

AWARD NUMBER: W81XWH-14-1-0132

TITLE: LAM Pilot Study with Imatinib Mesylate (LAMP-1)

PRINCIPAL INVESTIGATOR: Charlie Strange, MD

**CONTRACTING ORGANIZATION: Medical University of South Carolina
Charleston, SC 29425-8908**

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TYPE OF REPORT: Annual

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

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14. ABSTRACT Lymphangioleiomyomatosis (LAM) is a rare disease in which tumor cells (LAM cells) proliferate and destroy healthy lung tissue, leading to respiratory compromise or failure. Vascular endothelial growth factor-D (VEGF-D) is generated by LAM cells and is a robust biomarker for LAM disease activity and therapeutic response. Studies in the laboratory of Dr. D'Armiento suggest that imatinib mesylate (imatinib) could completely block the growth of LAM cells through initiation of targeted cell death. Currently, most LAM patients are treated with Sirolimus (rapamycin). Rapamycin growth inhibits but does not kill LAM cells. This pilot trial employs a dual agent design intended to generate safety and efficacy data sufficient to power and design a phase 3 study of imatinib vs placebo for LAM. The hypothesis is that imatinib will be equivalent to rapamycin in short term efficacy and safety. Importantly, VEGF-D level will be used as a marker for LAM disease activity in this small clinical trial design using 20 participants at two institutions. At the time of this abstract participants are not yet enrolled. IRB approvals are in place and HRPO submission is ready.					
15. SUBJECT TERMS Lymphangioleiomyomatosis (LAM), imatinib mesylate, VEGF-D					
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INTRODUCTION:

The LAMP-1 study is designed to generate short-term safety and efficacy data regarding imatinib mesylate (imatinib) in the treatment of Lymphangioleiomyomatosis (LAM) sufficient to power and design a phase 3 imatinib vs. placebo clinical trial. The hypothesis is that imatinib will be equivalent to rapamycin in short term efficacy and safety. Currently, most LAM patients are treated with rapamycin, which growth-inhibits but does not kill LAM cells. In the laboratory of Dr. D'Armiento, imatinib was shown to completely block the growth of LAM cells through initiation of targeted cell death. This study employs a small clinical trial design using 20 participants at two institutions. 10 participants will be enrolled at Medical University of South Carolina and 10 at Columbia University. Importantly, VEGF-D level will be used to monitor LAM disease activity and therapeutic response.

1. KEYWORDS:

Lymphangioleiomyomatosis (LAM), imatinib mesylate, VEGF-D

- 2. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

Major goals for year 2 as stated in the SOW built upon milestones that were expected in year 1. Per the SOW, year 2 goals included tasks toward:

Major task 1: Securing regulatory documents to begin study

Major task 4: Data analysis

However, due to delays incurred during year 1 and year 2, progress is behind the original expected timeline, and major goals also remain in areas of:

Major task 2: Coordinate Study Staff for Clinical Trials

Major task 3: Participant Recruitment, Therapy, Participant Evaluation

The approved SOW showing subtasks toward each major goal is below, with progress at the time of this annual report for each study site is noted.

Major Task 1: Secure Regulatory Documents to Begin Study	Months- per SOW	Site(s)- per SOW	MUSC Status	Columbia Status
Subtask 1: Prepare Regulatory Documents and Research Protocol for Study				
Coordinate with Sites for material transfer agreements (MTAs) and Clinical trial agreements (CTAs) submission	Current	MUSC, Columbia	Complete (Y1,Q1)	Complete (Y1,Q1)
Submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration	Within 60 days of grant notice	MUSC	Complete Submitted April 23, 2015, Exemption received (Y1,Q3)	N/A
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	MUSC, Columbia	Complete (Y1,Q1)	Complete (Y1,Q1)
Finalize consent form & human subjects protocol	1-3	MUSC, Columbia	Complete (Y1,Q1)	Complete (Y1, Q1)
Coordinate with Sites for IRB protocol submission	1-3	MUSC, Columbia	Complete, approved (Y1,Q3)	Complete, approved (Y2,Q3)
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	MUSC, Columbia	Pending; Ready to submit	Complete (Y2,Q4)
Submit amendments, adverse events and protocol deviations as needed	As Needed	MUSC, Columbia	Complete, As needed (Y2,Q3)	Complete, As needed (Y2,Q3)
Coordinate with Sites for annual IRB report for continuing review	Annually	MUSC, Columbia	Complete (Y2Q3)	Not yet needed
<i>Milestone Achieved: Local IRB approval at MUSC, and Columbia</i>	3	MUSC, Columbia	Complete; approved (Y1,Q3)	Complete, approved (Y2,Q3)
<i>Milestone Achieved: HRPO approval for all protocols</i>	6	MUSC, Columbia	Pending; Ready to submit	Complete (Y2,Q4)

