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TITLE:
Evaluating the Role of Genetic Markers in Prostate Cancer Progression: A Multiethnic Cohort Experience

PRINCIPAL INVESTIGATOR:
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CONTRACTING ORGANIZATION:
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14. ABSTRACT Most prostate cancer (PCa) research has focused on risk, little is known about predictors of progression and even less about how these factors differ by ethnicity/race. Strong racial disparities in mortality have shown that African-Americans are twice as likely to die from PCa compared to Caucasians; very little data are available in Hispanics. Our overall goal is to identify markers related to PCa progression in a multiethnic cohort of 773 Caucasians, 361 African-Americans, and 246 Mexican-Americans, for whom we have already collected information. We have abstracted medical records for 735 patients and are now requesting copies of outside medical records for those who received care outside our institution, as well as continuing to abstract medical records. Additionally, we are preparing a request for vital status from the National Death Index to obtain information on cause of death. Genotyping assays have been established in the Genotyping Core, and DNA has been extracted from 90% of the patients' blood. Our research may help explain ethnic/racial disparities in PCa progression and provide direction towards eliminating these disparities and may guide future studies to develop ethnic/racial specific interventions to improve outcome in the most common cancer in American men.

15. SUBJECT TERMS
Prostate cancer, race, ethnicity, prognosis

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	28	**19b. TELEPHONE NUMBER** *(include area code)*

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INTRODUCTION:

There is a paucity of information regarding markers/factors associated with prostate cancer (PCa) outcome in the United States, especially how these factors differ among racial/ethnic groups. African-American men are more likely to have poorer outcome relative to age and stage-matched Caucasian patients; and very little is known about prognosis and even less about factors that could predict progression among Hispanics. The overall goal of our research project is to identify molecular, epidemiological and clinical markers related to prostate cancer (PCa) progression in a multiethnic cohort of 1,380 PCa patients (773 Caucasians; 361 African Americans, and 246 Mexican Americans).

BODY:

Task 1 **Patient Follow-up.** (Months 1-30)

a. Update patient follow-up data by checking clinical schedules and medical charts for updated information. Using a validated medical abstraction form, all patient charts will be abstracted.

b. Signed medical releases of information will be requested for care received outside of our institution. Copies of medical records will be requested.

c. Death certificates will be obtained for all participants identified as deceased.

d. Patients' self-reported recurrences (and subsequent treatments) and secondary cancers will be verified.

e. Data will be entered into existing databases.

In the first year of this grant, we have completed medical record abstractions for 735 prostate cancer patients who have received follow-up care at our institution. Institutional patient records for each participant are being abstracted using the standardized form attached as Appendix A. The most recent clinical follow-up date at our institution is determined; this date is used as the "last date of contact" at the University of Texas MD Anderson Cancer Center (UTMDACC). In addition to baseline treatment information, we abstracted follow-up information, such as each prostate specific antigen (PSA) level and date, adjuvant care received, prostate-related care (including care related to complications following treatment (i.e., incontinence, impotence)), as well as additional cancer diagnoses. Institutional medical records are available electronically, and abstractions are performed using a paper form and are being entered into an existing clinical database. We are continuing to abstract institutional medical records for the remainder of the patients.

For patients for whom we do not have recent follow-up information at UTMDACC, we are conducting telephone interviews to request follow-up information. One of the greatest challenges we have faced has been in locating and contacting these individuals as several years have passed since we last spoke with them. We have explored several options for obtaining updated contact information; including general internet searches, reverse address searches, and credit records. The Acxiom Insight Collection service, which is an internet-based paid subscription database, has been the most useful tool for us. To-date, we have successfully completed 75 follow-up interviews by phone. The protocol to verify potentially valid contact information includes calling the individual at least 5 times at different times of the day, as well as on weekends, if needed; the calls are conducted using the telephone script included as Appendix B. In addition, if these call attempts are not successful, then we send a letter to the patient at the last known valid address (with address correction requested) explaining that we are trying to contact them regarding their follow-up in a study and requesting that they contact us at their earliest convenience. Updated health and risk factor information is collected by trained interviewers, using a standardized questionnaire modified for this project (Appendix C).

