

**AWARD NUMBER:** W81XWH-17-1-0576

**TITLE:** Agent Orange Exposure and Bladder Cancer

**PRINCIPAL INVESTIGATOR:** Stephen B. Williams, MD

**CONTRACTING ORGANIZATION:** The University of Texas Medical Branch  
301 University Blvd, Galveston, TX 77555

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

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> Dr. Williams has applied advanced degree coursework acquired during months 1-24 (MS graduation) to the project's objectives and training-specific tasks. Dr. Williams has and continues to attend meetings (Freedland, group, professional development advisory committee), albeit in a more remote capacity due to present circumstances. Research specific tasks, specific Aim 1, Subtask 1 complete (months 1-4), Subtask 2 complete (months 1-18), with database completion, and Subtask 3 (months 18-24) including matching and analyses being performed. Natural language processing auditing to verify and ensure integrity of data has been completed. Subtask 4 (months 12-24) manuscript preparation, submission and publication were delayed accordingly with NLP development, but submission still anticipated in months 24-36. Specific Aim 2, Subtask 1 (months 24-30) has begun and we have both VINCI mortality data and NDI date and cause of death data. Subtask 2 (months 30-36) and Subtask 3 (months 24-36) expected to be completed. Day to day management activities of the PI have been upheld during this time period. A no-cost extension was requested and approved for the project.					
<b>15. SUBJECT TERMS</b> Agent Orange, bladder cancer, statement of work (SOW), database, analysis					
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## TABLE OF CONTENTS

INTRODUCTION .....	4
ACCOMPLISHMENTS .....	5
IMPACT .....	14
CHANGES/PROBLEMS .....	14
PRODUCTS.....	15
PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS .....	15
SPECIAL REPORTING REQUIREMENTS .....	17
APPENDICES .....	18

## INTRODUCTION

To date, only limited data exist regarding the link between Agent Orange (AO) and bladder cancer (BC) risk and mortality. The Institute of Medicine (IOM) concluded the interplay between AO exposure and BC outcomes is an area of needed research. Based upon this, the Veterans Affairs (VA) is considering BC as an AO related disease. Indeed, the Department of Defense Peer Reviewed Cancer Research Program (PRCRP), for the first time, included a focus area on BC and AO. Therefore, our proposal is not only timely but will help answer two key questions: Is AO linked with BC risk and/or mortality? Using one of the largest databases ever assembled for BC research containing data on over 5.7 million people, we will test whether AO is linked with increased BC and death from BC. Hypothesis/Objective: We hypothesize AO exposure will be linked with increased BC and worse BC-specific survival. Aim 1. Determine whether AO exposure is linked with BC risk. We will develop a nation-wide cohort of people in the VA Health system since 2000. We will query this cohort for AO exposure to test if AO exposure is linked with increased BC risk. Results will be adjusted for potential confounders such as smoking, age, and race. Aim 2. Explore whether AO exposure is linked with BC-specific mortality. Using the cohort from Aim 1, we will ascertain cause of death from the national death index (NDI). Results will be adjusted for potential confounders as in Aim 1, but also clinical stage and treatment(s) received. The mentorship team has been directed under Stephen J. Freedland, M.D. Dr. Freedland (mentor) and Dr. Williams (PI) are located at different organizations with the proposed research to be conducted at the Durham VA. Dr. Freedland has supervised and mentored Dr. Williams through teleconferences, screen sharing via Microsoft Lync, as well as face-to-face meetings. The research findings will provide much needed information discerning if AO exposure is linked to increase risk of BC (Topic Area) in the VA population. The guidance/mentorship by Dr. Freedland and the entire professional development advisory committee will further reinforce Dr. Williams' research development and bring his current and future research to the next level. At the conclusion of 3 years, Dr. Williams will have a BC research team with the largest database ever created to study AO and BC (with patient tissues) to successfully apply for further grant funding opportunities.

**1. KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Agent Orange, bladder cancer, incidence, risk, mortality

## ACCOMPLISHMENTS

What were the major goals of the project?

