Award Number:  W81XWH-11-1-0566

TITLE:  Prostate Cancer Genetics in African Americans

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CONTRACTING ORGANIZATION:  Creighton University
                             Omaha, NE 68178

REPORT DATE: September 2013

TYPE OF REPORT: Annual

PREPARED FOR:  U.S. Army Medical Research and Materiel Command
               Fort Detrick, Maryland  21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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Prostate Cancer Genetics in African Americans

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Our intent has been to identify African American males diagnosed with prostate cancer between the ages of 40 and 75 and registering them along with their at risk relatives into a program of cancer education, cancer screening, and early intervention to reduce disparities in prostate cancer incidence and mortality rates in the African American community in Nebraska and Mississippi. Family history of prostate and other cancers is being recorded with the purpose of identifying any hereditary prostate cancer syndrome. This will be possible through the recruitment of a total of 800 African Americans who have been diagnosed with prostate cancer, through recruitment activities and screenings in Omaha, Nebraska, and Jackson, Mississippi. The most significant work during the first two years of this grant has involved (1) hiring and training of research personnel; (2) the establishment of a project-specific database; (3) recruitment of research participants and (4) data collection and pedigree development. Progress has been made in all four objectives. Although recruitment has been slow and challenging at both study sites, significant progress has been made. An initial analysis of the pedigrees has been conducted and reported within this report.

Prostate cancer, familial cancer, African American, participant recruitment, database

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PROSTATE CANCER GENETICS IN AFRICAN AMERICANS

REPORT DATE:
September 2013

REPORT TYPE:
Annual

DATES COVERED:
15 August 2012 – 14 August 2013

AUTHOR(S):
Henry T. Lynch, M.D.; Olugbemi T. Ekundayo, M.D.; Sade Kosoko-Lasaki, M.D.; Sarah Buxbaum, PhD; Carrie Snyder, M.S.N.; Ellastine Buckner; Dina Becirovic; Prince Andrew; Madisa Johnson

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland  21702-5012

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

14. ABSTRACT
Approximately 200 word summary of the most significant finding during the research period

Our intent has been to identify African American males diagnosed with prostate cancer between the ages of 40 and 75 and registering them along with their at risk relatives into a program of cancer education, cancer screening, and early intervention to reduce disparities in prostate cancer incidence and mortality rates in the African American community in Nebraska and Mississippi. Family history of prostate and other cancers is being recorded with the purpose of identifying any hereditary prostate cancer syndrome. This will be possible through the recruitment of a total of 800 African Americans who have been diagnosed with prostate cancer, through recruitment activities and screenings in Omaha, Nebraska, and Jackson, Mississippi. The most significant work during the first two years of this grant has involved (1) hiring and training of research personnel; (2) the establishment of a project-specific database; (3) recruitment of research participants and (4) data collection and pedigree development. Progress has been made in all four objectives. Although recruitment has been slow and challenging at both study sites, significant progress has been made. An initial analysis of the pedigrees has been conducted and reported within this report.

15. SUBJECT TERMS
Prostate cancer, familial cancer, African American, participant recruitment, database

16. SECURITY CLASSIFICATION OF:
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Van de Wiele, J.R.

19. NAME OF RESPONSIBLE PERSON
USAMRMC

20. TELEPHONE NUMBER (include area code)
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Introduction
Our intent has been to identify African American males diagnosed with prostate cancer between the ages of 40 and 75 and to enter them along with their at risk relatives into a program of cancer education, cancer screening, and early intervention to reduce disparities in prostate cancer incidence and mortality rates in the African American community in Nebraska and Mississippi. Family history of prostate and other cancers is being recorded with the purpose of identifying any hereditary prostate cancer syndrome. In addition, social and behavioral determinants are collected and recorded during the interview process for the final analysis. This will be possible through the recruitment of a total of 800 African Americans who have been diagnosed with prostate cancer, through recruitment activities and screenings in Omaha, Nebraska, and Jackson, Mississippi.

Body
Task 1: Participant Identification and Access (Years 1 and 2)
At Creighton University, recruitment of subjects has been ongoing through cooperation with local urologists (see letter in appendix) as well as through promotion to the community by study personnel’s appearance on two local television programs that target the African American community, Real Talk and Healthy Choices on Omaha CTI22; attendance at local health fair; publication of an article about the study in Omaha Star newspaper serving the Omaha African American community; an announcement of the study emailed to all online subscribers of the Omaha World Herald newspaper; an advertisement on the study emailed to all Creighton University physicians in their monthly School of Medicine newsletter; creation of a billboard to be displayed in a key location throughout September 2012; compilation of lists of church leaders and secretaries and neighborhood watch leaders received an email or written study invitations to share with their communities; and additional urologists have been identified at both study sites to increase recruitment efforts. (see appendix for material used for these recruitment efforts).

On-hundred and twelve participants have been identified at Creighton who meet the eligibility criteria. Twenty-four of these participants have been interviewed and data collected from the interviews has been entered into the study-specific database according to protocol. DNA has been collected and stored according to protocol for those eligible participants who have agreed. The remaining potential participants have received a letter introducing the study and informing them that the project coordinator will be contacting them regarding participation.

Project year 2 was utilized to recruit participants, train JSU research assistants whose positions as students necessitate changing their status. Overall, 33 participants were interviewed, of which 20 provided blood samples. Agreement by potential participants to participate dropped with recruitment of more participants. The recruitment pool has been upgraded to 560 from 255 and work is in full swing now, to enhance productivity and sample size yield. Urologists continue to inform patients of the study.

