AWARD NUMBER: HT9425-23-1-0042

TITLE: A Blood Test for Diastolic Dysfunction

PRINCIPAL INVESTIGATOR: Samuel C. Dudley, Jr.

CONTRACTING ORGANIZATION: University of Minnesota, Minneapolis, MN

REPORT DATE: January 2024

TYPE OF REPORT: Annual

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

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A Blood Test for Diastolic Dysfunction

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HT9425-23-1-0042

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Dr Samuel Dudley, MD, PhD

E-Mail:

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

UNIVERSITY OF MINNESOTA
200 OAK ST SE # 224
MINNEAPOLIS MN 55455-2009

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

: This application sets out to validate a simple, inexpensive blood test to identify DD. Currently, diagnosis depends on costly, time-consuming imaging procedures that are only undertaken after symptoms develop. We have shown in the heart tissues of DD animals (mice and monkeys) and humans that S-Glu-cMyBPC is likely responsible for reduced relaxation in DD and is elevated in the blood. We hypothesize that modified S-Glu-cMyBP-C will be a blood marker for DD. We propose to do a non-interventional human clinical study to validate our animal and preliminary human data

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRDC
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

This study sets out to validate a simple, inexpensive blood test to identify diastolic dysfunction (DD). Currently, diagnosis depends on costly, time-consuming imaging procedures that are only undertaken after symptoms develop. We have shown in the heart tissues of DD animals (mice and monkeys) and humans (preliminary study with N=8) that S-glutathionylated cardiac myosin binding protein C (cMyBP-C) is likely responsible for reduced relaxation in DD and is elevated in the blood of each species when DD is present. Specific to the heart, cMyBP-C has been developed as a blood test to predict myocardial infarction. We hypothesize that modified S-glutathionylated cMyBP-C (*S*-Glu-cMyBP-C) will be a blood marker for DD. We will test if plasma *S*-Glu-cMyBP-C is increased in the blood of DD patients without HF (N=40) when compared with age-matched control patients without DD or HF (N=40). Further, we will test if plasma *S*-Glu-cMyBP-C correlates with severity of DD as measured by echocardiography.

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

Diastolic dysfunction, a blood test, *S*-glutathionylated cardiac myosin binding protein C, HFpEF, oxidative stress,

3. **ACCOMPLISHMENTS:** (*The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*)

What were the major goals of the project? *(List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.)*

Specific Aim 1: Test if plasma *S*-Glu-cMyBP-C is increased in the blood of diastolic dysfunction (DD) patients without HF when compared with age-matched control patients without DD or HF.	**Timeline (month)**	**% complete**
Major Task 1: Test plasma *S*-Glu-cMyBP-C in the patients' blood and correlates plasma *S*-Glu-cMyBP-C with severity of DD as measured by echocardiography.	24 Months	
Subtask 1 – IRB/OHRO (Office of Human Research Oversight) approval.	1-3	100%, Feb 2, 2023
Subtask 2 – Patient screening and enrollment • Collect the serum from a total of N=80 subjects, with N=40 in each of two groups: 1) age-matched controls with no significant structural heart disease or history of HF and 2) patients with echocardiographically confirmed DD (E/e'>15) with no HF or significant structural heart disease.	3-12	11%, Dec 31, 2023
Subtask 3 - Collection of demographic data from hospital/clinic records for completion.	3-12	100%
Subtask 4 - Review and completion of patient history, physical exam data, active medications, laboratory data, electrocardiogram, echocardiography, and coronary angiography.	3-12	100%
Subtask 5 - Specimen analysis - Conduct S-Glu-cMyBP-C assays	3-21	11%, in progress

