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14. ABSTRACT

Men of African descent experience a disproportionately high prostate cancer mortality. We and others have shown that prostate tumors in African-Americans harbor a distinct immuneinflammation signature. Low-grade inflammation has been described as a prostate cancer risk factor that is associated with aggressive disease. We also reported that regular aspirin use reduces the risk of aggressive prostate cancer and disease recurrence in these men. Together, the observations suggest that a low-grade chronic inflammation related to ancestral factors and tumor biology could be a driver of prostate cancer mortality in men with African ancestry.

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1. Introduction

Men of African descent experience a disproportionately high prostate cancer mortality. We and others have shown that prostate tumors in African-Americans harbor a distinct immune-inflammation signature. Low-grade inflammation has been described as a prostate cancer risk factor that is associated with aggressive disease. We also reported that regular aspirin use reduces the risk of aggressive prostate cancer and disease recurrence in these men. Together, the observations suggest that a low-grade chronic inflammation related to ancestral factors and tumor biology could be a driver of prostate cancer mortality in men with African ancestry. We therefore proposed to examine whether a systemic low-grade inflammation is a prostate cancer risk factor in men of African descent and correlates with West African ancestry, genetic susceptibility, a distinct tumor biology, and aggressive disease. Our research aims included the analysis of a unique immune-inflammation signature in men of African ancestry that relates to prostate cancer. We also proposed to assess the genetic and ancestral basis of prostate cancer-associated inflammation using a genome-wide association approach. Lastly, in collaboration with our Co-PI, Dr. Clayton Yates at Tuskegee University, we will determine the prevalence and origin of an immune-inflammation signature in tumors of men of African and European ancestry.

2. Keywords

African American, Africa, ancestry, biomarker, case control study, chromatin, cyclooxygenase, disease progression, DNA, genetic variation, genomics, immunity, inflammation, mutation, RNA, risk factor, omega-3 fatty acid, tumor biology, transcriptome, urine.

3. Accomplishments

During the last 12 months, our group addressed the Major Task 1 for Specific Aims 1 & 2, as outlined in the Statement of Work for the grant. **For Specific Aim 1,** under Major Task 1, we described as subtask 1 the preparation of plasma and urine samples and their shipment to labs to measure immune-inflammation makers (n = 92), Omega-3 fatty acid levels (24 different metabolites), lipopolysaccharide (LPS), and urinary metabolites of the cyclooxygenase signaling pathway (5 metabolites were measured). This task had a timeline of 8 months and has been completed ahead of schedule. Major Task 1 describes as subtask 2 the measurements of these markers/metabolites at Olink (immune-

Specific Aim 1: Measure 97 markers in plasma/serum or urine and examine their association with prostate cancer (PCa), genetic ancestry, family history, and lifestyle factors.	**Timeline**	**Site 1** NCI	**Site 2** TU
Major Task 1: Measurement of 92 immune-inflammation markers, lipopolysaccharide, and Omega-3 fatty acids, respectively, in plasma/serum, and three metabolites of cyclooxygenases - PGE-M, thromboxane B2 and prostacyclin - in urine.	Months		
Subtask 1: Prepare plasma/serum and urine samples for shipment • Obtain IRB approval and MTAs covering the NCI-Maryland and NCI-Ghana Prostate studies and the two study sites, NCI and University of Tuskegee. • Receive (Ambs) and aliquot plasma/serum samples from 1650 cases (150 samples from Nigerian PCa cases) and 1650 controls (150 samples from Nigerian men) and ship to Olink (Watertown MA), Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research (Frederick, MD), and OmegaQuant LLC (Sioux Falls, SD). Also, aliquot urine samples from the NCI-Maryland Prostate Cancer Case-Control study (n = 1800) and ship to the Eicosanoid Core Laboratory at Vanderbilt University (Nashville, TN).	1-8	Ambs, Cook, Dorsey, Minas	Yates
Subtask 2: Measure plasma/serum and urine markers and build a database • Measurement of 92 inflammation-related and immune-modulatory analytes at Olink; lipopolysaccharide at Leidos Biomedical Research Inc.; three metabolites of cyclooxygenases, PGE-M, thromboxane B2 and prostacyclin at Eicosanoid Core Laboratory, Vanderbilt University; and Omega-3 fatty acids at OmegaQuant LLC. Obtain measurement data and create a database for analysis with a statistical software.	8-16(24)	Ambs, Dorsey, Minas	