Task 2: Data Collection and Management (Years 1 through 2.5)
The study-specific database has been constructed, including onscreen instructions for its use (see appendix for representative screenshots). As stated above, data collection is ongoing at Creighton and Jackson State University.

The database variables on social and behavioral determinants and risk exposure pathways suggested by the community partners were added to the database with appropriate quality controls incorporated into the program.

Work continues on the completion of the database manual.

Task 3. Prostate Cancer Prevention and Health Education and Referral (Years 1.5-3)
Screening interviews are ongoing at both study sites, with participants positive for prostate cancer family history being identified and receiving appropriate education, genetic counseling, and/or referral. During each interview the research coordinator identifies at risk family members and encourages the participant to discuss their risk with them as well as our screening recommendations. The participant can also ask the family member to call the research coordinator directly to discuss their risk and the recommendations. The Jackson State University team developed and gave a presentation to a prostate cancer support group at their meeting on July 19, 2011. This presentation has been shared with the Creighton University Community Engagement Team. The CU project coordinator has attended two health fairs in the community to provide awareness of prostate cancer and recruitment material for the study.
Challenges
However, in the drive to recruit participants, an oversight error occurred in which there was a lapse in IRB approval and five participants were erroneously interviewed. Also, erroneously, a message was sent to the DOD that no participant recruitment took place. Based on communication with Creighton University partners indicating that there were 2 participants on their records interviewed between May 6th 2013 and July 22nd 2013, the JSU team instituted a review of activities and an additional three participants were discovered to have been interviewed outside the IRB approval coverage period. While the review was ongoing, the following actions were also taken:

1. JSU and Creighton University IRB were informed and JSU IRB requested for the report on activities review when ready.
2. All research staff underwent CITI training in responsible conduct of research
3. A letter was written to the DOD detailing the errors and the JSU co-PI spoke with the DOD IRB contact on the telephone to explain the discrepancy. The team was asked to send the report with the determination of the JSU IRB when ready.
4. Steps were taken to prevent any other occurrence in the future.

Key Research Accomplishments
- Recruitment and training of study personnel: research project coordinators at both sites as well as two graduate students at Jackson State University.
- Development of a study specific Access database with embedded quality control measures that is used at both research sites.
- A collaborative meeting between the two research groups completed in year one.
- Subject recruitment measurements implemented through television, newspaper, community events, prostate cancer support groups, billboards and emails to community and church leaders, local urologists and all active physicians in the area.
- Identification of 112 eligible participants wherein 24 were interviewed at Creighton University. Their data has been entered into the database and DNA samples have been collected and stored on 6 participants who were eligible and volunteered to donate the sample. Five-hundred and sixty subjects have been identified at Jackson State University wherein 33 participants have been interviewed to date. Recruitment efforts are ongoing for the remaining.
- Prostate cancer prevention and health education occurring at each interview as well as during each television broadcast regarding the study. Jackson State University also provided an educational presentation to a prostate cancer support group.

Reportable Outcomes
Sarah Buxbaum, PhD Genetic Biostatistician has completed an analysis on the pedigrees generated to date.

Family data was coded in LINKAGE format for analysis. Then, the pedinfo program in the software package S.A.G.E. was used to generate the following statistics (all data reported here was covered by IRB approval):

Creighton University:

Of the families with LINKAGE coding, there are 22 pedigrees with number of family members ranging from 19 to 64, with mean size 38.45 (sd = 14.42). The families have a total of 189 sibships with mean size 3.3 (sd = 2.56). 55 men in these families have prostate cancer.

One family (family ID 5877) with 59 members has 10 men affected with prostate cancer.

Among the concordantly affected pairs there are 15 father-son pairs, 36 brother-brother pairs (of these, 24 are in family 5877), 1 grandfather-grandson pair, 29 uncle-nephew pairs, and 7 cousin pairs.
25 families with size ranging from 9 to 132, with a mean size of 57 members with a standard deviation of 30. There were 313 sibships with mean size 3.4 (+/- 2.4) with a maximum number of siblings in a sibship of 17. A total of 37 men were affected with prostate cancer. Among those affected, there were 8 parent-offspring pairs, 5 sib-pairs, 1 grandparent-grandchild pair, and 4 avuncular pairs.

In the Creighton sample, the affection status of brothers has a positive correlation of 34%. This is largely driven by family number 5877, without which the correlation drops to 10%, similar to what was seen in the JSU pedigrees, 6.5%.

In 2010 Whitman et al. and Hooker et al. identified at risk loci specific to prostate cancer in African Americans. These loci may be targets to test in the future on the stored DNA samples from participants in families with familial prostate cancer from this study.

References

Appendices

See Dgrny
June 14, 2012

Bruce Lundak, M.D.
President, Urological Society of Nebraska
Bergan Mercy Professional Center
7710 Mercy Road, Suite 406
Omaha, Nebraska 68124-2346

Dear Dr. Lundak:

Creighton University’s School of Medicine (Department of Preventive Medicine and Public Health and the Center for Promoting Health & Health Equality), in collaboration with Jackson State University, Jackson, Mississippi, has been awarded a grant by the Department of Defense to study the genetics of prostate cancer (PC) among African Americans (AAs).