**Training-Specific Tasks:** *(only applicable to training award mechanisms)*

	Target Months	Actual Completion Dates	Percentage of Completion
<b>Major Task 1: Complete coursework in data management and biostatistics methodology</b>			
Subtask 1: Coursework: Data management PHS 6210, Biostatistics PHS 6343	1-12	12/31/17	100
Milestone(s) Achieved: Complete coursework	1-12	6/1/18	100
<b>Major Task 2: Complete coursework in Population oriented research and research design</b>			
Subtask 1: Coursework: Research design PHS 6322, Population oriented research PHS 6213	12-24	6/1/18	100
Milestone(s) Achieved: Complete coursework	12-24	6/1/18	100
<b>Major Task 3: Meetings (Freedland, group, professional development advisory committee)</b>	1-36		
Subtask 1: Travel to Cedars-Sinai 2x per year	1-36		100
Subtask 2: Travel to DVAMC 5x per year	1-36		100
Subtask 3: Travel to American Urological Association (AUA) and Society of Urological Oncology (SUO) conferences and meet Dr. Freedland 2x per year	1-36	AUA: 5/17-5/19/18 and 5/3-6/19; SUO: 11/29-12/1/17 and 12/4-6/19	100
Subtask 4: Professional development committee meetings 4x per year	1-36	Quarterly with last 7/20	100
Subtask 5: Drs. Freedland/Williams every other week, one-hour telephone conference meetings.	1-36	Ongoing	100
Subtask 6: Dr. Freedland team weekly telephone research in progress meetings	1-36	Ongoing	100
Subtask 7: Programmer weekly telephone conference meetings to discuss and review: 1. Database development/data extraction 2. Database management 3. Data queries and audits	1-36	Ongoing	100

4. Natural language processing, extraction and audits			
Subtask 8: Database team weekly telephone conference meetings	1-36	Ongoing	100
Subtask 9: Statistician team weekly telephone conference meetings to discuss and review current and future analyses	1-36	Monthly at present - ongoing	100
Subtask 10: DVAMC/Freedland Lab Director bi-monthly telephone conference meetings to discuss database programmer, statisticians and proposal timeline	1-36	Monthly last 9/1/20	100
Subtask 11: UTMB Department of Surgery grants manager monthly meeting to go over proposal timeline, budget and future applications	1-36	Monthly last 9/1/20	100

**Research-Specific Tasks:**

<b>Specific Aim 1: Determine whether AO exposure is linked with risk of BC.</b>	1-24		
<b>Major Task 1: Determine whether AO exposure is linked with risk of BC.</b>			
Subtask 1: Regulatory review and approval by the USAMRMC Human Research Protection Office (HRPO)	1-4	11/15/17	100
Subtask 2: Identify VA patients according to AO exposure and determine BC risk. A total of 3.15 million patients will need to be identified to detect clinically insignificant results. <ol style="list-style-type: none"> <li>1. Identify patients in VINCI with and without AO exposure and query these patients using diagnoses (all ICD-9 and -10 codes), procedures (all CPT codes) and natural language processing</li> <li>2. Extract and develop an SQL server database with key data points</li> <li>3. Source to home data programming</li> <li>4. Self-auditing and clean data</li> </ol>	1-18	Ongoing	100
Subtask 3: Perform analyses. <ol style="list-style-type: none"> <li>1. Interaction testing between AO exposure and smoking, age (&lt; vs. &gt; median), gender, and obesity.</li> <li>2. Perform multivariable Cox hazards analysis</li> </ol>	18-24	Ongoing	