inflammation markers), at OmegaQuant (fatty acids), at Leidos (LPS), and at the Eicosanoid Core Laboratory at Vanderbilt University (urinary metabolites). This task had a timeline of 16 months and has been completed with the exception of the analysis of immune-inflammation markers in 150 plasma/serum samples from Nigerian prostate cancer patients which is being planned for early 2020. These Nigerian blood samples will come from the Yates laboratory and the measurements will be integrated with analysis described under Major Task 3. As to the measurements of the urinary metabolites, we observed a larger variation in the data for blinded duplicates than expected. We were told that these mass spectrometry-based assays typically generate coefficient of variation (CV) values between 10-15%. We observed larger CVs (Table 6). This is currently being investigated and may lead to a re-analysis of our urinary samples.

All plasma metabolites were measured in blood from 1520 prostate cancer cases and 1518 controls from the NCI-Maryland (Table 1) and NCI-Ghana studies (Table 2). In total, about 3190

Table 1. Characterstics of prostate cancer cases and population controls of NCI-MD Study used for the DoD research project

	Cases[a]			Population Controls		
Demographics	**All (n=846)**	**AA[b] (n=407)**	**EA[c] (n=439)**	**All (n=846)**	**AA (n=382)**	**EA (n=464)**
Age[d]						
Median (IQR[e]) in years	64 (11)	63 (11)	65 (11)	65 (12)	64 (10)	66.5 (13)
BMI						
Mean(SD[f]) in kg/m^2	28.0 (4.7)	28.0 (5.2)	28.0 (4.3)	28.7 (5.2)	29.7 (5.5)	27.8 (4.9)
Education, *N(%)*						
High school or less	304 (35)	191(47)	113 (26)	196 (23)	111(29)	85 (18)
Some college	249(29)	135 (33)	114 (26)	206 (24)	109 (29)	97 (21)
College	162 (19)	53 (13)	109 (25)	221 (26)	84 (22)	137 (30)
Graduate	130 (15)	27 (7)	103 (23)	222 (26)	77 (20)	145 (31)
Did not provide	1(<1)	1(<1)	-	1(<1)	1(<1)	
Baseline Health Factors						
Family history of prostate cancer[g], *N (%)*						
No	759 (90)	371 (91)	388 (88)	788 (93)	360 (94)	428 (92)
Yes	87 (10)	36 (9)	51 (12)	58 (7)	22 (6)	36 (8)
Smoking status[h], *N (%)*						
Current	199 (24)	133 (33)	66 (15)	113 (13)	70 (18)	43 (9)
Former	350 (41)	155 (38)	195 (44)	378 (45)	157 (41)	221 (48)
Never	292 (35)	116 (29)	176 (40)	346 (41)	152 (40)	194 (42)
Did not provide	5 (<1)	3 (<1)	2 (<1)	9 (1)	3 (<1)	6 (1)
Stage[i], *N(%)*						
T1	164 (19)	64 (16)	100 (23)			
T2	560 (66)	289 (71)	271 (62)			
T3	68 (8)	24 (6)	44 (10)			
T4	54 (6)	30 (7)	24 (5)			
Gleason score, *N (%)*						
≤7	702 (83)	338(83)	364 (83)			
>7	144 (17)	69 (17)	75 (17)			
Disease aggressiveness, *N (%)*						
Nonaggressive disease[j]	634 (75)	308 (76)	326 (74)			
Aggressive disease[k]	212 (25)	99 (24)	113 (26)			
PSA						
Median (IQR) in ng/ml	6.3 (5.8)	6.9 (7.6)	6 (4.8)	0.4 (0.6)	0.4 (0.6)	0.4 (0.6)

