FINAL Version 3.0 (May 31, 2006)

EARLY DETECTION RESEARCH NETWORK

Standard Specimen Reference Set: Prostate Biopsy Cohort Case-Control Blood Samples

Standard Operating Procedure - Blood Collection and Processing Guidelines

(Based on I Thompson et al EDRN GU-Prostate Group Request for Set Aside Funds 2005 and Prostate Reference Set SOP Consensus Panel Conference Calls, Oct – Dec 2005 – attendees M Sanda, J Kagan, (chairs), W Grizzle, D Chan, R Shah, Z Zheng, Betsy Higgins, Project Manager from UT-San Antonio, Leslie Mangold, Project Manager from Johns Hopkins; minutes/recommendations draft by Jackie Dahlgren reviewed and assembled by M Sanda)

Serum, Plasma and Blood Cellular Component Sample Collection, Processing, and Storage

1. Overview

1.1 **Background** (from I Thompson et al, request for set-aside funds 2005)

The Early Detection Research Network of the National Cancer Institute is charged with the discovery, development, and validation of biomarkers related to neoplastic disease. The Genitourinary (GU) Collaborative Group of the EDRN is responsible for these efforts related to cancers of the Genitourinary organs, currently including prostate, kidney and bladder. In addition to the discovery and validation efforts for new biomarkers, the GU Collaborative Group has on hand and continues to assemble a repository of biologic specimens for subjects with and without cancer with a companion clinical database with extensive information related to demographics as well as other risk factors for disease.

One of the major objectives of the EDRN GU Collaborative Group is to seek and identify the most promising biomarkers for GU cancers and to rapidly move these biomarkers into the clinical realm. To date, many initial reports on such markers have suffered from varying degrees of rigor in initial validation methodologies, making comparisons of the relative promise of each biomarker nearly impossible. To overcome this challenge, the GU Collaborative Group is assembling a large renewable standard set of biospecimens from subjects with and without cancer.

A request, in the form of a solicitation will be made to all EDRN investigators for proposals to utilize a fraction of these standard biomarkers specimen test sets. Submissions will be judged on the basis of merit and, based on the ability of the bio-specimen set to address issues related to performance (pre-validation) of specific biomarkers. A panel of promising biomarkers chosen fro, the requests taken from EDRN members and Associate members will be selected to be tested within the standard bio-specimen set. It is anticipated that the most promising of these biomarkers will be considered for further evaluation and standard larger EDRN sanctioned validation studies.

The GU Collaborative Group of the EDRN has recognized the need for a systematic evaluation of biomarkers of prostate cancer in a standardized, pre-validation fashion to allow a head-to-head evaluation of the markers in a standard reference set of biologic samples. The three applications noted below have been prioritized as the primary targets for men without a history of prostate cancer. Other potential groups include but are not limited to: history of high-grade PIN, atypia on a previous biopsy, individuals on an expectant management program, men with known metastatic disease (prognosis), patients with bladder cancer (superficial or invasive), patients with renal cell carcinoma. All samples will be collected under IRB approval with informed consent and aliquots made on site by the various EDRN groups. All samples will be stored and distributed by the EDRN out of the Frederick, Maryland Facility.

It is initially anticipated that the reference set of bio-specimens will be developed through contributions of four of the EDRN institutions (one Developmental and three CEVC's) prior to issue of an 'EDRN Request for Applications'. This potential RFA will allow EDRN and other institutions

to provide preliminary data to justify the promise of biomarkers for these applications. After a ranking of potential markers, de-identified samples from CVEC's will be sent to applicants for analysis in a blinded fashion. Data excluding personal health identifiers (PHI) will thereafter be transmitted to the DMCC, and the performance of the biomarkers evaluated.