<p>adjusting for age, gender, race, comorbidities, SES (median household income of home zip code), VA center and smoking status.</p> <ol style="list-style-type: none"> <li>3. ANOVA-tests for normally distributed continuous variables, Kruskal-Wallis tests for non-normally distributed continuous variables, and chi-square tests for categorical variables.</li> <li>4. Logistic regression to test if AO is related to muscle invasiveness.</li> </ol>			
<p>Subtask 4: Manuscript preparation, submission and publication</p>	<p>12-24</p>	<p>Ongoing</p>	
<p>Subtask 5: Day-to-day management activities of the PI.</p> <p>Monday (am/pm), Tuesday (am) and Wednesday (1/2am) coursework at GSBS.</p> <p>Tuesday (pm) and Wed/Thursday (pm) operative and clinic days, respectively.</p> <p>Wednesday (1/2am), Thursday (am) and Friday (am/pm) research days.</p> <p>Travel to Cedars-Sinai 2x per year, Travel to DVAMC 5x per year, Travel to American Urological Association and Society of Urological Oncology conferences and meet Dr. Freedland 2x per year</p> <p>Meet with professional development committee 4x per year</p> <ol style="list-style-type: none"> <li>1. UTMB Department of Surgery grants manager monthly one-hour meeting to go over proposal timeline, budget and future applications</li> <li>2. DVAMC/Freedland Lab Director bi-monthly one-hour telephone conference meetings to discuss database programmer, statisticians and proposal timeline</li> <li>3. DVAMC programmer weekly 1-2-hour telephone conference meetings to discuss and review Aim 1: database development/data extraction, database management, data queries and audits, natural language processing, extraction and audits, review timeline and goals</li> <li>4. DVAMC database team weekly telephone conference meetings</li> </ol>	<p>1-24</p>	<p>Ongoing</p>	<p>100</p>

<ul style="list-style-type: none"> <li>5. DVAMC statistician team weekly telephone conference meetings to discuss and review current and future analyses</li> <li>6. DVAMC statistician weekly telephone conference 1-2 hours telephone meeting (months 18-24)</li> <li>7. Drs. Freedland/Williams every other week, one-hour telephone conference meetings.</li> <li>8. Dr. Freedland team weekly telephone research in progress meetings</li> <li>9. Weekly ad-hoc 1-hour telephone conference calls to answer and go over any database or analysis questions</li> </ul>			
Milestone(s) Achieved: The DVAMC bladder cancer database is developed. The analyses determining the association and results pertaining to the risk of BC according to AO exposure will be published.	1-24	Complete	100
<b>Specific Aim 2: Explore whether AO exposure is linked with BC-specific mortality.</b>	24-36		
<b>Major Task 2: Explore whether AO exposure is linked with BC-specific mortality.</b>			
<p>Subtask 1: Identify and test the link between AO and BC death. Out of 3.15 million patients, an estimated 0.9% or 28,350 will have bladder cancer. Of these, an estimated 10% will die we expect 2,835 deaths will be needed to detect clinically insignificant results.</p> <ul style="list-style-type: none"> <li>1. Extract mortality data from aim 1 cohort using VINCI</li> <li>2. Determine cause of death linked to the NDI</li> <li>3. Extract treatment data from aim 1 cohort using diagnoses (all ICD-9 and -10 codes), procedures (all CPT codes) and natural language processing (NLP)</li> <li>4. Extract and develop an SQL server database with key data points</li> <li>5. Source to home data programming</li> <li>6. Self-auditing and clean data</li> </ul>	24-30	Ongoing with VINCI; (1,3,4) complete, NDI (2) data received and (6) being completed currently	83
Subtask 2: Perform analysis.	30-36	Ongoing	0