Subtask 6 - Quantitative analyses of S-Glu-cMyBP-C assay performance and discrimination.	3-21	11%, in progress
Subtask 7 - Statistical analysis: This is an observational cohort study with one control group for comparison with the asymptomatic diastolic dysfunction subjects, which will be age and sex matched. Factors known to affect oxidative stress such as smoking status and diabetes mellitus will be recorded and included in comparison analysis. The null hypothesis is that there is no difference in measures of oxidative stress between the groups. We will compare baseline clinical characteristics and levels of measured biomarkers between the groups using student's t-test and chi squared test for continuous and categorical variables respectively. Regression analysis will be performed to determine the relationship between baseline clinical characteristics and blood measurements. A p-value of $< .05$ will be considered statistically significant. All analyses will be performed using SAS or SPSS.	19-22	0%, not yet initiated.
Subtask 8 - Publication and presentation of results	20-24	0%, not yet initiated.
Subtask 9 - Plan to submit an FDA investigational device exemption (IDE) application	20-24	0%, not yet initiated.
Milestone(s) Achieved: *The central technological innovation is the prospect of a first-of-its-kind blood test that can identify diastolic dysfunction by assessing the state of a known, pathophysiologically relevant, altered protein that can be measured in the blood.* We are the first to describe that modified cMyBP-C exists in DD and that it is elevated in the plasma of animals (mice and monkeys) and humans with DD. Currently, there are no competing blood tests to diagnose diastolic HF, and the market is large as evidenced by BNP testing for general HF (~20 million tests/year). The ultimate goal would be to take this technology and develop an ELISA suitable for central laboratories or point-of-care testing for the diagnosis of DD. Since some percentage of patients with DD go on to develop DHF, this test might allow for directing future preventive therapies, predicting prognosis, and following efficacy of therapies in development for DD.	24	11%, in progress

What was accomplished under these goals? *(For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.)*

1) **Major activities:** IRB/OHRO (formerly known as HRPO) approval was initially accomplished in Feb 2023. Patient screening based on our criteria from clinical records and enrollment started in March 2023. Blood collection started in August 2023. Specimen analysis – *S*-Glu-cMyBP-C assay started in January 2024, together with quantitative analyses of *S*-Glu-cMyBP-C assay performance and discrimination.
2) **Specific objectives:** Our goal is to test if plasma *S*-Glu-cMyBP-C is increased in the blood of diastolic dysfunction (DD) patients without HF (N=40) when compared with age-matched control patients without DD or HF plasma (N=40). Further, we will test if plasma *S*-Glu-cMyBP-C correlates with severity of DD as measured by echocardiography.
3) **Significant results/key outcomes** (major findings, developments, conclusions-positive/negative):

1. IRB (ID STUDY00017627) was approved by the University of Minnesota IRB in Feb 2023.
2. OHRO (Proposal number PR220340) was approved in March 2023.
3. We screened Fairview patient clinical records between Nov 2022-Dec 2023 with criteria of inclusion and exclusion.
4. We have identified 131 DD patients without HF that met both the inclusion and exclusion. We have successfully enrolled 9 patients for blood collection so far.
5. Based on the age of the enrolled patients, we screened clinical records and identified age-matched (±10 years of age) healthy control patients and are in the process of enrollment.
6. Initial *S*-Glu-cMyBP-C assay of 9 DD patients are being analyzed now.

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4) **Other achievements:** none
5) **Goals not met:** Subtasks 2-7 are in process. Goals 8 and 9 await enrollment completion.
6) **Summary**:

To date we have enrolled 9 subjects with asymptomatic diastolic dysfunction. Ultimately, we were able to identify 131 subjects and > 150 controls that met eligibility criteria. Demographics of enrolled patients include 5 women, 4 blacks, one Asian, and one Indian, so the demographic mix implies wide applicability of the results.

Enrollment has fallen somewhat behind schedule because it took some time to access and identify suitable test subjects in the electronic record. Additionally, since the patients were identified post hoc, about 50% of patients contacted were not willing to return to give blood and enroll in the trial. Now, we have gone to a system of identifying patients while they are still in the echocardiography laboratory. This process seems likely to overcome some of the limitations of the former, records only based approach. Moreover, we have developed recruitment talking points for approaching patients for enrollment, improving the approach to consent ratio. With these enhancements, we believe we can reach our enrollment goals within an additional 3-6 months.

Current samples are being analyzed as they become available, and a REDCap database has been established and populated with required data from all patients currently enrolled.

A summary of IRB activity is as follows:

1. Initial IRB submission: 11/20/2022
2. Initial approval: 12/18/2022
3. Continuing review approved: 10/23/2023
4. Current approval end: 10/22/2024

There have been six minor modifications to expand study personnel and sites of potential enrollment to enhance enrollment success. To date, there have been no adverse events.

In summary, with changes to the enrollment approach, the trial is still on track to complete all tasks in the two-year timeframe.