After a discussion regarding potential applications of new biomarkers in the field of prostate cancer, three applications were identified after Collaborative Group discussions in association with input from Program Staff as well as the leadership of the EDRN DMCC. These initial application bio-specimen test sets will represent the first of anticipated such groups of such test sets to be included within the EDRN armamentarium to be used for pre-validation analysis of biomarkers. The initial prostate cancer reference set to be assembled by the EDRN-CVEC will focus on blood samples collected prior to prostate biopsy among men who have not previously been diagnosed with prostate cancer; applications represent the prime focus of the GU Collaborative group, are focused on Prostate Cancer, namely the "Prostate Biopsy Cohort Case-Control Reference Set." This reference set represents a refined standard operating procedure and plan for specimen collection, data annotation, previously referred to as application one in the request for set-aside funds issued by Thompson et al on behalf of the EDRN CVEC's in June 2005 (excerpt follows):

"Application One: Secondary Evaluation of Men with a PSA above 2.5 ng/ml, a rising PSA, abnormal DRE, or other indication for prostate biopsy. Despite the long-time use of a 4.0 ng/ml cutoff for a 'normal' PSA value, it has been acknowledged that only about 25% of men with such an elevated value will be found to have prostate cancer at prostate biopsy. Because of this, three-quarters of men with an elevated PSA who have a biopsy undergo the procedure unnecessarily. Recent data from large longitudinal screening programs and from the Prostate Cancer Prevention Trial now suggest that the risk of prostate cancer is equally elevated (20-25%) even among men with serum PSA levels from 2.5 ng/ml to 4.0 ng/ml. Additional indications for prostate biopsy include a rising PSA (oftentimes with the use of an increase of 0.75 ng/ml or a trend of increase in the biomarker, an abnormal digital rectal examination, or even a lower PSA value for a patient with other risk factors. For example, in accord with the initial demonstration from Hopkins that family history is linked to prostate cancer risk, the San Antonio EDRN group has demonstrated that for a 65 year old man with a first degree relative with prostate cancer, a PSA of 1.8 carries a 25% positive predictive value for prostate cancer. An opportunity exists for a biomarker in this application to reduce the number of unnecessary initial and repeat biopsies in men who are ultimately proven to not have prostate cancer while maintaining a very high level of sensitivity. A group of bio-specimens from men who fit these criteria will be provided by CVEC's for the prostate biopsy cohort case-control reference set."

1.2 Objective:

To collect biologic samples on men prior to prostate biopsy, in association with clinical information and common data elements appropriate for evaluation of risk and prognosis of prostate cancer.

1.3 Patient eligibility:

1. Male over age 40.
2. Patient scheduled for prostate biopsy for any of the following reasons:
   - PSA > 2.5 ng/ml
   - Rising PSA (>0.5 ng/ml/yr)
   - Lower PSA value with other risk factors for prostate cancer (e.g.; family history)
   - abnormal DRE
   - percent free PSA <15%
3. No prior history of prostate cancer or prostate biopsy.
4. Prostate biopsy with at least 10 cores taken in a laterally directed fashion.
5. Blood collected prior to prostate biopsy.

6. Prostate biopsy pathology report available.

1.4 Additional data elements to be obtained are described below (Section 8) and listed in Appendix C, "Prostate Biopsy Reference Set Common Data Elements"

1.5 Participating Institutions:
Johns Hopkins University – P.I. Alan W. Partin, MD, PhD
University of Texas Health Science Center at San Antonio – P.I. Ian Thompson, MD
Harvard Universityand University of Michigan – P.I. Martin Sanda, MD; co-PI John T. Wei, M.D.
MD Anderson Cancer Center – P.I. Bogdan Czerniak, MD, PhD

2. Materials

1. Serum: Two 10ml red top glass tube, no additive, no clot activator with silicone coated interior, (BD366430).
   http://catalog.bd.com/bdCat/viewProduct.doCustomer?productNumber=366430
2. Plasma-EDTA: One 6ml EDTA plastic tube (367899)
   http://catalog.bd.com/bdCat/viewProduct.doCustomer?productNumber=367899
3. Plasma-Citrate: One 4.0ml Citrate CPT tube (362760)
   http://www.bd.com/vacutainer/products/molecular/citrate/
4. Aliquot containers for all blood specimens: 0.5ml Polypropylene Micro Tubes, screw top, conical skirted (Sarstedt 72.730)
   http://www.sarstedt.com/php/main.php
5. 125 sets of 2-D barcode labels, one for each person contributing specimens