Our primary objective is to identify familial and/or hereditary patterns of PC’s occurrence in AAs. Attention will be given to cancer of all anatomic sites within the family of each index case, as ongoing research at Creighton has shown that virtually all forms of hereditary cancer involve multiple anatomic sites wherein the pattern of these cancers’ occurrence can be used beneficially for hereditary cancer syndrome diagnosis leading to targeted screening regimens.

We believe that the familial/hereditary predisposition of PC among AAs may differ strikingly from Caucasians given the fact that AAs have a more than two-fold increased lifetime risk for PC and their response to conventional management is also less effective. In addition to garnering a better understanding of PC’s etiology among AAs, we believe that this knowledge will prove useful for screening and management.

We would greatly appreciate your help in this project. Please let us know if we can be of help in getting the word out to the members of the Urological Society of Nebraska, as we need to recruit 300 AAs with PC for the study. We would welcome any opportunity available for us to present the study to the members at a society meeting.

Attached is a summary of study needs as a document that may be distributed for patient referral.

Sincerely,

Henry T. Lynch, M.D.
Principle Investigator
Professor of Medicine & Chairman of Dept. of Preventive Medicine & Public Health

Paulos Yohannes, M.D.
Clinical Professor of Surgery
CEO Urorobotics, PC

Sade Kosoko-Lasaki, M.D.
Co-Investigator
Assoc. VP Health Science
Professor of Surgery & Preventive Medicine & Public Health

Attachment

cc: Euclid De Souza, M.D.
Summary of Need for Creighton University Prostate Cancer Study

Purpose: To describe the patterns of cancer occurrences and epidemiologic factors in African-American families that have demonstrated an increased amount of prostate cancer.

- Subject criteria: African-American male diagnosed with prostate cancer between the ages of 40-75 years.
- Recruitment need: 300 subjects within the first two years of the grant (August 2011 – August 2013).
- Participation includes:
  - Completion of a family history questionnaire;
  - Completion of an epidemiologic questionnaire;
  - For those who have another family member with prostate cancer, drawing of blood and storage of a blood-derived DNA sample.
- All data and DNA samples will be stored in Creighton University’s Hereditary Cancer Center secure registry and bio-repository.
- None of the candidate subjects will be contacted regarding the study without their or their physician’s permission.
- Once a candidate subject has agreed to be contacted for the study, his name and telephone number can be provided to our project coordinator, Carrie Snyder, MSN, RN, APNG. Ms. Snyder will then contact the individual, explain the study, and obtain informed consent for those who agree to participate. Contact information is as follows:

  Carrie Snyder, MSN, RN, APNG
  Telephone: 402-280-2634
  Fax: 402-280-1734
  Email: csnyder@creighton.edu
A Healthy Family Is The Heart of Our Community

14th Annual FREE HEALTH FAIR and SCREENINGS
SATURDAY, March 31, 2012
8 a.m.—1 p.m.
Omaha North High School
4410 N. 36th Street
For More Information
visit www.bfhwa.com
African American Men and Prostate Cancer

African-American men are twice as likely to get prostate cancer - and twice as likely to die from it - as are Caucasians. African ancestry (having ancestors from Africa south of the Sahara Desert) by itself puts black men at high risk for getting prostate cancer. Because it's not known why this is so, Creighton University research may help to find a piece of the puzzle.

Creighton University researchers would like to talk to 300 African American men from the Omaha area who were told by their doctors that they had prostate cancer when they were between the ages of 40 and 75. They want to talk to men, who have relatives with prostate cancer as well as those who don't.

Why do the researchers want to involve men with prostate cancer running in their families and those who don't? Because they want to compare the two groups and see if there is a difference between prostate cancer that runs in families and prostate cancer that doesn't. Having more than one close relative who has had prostate cancer also puts a man at higher risk, and the more relatives who have had this disease the higher the risk. Men who have a father or brother with prostate cancer are twice as likely to develop it as men with no relatives affected.

Besides the questions the research is trying to answer, the study is important to the community because men with African ancestry and those with prostate cancer running in their families need to know about their high risk for prostate cancer and should be screened for it more often and earlier than other men. Screening can detect the cancer while it is still early enough to cure. In addition, for men in the study who already have prostate cancer, the information they will receive through the study can help them, their close relatives, the community and their doctors decide on the best plan for screening.

Each man participating in the study will be interviewed about personal and family health history and other known risks related to prostate cancer. Family histories will be collected; research participants will learn the meaning of their own family histories and will be given information about screening and other research studies.

The funds for this study have been awarded by the Department of Defense. The same research is being done in partnership with researchers at Jackson State University in Jackson, Mississippi, a Historically Black University. Most of the African Americans in Omaha have family in Mississippi.

The study has been approved by the Creighton and Jackson State's Institutional Review Boards (IRB) and this ensures that the program is safe, sound and beneficial. Everything about the study will be strictly confidential, and personal information will be kept securely private. Anyone may decline participation in this study at any time with no penalty, even after the study has started.

Any African-American man who has had prostate cancer between the ages of 40 and 75 is invited to contact Creighton's Department of Preventive Medicine and Public Health to find out how to become part of the study. Please phone Carrie Snyder at 402.280.2942 or email her at csnyder@creighton.edu. If you'd like to speak with a study doctor, she can put you in touch with them.