<ol style="list-style-type: none"> <li>1. Perform multivariable modeling as outlined above in Aim 1 but using a competing-risk model.</li> <li>2. Interaction testing and evaluating descriptive statistics will be performed as in Aim 1. As mentioned in Aim 1, if no significant interaction between AO and age, gender, obesity, and smoking status is found, data will be analyzed together and not stratified by these factors. If a significant interaction is found, only stratified results will be reported.</li> <li>3. We will include the propensity score variable described above predicting which treatment was received.</li> </ol>			
<p>Subtask 3: Manuscript preparation, submission and publication</p>	24-36	Ongoing	0
<p>Subtask 4: Day-to-day management activities of the PI.</p> <p>Monday (am/pm) and Tuesday (am/pm) clinic and operative days, respectively.</p> <p>Wednesday (am/pm) and Friday (am/pm) research days.</p> <p>Travel to Cedars-Sinai 2x per year, Travel to DVAMC 5x per year, Travel to American Urological Association and Society of Urological Oncology conferences and meet Dr. Freedland 2x per year</p> <p>Meet with professional development committee 4x per year</p> <ol style="list-style-type: none"> <li>1. UTMB Department of Surgery grants manager monthly one-hour meeting to go over proposal timeline, budget and future applications</li> <li>2. DVAMC/Freedland Lab Director bi-monthly one-hour telephone conference meetings to discuss database programmer, statisticians and proposal timeline</li> <li>3. DVAMC programmer weekly 1-2-hour telephone conference meetings to discuss and review Aim 2: database development/data extraction, database management, data queries and audits, natural language processing, extraction and audits, review timeline and goals</li> </ol>	24-36	Ongoing	0

<ol style="list-style-type: none"> <li>4. DVAMC database team weekly one-hour telephone conference meetings</li> <li>5. DVAMC statistician team weekly one-hour telephone conference meetings to discuss and review current and future analyses</li> <li>6. DVAMC statistician weekly telephone conference 1-2 hours telephone meeting (months 30-36)</li> <li>7. Drs. Freedland/Williams every other week, one-hour telephone conference meetings review Aim 2 and future grant submissions.</li> <li>8. Dr. Freedland team weekly one-hour telephone research in progress meetings</li> <li>9. Weekly ad-hoc one-hour telephone conference calls to answer and go over any database or analysis questions</li> </ol>			
<p>Milestone(s) Achieved: The analyses and results determining BC-specific mortality according to AO exposure will be published.</p>	24-36	Ongoing	10

**What was accomplished under these goals?**

(See training-specific task accomplishments in following section, “*Opportunities for training and development provided by this project.*”)

**Research-Specific Tasks:**

**Major Task 1: Determine whether AO exposure is linked with risk of BC.**

Subtask 1: Regulatory review and approval by the USAMRMC Human Research Protection Office (HRPO). *This was approved by HRPO on 11/15/17.*

Subtask 2: Identify VA patients according to AO exposure and determine BC risk. A total of 3.15 million patients will need to be identified to detect clinically insignificant results. This has been completed.

1. Identify patients in VINCI with and without AO exposure and query these patients using diagnoses (all ICD-9 and -10 codes), procedures (all CPT codes) and natural language processing (NLP)

2. Extract and develop an SQL server database with key data points
3. Source to home data programming
4. Self-auditing and clean data

Subtask 5: Day-to-day management activities of the PI.

Monday (am/pm), Tuesday (am) and Wednesday (1/2am) coursework at GSBS. - *Dr. Williams confirms.*

Tuesday (pm) and Wed/Thursday (pm) operative and clinic days, respectively. - *Dr. Williams confirms.*

Wednesday (1/2am), Thursday (am) and Friday (am/pm) research days. - *Dr. Williams confirms.*

Travel to Cedars-Sinai 2x per year, Travel to DVAMC 5x per year, Travel to American Urological Association and Society of Urological Oncology conferences and meet Dr. Freedland 2x per year

Meet with professional development committee 4x per year - *Dr. Williams confirms.*

1. UTMB Department of Surgery grants manager monthly one-hour meeting to go over proposal timeline, budget and future applications - *Dr. Williams confirms.*
2. DVAMC research manager bi-monthly one-hour telephone conference meetings to discuss database programmer, statisticians and proposal timeline - *Dr. Williams confirms.*
3. DVAMC programmer weekly 1-2-hour telephone conference meetings to discuss and review Aim 1: database development/data extraction, database management, data queries and audits, natural language processing, extraction and audits, review timeline and goals. Database programmer and senior programmer additions have assisted in meeting goals across Aim 1. - *Dr. Williams confirms*
4. DVAMC database team weekly telephone conference meetings-These meetings have occurred every 2 weeks.