Patients who are receiving follow-up care outside of UTMDACC are asked to sign a medical record release form (Appendix D) to allow us to obtain copies of the relevant records from their healthcare providers. Outside medical records are abstracted using the same standardized forms as used for UTMDACC records. Clinical recurrences and related treatments are noted on the abstraction forms and verified by the study clinical personnel.

We are preparing the Centers for Disease Control Institutional Review Board application to obtain approval to request vital status from the National Death Index, as well as immediate and underlying causes of death for deceased individuals.

Task 2 **Evaluate Constitutional Markers of Genetic Susceptibility.** (Months 1-30)

a. Genotyping assays for all genes will be established, tested and validated by the Department of Epidemiology Genotyping Core (Months 1-24).

The necessary laboratory equipment has been calibrated and tested. The primers and reagents have been purchased and quality-control tested. Conditions for all the genes proposed have been optimized on a test set available in the lab.

b. Biological samples for all participants will be located and retrieved from study archive freezers (Months 1-3).

Using our laboratory tracking database, biological samples for this study have been identified, located and retrieved from our freezer facility. Samples that will be used have been mapped and transferred to the genotyping facility. All

specimens are currently stored at -80° in the on-site freezers until analyses are conducted.

c. DNA will be extracted from banked specimens (Months 1-12).
DNA has been extracted from 90% of banked specimens; the remainder are expected to be completed within the next 30 days. DNA quality has been tested for the extracted samples to ensure the success of the analyses.

d. DNA samples will be plated for genotyping analyses – half the samples will be done in Year 2 and the other half will be done in Year 3 (Months 13 & 25)
N/A

e. Genotyping will be done for half the samples in Year 1 (Months 13-24) and the other half in Year 2 (Months 25-30).
N/A

Task 3 **Final Analysis and Preparation of Reports.** (Months 30-36) – N/A

KEY RESEARCH ACCOMPLISHMENTS:

There are no key research accomplishments to report at this time; we are still in the process of collecting follow-up data. No interim analyses have been performed, nor were any planned to be conducted at this time-point.

REPORTABLE OUTCOMES:

Currently, there have been no manuscripts, abstracts, presentations, patents or licenses applied for based on this award. Additionally, there have not been any degrees supported by this award; no cell lines, tissue or serum repositories developed; no informatics nor funding applied for based on work from this award; no employment nor research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSION:

Our research may help explain ethnic/racial disparities in PCa progression and provide direction towards eliminating these disparities. Additionally, our results may guide future studies to develop ethnic/racial specific interventions (i.e., behavioral, clinical) to improve outcome in the most common cancer in American men.

REFERENCES: N/A

APPENDICES:

APPENDIX A:

Medical record abstraction form

Medical Records Abstraction Form

Name

_____

Address

_____

_____

_____

MDACC# _____

MDA registration date _____/_____/____

Date of birth ____/_____/_____

Age at diagnosis _____years

Phone number _____

Ethnicity

☐ White ☐ Hispanic → ☐ African-American ☐ Asian ☐ Other _____	☐ Mexican ☐ Cuban ☐ S. American ☐ Other _____

Vital status ☐ Living ☐ Deceased → Date of death ____/____/____

Place of death _____

Cause of death _____

Last date of contact _____/_____/_____ Place of contact_____

Height: _____cm
_____ft/inches

Weight: _____kg
_____Ibs

Prostate cancer diagnosis

Date of diagnosis ____/_____/_____

Place of diagnosis: MDACC ☐ Yes ☐ No

Diagnostic tests ☐ Biopsy ☐ POS ☐ NEG ↓

☐ TURP ☐ POS ☐ NEG Where_____

☐ Chest x-ray ☐ POS ☐ NEG _____

☐ Bone scan ☐ POS ☐ NEG _____

☐ CT scan ☐ POS ☐ NEG

☐ Other _____☐ POS ☐ NEG When ____/_____/_____

Comments _____

_____

_____

Clinical stage of diagnosis

☐ Organ confined disease

☐ Regional disease

☐ Metastatic disease → date of confirmation ____/____/____

Sites: ☐ Bones ☐ Liver ☐ Adrenal gland ☐ Kidney ☐ Brain

☐ Other _____

TNM stage

T1 → ☐ x ☐ 0 ☐ a ☐ b ☐ c **T2** → ☐ a ☐ b ☐ c **T3** → ☐ a ☐ b **T4**

N → ☐ x ☐ 0 ☐ 1 ☐ 2 ☐ 3

M → ☐ x ☐ 0 ☐ 1 Summary _____

Comments _____

_____

Laboratory results

Post-treatment values

Most recent post-treatment PSA value _____ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Follow-up PSA Values _____ ng/ml Date _____/_____/_____