Creighton researchers plan to share the results of the research with members of the African American community after the study is over. We greatly appreciate those who can help in this research study on prostate cancer in African-American men.

Henry T. Lynch, M.D.
Sade Kosoko-Lasaki, M.D.
Paulos Yohannes, M.D.
Carrie Snyder, M.S.N., R.N., A.P.N.G.

Call... 402.280.2942 for more information.
Creighton Study to Look at Hereditary Prostate Cancer in African Americans
For Immediate Release: Aug. 18, 2011

OMAHA, Neb. – Creighton University’s Hereditary Cancer Center, has received a three-year, $731,278 grant from the U.S. Department of Defense to study the role heredity plays in prostate cancer among African Americans.

“Prostate cancer is the leading cause of cancer death among men in the United States. African American men have two times the occurrence of prostate cancer as do Caucasian men and suffer a significantly higher mortality as well,” said Henry Lynch, M.D., principal investigator and Creighton Hereditary Cancer Center director.

While it’s estimated that about 10 percent of all prostate cancers have a hereditary link, the problem has been understudied in African Americans. With few exceptions, relatively little is known about the role genetics play in this population, noted Lynch, the Charles F. and Mary C. Heider Endowed Chair in Cancer Research.

The study will focus on identifying the hereditary factors of the disease that are specific to African Americans. The goal is to develop early and intensive screening and prevention management strategies that will decrease African Americans’ incidence of as well as death rate from hereditary prostate cancer, he said.

Jackson State University in Mississippi is collaborating in the study. The goal is to involve 300 African American prostate cancer patients from the Omaha area and about 500 from Jackson, Miss., in the effort.

The research team includes members of Creighton’s Hereditary Cancer Center; Olúgbémiga Ekúndayò, M.D., associate professor of epidemiology at Jackson State University,
and his staff; Sade Kosoko-Lasaki, M. D., associate vice president of Health Sciences Multicultural and Community Affairs and co-director of Creighton’s Center for Promoting Health and Health Equality; and Paulos Yohannes, M. D., Creighton assistant clinical professor of surgery.

If you are an African American who has been diagnosed with prostate cancer, and are interested in participating in the study, contact Carrie Snyder, cancer genetics nurse specialist, at 402.280.2634 or e-mail csnyder@creighton.edu and include “prostate cancer study” in the subject line.

To learn more about the work of Creighton’s Hereditary Cancer Center, visit http://medicine.creighton.edu/HCC.

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*About Creighton University:* Creighton University, a Catholic, Jesuit institution located in Omaha, Neb., enrolls more than 4,100 undergraduate and 3,200 professional school and graduate students. Nationally recognized for providing a balanced educational experience, the University offers a rigorous academic agenda with a broad range of disciplines, providing undergraduate, graduate and professional degree programs that emphasize educating the whole person: academically, socially and spiritually. Creighton has been a top-ranked Midwestern university in the college edition of *U.S. News & World Report* magazine for more than 20 years. For more information, visit our website at: www.creighton.edu.
Creighton gets grant to study heredity-cancer link

OMAHA, Neb. (AP) — Researchers at Creighton University have gotten a federal grant to study how heredity affects prostate cancer in black men.

Creighton Hereditary Cancer Center director Henry Lynch says prostate cancer is the leading cause of cancer deaths among American men and is more prevalent among black men than whites. Heredity is believed to be a link in 10 percent of cases.

Creighton is partnering with Jackson State University in Mississippi on the study. They’re seeking 300 black men diagnosed with prostate cancer from eastern Nebraska and about 500 from Jackson, Miss. For details, visit http://bit.ly/dn25uy.

The grant money comes from the U.S. Department of Defense.
Hereditary, prostate cancer to be studied

By Bob Glisemann
WORLD-HERALD STAFF WRITER

It’s estimated that about 10 percent of all prostate cancers have a hereditary link. But relatively little is known about the role heredity plays in the incidence of prostate cancer among blacks.

To study that link, Creighton University’s Hereditary Cancer Center has received a three-year, $731,278 grant from the U.S. Department of Defense.

"African-American men have two times the occurrence of prostate cancer as do Caucasian men and suffer a significantly higher mortality as well," said Dr. Henry Lynch, principal investigator and the director of the Creighton center.

The study will focus on identifying the hereditary factors of the disease that are specific to African-Americans. The goal is to develop early and intensive screening and prevention-management strategies, Lynch said.

Jackson State University in Mississippi is collaborating in the study. The goal is to involve 300 African-American prostate cancer patients from the Omaha area and about 500 from Jackson, Miss.

If you are a black man who has been diagnosed with prostate cancer and are interested in participating in the study, contact Carrie Snyder at 402-280-2634 or email csnyder@creighton.edu and include “prostate cancer study” in the subject line.

