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TITLE: Multicenter Randomized Trial of Everolimus in Pediatric Heart Transplantation

PRINCIPAL INVESTIGATOR: Sleeper, Lynn A.

CONTRACTING ORGANIZATION: Boston Children's Hospital, Boston, MA

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Fort Detrick, Maryland 21702-5012

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Lynn A. Sleeper, ScD

5d. PROJECT NUMBER

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Children's Hospital Corporation, The
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Boston, MA 02115-5724

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14. ABSTRACT

TEAMMATE is a multicenter randomized clinical trial of a novel immunosuppressive therapy that is studing children who have undergone recent heart transplantation. The primary goal is to determine whether a new rejection treatment (everolimus and low-dose tacrolimus) can reduce or prevent complications of transplant, including rejection, coronary artery disease, and kidney disease, when compared to usual care (tacrolimus and mycophenolate mofetil). The secondary goal is to acquire FDA approval of the first immunosuppression regimen for pediatric heart transplantation. The primary trial endpoint is a validated surrogate measure—the major adverse transplant event (MATE) score—which efficiently predicts long-term survival, and that has been accepted by the FDA (IND# 127980). The trial is being conducted at 25 centers, with leadership at Boston Children's Hospital (Data Coordinating Center) and Stanford University (Clinical Coordinating Center). At the time of this annual report, enrollment is complete and the target has been met, with 211 patients randomized (60 in the last year). Each participant will be followed for 30 months. Additional accomplishments in Year 03 include one in-person Protocol Certification Training; successful execution of one Data and Safety Monitoring Board meeting; national presentation of research on everolimus dosing, baseline characteristics and recruitment strategies; and the continuation of endpoint adjudication and regulatory/data audit site visits.

15. SUBJECT TERMS

Heart transplantation; children; immunosuppression; randomized clinical trial

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	20	**19b. TELEPHONE NUMBER** *(include area code)*

TABLE OF CONTENTS

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

Median survival after pediatric heart transplantation is only 15 years in the current era, due to the occurrence of late complications after heart transplant, most of which stem from the medications used to suppress the immune system in order to prevent graft rejection. While graft survival has improved significantly with the current standard of care, tacrolimus (TAC) and mycophenolate mofitil (MMF), most of the improvement has come from a reduction in early mortality. Preliminary studies suggest that everolimus in combination with low-dose TAC may prevent rejection, coronary artery disease, and kidney failure more effectively than TAC-MMF. However, these studies are limited by single-center design, inconsistent endpoint definitions and use of historical controls. In contrast to adults, children have a substantially longer *potential* life expectancy in the absence of late transplant complications, making the prevention of such complications an urgent priority for the pediatric heart transplant community

The research that is the subject of this report, the TEAMMATE trial, is a multicenter randomized clinical trial of a novel immunosuppressive therapy that is studying a target of 210 children who have undergone recent heart transplantation. The primary goal is to determine whether a new rejection treatment (everolimus and low-dose TAC) can reduce or prevent complications of transplant when compared to usual care (TAC-MMF). The secondary goal is to acquire FDA approval of the first immunosuppression regimen for pediatric heart transplantation. The primary trial endpoint is a validated surrogate measure—the major adverse transplant event (MATE) score—which efficiently predicts long-term survival, and that has been accepted by the FDA (IND# 127980). The trial is being conducted at 25 centers, with leadership at Boston Children's Hospital (Data Coordinating Center) and Stanford University (Clinical Coordinating Center).

This trial has high military relevance: 1) pediatric heart transplant is most often performed in those with congenital heart disease, which may be more common in military families due to *in utero* exposures such as hazardous chemicals, poor air quality, ground water contamination, and infectious diseases that may be more prevalent when serving abroad; 2) the evaluation of everolimus may have medical applications for treating military injuries that require a vascular composite allograft, such as hand transplantation; and 3) proliferation signal inhibitors (such as everolimus) are uniquely known for their ability to alter healing of human tissues, and therefore may provide insights into mechanistic pathways necessary to expedite wound healing.