Initial post-treatment PSA value _____ ng/ml Date _____/_____/_____

Pre-treatment values

Highest pre-treatment PSA value_____ ng/ml Date ____/_____/_____

Initial pre-treatment PSA value _____ ng/ml Date ____/_____/_____

Comments: _____

_____

Pathology report **Pathology report #:** _____

Specimen type ➲ ☐ **Prostatectomy**

MDACC grade ⇐ ☐ I ☐ II ☐ III ☐ IV ☐ other _____

Seminal Vesicle involvement ☐Yes ☐No **S/Margins** ☐ Positive ☐ Negative

Combined Gleason score

☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 _____

Dominant focus size /size _____cm Prostate volume _____ cm

Tumor locations ☐ Peripheral zone ☐ Central zone ☐ Transitional zone ☐ AFM zone

Comments_____
_____

Pathology report **Pathology report #:** _____

Specimen type ⇐ ☐ **Biopsy**

MDACC grade ⇐ ☐I ☐ II ☐ III ☐ IV ☐ other _____

Combined Gleason score

☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Dominant focus size /size _____cm Prostate volume _____ cm

Tumor locations ☐ Peripheral zone ☐ Central zone ☐ Transitional zone ☐ AFM zone

Comments_____
_____

History of prostate cancer screening

☐ No

☐Yes → Type of screening test ☐ Prostate-specific antigen (PSA)

☐ Digital rectal examination (DRE)

☐ Trans-rectal ultrasound (TRUS)

☐ Other _____

Presence of urinary symptoms ☐ Yes ☐ No

Coments: _____
_____

Prostate cancer treatment received

☐ Radical prostatectomy Type → ☐ Radical Retropubic Prostatectomy (RRP) Date _____/_____/_____

☐ Radical perineal prostatectomy (RPP)

☐ Nerve-sparing

☐ Pelvic lymphadenectomy

☐ Orchiectomy → Date _____/_____/_____

☐ Cryosurgery → Date _____/_____/_____

		Onset of treatment	End of treatment
☐ Radiotherapy (EBRT)	→	Date _____/_____/_____	Date _____/____/____
☐ Brachytherapy	→	Date _____/_____/_____	Date _____/____/____
☐ Hormonal therapy	→	Date _____/_____/_____	Date _____/____/____
☐ Immunotherapy	→	Date _____/_____/_____	Date _____/____/____
☐ Surveillance	→	Date _____/_____/_____	Date _____/____/____
☐ Chemotherapy	→	Date _____/_____/_____	Date _____/____/____
☐ Other (specify) _____		Date _____/_____/_____	Date _____/____/____

Comments _____
_____

Complications of treatment

Urinary
Incontinence ☐ No
☐ Yes → Uses sanitary pad ☐ No
☐ Yes → number /day_____

Treatment received_____

Post-treatment status (1yr.) Number of pads/day _____ Date ____/____/____

Impotence ☐ No
☐ Yes → Treatment received _____
Post-treatment status (1yr.)_____

Urinary retention ☐ No
☐ Yes Treatment received _____

Other_____
_____
_____

Comorbid conditions prior to diagnosis of prostate cancer

☐ No ☐ Yes

↓

☐ Diabetes (IDDM, NIDDM)	Date of diagnosis ___/___/___
☐ Hemorrhage	Date of diagnosis ___/___/___
☐ Hypertension	Date of diagnosis ___/___/___
☐ Peptic ulcer disease	Date of diagnosis ___/___/___
☐ Congestive heart failure	Date of diagnosis ___/___/___
☐ Pancreatitis	Date of diagnosis ___/___/___
☐ Myocardial infarction	Date of diagnosis ___/___/___
☐ Cholelithiasis	Date of diagnosis ___/___/___
☐ Stroke	Date of diagnosis ___/___/___
☐ Alcoholism	Date of diagnosis ___/___/___
☐ Chronic obstructive pulmonary disease	Date of diagnosis ___/___/___
☐ Lupus erythematosus	Date of diagnosis ___/___/___
☐ Other _____	Date of diagnosis ___/___/___