### **Major Task 1 Summation**

Approval by the USAMRMC Human Research Protection Office (HRPO). Adherence to weekly schedule, research planning, hiring programmer, integrating existing Freedland research team into project-initiated data mining in January 2018 with all data fields populated with natural language processing. Database for Aim 1 complete and analyses underway.

## **Major Task 2: Explore whether AO exposure is linked with BC-specific mortality.**

Subtask 1: Identify and test the link between AO and BC death. Out of 3.15 million patients, an estimated 0.9% or 28,350 will have bladder cancer. Of these, an estimated 10% will die, thus we expect 2,835 deaths will be needed to detect clinically insignificant results. We have all mortality data, treatment data, extracted and developed SQL server database with key data points with source to home data programing from Aim 1 and have incorporated NDI cause of death data. This subtask is nearly complete.

Subtask 2: Analyses begun as we have received NDI mortality data and all SQL queries performed.

## **Major Task 2 Summation**

We have all mortality data, treatment data, extracted and developed SQL server database with key data points with source to home data programing from aim 1 and have received and incorporated the requested NDI cause of death information. We expect to perform analyses and manuscript preparation, submission and publication on time (months 30-36).

## **Below are the patient counts from our active user cohort:**

Total active user patient count: 11,692,562  
Bladder Cancer dx: 181,200  
Agent Orange: 962,287  
BC + AO: 16,447

## **What opportunities for training and professional development has the project provided?**

**Major Task 1: Complete coursework in data management and biostatistics methodology.**

**Major Task 2: Complete coursework in Population oriented research and research design**

Completed above and additional coursework including Translational Epidemiology I: Patient Oriented Research PHS 6212, Translational Epidemiology II: Population Oriented Research PHS 6213, Research Design PHS 6322, Introduction to Linear Models PHS 6344, Seminar PHS 6195 and Research PHS 6097. I have taken this coursework and graduated with an MS degree, Clinical Sciences, Health Services Research Track.

**Major Task 3: Meetings (Freedland, group, professional development advisory committee).**

Subtask 1: Travel to Cedars-Sinai 2x per year-Dr. Williams visited Cedars-Sinai in December 20, 2018 and July 29, 2019. Dr. Williams visited again in November 2019 and June 2020.

Subtask 2: Travel to DVAMC 5x per year-Dr. Williams traveled to DVAMC: Year 9/18, 11/18, 3/19, 5/19, and 7/19. My next visit is 9/19 and will continue 5x/yr as scheduled.

Subtask 3: Travel to American Urological Association and Society of Urological Oncology conferences and meet Dr. Freedland 2x per year-Dr. Williams/Freedland attended/met at Society of Urologic Oncology Meeting 12/1/18; Dr. Williams/Freedland met at the American Urological Association Meeting May 2019. They have and continue to meet as scheduled.

Subtask 4: Professional development committee meetings 4x per year-Dr. Williams met with committee in 9/18, 11/18, 3/19, and 7/19 and continue to meet quarterly as scheduled.

Subtask 5: Drs. Freedland/Williams every other week, one-hour telephone conference meetings. Dr. Freedland/Williams have one-hour telephone meetings every other week and sometimes weekly.

Subtask 6: Dr. Freedland team weekly telephone research in progress meetings. Dr. Williams attends research in progress meetings which have occurred monthly as research project IRB approvals, project getting started.

Subtask 7: Programmer weekly telephone conference meetings to discuss and review:

1. Database development/data extraction
2. Database management
3. Data queries and audits
4. Natural language processing, extraction and audits

Aim 1 cohort has been completed. Delay from subtask 2 (months 1-18), database completion, was due to natural language processing (NLP) development, needed to define, audit, and validate stage information; NLP development completed and implemented, and model applied to bladder cancer cohort. Subtask 3 (months 18-24) analyses which were subsequently delayed are to be complete soon. Aim 2 analyses near complete as all queried data and NDI mortality data received; associated subtasks being completed as scheduled.