			Enter information regarding number of subjects					
HRPO Protocol Number	Protocol PI Name	Organization (Site)	# Target	# Enrolled	# Completed	# Screened	# Recruited	Other
STUDY00017627	Samuel Dudley	University of Minnesota	80	9	9	281	9	

What opportunities for training and professional development has the project provided? *(If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report.") (Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.)*

Nothing to report

How were the results disseminated to communities of interest? *(If there is nothing significant to report during this reporting period, state "Nothing to Report.") (Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.)*

No results have been communicated to date, although we expect that to change in the next year.

What do you plan to do during the next reporting period to accomplish the goals? *(If this is not the final report, state "Nothing to Report.") (Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.)*

As discussed above, we have refined our enrollment approach so that we anticipate completing enrollment in the first two quarters of 2024. Subtasks 3-6 occur at the time of enrollment. We anticipate subtasks 7-9 (i.e. statistical analysis, results presentation, and FDA IDE filing) will occur on schedule in months 19-24.

4. **IMPACT:** (D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to*☺

This study sets out to validate a simple, inexpensive blood test to identify diastolic dysfunction (DD). Previously published and preliminary analysis suggests that a novel, innovative blood test for DD is possible by measuring *S*-glutathionylated cMyBP-C levels in blood. Useful roles for a biomarker of DD could include screening of asymptomatic populations at risk for HFpEF for future preventive therapy, assisting in rapid diagnosis of acute heart failure occurrences, and assessing efficacy of future therapies. The validation of a blood test would also support the current hypothesis that diastolic dysfunction occurs because of oxidative modification of myocardial contractile proteins. This confirmation could help direct future drug development by establishing a mechanism for diastolic dysfunction.

What was the impact on the development of the principal discipline(s) of the project? *(If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how findings, results,*

techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).)

The validation of a blood test would also support the current hypothesis that diastolic dysfunction occurs because of oxidative modification of myocardial contractile proteins. This confirmation could help direct future drug development by establishing a mechanism for diastolic dysfunction. Drug development along this line would represent an entirely new strategy to treat a common cause of heart failure.

What was the impact on other disciplines? *(If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.)*

Nothing to report

What was the impact on technology transfer? *(If there is nothing significant to report during this reporting period, state "Nothing to Report.")*
(Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.)*

A method of use patent was filed prior to initiation of this study. There are no competing technologies that specifically identify DD. Should this proof-of-concept trial turn out as expected, Diastol Therapeutics LLC, a company developing a small molecule therapy for diastolic heart failure, would license the technology for further development. Future development would include refining the current detection methodology by creating an ELISA and seeking FDA approval in a 510k application.

What was the impact on society beyond science and technology? *(If there is nothing significant to report during this reporting period, state "Nothing to Report.")*
(Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.)*

Currently, heart failure is the leading cause of hospital admissions. Half of all heart failure is heart failure with preserved ejection fraction (HFpEF). The 5-year survival from HFpEF is <30%. Currently, there are limited therapies for HFpEF and none that have been shown to alter mortality. Diastolic dysfunction underlies most HFpEF, and there is a long period where patients have diastolic dysfunction before they develop heart failure. This latent period is an ideal time to intervene to prevent progression of disease, but currently there is no easy way to identify patients in the latent period. This test would provide an convenient way of identifying this latent period. Furthermore, the test would allow confirmation of a diagnosis of HFpEF, which is based on exclusion now, and would also allow assessment of efficacy of any new therapies for HFpEF.

5. CHANGES/PROBLEMS: **(***The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:)*

Changes in approach and reasons for change *(Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.)*

There have been no changes in our protocol.

Actual or anticipated problems or delays and actions or plans to resolve them *(Describe problems or delays encountered during the reporting period and actions or plans to resolve them.)*

As discussed above, enrollment been slower than desired because it took some time to access and identify suitable test subjects in the electronic record. Additionally, since the patients were identified post hoc, about 50% of patients contacted were not willing to return to give blood and enroll in the trial.

To address this, we have expanded the sites of enrollment, the size of the recruitment team, done additional screening of patients not included in our initial screen, developed recruitment talking points, and initiated screening in real time in the echocardiography laboratory. So far, these efforts have identified > 60 additional patients suitable for enrollment. Therefore, we anticipate enrollment will improve dramatically in the next two quarters.