Other pertinent information

Recurrence of prostate cancer

☐ No

☐ Yes → Date of diagnosis _____/_____/_____

Place of diagnosis _____

Type of treatment _____

Basis of diagnosis _____
_____
_____

Diagnostic tests			
	☐ Biopsy	☐POS	☐NEG
	☐ TURP	☐POS	☐NEG
	☐ Chest x-ray	☐POS	☐NEG
	☐ Bone scan	☐POS	☐NEG
	☐ CT scan	☐POS	☐NEG
	☐ Other _____	☐POS	☐NEG

Conditions diagnosed after diagnosis of prostate cancer

☐ No ☐ Yes
↓

Date of diagnosis _____/_____/_____
Type of disease _____

Place of diagnosis _____
Type of treatment received_____

Date of diagnosis _____/_____/_____
Type of disease _____

Place of diagnosis _____
Type of treatment received_____

Comments _____
_____

Last clinic visit **Date _____/_____/_____**

Notes

APPENDIX B:

Follow-up telephone recruitment script

SCRIPT 1 (Speaking to person who answers phone) –

Hello, my name is (INTERVIEWER'S NAME) and I am calling on behalf of MD Anderson Cancer Center, here in Houston. May I please speak with (PATIENT'S NAME)?

- NOT AVAILABLE – Verify (PATIENT'S NAME) lives at this residence. Ask "Is there a time that I could call back and speak with him?" OR "would you please ask him to call me (INTERVIEWER'S NAME) at (PHONE NUMBER) at his earliest convenience? Thank you for your assistance.

- YES – Thank you…(Wait for (PATIENT'S NAME) come to phone) Hello, my name is (INTERVIEWER'S NAME) and I am calling on behalf of MD Anderson Cancer Center, here in Houston. You participated in one of our prostate cancer studies a few years ago, and we are conducting a follow-up study to see how you are doing. Would it be all right with you if I asked you a few questions about your health and updated your information?

  - NO – thank you for your time. If you change your mind and would like to participate, please contact me (INTERVIEWER'S NAME) at (PHONE NUMBER).

  - YES – I want to let you know that answering these questions is completely voluntary, and you may decide not to answer any or all of them. (Administer risk factor questionnaire (Appendix D))

Following each call, the interviewer logs each call made onto the tracking log for each file, documenting the date, time, phone number dialed, and with whom they spoke. These logs are maintained in the individual patient's study chart, kept in a locked office coded by study identification number.

APPENDIX C:

Follow-Up questionnaire

PROSTATE CANCER FOLLOW-UP STUDY

M.D. A *M.D. Anderson Cancer Center* *Department of Epidemiology*

STUDY NUMBER:_____

DATE OF PC DIAGNOSIS: _____/_____/_____

MED RECORD/PATIENT #:_____

DATE OF BASELINE INTERVIEW: _____/_____/_____

PATIENT RECEIVING FOLLOW-UP CARE AT MDACC: __(1)YES
__(2) NO

DATE OF MOST RECENT MDACC VISIT: ___/____/____

_____
FIRST NAME **M.I.** **LAST NAME**

HOME PHONE: (____)_____

_____
STREET ADDRESS

WORK PHONE: (____)_____

_____
CITY **STATE** **ZIP CODE**

SSN: _____

INTERVIEW DATE: _____/_____/_____

INTERVIEWER'S INITIALS: _____

WHO IS COMPLETING QUESTIONNAIRE? O **PATIENT** O **PROXY**

IF PATIENT IS DECEASED, DATE OF DEATH _____ **COUNTY & STATE OF DEATH** _____

As you may remember, you participated in a study of prostate cancer. We are currently updating our information, and we wanted to see how you are doing. Do you have a few moments to talk to me now or when can I call you back?

1. Are you currently being followed-up for your previous prostate cancer? _____ YES (1) _____ NO (2)

2. Where are/were you receiving follow-up care? _____

3. When was your most recent follow-up visit? _____ (Date)

When was the last time you had (the following test(s))? What were the results?