See Appendix B

3. Serum Specimens (processing consistent with http://www.bd.com/vacutainer/pdfs/blood_collection_tubes_product_insert_VDP40035.pdf)

Serum is obtained from whole blood collected in red top vacutainer tubes with no additives or clot activators. The blood specimen should be allowed to clot for minimum of 30 minutes and maximum of 60 minutes at room temperature, stored at 4^0C for up to 18 hours and then centrifuged 20 minutes at 1300g-force, 4 degrees Celsius. Serum (supernatant post-centrifugation) will then be placed in 100 microliter aliquots. The goal is for the serum to be centrifuged and transferred to the Micro Tubes **within 4 hours of collection**, (however up to 18 hours is acceptable; time at 4^0C will be recorded as a specimen-specific CDE). Samples are then frozen at -80^0C or colder until shipping to NCI-Frederick. Hemolyzed serum samples are to be excluded.

4. Plasma and cellular fraction specimens (processing consistent with http://www.bd.com/vacutainer/pdfs/blood_collection_tubes_product_insert_VDP40035.pdf)

Two types of Plasma and cellular fractions are being collected: one set using EDTA, another using Citrate-based CPT separator tubes:

4.1 EDTA

4.1.1 Plasma is obtained from whole blood collected in plastic vacutainer tubes containing EDTA from Becton-Dickinson. Tubes are inverted for mixing as per phlebotomy routine and BD instructions. The blood specimen should be placed immediately on ice or 4^0C and centrifuged 10 minutes at 1500g-force. Plasma should be stored at 4^0C until aliquotted. The goal is for the plasma to be centrifuged and transferred to the Micro Tubes **within 4 hours of collection**, however up to 18 hours is acceptable. Plasma samples are then frozen at -80^0C or colder until shipping to NCI-Frederick.

4.1.2 The remaining cellular fraction after removal of EDTA-plasma includes red cells and white cells, and will be admixed by gentle vortexing for 10 seconds, after which the admixed cellular fraction will be divided into 100 microliter aliquots and then frozen at -80^0C or colder until shipping to NCI-Frederick.

4.2 Citrate-CPT Buffy Cell Layer Separation (as described in http://www.bd.com/vacutainer/products/molecular/citrate/procedure.asp)

4.2.1 Citrate Plasma is obtained from whole blood collected in BD CPT Cell Preparation tubes with sodium citrate. Tubes are inverted for mixing as per phlebotomy routine and BD instructions. CPT tube samples should then be stored at room temperature until centrifugation. The goal is for the subsequent centrifugation and cell/plasma separation to be performed **within 1 to 2 hours if possible**. To process samples, resuspend the sample (if cells have settled after initial draw and transport) by inverting the sample, then centrifuge at 1500g (RCF) for 15-25 minutes at room temperature. Remove top (plasma) layer, aliquot plasma in 100 microliter aliquots and store at -80^0C or colder until shipping to NCI-Frederick.

4.2.2 Isolation of cellular fraction from CPT tube is accomplished (after removal of the plasma fraction) by then removing the lymphocyte and monocyte band, transferring to a 15 ml conical centrifuge tube, adding PBS (pH=7.0) to attain 10 ml final volume, then inverting the sample 5 times to remix the sample, and then centrifuge at 300g (RCF) for 15 minutes at room temperature. Aspirate and discard supernatant without disturbing the pellet, then resuspend pellet and then add 10 ml PBS, mix sample by inverting 5 times, and centrifuge at 300g (RCF) for 15 minutes at room temperature. Repeat the PBS wash step once, then resuspend pellet in 500 microliters PBS, then divide the cellular fraction into 100 microliter aliquots. Store at -80^0C or colder until shipping to NCI-Frederick.

5. Sample Aliquots

1. Sites are being asked to ship a minimum of forty 100µl serum aliquots to NCI-Frederick. The remaining serum can be kept locally. If a site is unable to provide forty aliquots, please send what is obtained.