### **How were the results disseminated to communities of interest?**

Nothing to Report

### **What do you plan to do during the next reporting period to accomplish the goals?**

The database is now complete and NLP stage info was the rate limiting step. We are now prepared for analyses for Aims 1 and 2. Moreover, we have approved no cost extension for up to one year which we will complete all goals in SOW.

## **IMPACT**

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to Report

**What was the impact on other disciplines?**

Nothing to Report

**What was the impact on technology transfer?**

Nothing to Report

**What was the impact on society beyond science and technology?**

Nothing to Report

## **CHANGES/PROBLEMS**

**Changes in approach and reasons for change**

Nothing to Report

**Actual or anticipated problems or delays and actions or plans to resolve them**

Delay from Aim 1, Subtask 2 (months 1-18): database completion, due to natural language processing, needed to define, audit, and validate stage information; completed this in months 24-26. Subtask 3 (months 18-24) analyses subsequently delayed and have commenced. We do not expect any delay in Aim 2 and subtasks to be completed as scheduled.

**Changes that had a significant impact on expenditures**

Nothing to Report

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**Significant changes in use or care of human subjects**

Nothing to Report

**Significant changes in use or care of vertebrate animals**

Nothing to Report

### **Significant changes in use of biohazards and/or select agents**

Nothing to Report

## **PRODUCTS**

- **Publications, conference papers, and presentations**

**Journal publications.** Nothing to Report

**Books or other non-periodical, one-time publications.** Nothing to Report

**Other publications, conference papers and presentations.** Nothing to Report

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

## **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

### **What individuals have worked on the project?**

1. Name: Stephen B. Williams  
Project role: PI  
Researcher Identifier: 226832185  
Nearest person month worked: 4

- Contribution to Project: Dr. Williams has performed work in the area of IRB, HRPO and DVMAC protocol submission/approval, research personnel organization, hiring, and implementation.
2. Name: Stephen J. Freedland
- Project role: Mentor
- Researcher Identifier: NA
- Nearest person month worked: 1 (effort as needed)
- Contribution to Project: Dr. Freedland has performed work in the area of mentoring Dr. Williams on IRB, HRPO and DVMAC protocol submission/approval, research personnel organization, hiring, and implementation as well as direct supervision.
3. Name: Amanda De Hoedt
- Project role: Director, Freedland Laboratory, DVAMC/IMR
- Researcher Identifier: NA
- Nearest person month worked: 5
- Contribution to Project: Ms. De Hoedt has performed work in the area of IRB, HRPO and DVMAC protocol preparation, submission and approval. She has recruited a programmer to work on the project and coordinated integration of the Freedland research team.
4. Name: Megan Foster
- Project role: Data Operations Manager, DVAMC/IMR
- Researcher Identifier: NA
- Nearest person month worked:
- Contribution to Project: Ms. Foster oversees all data operations and coordinates the activities of and oversees the work produced by the programmers.
5. Name: Ruixin Yang
- Project role: Data Scientist, DVAMC/IMR
- Researcher Identifier: NA
- Nearest person month worked:
- Contribution to Project: Mr. Yang trained and developed the natural language processing (NLP) model.

6. Name: Dan Long  
Project role: Database Programmer, DVAMC/IMR  
Researcher Identifier: NA  
Nearest person month worked:  
Contribution to Project: Mr. Long has developed SQL queries utilized to perform the data queries associated with the project.
7. Name: Lauren Howard  
Project role: Statistician, DVAMC  
Researcher Identifier: NA  
Nearest person month worked:  
Contribution to Project: Ms. Howard has performed work as a research statistician with the Durham VA and performs data analysis across all Aims on this project.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

**What other organizations were involved as partners?**

**Organization Name:** Durham VA Health Care System (DVAMC)/Institute for Medical Research (IMR)

**Location of Organization:** Durham, North Carolina

**Partner’s contribution to the project:** Dr. Freedland is the PI’s mentor. The team at DVAMC/IMR provides database development, protocol/regulatory, and data analysis support.

**SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** Nothing to Report

**QUAD CHARTS:** Nothing to Report

**APPENDICES**

Nothing to Report