[a] Cases recruited within 2 years after disease diagnosis with an average interval between diagnosis and enrollment of 6.7 months
[b] AA: African-American
[c] EA: European American
[d] Age at study interview
[e] IQR: Interquartile range
[f] SD: Standard deviation
[g] First-degree relative with prostate cancer
[h] Smoking status describes cigarette smoking
[i] Pathologically confirmed using American Joint Committee on Cancer (AJCC) 7th Edition
[j] Cases with pathologically confirmed T1 or T2 and Gleason score ≤7
[k] Cases with pathologically confirmed T3 or T4 or Gleason score >7
[l] PSA: Prostate specific antigen

measurements (including blinded duplicates) were performed for each assay type (Table 3). For the 92 immune-inflammation markers, measurements of duplicates showed very small sample-to-sample variation (Table 3), indicating a generally very solid platform that was developed by Olink. We could detect 61 of the analytes in all samples and 78 in 50% of the samples. Missing values mostly indicated that the abundance of these metabolites was below the detection limit in a subset of the samples. However, for a few of the immune-inflammation markers (5-10), the Olink multiplex assay may not have worked well, leading to a failure of detecting these markers in almost all samples (e.g., TNFα, IFNγ). We reported this experience back to the company. However, the metabolites in question cannot be re-measured and will be excluded from analysis.

Table 2. Characterstics of prostate cancer cases and population controls of NCI-Ghana Study used for DoD research project

Demographics	**Cases (n=659)**	**Controls (n=659)**
Age		
Median (IQR[a]) in years	70 (11)	59 (11)
BMI		
Mean(SD[b]) in kg/m^2	25.4 (4.6)	24.3 (4.4)
Education, *N(%)*		
Primary	92 (14)	146 (22)
Middle (junior secondary)	197 (30)	293 (44)
Secondary (senior secondary)	127 (19)	126 (19)
Higher	239 (36)	87 (13)
Did not provide	4 (<1)	7 (1)
Baseline Health Factors		
Smoking status[c], *N (%)*		
Current	16 (2)	95 (14)
Former	206 (31)	188 (29)
Never	427 (65)	348 (53)
Did not provide	10 (2)	28 (4)
Gleason score, *N (%)*		
≤7	415 (63)	
>7	205 (31)	
Did not provide	39 (6)	
PSA[d]		
Median (IQR) in ng/ml	44.2 (96)	0.98 (1.46)

[a]IQR: Interquartile range
[b]SD: Standard deviation
[c]Smoking status describes cigarette smoking
[d]PSA: Prostate specific antigen

Table 3: Completed Assays for Plasma Markers in the DoD Research Project

	Number of Analytes	# Analytes detected in all samples	# Analytes detected in 50% samples	QC criteria	Passed QC	Average CV (duplicates and across plates)	# cases	# controls	# total (with blinded duplicates)
Olink Immune-inflammation markers	92	61	78	Internal controls on each plate	95%	1.7% intra 2.6% inter	1520	1518	3195
OmegaQuant Omega-3 fatty acids	24	24	24	CLIA-certified assay at lab	100%	8.7%	1520	1518	3192
Leidos LPS assay	1		LPS detectable in 14% of samples	Random duplicates; added positive control samples	99.4%	Average 2.8%; 28% with high LPS	1520	1518	3190

As to the measurements of the Omega-3 fatty acids, all assays performed very well, and the 24 fatty acids were measured in all samples. The estimated CV of 8.7% indicates very good performance of the assays, which is rather expected from a CLIA certified assay that is applied to measure fatty acid contents in clinical samples as a routine task by OmegaQuant. Lastly, our LPS assay detected LPS, also called endotoxin, in about 14% of the samples (Table 3). We did not expect to detect LPS in a large number of samples, as it indicate an ongoing infection with gram-negative bacteria, and will use the LPS readings to see if immune-inflammation marker measurements are affected by infections.