Major Task 2: Coordinate Study Staff for Clinical Trials				
Subtask1: Hiring and Training of Study Staff				
Select and Establish DSMB members	1-3	MUSC	Complete (Y1,Q3)	N/A
Training of Study coordinators in protocol specific tasks	1-3	MUSC, Columbia	Complete (Y1,Q2)	Completed (Y1,Q4); Pending (Staffing change Y2,Q4)
<i>Milestone Achieved: Research staff trained</i>	6	MUSC, Columbia	Complete (Y1,Q2)	Pending (Staffing change Y2,Q4)

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation				
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-8	MUSC, Columbia	Complete (Y2,Q3)	Complete (Y2,Q3)
Purchase drug immediately prior to first patient	6	MUSC	Pending	N/A
Finalize assessment measurements	1-4	MUSC, Columbia	Complete (Y1,Q1)	Complete (Y1,Q1)
<i>Milestone Achieved: 1st participant consented, screened and enrolled</i>	12	MUSC, Columbia	Future	Future
Begin subject recruitment	6-12	MUSC, Columbia	Future	Future
Complete follow-up assessments 2 months after initiation for first patient	14	MUSC, Columbia	Future	Future
Last patient enrolled	18	MUSC, Columbia	Future	Future
Last patient, last data entered	21	MUSC, Columbia	Future	Future

Major Task 4: Data Analysis				
Coordinate with Sites & Data Core for monitoring data collection rates and data quality	6-18	MUSC, Columbia	Future	Future
Perform all analyses according to specifications, share output and finding with all investigators	23	MUSC, Columbia	Future	Future
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD)	24	MUSC, Columbia	Future	Future
<i>Milestone Achieved: Report findings from 2 month follow-up assessments</i>	24	MUSC, Columbia	Future	Future

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.

Accomplishments for year 2 quarters 1-3 are detailed in quarterly reports. A summary of LAMP-1 year 2 quarters 1-3 is below, with details of 4th quarter activities and overall progress.

Major Task 1) Securing Regulatory Documents to Begin Study

MUSC obtained IRB approval and IND for this study in year 1. In year 2 MUSC submitted the IRB approved protocol and documents for preliminary HRPO review. Changes and additional documents were requested and subsequent efforts in compliance with the requests were made. The HRPO reviewer re-reviewed study documents and recommended submission to the MUSC IRB. An amendment was submitted with the HRPO changes and approved on 14 June, 2016. In the same quarter (Y2,Q3) the MUSC annual continuing review was submitted and approved on 29 June, 2016. A data sharing agreement was implemented between MUSC and CUMC.

In year 2 CUMC IRB approval was obtained. Communication between MUSC and CUMC allowed for their IRB-approved documents to be congruent with HRPO requests at initial submission. CUMC submitted for HRPO review and received approval on 13 May, 2016.

MUSC is ready to submit IRB-approved documents for final HRPO review and this is the last regulatory step before recruiting and enrolling participants at both sites. However, problems have been encountered in obtaining imatinib mesylate (imatinib) and the PI has been advised to delay final HRPO submission until this is resolved. This issue and efforts toward resolution are detailed in report section 5) Changes/Problems.

In the 4th quarter of year 2 a request for a one year no-cost extension was submitted. At the time of this report expenditures on this study have ceased and there will be no further expenditure of funds without imatinib and final HRPO approval. If imatinib is received then the no-cost extension will be implemented, as acquisition of imatinib remains the only barrier to completing enrollment and the SOW in the year to follow.

Major Task 2) Coordinate Study Staff for Clinical Trials

Study staff were hired and fully trained on the scope of this project and coordinator responsibilities in year 1; however, in the most recent quarter (Y2,Q4) a staffing change occurred at CUMC. Caitlin Clancy, study coordinator, is pursuing new opportunities outside of CUMC. Her replacement will be selected, trained, and approved by the CUMC IRB.

A DoD-required research monitor was named with roles defined in year 2 in accordance with HRPO and DoD requirements. A delegation of authority log was created for each site at HRPO recommendation and individual roles were clearly defined with the respective IRBs. All staff affiliated with this study maintained CITI research certifications and are trained in accordance with research standards of their respective institutions.

Major Task 3) Participant Recruitment, Therapy, Participant Evaluation

In the approved SOW participant recruitment and enrollment would be complete at the time of this report. While the assessment measures, database requirements and data capture are finalized, the other subtasks toward Major Task 3 have not been met.