Contact the writer: 402-444-1109, bob.glisemann@owh.com

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http://www.omaha.com/article/20110823/LIVEWELL01/708239936/1165
## Medical History

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<th>Wt at 18</th>
<th>Wt at 30</th>
<th>Wt at 40</th>
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</table>

| Both | | | | | |

- Take aspirin: No, Yes, for pain, heart/stroke prev, How long:
- Take other:

## Cancer History

- Ever diagnosed with cancer: No, Yes
- Date:
- Site:
- How detected: checkup, symptoms, type:
- Diagnosed with hereditary disorder: No, Yes
- Specify:

## Prostate Cancer History

- Digital rectal exam: No, Yes, Age of 1st:
- Blood test: No, Yes, Age of 1st:
- Enlarged prostate: No, Yes
- Positive PSA: No, Yes

## Other Medical Conditions

- Anemia (Chronic), Sleep problems, Chronic's disease, Alcoholism
- Diabetes, Heartburn, Ulcerative colitis, Psychiatric problem
- Hypertension, Glaucoma, Obesity, Other

## Physical Activity

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- How frequently exercise:
- Work involves physical activity: None, Little, Some, Most, Nearly All, All
- Daily routine involves physical activity: None, Little, Some, Most, Nearly All, All
### Social History

- **Education**: 
  - Elementary
  - Middle
  - High School
  - GED
  - Tech/Vocation certificate
  - College/Postgraduate

- **Income and Employment**

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<th>Income during Now</th>
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<tr>
<td>600,000-649,999</td>
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<td>700,000-749,999</td>
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<td>750,000-799,999</td>
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<tr>
<td>900,000-949,999</td>
<td>900,000-949,999</td>
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</tr>
<tr>
<td>950,000-999,999</td>
<td>950,000-999,999</td>
<td></td>
</tr>
</tbody>
</table>

- **Housing**

<table>
<thead>
<tr>
<th>Housing Type</th>
<th>Live With</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own</td>
<td>Alone</td>
</tr>
<tr>
<td>Rent</td>
<td>Family</td>
</tr>
<tr>
<td>Home</td>
<td>Friends</td>
</tr>
<tr>
<td>Apt</td>
<td>Num O</td>
</tr>
<tr>
<td>Condo</td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td></td>
</tr>
</tbody>
</table>

- **Neighborhood**

<table>
<thead>
<tr>
<th>Neighborhood Feature</th>
<th>Present</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>is safe</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>know parks</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>use parks</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>know recreation</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

- **Transportation**

<table>
<thead>
<tr>
<th>Transportation Feature</th>
<th>Present</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have a vehicle</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Travel by</td>
<td>Taxi</td>
<td>Bus</td>
</tr>
<tr>
<td>Miles travel to doctor</td>
<td>Miles travel for food:</td>
<td></td>
</tr>
<tr>
<td>Go out mostly with</td>
<td>Family</td>
<td>Friends</td>
</tr>
</tbody>
</table>

---

**Click to enter or review Employment History**

**Hours worked/day**: 

**Gov’t assistance**: Yes | No | Decline to answer

---

**Walk or run**

- weekly
- daily
- 2/month
- 4/week
- less 2/month
- 2/week
- never

**Ratinnag**: Most people can be trusted | Have to be alert or they take advantage

**Most people willing to help**: People do not trust in money matters

**Transportation**

- Have a vehicle: | Yes | No
- Travel by: | Taxi | Bus | Friend/neighbor | Family member
- Miles travel for food: | Miles travel to see doctor:
- Go out mostly with: | Family | Friends | Neighbors | Co-workers | Self | Other

**Close Form**
Psychosocial History

Childhood
- Grew up with:
  - Mother
  - Father
  - GrandParent
  - Aunt/Uncle
  - Cousin
  - Adopted
  - Siblings
  - Other
- Lived in:
  - Big City
  - Small City
  - Small Town
  - Suburb
  - Rural
  - Farm
- Mississippi Participants:
  - Delta
  - Southern MS
  - Northeast MS
  - Coastal MS
  - Northwest MS
  - Central MS
  - Southwest
  - Other
- Nebraska Participants:
  - North Omaha
  - South Omaha
  - Midtown
  - West Omaha
  - Other

Communication
- Anyone discuss health with:
  - No
  - Yes
- Discuss with:
  - Father
  - Mother
  - Siblings
  - Cousin
  - Friend
  - Doctor
  - Husband
  - Pastoral
  - Counselor

Trust
- To what extend do you trust:
  - Extremely
  - Quite a bit
  - Moderately
  - Little bit
  - None

Atitudes toward Self
- Agreement with statements:
  - Embarrassed to see doctor
  - Care and respect from health care provider

How often feel:
- Stressed
- Misunderstood
- Not listened to

Attitudes toward Self
- Agreement with statements:
  - Embarrassed to see doctor
  - Care and respect from health care provider

How often feel:
- Stressed
- Misunderstood
- Not listened to

Closed Form
Environmental History

Used tobacco  □ No
  □ Yes  □ cigarettes packs/day: □
  □ Pipe  □ cigars
  □ chewing tobacco  □ snuff
  age start □  age stop □ years smoked □

Lived with a smoker  □ No  □ Yes □ years:

Ever consumed alcohol  □ No
  □ Yes  □ alcoholic drinks per week  □ 0-3 □ 4-9 □ 10+
  □ Alcohol: □
  □ Age Start: □
  □ Age Stop: □
  □ Years:

Close Form
Overview
Two identical Microsoft Access databases are used to record questionnaire responses. One, located in Omaha and named Prostate_CU, is used for Creighton managed interviews. The other, located in Jackson and named Prostate_JSU, is used for Jackson State managed interviews. They are designed to run with the 2007 version of MS Access.