The five urinary metabolites (PGD-M, PGE-M, PGI-M, 11dTxB2, TNE) that are surrogates for cyclooxygenase signaling, a pro-inflammatory and oncogenic signaling pathway, were only

Table 4. Characterstics of prostate cancer cases and population controls of NCI-MD Study used for the urine study

	Cases[a]			Population Controls		
Demographics	**All (n=977)**	**AA[b] (n=490)**	**EA[c] (n=487)**	**All (n=1,023)**	**AA (n=480)**	**EA (n=543)**
Age[d]						
Median (IQR[e]) in years	64 (11)	63 (10)	65 (11)	64 (12)	64 (10)	66 (13)
BMI						
Mean(SD[f]) in kg/m^2	28.0 (5.1)	28.0 (5.0)	28.0 (5.2)	28.8 (5.2)	29.0 (5.3)	28.6 (5.0)
Education, *N(%)*						
High school or less	353 (36)	227 (46)	126 (26)	243 (24)	138 (29)	105 (19)
Some college	295 (30)	167 (34)	128 (26)	261 (26)	140 (29)	121 (22)
College	173 (18)	58 (12)	115 (24)	256 (25)	103 (21)	153 (28)
Graduate	140 (14)	29 (6)	111 (23)	250 (24)	90 (19)	160 (30)
Did not provide	16 (2)	9 (2)	7 (1)	13 (1)	9 (2)	4 (1)
Baseline Health Factors						
Family history of prostate cancer[g], *N (%)*						
No	746 (76)	346 (71)	400 (82)	726 (71)	299 (62)	427 (79)
Yes	211 (22)	135 (27)	76 (16)	281 (27)	173 (36)	108 (20)
Did not provide	20 (2)	9 (2)	11 (2)	16 (2)	8 (2)	6 (1)
Smoking status[h], *N (%)*						
Current	240 (25)	164 (33)	76 (16)	150 (15)	96 (20)	54 (10)
Former	393 (40)	176 (36)	217 (44)	457 (44)	196 (41)	261 (48)
Never	320 (33)	137 (28)	183 (38)	396 (39)	178 (37)	218 (40)
Did not provide	24 (2)	13 (3)	11 (2)	20 (2)	10 (2)	10 (2)
Stage[i], *N(%)*						
T1	180 (18)	72 (15)	108 (22)			
T2	636 (65)	342 (70)	294 (61)			
T3	75 (8)	25 (5)	50 (10)			
T4	58 (6)	34 (7)	24 (5)			
Missing	28 (3)	17 (3)	11 (2)			
Gleason score, *N (%)*						
≤7	799 (81)	400 (82)	399 (82)			
>7	162 (17)	82 (16)	80 (16)			
Missing	16 (2)	8 (2)	8 (2)			
Disease aggressiveness, *N (%)*						
Nonaggressive disease[j]	722 (74)	368 (75)	354 (73)			
Aggressive disease[k]	240 (25)	114 (23)	126 (26)			
Missing	15 (1)	8 (2)	7 (1)			
PSA						
Median (IQR) in ng/ml	5.4 (3.5)	6.7 (5.1)	4.6 (3.8)			

[a] Cases recruited within 2 years after disease diagnosis with an average interval between diagnosis and enrollment of 6.7 months
[b] AA: African-American
[c] EA: European American
[d] Age at study interview
[e] IQR: Interquartile range
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[j] Cases with pathologically confirmed T1 or T2 and Gleason score ≤7
[k] Cases with pathologically confirmed T3 or T4 or Gleason score >7
[l] PSA: Prostate specific antigen

Table 5. Summary of Samples Sent for Analysis		
Number of Patient Samples (N)		2000
Number of Duplicates (N)	Pilot Study	22
	Duplicates in Main Study	107
Negative Controls (N)		2
Total of samples sent for analysis (main study + pilot study)		2131

measured in the NCI-Maryland Study, as outlined in the SOW, because urine was not collected in the NCI-Ghana study. The characteristics of the study population is shown in Table 4. We sent a total of 2131 samples (Table 5) to the Eicosanoid Core Laboratory at Vanderbilt University to be analyzed by mass spectrometry using assays that have previously been validated at the facility. The core facility measures these metabolites and then standardizes the measurements to urinary creatinine content, which is determined by a separate colorimetric assay. A pilot