2. Sites are being asked to ship a minimum of fifteen 100µl EDTA plasma aliquots to NCI-Frederick. The remaining plasma from the EDTA tube can be kept locally. If a site is unable to provide fifteen aliquots, please send what is obtained.
3. Sites are being asked to ship a minimum of twelve 100µl Citrate plasma aliquots to NCI-Frederick. The remaining plasma from the Citrate tube can be kept locally. If a site is unable to provide twelve aliquots, please send what is obtained.
4. Sites are being asked to ship a minimum of six 100µl EDTA cellular component aliquots to NCI-Frederick. The remaining cellular component from the EDTA tube can be kept locally. If a site is unable to provide six aliquots, please send what is obtained.
5. Sites are being asked to ship a minimum of four 100 µl Citrate cellular component aliquots to NCI-Frederick. The remaining cellular component from the Citrate tube can be kept locally. If a site is unable to provide four aliquots, please send what is obtained.

6. Shipping Procedure

Samples will be stored locally until the contributing site receives notification from the DMCC of what specimens have been selected for contribution to the reference set. Once specimens are identified, specimens will be shipped, using VSIMS, to NCI-Frederick.

Judith Frank
NCI Frederick
4600 Wedgewood Blvd, Suite H
Frederick, MD 21703

7. Statistical Considerations

Sample Size Calculation

Rapid Pre-validation Set:
The objective for this set is to provide a rapid assessment for a biomarker or a biomarker panel that has passed the Phase I in a single site and is proposed for a Phase II validation study. The results of the assessment will decide whether this biomarker or biomarker panel should move forward for a multi-center validation study.
A total of 125 sample sets (anticipating 55 cases and 70 controls) will be enrolled per site in this study. It is felt that this total will allow an initial review of the sensitivity, specificity, and positive predictive value of new prostate cancer biomarkers. This sample size is chosen based on three considerations. 1) For a biomarker to be considered for further validation, it should be significantly better than sensitivity 80% and specificity 45% (corresponding to PPV=33% and NPV=87%), the unacceptable lower bound, jointly at a one-sided test of binomial proportion at alpha level 0.20. 2) At the same time, we also want high probability that a biomarker will be selected if it is not significantly worse than the target sensitivity 95% and specificity 65% (corresponding to PPV=47% and NPV=97.5), the desired upper bound, at alpha=0.10 for a joint one-sided test. The rationale for these parameters is that at current EDRN GU situation, we want to make sure the good biomarkers to be selected with high probability (90%) and allow 20% chance that an inadequate biomarker will be selected for validation 3) We want the joint confidence region for sensitivity and specificity tight enough such that if the observed sensitivity

and specificity of a biomarker on the pre-validation set is between the upper bound and lower bound, the 90% confidence region will not cross both upper and lower bounds to allow a clear decision.
At this sample size, if a biomarker's true performance is at the upper bound, it has more than 90% probability to be selected for validation. If a biomarker's true performance is at the low bound, we have about 95% power to conclude that it is significantly worse than the upper bound. When the biomarker's true performance is in the grey zone (between lower bound and upper bound), we have 90% confidence to conclude whether it is significantly better than the lower bound and not significantly worse than the upper bound (so it should move forward for validation study), or it is significantly worse than the up bound and not significantly better than the low bound (so it should not move forward). The criterion for having access to this sample set is that the biomarker performance, reported from a single site, is significantly better than the lower bound (completion of Phase I) and there is no obvious fatal flaw in the study design.

8. Common Data Elements to be Measured – see Appendix C

8.1 Identifiers

Subject ID

Date of Consent

8.2 Demographic

Age
Race/Ethnicity
Weight/Height
Smoking History

8.2 Clinical

Prostate Health History
Medications
Prostate Biopsy History and Exam
Labs(PSA)
TRUS Procedure Details

8.3 Pathology and TNM Staging

Prostate Cancer Details
Non-cancer prostate biopsy pathology details

8.4 Specimen Collection and Processing

Aliquot number
Time from blood call collection and freezer
Blood collected before or after DRE
Specimen type
Additive used
Storage temperature before shipping to NCI facility

Appendix B: Phlebotomy Materials and Procedure

(Recommendation from DCC at FHCC; not discussed by Prostate Reference Set SOP Consensus panel)

Collection Procedure

See http://www.bd.com/vacutainer/pdfs/blood_collection_tubes_product_insert_VDP40035.pdf

NOTE: Tubes with additives must be thoroughly mixed. Erroneous test results may be obtained when the blood is not thoroughly mixed with the additive.