Earlier delays including time to IND and time to IRB approvals and HRPO feedback resulted in progress being behind the SOW timeline. The major barrier encountered in year 2 toward Major Task 3 has been difficulty obtaining study drug. Without imatinib, procedures of participant recruitment, therapy and evaluation cannot proceed. The degree of difficulty encountered in imatinib acquisition was unanticipated and has been of key importance in Y2,Q4 now that regulatory approvals are otherwise in place, barring final MUSC HRPO approval that is expected rapidly once imatinib is secured.

All tasks toward participant recruitment, therapy and evaluation would occur rapidly, within one year, once study drug is obtained. Thus a one year no-cost extension was requested with the hope that this study can proceed. Both study sites have patients who are seen clinically for their LAM disease who are aware and interested in participating as soon as enrollment can begin.

Major Task 4) Data Analysis

All Major Task 4 subtasks were initially expected to occur in year 2 according to the SOW. All subtasks in this category first require enrolled participants, and due to delays described above, progress in these areas has not yet occurred. Coordinating with Sites & Data Core for monitoring data collection rates and data quality will begin when participants are enrolled and data is being collected. Analysis and dissemination of findings would follow.

Summary:

Excellent progress has been made over the course of this second year toward all regulatory requirements: IRB, HRPO and data sharing between the study sites. A one year no-cost extension was requested due to the delays that put both sites behind the expected SOW. A final step before participant enrollment at both sites is acquisition/purchase of imatinib. Until this necessary step can happen no further expenditures or invoices will occur. As soon as imatinib is obtained, MUSC HRPO documents will be submitted for final approval, with rapid turnaround expected. At that point all remaining tasks in the SOW would be completed within one year.

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

Nothing to Report.

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?

In the upcoming period Novartis has agreed to re-review our request for imatinib. The request was submitted on 14 October, 2016. If imatinib is granted then MUSC will submit final HRPO and proceed with enrollment and treatment procedures upon approval. CUMC will identify and train a new study coordinator to enroll participants at that site if study drug is granted. In the meantime, we will not draw additional funds for this project and will incur no additional expenses. We will maintain good regulatory standing with both IRBs in the hope that we will obtain study drug and be able to proceed.

- 4. IMPACT:** Describe 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:

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?

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.*

Nothing to Report.

What was the impact on society beyond science and technology?

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.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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

Nothing to Report.

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

The significant problem encountered has been obtaining imatinib mesylate. This was designated to occur just prior to enrollment of the first patient; however as we otherwise approached enrollment readiness all avenues to drug acquisition stalled. We are hopeful for a resolution in the upcoming period that will allow this study to continue.

To detail the issue,

- 1) At the time of grant submission, Novartis Gleevec was scheduled to come off patent in early 2015. This was challenged after grant submission by Novartis and a court found in their opinion delaying generic access until February 2016. This delayed anticipated price reduction.
- 2) The process of obtaining a waiver of IND from the FDA was completed in 2015. This was predicated on the fact that we would use Novartis Gleevec. Simultaneously, we sought access to Novartis Gleevec through Novartis, sought access to the now licensed (March 2016) generic imatinib by Sun Pharmaceuticals, and sought access through Canadian purchase. We were fully prepared and remain prepared to amend our IND should another manufacturer of imatinib mesylate allow drug purchase. With all of this in the air, and knowing that HRPO approval would be drug manufacturer dependent, we have the HRPO submission prepared, but sought advice from our program officer on what to do in the 4th quarter of year 2 and were advised to wait.

A. We have been denied the drug imatinib mesylate by Novartis on 2 indications. The response was that now that this drug is generic, all the R&D has transitioned to nilotinib, their second generation PDGF inhibitor. They were willing to give Nilotinib to this study under their IND. We took nilotinib into the laboratory and tested it on the LAM cells and found identical killing as occurred with the imatinib. We then approached the grant program officers with a request for using nilotinib. This was declined since in program officer opinion this is a different drug and would need to go out to peer review again. At the current time, the senior board of directors of Novartis has been approached and we still remain optimistic that drug can be obtained.

B. When the Novartis patent expired in 2016 we approached Sun Pharmaceuticals who declined (by silence) access to their generic imatinib. Next, communication with the CEO of a Canadian generic company and found that they would be supportive, but unable to get drug into the US legally, even for research studies.

C. Purchase of Gleevec on the US market for the 560 pills that we need is still \$179,344. Gleevec prices on the US market have not declined as anticipated. US prices offered to MUSC on 8/18/16 are \$320.24 per pill for brand name Gleevec and \$227.085 for generic drug. If we purchase generic drug at \$127,168, we have very little money to work with for the study.