Table 6: Coefficient of variation for urinary metabolites

Urinary Markers CV	# of duplicates	% CV	PGE-M (ng/mgCr)	PGD-M (ng/mgCr)	PGI-M (ng/mgCr)	11dTxB2 (ng/mgCr)	TNE (ng/mgCr)
Inter-plate CV	124	Average Inter-plate CV	23.97	29.68	44.10	19.33	24.06
Intra-plate CV	3	Average Intra-plate CV	14.26	13.33	33.27	16.34	20.29

study that we conducted with 22 blinded duplicates indicated that duplicate measurements would have the expected CV of 10-15%. However, additional analysis of blinded duplicates in the main study showed that the CV values were substantially higher (Table 6). The reason for the discrepancy between the pilot and the main study is currently unknown but is investigated. Possible factors are a batch effect, as the large number of samples was analyzed in batches, or a performance change of the mass spectrometer, as it went under repair while the measurements were performed. Yet, we are not sure if either one of these factors can explain the variations in the measurement results.

For Specific Aim 2, Major Task 1 describes as subtask 1 the preparation of DNA samples and shipment to the genotyping samples at Cancer Genomics Research Laboratory (CGRL), NCI. We completed this task within the projected time frame of 8 months. However, further quality control (QC) testing at the facility indicated that the quality and DNA

Specific Aim 2: Assess whether germline genetic variants are associated with immune-inflammation markers and PCa using a genome-wide association approach (GWAS).		NCI
Major Task 1: Perform GWAS genotyping with Infinium HumanOmni5-Quad BeadChip	Months	
Subtask 1: Prepare DNA samples for shipment • Obtain IRB approval covering the NCI-Maryland Prostate study • Aliquot DNA samples from 900 cases and 900 controls, perform quality control, and ship to Cancer Genomics Research Laboratory, DCEG/NCI	1-8	Ambs, Dorsey, Minas
Subtask 2: Genotyping with Infinium HumanOmni5-Quad BeadChip, covering more than 4 million SNPs • Perform genotyping and preliminary data analysis at Cancer Genomics Research Laboratory. Receive data and add to database.	8-14	Ambs, Minas, Tang

content for about 800 of the submitted samples was not sufficiently high to continue with the genotyping work (the requirements are stringent). Replacement of these samples needed re-extraction of DNA from the original sample collection and was only recently completed. Currently, we have isolated germline DNA from 855 cases and 948 controls. 1041 of these DNA samples already passed QC control. 397 resubmitted samples passed DNA quantitation and should also be good for genotyping while the remaining 365 samples are still in the pipeline for QC testing. If all goes well, we expect that the genotyping work with the HumanOmni5-Quad Bead Chip, described as subtask 2 in the SOW, will start in early 2020. A major time-limiting factor with Specific Aim 2 is the allocation of slots by CGRL when QC analysis and genotyping can be performed for a project. The core facility is busy, and any requested task can take months to be completed.

Work covering **Specific Aim 3** primarily falls under the responsibility of Dr. Clayton Yates, our co-investigator at Tuskegee University. However, we will continue to work collaboratively with his laboratory on these tasks, as described in the SOW, as most of the sequencing of tissue samples will be performed at Leidos-NCI. Currently, we are in the process of obtaining four core samples from 100 FFPE tumor blocks collected from 50 African-American and 50 European-American prostate cancer patients in the NCI-Maryland study. It is our goal to obtain two tumor cores and two adjacent non-cancerous tissue cores from each tumor for whole exosome and RNA sequencing, as proposed under the SOW. The tissue cores are being extracted by a pathologist at the University of Maryland and will be combined with tissue cores obtained from Nigerian prostate cancer patients. We were assured that all cores should be available to us by end of 2019. From there, we can start the sequencing work. In summary, we are on track with this project.

