBUTES: Presence of: High Grade Prostatic Intraepithelial Neoplasia (PIN); Perineural Invasion (PN); Angiolymphatic Invasion (AL). (circle all that apply) | | | | | | |
| PIN | PN | AL | None | | | |
| | | | | | | |
| | | | | | | |
| 134d. Biopsy Matrix: block comments | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| 126e. Biopsy Matrix: Accession and B | lock # (i.e. S | | | | |
|---|----------------|-----------------|--|--------------------|--|
| 127e. Biopsy Matrix: (Circle One) | Most Promi | nent Histolog | jical Type of In | vasive Cancer: | |
| Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma | | | | | |
| Mucinous adenocarcino | ma S | Signet ring ade | nocarcinoma | Lymphoma | |
| Transitional (not prima | ry) Ductal | adenocarcinor | ma Neuroend | ocrine carcinoma | |
| Small cell anaplastic ca | rcinoma S | Sarcomatoid ca | ircinoma Ba | sal cell carcinoma | |
| Squamous or adenosqu | ıamous carcir | noma N | Mesenchymal tur | mor (NOS) | |
| PIN only U | nknown | Other (s | specify in comme | ents) | |
| 128e. Biopsy Matrix: | Primary Gle | eason Grade: | (Circle One) | | |
| Gleason grade: 1 | 2 | 3 | 4 | 5 | |
| not adenocarcinoma | not prin | nary tumor | Unknown | PIN only | |
| 129e. Biopsy Matrix: | Secondary | Gleason Grad | e: (Circle One) | | |
| Gleason grade: 1 | 2 | 3 | 4 | 5 | |
| not adenocarcinoma | not prin | nary tumor | Unknown | PIN only | |
| 130e. Biopsy Matrix: (in cm) — — | | | al Nodule of In 0.0 – 99.9 cm) | vasive Cancer | |
| (131e-133e) BIOPS' High Grade Prostatic (PN); Angiolymphatic | Intraepithe | lial Neoplasia | a (PIN); Perine | | |
| PIN PN | AL | None | | | |
| 134e. Biopsy Matrix: block comments | | | | | |

OVERALL NEEDLE BIOPSY ATTRIBUTES:

- Enter the overall characteristics of the biopsy.
- For "biopsy-only" cases, the subsequent prostatectomy field is a required field.

NOTE: "Biopsy-Only" cases are cases due to advance disease or other reasons that did NOT lead to a prostatectomy.

135. Biopsy: Most Prominent Histological Type of Invasive Cancer (Circle One)

Adenocarcinoma NOS (aka acinar) Undifferentiated non-small cell carcinoma Mucinous adenocarcinoma Signet ring adenocarcinoma Lymphoma Transitional (not primary) Ductal adenocarcinoma Neuroendocrine carcinoma Small cell anaplastic carcinoma Sarcomatoid carcinoma Basal cell carcinoma Squamous or adenosquamous carcinoma Mesenchymal tumor (NOS) PIN only Other (specify in comments) Unknown

136. Biopsy: Primary Gleason Grade: (Circle One)

Gleason grade: 1 2 3 4 5

not adenocarcinoma not primary tumor Unknown PIN only

137. Biopsy: Secondary Gleason Grade: (Circle One)

Gleason grade: 1 2 3 4 5

not adenocarcinoma not primary tumor Unknown PIN only

138. Biopsy: Gleason Sum Score: (Circle One)

Gleason score 2 Gleason score 3 Gleason score 4
Gleason score 5 Gleason score 6 Gleason score 7
Gleason score 8 Gleason score 9 Gleason score 10
not adenocarcinoma not primary tumor unknown

139. Biopsy: Percentage of Gleason 4/5 grade (in all of 6's and 7's)

__ __ % (0.x - 100 %, -1 = unknown)

| 140. | Percentage of Biopsy Occupied by Tumor: (Circle One) | | | | | |
|-------|---|---------------|------------------------|-------------------|--|--|
| | <5% | 5 to 25% | >25% | Unknown | | |
| 141. | Biopsy: Presence (Circle One) | of High Grade | Prostatic Intraepith | nelial Neoplasia: | | |
| Yes - | # of foci unknown | | Yes – 1 or 2 foci in i | region of tumor | | |
| Yes – | 1 or 2 foci away fr | om tumor | Yes – multifocal | | | |
| No | | | Unknown | | | |
| 142. | Biopsy: Non-Neop Accession and Block | | 645-1A): | | | |
| 143. | . Subsequent Prostatectomy:** (Circle One) Definition: Specifies whether a subsequent prostatectomy occurred. This field will help clarify cases where only biopsy specimens are available. | | | | | |
| | Yes | No | Unknown | | | |
| 144. | Subsequent Prosta | atectomy com | ments: | | | |
| | | | | | | |
| 145. | General Comment | s on Biopsy: | | | | |
| | | | | | | |
| | | | | | | |