D. We asked the LAM Foundation if they had bandwidth to acquire drug and the answer was negative.

D. We were asked to provide proof that we could purchase medication if we needed to on the current grant. We have spent minimal amounts of this grant knowing that we may need the money for drug purchase. We have sufficient funds to purchase generic drug from Canada; however, all drug purchases inside the Medical University of South Carolina must occur through the MUSC pharmacy who decline to purchase international drug. We do have an accepted IND plan to overencapsulate Gleevec and manufacture placebo at MUSC that was approved by the FDA.

Potential Resolution:

Jeanine D'Armiento, co-investigator at CUMC, was connected to a new high level contact at Novartis through a patient with LAM. A phone call between members of the Novartis board and the co-investigators of this study led to agreement for re-review of our request for imatinib. The formal request was submitted on 14 October, 2016 and we hopefully await their response.

Other delays include the regulatory and IND processes taking longer than anticipated and this resulted in our actual timeline being behind the SOW. All other delays have been resolved and we applied for a one year no-cost extension, where if imatinib is obtained then completion of all study procedures is expected within one year.

CUMC will identify and train a new study coordinator, as the previous coordinator resigned in quarter 4 of this year.

Changes that had a significant impact on expenditures

Due to problems and delays described above we are not currently drawing funds for this study. Our next milestone invoice would be at MUSC HRPO approval, which will occur if and after imatinib mesylate is obtained. In accordance with this, there are no current expenditures.

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

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 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.”

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

Report only the major publication(s) resulting from the work under this award.

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).*

Nothing to Report.

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).*

Nothing to Report.

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.*

Nothing to Report.

- **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.

Nothing to Report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to Report.

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. 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.

Nothing to Report.

- **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;
- biospecimen 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.*

Nothing to Report.

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.”

Example:

Name: Mary Smith
Project Role: Graduate Student
Researcher Identifier (e.g. ORCID ID): 1234567
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.
Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award).

Name: Charlie Strange
Project Role: Principal Investigator
Researcher Identifier (ORCID ID): 0000-0002-8109-8067
Nearest person month worked: 3
Contribution to Project: Dr. Strange supervised all study activities. He collaborated with co-investigator and study coordinators on addressing HRPO and IRB requests for changes and additional documentation. He submitted the annual IRB continuing review to maintain good regulatory standing at MUSC. Dr. Strange identified an independent research monitor. He participated in significant efforts toward obtaining imatinib for this study and communicated with our program officers. Dr. Strange facilitated submission of the request for no-cost extension. Dr. Strange maintained communications per the terms of the grant.
Funding Support: NIH/NHLBI U01 HL 112707, NIH/5 UL1TR000062-05, U01HL112694, Alpha-1 Foundation, CSL Behring, Grifols Therapeutics, PneumRx, Inc.

Name: Jeanine D'Armiento
 Project Role: Co-Investigator
 Researcher Identifier (ORCID ID): none
 Nearest person month worked: 2
 Contribution to Project: Dr. D'Armiento supervised study activities at CUMC. She collaborated with the principal investigator and study coordinators on addressing HRPO and IRB requests for changes and additional documentation. She pursued avenues for imatinib acquisition that led to Novartis re-review of the request for imatinib.
 Funding Support: HL116346, HL086936, R21 A102239, Alpha-1 Foundation

Name: Kimberly Brown
 Project Role: Study Coordinator
 Researcher Identifier (ORCID ID):
 Nearest person month worked: 3
 Contribution to Project: Ms. Brown assisted with preparation of study documents, initial HRPO submission, IRB amendment, IRB continuing review and preparation of reports. She collaborated with Dr. Strange to ensure that successful staffing and data infrastructure are in place for this study. She is familiar with the protocol and ready to implement recruitment and study steps once participants may be enrolled.
 Funding Support: Alpha-1 Foundation, Cystic Fibrosis Foundation, Alpha-1 Coded Testing Study

Name: Caitlin Clancy
 Project Role: Study Coordinator
 Researcher Identifier (ORCID ID):
 Nearest person month worked: 2
 Contribution to Project: Ms. Clancy assisted with IRB and HRPO documents and submissions. She collaborated with Dr. D'Armiento to ensure that successful staffing and data infrastructure are in place for this study.
 Funding Support: Departmental (LAM Center)

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.

Nothing to Report.

What other organizations were involved as partners?

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: (if foreign location list country)

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.*

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: N/A

9. APPENDICES: N/A