Materials: Gloves, sharps Container, vacutainer needles, vacutainer hub or Butterfly needle, attached tubing and Luer adapter, Tourniquet, Antiseptic wipes, bandages, centrifuge as per routine phlebotomy procedures at clinical sites

1. Assemble the supplies to be used in obtaining the specimen. Do not label the vacutainer tubes until specimen is obtained.
2. Put on disposable gloves.
3. The patient should be comfortably seated in a venipuncture chair. The arm should be positioned on a slanting armrest in a straight line from the shoulder to the wrist. The arm should not be bent at the elbow.
4. Apply a tourniquet 2 inches above the antecubital fossa or above area to be drawn with enough pressure to provide adequate vein visibility. Have the patient form a fist. Select the site for venipuncture.
5. Clean the forearm of the patient with antiseptic wipe in a circular motion beginning at the insertion site. Allow the antiseptic to dry.
6. Anchor the vein by placing the thumb 2 inches below the site and pulling the skin taut to prevent the vein from moving. The holding finger is placed below the site, not above, to prevent accidentally sticking the finger with the needle.
7. Using the dominant hand, insert either the vacutainer needle or the butterfly needle (if using vacutainer needle, attach hub first). Push the evacuated tube onto the vacutainer hub or the Luer adapter if using a butterfly.
8. Release the tourniquet once blood flow is established.
9. Carefully remove the tubes when full without dislodging the needle. The tube will automatically stop filling when the vacuum is gone leaving the tube approximately three-fourths full.
10. Lightly place a sterile gauze pad over the venipuncture site. Gently remove the needle.
11. Apply pressure to the site with sterile gauze. Apply bandage. Instruct the patient to leave the bandage on for at least 15 minutes.
12. Dispose of the needle in a sharps container.

Remove gloves and wash hands.

Appendix C – Common Data Elements to be Collected

** is Primary Key.
* is requried field.

Prostate Reference Set (Form ID: 408)
Baseline
Standard Specimen Reference Set: Prostate
EDRN Validation Study and Reference Set

** 421 EDRN Participant ID (Go To: **1288)** ⌊_____⌋

** 1288 Date participant signed consent form (Go To: **423)**

423 EDRN Protocol ID (Go To: **422)** ⌊___⌋

422 EDRN Site ID (Go To: **1292)** ⌊___⌋

Demographics

1292 Height [in inches] (What is your total current height in inches?) (Go To: **1295)**
⌊___⌋

1295 Weight [in pounds] (What is your current weight [in pounds]? (Go To: **1293)**
⌊___⌋

1293 Hispanic or Latino (Are you Hispanic or Latino?) (Go To: **1315)**

☐0 No ☐1 Yes
☐9 Unknown/refused

1315 Race (What is your race? Check all that apply.) (Go To: **1567 if more than once race selected below, otherwise Go to 578)**

☐1 White ☐2 Black or African-American
☐3 American Indian or Alaska Native ☐4 Asian
☐7 Native Hawaiian or other Pacific Islander ☐97 Other, specify: (Go To: **1294)**
☐99 Unknown/refused

1294 Race (Other,specify) (Go To: **1567 if more than one race selected above, otherwise Go to 578)**

1567 Which race do you consider to be your primary racial background? (Go To: **578)**

- ☐1 White
- ☐2 Black or African-American
- ☐3 American Indian or Alaska Native
- ☐4 Asian
- ☐7 Native Hawaiian or other Pacific Islander
- ☐97 Other, specify: (Go To: **1579)**
- ☐99 Unknown/refused

1579 Primary racial background (Other, specify) (Go To: **578)**

578 Age at specimen collection (Go To: **1300)** ⌊__⌋

Smoking History

1300 Ever smoke cigarettes regularly, at least one a day for a year or more? (Did you ever smoke cigarettes regularly, at least one a day for a year or more?) (Go To: **1568)**