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

Children, heart transplant, immunosuppression, randomized clinical trial, everolimus

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The OVERALL AIM *of the research is to execute a multicenter randomized trial enrolling 210 pediatric heart transplant recipients from 25 sites to evaluate the efficacy, safety and tolerability of everolimus+low-dose tacrolimus and to secure its FDA approval.*

Major Tasks per SOW include:

1. *Regulatory & Contractual Activities required for Study Launch* — *Months -6 to 3*
2. *Prepare Study Staff and Systems to Execute Trial* — *Months 1 to 3*
3. *Participant Recruitment* — *Months 4 to 18*
4. *Participant Follow-up and Evaluation* — *Months 4 to 48*
5. *Study Closeout and Analysis* — *Months 36 to 48*

Shaded rows indicate tasks completed at time of last Annual Report.

Table 1. Statement of Work Tasks and Completion Status

Major Task 1: Regulatory & Contractual Activities required for Study Launch	**Timeline (mo)**	**Status**
Subtask 1: Obtain regulatory approvals for study protocol		
Submit final protocol to U.S. FDA for review and approval of amendments to Investigational New Drug (IND) application #127980	-6 to -3	✓ 11/20/17
Submit final protocol for Military IRB (ORP/HRPO) review and approval	-3 to 0	✓ 9/21/17 (v1)
Coordinate with Sites for IRB submission of protocol and ICF	1-3	✓ 27 fully approved
DSMB organizational and protocol review meeting, arranged by DCC	2	✓ 11/01/17
Submit amendments, adverse events and protocol deviations as needed	As Needed	Amendment #17 approved 08/06/2019
Submit annual single IRB report for continuing review	Annually	✓

Milestone Achieved: Approval by Military HRPO and FDA	1	✓
Milestone Achieved: Local IRB approval at Study Sites and Angio Core Laboratory	3	**COMPLETE**
Subtask 2: Execute financial agreements / subawards		
Coordinate with CCC, 25 Sites (22 original, 5 new, minus 2 terminated = 25 currently) and Core Lab to execute Subcontracts/ CTAs	1-3	✓ All fully executed
Execute Consultant Agreements with Adjudication Committee members	1-3	✓
Milestone Achieved: All Subcontracts and Consultant Agreements executed	1-3	**COMPLETE**
Major Task 2: Prepare Study Staff and Systems to Execute Trial		
Subtask 1: Training of Research Staff		
DCC/CCC to conduct in-person training session for certification on study protocol	2-3	✓ 11/10/17 in Anaheim, CA; 7/19/18 in Palo Alto, CA 1/11/19 in Boston, MA
DCC/CCC to conduct webinars for SCs to review study protocol procedures	2-3	✓ (occurs monthly)
Angio Core Lab to conduct webinar with site angiographers and site study coordinators regarding data transfer and image acquisition	3	✓ (held 2/1/18)
Adjudication Committee webinar to standardize AE review procedures	3	✓ (calls held Jan, Feb, April, May 2018)
Retrain site study coordinators/Train new coordinators as needed via Webinar	As Needed	✓ 72 Study & Transplant Coords + 33 PIs

		trained
Milestone Achieved: Research staff trained	3	**COMPLETE**
Subtask 2: Build Trial materials and communications and database system		
Finalize case report forms, including pilot testing with core site SCs	1-3	✓ 53 CRFs finalized
Create Trial and Angio Core Lab Manuals of Operation (MOO)	2-3	✓
Develop Administrative website to post trial materials and secure documents	1-3	✓
Develop and test database management and randomization systems	2-3	✓ 53 of 53 CRFs in use (100%)
Angio Core Lab to obtain license from Ambra Health for secure image transfer	1	✓ 12/14/17
Milestone Achieved: Study systems developed and functional for trial launch	3	**COMPLETE**
Major Task 3: Participant Recruitment		
Site Study Coordinators screen records for eligibility and randomize consented patients; CCC on call for eligibility questions from sites	4-18	735 screened **Complete**- 211 randomized of 210 Target ✓
Teleconference with SCs every other week and site PIs monthly	4-18	✓
Milestone Achieved: Recruitment and randomization of 210 participants	18	**COMPLETE**
Major Task 4: Participant Follow-up and Evaluation (0,3,6,9,12,18,24,30 mo post-randomization)		
Subtask 1: Data collection - Complete participant study visits		
Complete required study visits, including QOL/functional status assessments	4-48	Ongoing
Obtain prescription records from local pharmacies to monitor compliance	4-48	Ongoing