Each database has a main screen plus a screen for each section of the questionnaire. The section screens (Demographics, Medical, Social, etc.) roughly mimic the layout of the questionnaire. Each input item has a label that is abbreviated from the question. Two items, employment history and places lived, have a button that opens a screen where multiple responses can be listed. The demographics screen also serves as a control for the person since it contains buttons that open each of the other screens for that individual. The database contains edit checks on the input data. There are buttons that list problems, and message boxes that alert to a probable error.

Each person is identified in the database with a Family – Individual number (Fam-Indiv). When a person is first input, the database assigns an ID number to the person that is used by the database to coordinate the records for that person. Although the ID is shown on the screens, it can be ignored by someone doing data input. It is assumed there will be only one questionnaire in the database for each individual.

Data Input and Navigation
When the database is opened, the Main Form automatically appears. This form is used for control purposes. There are 2 ways to open the data for a person.

1) Use the Open Selected Person button. This goes directly to the data for the individual highlighted in the Select Person drop down box at the upper left of the screen. Click on the down arrow to see a list of Fam-Indiv numbers, then click on the desired person. After selecting the person, click the Open Selected Person button to go to the Demographics screen. To have a complete list in the drop down box, there is an Update List button that must be clicked after new individuals have been added. This method is used to return to a previously entered person for edit or review.

2) Use the Open New Person button. This will open a blank Demographics screen. Start by entering the Fam-Indiv numbers, then proceed with the remainder of the data.

The Demographics screen contains the personal and demographic inputs for the individual. It also contains buttons to open the four history sections of the questionnaire. Always use these buttons to open the history forms.

Always close each history form before going to another form. This is important because forms left open can cause data to be linked to the wrong person! Use the Close Form button on each form, because some include edit checks. When a history form is closed, the process returns to the Demographics form, and another history form can be selected.

The Social History form has a button to open the Employment History form. The Psychosocial History form has a button to open the Places Lived form. Multiple items can be entered on these forms. Always close these forms, and use the Close Form button to do so.

Much of the input is to check boxes. Use the mouse to check the box corresponding to the answer checked on the questionnaire. Some of the forms have date inputs, and a small calendar appears to the right when the input is selected. The format is mm/dd/yyyy, and it may be easier to type the date than to scroll the calendar. Exceptions are the employment history and places lived, which are free-form entry text boxes. The tab order on the forms often skips the check boxes. When using the tab key, it is possible to tab past the current form which opens a new form. This should be avoided, and a red warning to close the form will appear below the Close Form button.

The Demographics screen also has a Check Problems button which runs a query listing any input problems found for the person. The query is closed by clicking the x to the right of the qProblems tab. Use the Close Form button on the Demographics form to return to the main form.

The Main Form has a Check Problems –All Indiv button which runs a query listing input problems found by the edit checks for all persons in the database. More on these edits in the Edit Checks section below. The query is closed by
clicking the x to the right of the qProblems tab. The Check Sections button runs a query that reports, for any person entered in the Demographics section, any history sections which have no data entered. In this case “None” will appear under the section name. The query is closed by clicking the x to the right of the qCheckSections tab. The form also has a Close Database button, used to exit the database.

**Edit Checks**

Many of the questions have edit checks. These cause message boxes to appear stating the problem. Clicking OK closes the message, but the input person needs to fix the problem or it will remain in the saved data. A common check is conflicting answers, e.g. both Yes and No, Male and Female, Twin and Triplet, Light and Hard, None and All. Checks where only one should be selected are included, e.g. Title, Marital Status, Income level, Housing Type. Ratings must be 1 through 5. Questions with additional information if Yes may show a message if No is checked and the Yes information is entered. If the weight at any age is more than Heaviest Wt, a message will appear.

These edits also appear on the lists from the Check Problems buttons if not resolved before the button is clicked. Additional checks on the lists are for questions that are not answered. The lists can be printed for follow-up.

**Database Structure**

Each form (except frm_Main) has a table to hold data for that form. The demographics table (tbl_Demogr) has field “ID” which is an autonumber, meaning the database automatically creates the ID when data is first entered for a person on the demographics form. All other tables contain the ID field, which is the link to the person’s identity in the demographics table (including the Fam-Indiv number). Each table has its’ own sysid field, which is an autonumber that provides a unique identifier for that record. Table ErrorList is a temporary table for holding the results from the Check Problems buttons, driven by VBA code in module ErrorFind. Each form has VBA code for navigation and error checking purposes, often using Click and AfterUpdate methods.
SECTION 1: DEMOGRAPHICS and PERSONAL INFORMATION

D.1. Title
☐ Mr. ☐ Mrs. ☐ Ms. ☐ Miss ☐ Other_______

D.2. Name:

<table>
<thead>
<tr>
<th>Last</th>
<th>First</th>
<th>Middle</th>
<th>Maiden</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Street    City    State    Zip

D.3 Home/Cell Phone: _______________  D.4. Work Phone: _______________________

D.5. E-mail Address: _______________________

1.1 Birth Date: __________ (MMDDYYYY)

1.2 Part of a multiple birth? ☐ No ☐ Yes _____________ (birth order)

☐ Twin ☐ Triplet

1.3. Gender:  Female ☐  Male ☐

1.4. Marital Status: ☐ Never Married ☐ Single ☐ Widow(er) ☐ Married ☐ Divorced
☐ Separated ☐ Co-habiting

1.5. Race: Do you identify yourself as being African American?
☐ Yes ☐ No ☐ Multiple ☐ Decline to Answer

Please specify all racial groups you identify with by blood _______________________

1.6. Do you have: ☐ health care insurance?
☐ private/group ☐ Medicare/Medicaid

1.7. ☐ life insurance?