Test	Most Recent Date	Result (most recent)	
4. Prostate Specific Antigen/ (PSA)			___ Normal (1) **go to Q.8** ___ Abnormal (2) **go to Q.5**
5. Ultrasound (TRUS)			
6. Biopsy or Transurethral Resection of Prostate (TURP)			
7. Other (specify)			

8. Have you received any prostate treatment since you were last seen at MD Anderson/Kelsey-Seyboldt/VAMC/Dr. _____ (select provider) in _____ (fill in last date)?

____ (1)YES _____(2) NO → Skip to Q. 12

9. When and where were/are you receiving treatment? (*e.g., MD/Clinic Name, Address, Phone #*)

Office Note: Obtain signed medical release of information

_____

_____

10. What type(s) of treatment did you receive? (e.g., radiation, hormone shots, hormone pills, chemotherapy)

_____

_____

11. Why was the treatment necessary?

_____

_____

Have you ever been told by a doctor or another health care professional that you have any of the following conditions?

CONDITION	BEEN TOLD?	DATE/AGE DIAGNOSED	TREATMENT/MEDICATION NAME
12. Diabetes (or sugar in urine)	_____ (1) YES _____ (2) NO		
13. Hypertension (high blood pressure)	_____ (1) YES _____ (2) NO		
14. Angina (angina pectoris)	_____ (1) YES _____ (2) NO		
15. Heart attack (myocardial infarction)	_____ (1) YES _____ (2) NO		
16. Any other kind of heart condition or disease (not mentioned above) SPECIFY: _____	_____ (1) YES _____ (2) NO		

CONDITION	BEEN TOLD?	DATE/AGE DIAGNOSED	TREATMENT/MEDICATION NAME
17. High cholesterol	_____ (1) YES _____ (2) NO		
18. Arthritis TYPE: _____	_____ (1) YES _____ (2) NO		
19. Any other cancer(s)? SPECIFY	_____ (1) YES _____ (2) NO		
20. Any other condition(s)? SPECIFY	_____ (1) YES _____ (2) NO		

TOBACCO

Previous Smoking Status
____ Current ____ Former ____ Never

The next questions are about smoking.

21. Since your prostate cancer diagnosis, has your smoking status changed? ___(1)YES ___(2) NO → **Fmr/Never smoker** Go to Q.24 **Currt smkr** Go to Q.23

22. Are you currently smoking cigarettes? ____ (1)YES ____(2) NO → When did you stop? _____ (Year)

23. On average, how many cigarettes per day do you/did you smoke? _____

MEDICATION/SUPPLEMENT USE

The next questions are medications and supplement use

24. Have you taken any supplements, over the counter medications or prescription medications at least once a month since your diagnosis? This would include all vitamins, minerals, herbal and non-herbal supplements of any kind.

_____ (2) No, GO TO Q. 26

_____ (1) Yes, Fairly regularly _____ (3)Yes, but NOT regularly

25. Please list the names of any supplements (including vitamins, minerals and herbal supplements), over-the-counter medications or prescription medications that you have taken. Also include the number of pills or tablets taken daily, weekly, monthly or yearly?

For Office Use:	_____ code

Supplement, Over-the-counter or prescription medication	**Number per Day**	**Number per Week**	**Number per Month**	**Number per Year**	**Rarely / Never (✓)**	**How many years?**	**Dose**
Brand:_____ Name on bottle: _____							
Brand:_____ Name on bottle: _____							
Brand:_____ Name on bottle: _____							
Brand:_____ Name on bottle: _____							

DIET

The following questions are regarding diet changes

Since your diagnosis, have you changed your consumption of the following types of foods?

FOOD TYPE	INCREASED
26. Fat	____(1) increased ____(2) decreased ____(3) no change
27. Fruits	____(1) increased ____(2) decreased ____(3) no change
28. Vegetables	____(1) increased ____(2) decreased ____(3) no change
29. Fiber	____(1) increased ____(2) decreased ____(3) no change
30. Soy products	____(1) increased ____(2) decreased ____(3) no change

31. Are there any comments that you would like to add about your diet or about the way you have changed your diet?

_____

_____

FAMILY HISTORY

In this section, I would like to ask you some questions about your family

+

FAMILY HISTORY PRE-CODE:

Previously reported family members WITH cancer:

Sex	Relative	Side of Family	Type of Cancer	Sex	Relative	Side of Family	Type of Cancer

32. Previously, you told us that your _____ (insert previous history here) had cancer, have any other immediate family members been diagnosed with cancer? ____ YES (1) ____ NO (2) → Go to Q. 34

33. Would you please give us some information about these NEW family members diagnosed with cancer? (DON'T include those previously reported)

Rel Code	Sex	Relative	Rel UIN	When was he/she born?	What kind of cancer?	ICD-9	When was he/she diagnosed?	Is he/she still living?	When did he/she die?
								____(1) Yes ____(2) No	
								____(1) Yes ____(2) No	
								____(1) Yes ____(2) No	
								____(1) Yes ____(2) No	
								____(1) Yes ____(2) No	

OCCUPATIONAL HISTORY

In this section, I would like to ask you some questions about your current occupation

34.

What is your job or occupation?	Years employed	Major duties	Equipment used (Any Chemicals?)	Work done by company	SIC	OCC
Current Job:	_____**To**_____					
Spec						

If we need additional information from you in the future, can we contact you by telephone? ____ (1)YES ____ (2)NO

This is the end of our interview. I would like to thank you for your help with our research. If you have any questions that I or Dr. Strom can answer in the future, please feel free to contact us. We would also like to verify that we have your current address correctly recorded. We have your current address as: ***READ ADDRESS FROM FILE RECORD***

Is this address correct? _____(1) YES _____ (2)NO *(If NO, please provide correct information below)*

_____ _____ _____
First Name Middle Name Last Name

_____
Street Address

_____ _____ _____
City State Zip Code

Also, so that we may keep contact with you, would you please give me that name, address, and telephone number of a person who does not live with you who will know your whereabouts in the future:

_____ _____ _____
First Name Middle Name Last Name

_____
Street Address

_____ _____ _____
City State Zip Code

Thank you once again for your time and help with our research project. If we have any more questions in the future, we hope we can call you again.

INTERVIEW ASSESSMENT

Date of interview: ____/____/____ Interviewer's Initials: _____

Time Interview began: _____ Time Interview ended: _____

1. Respondent's cooperation was:

_____ Very Good (1)

_____ Good (2)

_____ Fair (3)

_____ Poor (4)

2. The quality of the interview was:

_____ Highly Reliable (1)

_____ Generally Reliable (2)

_____ Questionable (3)

_____ Unsatisfactory (4)

Please write comments about the interview: _____

_____

_____

_____

APPENDIX D:

Medical release of information form

AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION

(1) I hereby authorize _____ to disclose the following information from the health records of:

Patient Name: _____
Last First MI. Date of Birth MDA #

Address:_____
_____
Street City State Zip Code
Phone

covering the period of healthcare from _____ to _____.

(2) Information to be disclosed:

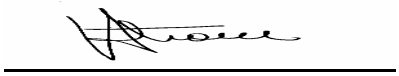
- ❑ Complete Health Record
- ❑ Primary Medical Evaluation
- ❑ Progress Notes
- ❑ X-Ray Reports
- ❑ Discharge Summary
- ❑ Consultation Reports
- ❑ Laboratory Tests
- ❑ Radiotherapy Notes
- ❑ Chemotherapy Notes
- ❑ Nurse's Notes

❑ Other (specify) _____

I understand that this will include information relating to (check if applicable):

- ❑ Acquired Immunodeficiency Syndrome (AIDS) or infection with HIV (Human Immunodeficiency Virus)
- ❑ Psychiatric care
- ❑ Treatment for alcohol and/or drug abuse

(3) This information is to be disclosed to: Dr. Sara Strom



Investigator's signature

UT MD Anderson Cancer Center

1515 Holcombe, Houston, Texas 77030

for the purpose of: **Medical Record completion for research protocol M91-004**.

(4) I understand this authorization may be revoked in writing at any time, except to the extent that action has been taken in reliance on this authorization. Unless otherwise evoked, this authorization will expire on the following date, event, or condition:

_____

(5) The facility, its employees, officers, and physicians are hereby released from any legal responsibility or liability for disclosure of the above information to the extent indicated and authorized herein.

Signed: _____
(patient) (date)

or _____
(Legal Representative)(Relationship to Patient) (date)

SUPPORTING DATA: N/A