Submit participant clinical data to DCC database management system	4-48	Ongoing
De-identify angiograms and submit to Angio Core Lab	4-48	Ongoing
Collect blood/urine samples for ancillary studies, if funded	4-48	Starting in Y4
Submit adverse event reports to DCC and local IRB (if applicable) per required time frames	As needed	Ongoing
Milestone Achieved: Data collection complete	48	**CONTINUING**
Subtask 2: Event Reporting and Monitoring, Quality Assurance and Centralized Assessments		
DCC securely posts SAEs and Committee submits adjudications	7-30	Ongoing
DCC submits SAEs to DoD and DSMB per required time frames	7-30	Ongoing
DSMB reviews 6-mo outcomes of first 5 participants assigned to EVL/LDTAC	10	✓ Mtg held 10JAN2019
ACL performs angio readings and submits assessments to DCC	10-33	Ongoing
Site visits and data audits performed in person, 1 per site and for-cause;	12-40	First visit July 2019; COVID hiatus winter/spring 2020, Now Ongoing
Ongoing monitoring of site and ACL data quality and completeness by DCC		Ongoing
Write and publish trial design manuscript prior to interim look	8-14	Pending
DSMB meeting for one interim look at efficacy outcome (estimated timing)	30	Estimated date 2021
DCC coordinates DSMB meetings, prepares and securely post reports	10-43	Ongoing
Milestone Achieved: Standardized assessments and QA/QC measures executed	48	**CONTINUING**

What was accomplished under these goals?

In this Reporting Period (Year 3), trial execution has proceeded successfully on many fronts.

Study Sites: Business agreements with all 24 (non-BCH) study sites and core laboratory are renewed each year. A Central IRB and full Reliance is in use for 24 of 25 sites.

Communications: Biweekly Operations Committee, monthly Executive Committee and monthly Steering Committee and Study Coordinator conference calls are held.

Protocol Execution and Monitoring: The InForm database management system, randomization system, and core laboratory and event adjudication systems are in full use. One DSMB meeting was held in Year 03 (Feb 2020), with the second meeting shifted to December 2020 due to COVID-19. Qualifying SAEs are sent to the DSMB Chair in real time as needed. A total of 14 regulatory/data audit site visits have occurred to date.

Trial Tools:
a) The informed consent videos produced in Y01 (English) and in Y02 (Spanish) as an informational tool for families, are described and available at http://med.stanford.edu/teammate.html, https://www.youtube.com/watch?v=KnWwkHUZCv8.
To date, the informed consent videos in English and Spanish have acquired over 500 hits.

b) A video demonstrating the preparation procedure for liquid everolimus to be used by families with infants and young children randomized to everolimus (created in Y02):

https://www.youtube.com/watch?v=CO7VtATeofU&feature=youtu.be

To date this video has 73 hits. About 25% of the patients in the Everolimus treatment arm are infants/young children (i.e., approximately 30 patients).

Enrollment: A total of 735 patients were screened for the trial. Of the 408 potentially eligible, the consent rate was 54%. Sixty patients have been randomized since the last annual report. Although there was a hiatus due to COVID-19, **Enrollment was completed for the trial** in August 2020 (30 months duration). **The final total is 211 participants** (target of 210 (occurred on 31JUL2020), plus one patient who was consented prior to the 210th randomization, who was allowed to proceed to randomization (07AUG2020).

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

Drs. Sleeper and Almond attended the American Heart Association Scientific Sessions in November, 2019.

How were the results disseminated to communities of interest?

Not applicable (trial not complete).

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

1. Continue follow-up of enrolled patients
2. Complete the trial design manuscript
3. Complete the Statistical Analysis Plan (SAP).
4. Continue Adjudication Committee case reviews and submission of scores.
5. Continue Angiography Core Laboratory image reviews and submission of data.
6. Conduct regulatory/data audit site visits at the remaining 11 sites.
7. Conduct two DSMB meetings for assessment of patient safety and data quality.