1.7. Are you or other relatives adopted?

☐ No ☐ Yes → Name: _______________ Relationship: _______________

Name: _______________ Relationship: _______________

SECTION 2: MEDICAL HISTORY

2.1 a. Height in feet and inches______ Current Weight in lbs ___________

Wt. at age 18 _________ Wt. at age 30 _________ Wt. at age 40 _________

Heaviest Wt. _________ at age_______

b. Do you take aspirin or an aspirin substitute daily or every other day? ☐ No ☐ Yes

If yes, ☐ for pain? ☐ for heart/stroke prevention? ☐ Other: _______________________

How long? _______________________

(years and months)

2.2 Cancer History

a. Have you ever been diagnosed with cancer?

☐ No ☐ Yes → Please list date(s) of diagnosis, original site(s)/type(s) of cancer (such as colon cancer, leukemia, breast cancer), and how the cancer was detected.
b. Have you or one of your relatives been diagnosed with a **hereditary disorder**?
   - ☐ No
   - ☐ Yes → please specify ________________________________

### 2.3 Prostate Cancer History
Have you had any of the following screenings:

#### a. **digital rectal exam**?
   - ☐ No
   - ☐ Yes → age of first? ________
   - on a regular basis?
     - ☐ No
     - ☐ Yes → How often? ______

#### b. **blood test for prostate cancer** (PSA-prostate specific antigen)?
   - ☐ No
   - ☐ Yes → age of first? ________
   - on a regular basis?
     - ☐ No
     - ☐ Yes → How often? ______

Have you ever had:

#### a. **an enlarged prostate**?
   - ☐ No
   - ☐ Yes; Date: _________
   - if yes, did you have surgery?
     - ☐ No
     - ☐ Yes; Date: _________

#### b. **a positive PSA level**?
   - ☐ No
   - ☐ Yes; Date: _________

### 2.4 Other Medical Conditions
Have you been diagnosed with any of the following conditions? (Please select all that apply)

- ☐ anemia (chronic)
- ☐ Crohn's disease
- ☐ diabetes
- ☐ ulcerative colitis
- ☐ hypertension (high blood pressure)
- ☐ obesity
- ☐ sleep problems
- ☐ alcoholism
- ☐ heartburn (GERD)
- ☐ psychiatric problem
- ☐ glaucoma
- ☐ Other: ________________________________

### 2.5 Physical Activity

#### a. None Very light Light Moderate Somewhat hard Hard Very hard
   - Childhood
   - High school
   - 19-29
   - 30-39
   - 40-49
   - 50-59
   - 60-69
   - 70-79

#### b. Currently how frequently do you exercise? ________________________________

#### c. How much of your work involves physical activity?
   - ☐ None
   - ☐ A little
   - ☐ Some
   - ☐ Most
   - ☐ Nearly all
   - ☐ All

#### d. How much of your daily routine involves physical activity?
   - ☐ None
   - ☐ A little
   - ☐ Some
   - ☐ Most
   - ☐ Nearly all
   - ☐ All
SECTION 3: SOCIAL HISTORY

3.1: Highest level of education
☐ Elementary School  ☐ Middle School  ☐ High School  ☐ GED
☐ Technical/Vocational Certificate Degree  ☐ College/Postgraduate

3.2: Income and Employment:
a. Income during: Childhood  Now
- None
- Up to 4,999
- 5,000-14,999
- 15,000-29,999
- 30,000-49,000
- 50,000-59,000
- 60,000-69,000
- 70,000-79,000
- 80,000 and above

b. Current Employment Status
- Full time
- Part time
- Unemployed
- Retired
- Self-employed

c. Employment History

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Type of work or title</th>
<th># of years</th>
<th>Exposure to any of the following? (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Asbestos  Paints/Solvents  Benzene  Engine exhaust  Lead</td>
</tr>
</tbody>
</table>

- Yes
- No
- Decline to answer

d. Do you receive government assistance? ☐ Yes  ☐ No  ☐ Decline to answer

e. Total hours worked each day: ________

3.3. Housing Type:
- ☐ Homeowner  ☐ Rent  ☐ Home  ☐ Apartment  ☐ Condominium  ☐ Mobile Home

- I live: ☐ alone  ☐ with family  ☐ with friends

d. How many people live in your household? ________

3.4. Neighborhood:
- ☐ I feel that my neighborhood is safe.
- ☐ Yes  ☐ No

- ☐ I know where the parks are in my neighborhood.
- ☐ Yes  ☐ No

- ☐ I use the parks in my neighborhood.
- ☐ Yes  ☐ No

- ☐ I know the recreational organizations in my neighborhood.
- ☐ Yes  ☐ No

- ☐ My neighborhood has places where I can walk.
- ☐ Yes  ☐ No

- ☐ I walk or run there: ☐ Daily  ☐ 4 Times/week  ☐ Twice/week  ☐ Weekly  ☐ Twice a month  ☐ Less than twice a month  ☐ Never

3.5. Please rate how much you agree with the following statements regarding your neighborhood?

1= Strongly Agree  2= Agree  3= Neutral  4= Disagree  5= Strongly Disagree

- Most people in my neighborhood can be trusted.
- ☐ Yes  ☐ No

- In my neighborhood you have to be alert or someone is likely to take advantage of you.
- ☐ Yes  ☐ No