- ☐0 No
- ☐1 Yes (Go To: **1299)**
- ☐9 Unknown/refused

1299 Currently smoke at least one cigarette a day? (Do you currently smoke cigarettes regularly, at least one a day?) (Go To: **1297)**

- ☐0 No (Go To: **1298)**
- ☐1 Yes
- ☐9 Unknown/refused

1298 Age quit smoking cigarettes? (How old were you when you permanently quit smoking cigarettes?) (Go To: **1297)**

1297 Age first began smoking cigarettes regularly, at least one a day? (How old were you when you began smoking cigarettes regularly, at least one a day?) (Go To: **1325)**

1325 Average number of cigarettes smoked per day? (During the time you have smoked, on average, how many cigarettes did you smoke per day?) (Go To: **1568)** ⌊__⌋ Cigarettes

Family Cancer History

1568 Have any of the participants living or deceased first or second-degree blood relatives been diagnosed with prostate cancer? (Go To: **886)**

- ☐0 No
- ☐1 Yes (Go To: **1569)**
- ☐9 Unknown/refused

1569 How many of the participant´s living or deceased first or second-degree blood relatives have been diagnosed with prostate cancer? (Go To: **1570)** ⌊__⌋

1570 How many of the participant´s living or deceased first or second-degree blood relatives have died of prostate cancer? (Go To: **886)**

Prostate Health History

886 Have you ever been told by a doctor that you have any of the following genitourinary conditions? (Check all that apply.) (Go To: **1571)**

- ☐1 [Males only] BPH (Benign prostatic hypertrophy)
- ☐2 Hematuria (blood in the urine)
- ☐3 [Males only] Prostatitis (an inflamed prostate)
- ☐6 Urethritis (inflammation of the urethra)
- ☐7 Other type of genitourinary tract infection
- ☐44 None

1571 Have you ever had any of the following procedures or problems? (Check all that apply.) (Go To: **1576)**

- ☐1 [Males only] Transurethral resection of the prostate (TURP)
- ☐2 [Males only] Transurethral incision of the prostate (TUIP)
- ☐3 [Males only] Laser treatment for the prostate (interstitial laser or Niagra PVP)
- ☐4 [Males only] Microwave or heat treatment for the prostate (TUNA or TUMT)
- ☐5 [Males only] Balloon dilation
- ☐44 None

1576 American Urological Association (AUA) symptom score: (Go To: **1691)** ⌊_⌋

1691 Quality of life due to urinary symptoms: (Go To: **1572)**

- ☐1 Delighted
- ☐2 Pleased
- ☐3 Mostly satisfied
- ☐4 Mixed
- ☐5 Mostly dissatisfied
- ☐6 Unhappy
- ☐7 Terrible

Medication Use

1572 Have you ever taken any of the following medications or supplements for a prostate or

genitourinary condtion? (Check all that apply.) (Go To: **1577)**

☐1	5-alpha reductase inhibitors (ed Avodart or Proscar)	☐2	Alpha-blockers (eg Doxazoin, Terazosin, Tamsulosin, others)
☐3	Anit-cholinergics	☐4	Androgens (eg Testosterone, Androgel, others)
☐5	Saw Palmetto	☐44	None
☐97	Other medications for prostate related conditions, specify: (Go To: **1573)**		

1573 Other prostate or genitourinary medications, specify: (Go To: **1574)**

1574 When were the medications or supplements for your prostate or genitourinary condition last taken? (Go To: **1575)**

☐1 Within the past month ☐2 More than 1 month ago

1575 Total number of months taken (Go To: **1318)** ⌊__⌋

Prostate Biopsy History and Exam

1318 Previous prostate biopsy? (Go To: **1699)**

☐0 No ☐1 Yes (Go To: **1698)**

1698 How many prostate biopsies have you previously had? (Go To: **1699)** ⌊__⌋

1699 Date of current prostate biopsy: (Go To: **1577)** ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ Month Day Year