Opportunities for training and professional development. The work that was completed in the last 12 months did not provide much of an opportunity for training and professional development. These were all routine tasks of sample preparation, QC analysis, and shipment, and included study design tasks for pilot studies and the main study. However, we hosted Jason White from the Yates laboratory at our NCI laboratory for several months. Jason White is a PhD student at Tuskegee University and will participate in data analysis of tumor data (mutation and RNA expression analysis) for this DoD grant. Jason received mentoring in the analysis of whole exome sequencing data by our Staff Scientist and data science expert, Dr. Wei Tang, and received access to use the NIH Biowulf Cluster for high-performance computing. Jason is now a volunteer with the NCI and can use the NIH high-performance computing capabilities remotely when working in the Yates lab.

Dissemination of results to communities of interest. Since the data are only recently available, there have been no formal dissemination of the data. However, Tsion Minas, a postdoctoral fellow in my lab, and Dr. Michael Cook, a co-investigator for the grant, have begun to analyze the immune-inflammation marker data – starting with the QC analysis and data cleaning. Tsion will give a first data presentation at the AORTIC 2019 conference in Maputo, Mozambique, on November 6, 2019, with findings from this grant. She was selected for a Lightning Talk entitled: Distinct circulating immune-oncological markers in men of African descent. She was also selected to be on the African Cancer Leadership Institute associated with this international cancer conference. In addition, Tsion will present more of her findings as the speaker at an NCI Interlaboratory Seminar, on November 24, 2019.

Goals to accomplish during the next reporting period. We expect to have most, if not all, of the finalized data for the plasma and urine markers by the beginning of 2020. We are also hopeful that data from the Genome-Wide Association Study will become available to us in spring of 2020. This would conclude all data acquisition/experimental work under Specific Aims 1 and 2, allowing us to focus solely on data analysis and result dissemination – as described in the SOW for Specific Aims 1 and 2, between months 12-36 of the grant award. As such, we are on track with the proposed work. With the data in hand, two postdoctoral fellows, Tsion Minas and Maeve Bailey-Whyte, an NCI Cancer Prevention Fellow in my laboratory, will concentrate on the analysis of these data for preparation of manuscripts. They can be joined by Margaret Pichardo, a PhD student in Epidemiology at Yale, who is also a fellow with our laboratory and can perform additional data analysis for this grant. I am scheduled to chair a session at the third NCI Cancer Health Disparities Research Symposium and will give a presentation at the meeting focusing on the findings from this grant.

4. Impact

There is “Nothing to report” at this time. As our initial tasks covered routine laboratory procedures, we do not have any study results to report at this time. However, our research appears to have significant impact on performance measures at both Olink and the Eicosanoid Core Laboratory at Vanderbilt. We learned a few valuable things about the Olink technology. We provided the company with perhaps its first feedback on the performance of their technology to measure the Immuno-Oncology panel in a large sample set. This panel is a high-throughput, multiplexed immunoassay using proprietary technology enabling analysis of 92 protein biomarkers. We reported back to the company what we thought were non-performing assays among the 92 assays. We had a very constructive conference call with them and noticed that the company - not long after they received our feedback - sent out an email to all customers that they optimized certain assays in the Immuno-Oncology panel for better performance. We are also working with the Eicosanoid Core Laboratory to optimize their

performance. We are not sure either to what extent they had feedback on intra- and inter-plate variability from customers with a large sample set. When we performed the pilot study with them, we noticed that the urine samples were not spun prior to measurement of creatinine. We changed this procedure because urine samples can contain insoluble substances that have to be removed as they can interfere with a colorimetric assay. The laboratory manager, Ginger Milne, has been very receptive to our feedback and is actively working with us to improve their measurement and analysis pipeline. I hope that our discussions with them, and additional measurements, will lead to a better assay performance. As such, the project will likely improve knowledge and practices at these two places.