Changes that had a significant impact on expenditures: *("Nothing to Report," if applicable. Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.)*

Changes have not altered our anticipated expenditures.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents: *("Nothing to Report," if applicable. Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.)*

Significant changes in use or care of human subjects:

Nothing to Report

Significant changes in use or care of vertebrate animals:

N/A

Significant changes in use of biohazards and/or select agents:

Nothing to Report

6. **PRODUCTS:** *(List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report.")*

Nothing to Report.

- **Publications, conference papers, and presentations** *(Report only the major publication(s) resulting from the work under this award.)*

Nothing to Report.

Journal publications. *(List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).)*

Books or other non-periodical, one-time publications. *(Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).)*

Other publications, conference papers and presentations. *(Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript(*

- **Website(s) or other Internet site(s)** *(List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.)*

- **Technologies or techniques** *(Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.)*

- **Inventions, patent applications, and/or licenses** *(Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.)*

- **Other Products** *(Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:)*

- data or databases;
- physical collections;
- audio or video products;
- software;
- models;
- educational aids or curricula;
- instruments or equipment;
- research material (e.g., Germplasm; cell lines, DNA probes, animal models);
- clinical interventions;
- new business creation; and
- other.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project? *(Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".)*

Name:	*Samuel C. Dudley Jr., MD. PhD.*
Project Role:	*PI*
Researcher Identifier (e.g., ORCID ID):	0000-0001-5843-5961
Nearest person month worked:	*1.2*
Contribution to Project:	*Dr. Dudley has performed work in the area of IRB application, patient enrollment, review of patient clinical records, and data analysis.*
Funding Support:	*(Complete only if the funding support is provided from other than this award.)*

Name:	*Man Liu, PhD*
Project Role:	*Research Assistant Professor*
Researcher Identifier (e.g., ORCID ID):	*0000-0002-1390-7862*
Nearest person month worked:	*6*
Contribution to Project:	*Dr. Liu has performed work in the area of IRB application, RedCap database construction, specimen analysis, review and completion of patient clinical records, quantitative analyses of S-Glu-cMyBP-C assay performance and discrimination, and data statistical analysis.*
Funding Support:	

Name:	*Yugene Guo.*
Project Role:	*Medical School Student*
Researcher Identifier (e.g., ORCID ID):	

Nearest person month worked:

Contribution to Project:	*Mr. Guo has performed work in the area of RedCap database construction and review and completion of patient clinical records.*
Funding Support:	*Volunteer*

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.)

Changes to Dr. Dudley's other support are listed below:

*Title: Resolution of inflammation and atrial fibrillation

*Major Goals: Atrial fibrillation (AF) is one of the most common human cardiac arrhythmias and DM is an independent risk factor for AF. This application explores new treatment paradigms of encouraging inflammation resolution to prevent DM-associated AF.

*Status of Support: Active

Project Number: R01 HL165704

Name of PD/PI: Dudley, SC

*Source of Support: NIH

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/20/2023 - 1/31/2028

*Total Award Amount (including Indirect Costs):

*Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2023 - 2024	1.2 calendar
2. 2024 - 2025	1.2 calendar
3. 2025 - 2026	1.2 calendar
4. 2026 - 2027	1.2 calendar
5. 2027 - 2028	1.2 calendar

*Title: REVEAL - Research Evaluating Vagal Excitation and Anatomical Linkages

*Major Goals: The goal of the REVEAL Center aims to conduct groundbreaking research on the effect of VNS on four key autonomic systems: the autonomic nervous system (ANS), the cardiovascular system, the immune system, and metabolic system.

*Status of Support: Active

Project Number: U54 AT012307

Name of PD/PI: Osborn, JW

*Source of Support: NIH

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/23/2022 - 08/31/2025

*Total Award Amount (including Indirect Costs): (clinical core awarded to date)

*Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022 - 2023	0.6 calendar
2. 2023 - 2024	0.6 calendar
3. 2024 - 2025	0.6 calendar

What other organizations were involved as partners? *(If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.)*
(Provide the following information for each partnership)

Organization Name:

Location of Organization:

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

8. **SPECIAL REPORTING REQUIREMENTS**

COLLABORATIVE AWARDS: *(For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.)*

N/A

QUAD CHARTS: *(If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.)*

Not required.

9. APPENDICES: *(Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.)*

Nothing to report