1577 Indication for current prostate biopsy (Check all that apply.) (Go To: **979)**

☐1	Rising PSA	☐2	Elevated PSA
☐3	Abnormal DRE	☐4	Abnormal biopsy
☐5	Atypia	☐6	Atypical small acinar proliferation (ASAP)
☐7	Family history	☐8	High grade PIN
☐97	Other, specify: (Go To: **1578)**		

1578 Indication for prostate biopsy, other specify: (Go To: **979)**

979 Date of digital rectal exam (DRE) (Go To: **976)** ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ Month Day Year

976 Digital rectal exam results (Go To: **1580)**

☐1 Normal ☐3 Enlarged, benign

☐4 Enlarged/Asymmetry

☐5 Abnormal (firm/induration/nodularity), suspicious for cancer

☐99 Unknown/refused

1580 Amount of induration/nodularity on digital rectal exam (DRE), if not normal: (Go To: **1582)**

☐1 < 50% right

☐2 ≥ 50% right

☐3 < 50% left

☐4 ≥ 50% left

☐5 Bilateral

☐6 Abnormal DRE but extent not specified

Labs

1582 Date of PSA: (Go To: **947)** Month Day Year

947 PSA (ng/ml) (Go To: **1692)**

TRUS Procedure Details

1692 Prostate size (by TRUS) (Go To: **1581)** ⌊__⌋

1581 Hypoechoic or suspicious foci seen? (Go To: **1583)**

☐0 No

☐1 Yes

1583 Number of cores biopsied on left: (Go To: **1584)**

1584 Number of cores biopsied on right: (Go To: **1693)**

1693 Number of other cores biopsied: (Go To: **1585)** ⌊__⌋

1585 Types of other cores biopsied, specify: (Go To: **1586)**

1586 Presence of prostate adenocarcinoma: (Go To: **984)**

☐1 Malignancy absent

☐2 Malignancy present (Go To: **1587)**

Prostate Cancer Details

1587 Number of positive cores involved on left: (Go To: **1589)**

1588 Number of positive cores involved on right: (Go To: **1589)**

1589 Primary Gleason grade (Go To: **1590)**

1590 Secondary Gleason grade: (Go To: **1696)**

1696 Tertiary Gleason Pattern: (Go To: **1697)** ⌊__⌋

1697 Overall Gleason Score: (Go To: **1591)** ⌊_⌋

1591 Perineural invasion: (Go To: **1592)**

☐1 Present ☐2 Absent

1592 Percent of cancer in core with most cancer: (Go To: **1593)**

1593 Length of core with most cancer (mm): (Go To: **975)**

975 Prostate T-Stage, Clinical (Go To: **1594)**

☐2 T0	☐3 T1
☐4 T1a	☐5 T1b
☐6 T1c	☐7 T2
☐8 T2a	☐9 T2b
☐10 T2c	☐11 T3
☐12 T3a	☐13 T3b
☐14 T4	☐15 TX

1594 Prostate N-Stage, Clinical (Go To: **1694)**

☐1 NX	☐2 N0
☐3 N1	

1694 Prostate M-Stage, Clinical (Go To: **984)**

☐1 MX	☐2 M0
☐3 M1	☐4 M1a
☐5 M1b	☐6 M1c

Non-cancer Prostate Biopsy Pathology Details

984 High grade prostatic intraepithelial neoplasia (PIN)? (Go To: **1595)**

☐0 No ☐1 Yes

1595 Inflammation present? (Go To: **1596)**

☐0 No ☐1 Yes

1596 Atypical small acinar proliferation (ASAP)? (Go To: **1597)**

☐0 No ☐1 Yes

1597 Atypia/Suspicious? (Go To: **1598)**

☐0 No ☐1 Yes

1598	Atrophy? (Go To: **1599)**		
	☐0 No	☐1 Yes	
	Specimen Details		
1599	Was blood collected after the DRE performed on the same day as specimen collection? (Go To: **Specimen Database Section**)		
	☐1 Yes, specimen collected after DRE	☐2 No, DRE before specimen collection	

-80° C Freezer

Final Version: 1.0
Created Date: 5/4/2006
Last Modificated Date: 5/4/2006