5. Changes/Problems

We have no changes to report for this award period. At this time, all procedures and measurements will continue as planned. We had a minor problem with the amount and quality of the DNA that we sent out to the genotyping core facility at the NCI. This DNA was obtained from an existing stock. It seems that previous concentration measurements had overestimated the content of intact DNA. This problem has been resolved. However, we needed new DNA extractions from the originally collected biospecimens, and this required more time than expected. We are very much in continuous discussion with the genotyping core facility and used their recommended assays for extraction and QC analysis to replace all samples. There is also an issue with the variability of duplicate measurements at the Eicosanoid Core Laboratory, as outlined previously. This issue will have to be resolved at the Core, but we are helping them as much as possible with our own analyses and feedback. None of the aforementioned problems affected the expenditures by this award and should not substantially delay the data collection for these projects. One time-limiting factor for completing the GWAS study, described under Major Task 2, could be the allocation of a slot to perform the genotyping. As CGRL has many customers, we will only know after the DNA QC analysis is completed by CGRL when our samples will actually be assayed. Lastly, there are no changes in use of human subject data.

Changes to vertebrate animals and select agents do not apply.

6. Products

Nothing to report.

7. Participants and Other Collaborating Organizations

The following individuals have worked on the DoD grant in the past 12 months. The preparation of thousands of plasma, urine, and DNA samples for shipment to the service providers was a major task for the Ambs laboratory involving most of the laboratory members.

Name	Tsion Minas
Project Role	Postdoctoral Fellow
Researcher Identifier	
Nearest person month worked	10
Contribution to Project	Project manager for the plasma marker and GWAS studies; communication with service providers; aliquoting of plasma; DNA extraction and aliquoting; development of template for sample analysis including random distribution and blinded duplicates across plates; data analysis: QC analysis for all plasma markers; preliminary analysis of immune-inflammation markers
Funding support	NCI intramural program

Name	Tiffany Dorsey
Project Role	Laboratory Manager/Microbiologist
Researcher Identifier	
Nearest person month worked	8
Contribution to Project	Key person for all biospecimen-related tasks; communication with service providers; shipment of samples from repository to laboratory and from laboratory to service providers; aliquoting of plasma; DNA extraction and aliquoting; supervision of Post-baccalaureate fellows
Funding support	NCI intramural program

Name	Maeve Bailey-Whyte
Project Role	NCI Cancer Prevention Fellow
Researcher Identifier	
Nearest person month worked	3
Contribution to Project	Project manager for the urine metabolite study; communication with Eicosanoid Core Laboratory; troubleshooting; aliquoted urine samples; performed pilot study; development of template for sample analysis including random distribution and blinded duplicates across plates; QC analysis for all urine markers
Funding support	NCI intramural program

Name	Anuoluwapo Ajao
Project Role	NIH Academy Post-baccalaureate fellow
Researcher Identifier	
Nearest person month worked	2
Contribution to Project	Re-extraction of DNA
Funding support	NCI intramural program

Name	Francine Baker
Project Role	NIH Academy Post-baccalaureate fellow
Researcher Identifier	
Nearest person month worked	1
Contribution to Project	Sample labeling
Funding support	NCI intramural program

Name	Wei Tang
Project Role	Staff Scientist
Researcher Identifier	
Nearest person month worked	2
Contribution to Project	Mentor of Jason White (PhD student from Tuskegee U)
Funding support	NCI intramural program

Name	Michael Cook
Project Role	Principal Investigator
Researcher Identifier	
Nearest person month worked	1
Contribution to Project	Data analysis: Immune-inflammation markers
Funding support	NCI intramural program

Name	Stefan Ambs
Project Role	Principal Investigator
Researcher Identifier	ORCID ID: https://orcid.org/0000-0001-7651-9309
Nearest person month worked	1
Contribution to Project	Project management including staff, service providers, and Geneva Foundation; guidance with data analysis
Funding support	NCI intramural program

Changes in active other support: We have no changes in the support for the PI or other key personnel to report.

What other organizations were involved as partners? We have established a collaboration with the University of Maryland Medical School, Department of Pathology, to have a collaborating pathologist taking the cores from FFPE tumor blocks, supporting Major Task 3. This collaboration includes our laboratory, the Co-PI Clayton Yates, and the Department of Pathology.

8. Special Reporting Requirements

This is a collaborative award. The initiating PI, Stefan Ambs, and the Collaborating/Partnering PI, Clayton Yates, will submit separate reports.

9. Appendices

Nothing attached.