- Most people in my neighborhood are willing to help if needed.
- ☐ Yes  ☐ No

- In my neighborhood people generally do not trust each other in matters of lending or borrowing money.
- ☐ Yes  ☐ No
3.6. **Transportation:**
   a. I have a vehicle. ☐ Yes ☐ No
   b. If no, I travel by: ☐ taxi ☐ bus ☐ friend/neighbor ☐ family member
   c. I have to travel ____ miles to buy food.
   d. I have to travel ____ miles to see my doctor.
   e. When I go out I mostly go with: (check only one)
      ☐ Family ☐ Friends ☐ Neighbors ☐ Co-workers ☐ Self ☐ Other ______

---

**SECTION 4: PSYCHOSOCIAL HISTORY**

4.1. **Childhood:**
   a. I grew up in the same household with: (Please check all that apply.)
      ☐ My mother ☐ Grandparent(s) ☐ Cousin(s) ☐ Sibling(s)
      ☐ My father ☐ Aunt/Uncle ☐ Adopted ☐ Other;

   b. As a child I lived in: ☐ a big city ☐ a small city ☐ a small town ☐ a suburb ☐ a rural area ☐ a farm

   c. For Mississippi Participants:
      As a child I lived in:
      ☐ The Delta area ☐ Northeast MS ☐ Central MS
      ☐ Southern MS ☐ Coastal MS ☐ Southwest MS
      ☐ Other: ___________

   d. For Nebraska Participants:
      As a child I lived in:
      ☐ North Omaha ☐ South Omaha ☐ Midtown
      ☐ West Omaha ☐ Other: ___________

   e. Please indicate the places you have lived (all participants)

<table>
<thead>
<tr>
<th>Dates or Ages</th>
<th>Place (City, State)</th>
<th># of Years</th>
<th>Exposure to any of the following? (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Asbestos ☐ Paints/Solvents ☐ Benzene ☐ Engine exhaust ☐ Lead ☐ Contaminated Water</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
</tr>
</tbody>
</table>

   f. As a child we attended religious services: ☐ regularly ☐ occasionally ☐ on holidays ☐ never

4.2. **Communication, Trust and Attitudes towards Self**
   a. Do you have anyone you discuss your health concerns with? ☐ No ☐ Yes
   b. If yes, please indicate who. (Please check as many as apply.)
      ☐ Father ☐ Sibling(s) ☐ Friend ☐ Doctor
      ☐ Mother ☐ Children ☐ Cousin ☐ Counselor
      ☐ Wife ☐ Uncle ☐ Co-Worker ☐ Other,

      ☐ Husband ☐ Aunt ☐ Pastor
b. To what extent do you trust the following groups of people?

<table>
<thead>
<tr>
<th>Trust Level</th>
<th>Extremely</th>
<th>Quite a bit</th>
<th>Moderately</th>
<th>A little bit</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. People from your race/ethnic group</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>ii. People from other race/ethnic groups</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>iii. Local government officials</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>iv. State government officials</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>v. Federal government officials</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>vi. Police</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>vii. Your health care provider</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

c. How much do you agree with the following statements with regard to your attitudes towards yourself?

1 = Strongly Agree  2 = Agree  3 = Neutral  4 = Disagree  5 = Strongly Disagree

i. I am embarrassed to go see the doctor. ________

ii. I feel I am treated with care and respect by my health care provider(s) ________

d. How often do you feel the following:

<table>
<thead>
<tr>
<th>Feeling</th>
<th>Always</th>
<th>Often</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. stressed</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>ii. misunderstood</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>iii. not listened to</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

SECTION 5: ENVIRONMENTAL HISTORY

5.1. Environmental

a. Have you used any form of tobacco regularly?
   ☐ No
   ☐ Yes → what type(s)?
   ☐ cigarettes → number of packs per day? ________
   ☐ pipe
   ☐ cigars
   ☐ chewing tobacco
   ☐ snuff

b. at what age did you start? ________
c. at what age did you stop? ________
d. total numbers of years smoked? ________
e. lived in the same house with a smoker (if a nonsmoker)?
   ☐ No
   ☐ Yes → # of years? ________

5.2. Have you ever consumed alcoholic drinks?
   ☐ No
   ☐ Yes → how many per week? 0-3 ☐ 4-9 ☐ 10+
   what type(s)? ________________________________

b. at what age did you start? ________
c. at what age did you stop? ________
d. total numbers of years? ________

THANK YOU FOR YOUR TIME AND CONTRIBUTION!
Time Ended: __________  Interviewer Initials: __________
Family A

Pedigree Abbreviations

- Csu: Cancer site unknown
- Leu: Leukemia
- Lu: Lung
- Pro: Prostate

LEGEND

- Individual number
- Unaffected
- Current age
- Cancer by Pathology, age at diagnosis, Current age
- Cancer by Family History, age at death
- Multiple Primary Cancers Unverified
- Multiple Primary Cancers by Medical Records or Death Certificates
- Multiple Primary Cancers by Pathology
- Cancer by Death Certificate or Medical Records
- Number of Unaffected Progeny (Both Sexes)
- Proband

CONFIDENTIAL MEDICAL REPORT - NOT FOR FURTHER DISCLOSURE

Pedigree drawn by Toni Richardson-Nelson, B.G.S.