4. **IMPACT:**

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

This randomized trial has made an impact on the field of pediatric heart transplantation by demonstrating for the first time that a collaborative clinical research network specific to pediatric heart transplantation can be successfully formed to efficiently execute multicenter research studies to improve the management and outcomes of children who have undergone heart transplantation.

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.

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

The planned 15-month accrual (enrollment) period required almost 30 months to attain the target sample size. The follow-up period of 30 months per participant is fixed; therefore, we will request a one year no-cost extension in the final year of the award (to 9/14/22) to complete the trial. However, the final study visit for the last-enrolled patients will occur at 30±2 months post-randomization, November 2022 to March 2023. We are hoping to be invited by the DoD to submit an Extension Award in FY21 to fully complete the trial and to perform the key analyses for the trial and disseminate the findings.

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.

We had additional delays in enrollment due to COVID-19 in the winter and spring of 2020. However, we have reached our target enrollment, which is a major milestone for our TEAMMATE network and for the field of heart transplantation. We will now complete the 30-month follow-up for all trial participants. In addition to the planned request for a no-cost extension, we are simultaneously planning ancillary, correlative studies to the parent TEAMMATE Trial and I intend to submit a CDMRP Investigator-Initiated Research Award application in 2021. These approaches will allow for completion of the trial, analysis of the data, research publications, and the conduct of biospecimen-based and imaging mechanistic studies.

Changes that had a significant impact on expenditures

Enrollment for TEAMMATE required an additional 14-15 months; therefore, the expenditures to reimburse study sites for the enrollment milestone expected to be made primarily in Y02 have extended through Y03. Similarly, the end-of-study milestone payments to sites planned for Y03 and Y04 as well as event adjudication costs will now occur in Y04 and during the requested no-cost extension year. In addition, due to COVID-19, the site monitoring visits planned for most of 2020 were postponed are now scheduled to occur in Y04 with associated expenditures to be made in Y04.

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

- The trial protocol has had 21 amendments approved and 1 withdrawn. Amendment #22 was approved by the single IRB at Boston Children's Hospital 8/11/20.
- The continuing review to the Central IRB (Boston Children's Hospital) was approved on 04/13/20.
- The continuing review by the DoD HRPO for Columbia University was approved on 5/2/20.
- The continuing review by the DoD HRPO was submitted on 06/5/2020. Unfortunately that e-mail was filtered out by the DoD e-mail system since it contained a .zip file and was not received. After further correspondence , the e-mail was resent on 8/5/2020 as multiple separate documents. Approval for study sites under the single IRB was received on 8/11/2020.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

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

Journal publications.

Published Abstracts:

1. Sleeper LA, Daly KP, Addonizio LJ, Alejos JC, Auberbach S, Bock MJ, Butto A, Carlo WF, Castleberry C, Dreyer WJ, Feingold B, Lamour J, Friedland-Little J, Hollander S, Klein G, Lal A, Pahl E, Peng D, Pietra B, Punnoose AR, Ryan TD, Su J, Sutcliffe DL, Zangwill S, Rossano JW, Almond CS. Recruitment in the TEAMMATE Trial: Observed vs. Expected. Select Abstracts From Cardiology 2020: 23rd Annual Update on Pediatric and Congenital Cardiovascular Disease. *World J Ped Congenit Heart Surg* 2020; 11(2), NP1–NP77. https://doi.org/10.1177/2150135120904324

2. Lee J, Castleberry C, Bock M, Auerbach SR, Rossano JW, Hollander SA, Lal AK, Pahl E, Barkoff L, Klein GL, Almond CS, Sleeper LA**,** Daly KP. Accuracy of Initial Everolimus Dosing in the TEAMMATE Trial: How Well Does It Work in Pediatric Heart Transplantation? *Circulation* 2019; Abstract 16528, Vol. 140, Suppl_1.

3. Almond, C., Sleeper, L.A., Rossano, J.W., Pahl, E., Lal, A.K., Castleberry, C.D., Lee, J., Hollander, S., Klein, G., Barkoff, L.M., Bock, M., Fenton, M., Daly, K.P. The TEAMMATE Trial: Study Design and Rationale of the First Pediatric Heart Transplant Randomized Clinical Trial. *The Journal of Heart and Lung Transplantation 2020;* 39, S207–S208. https://doi.org/10.1016/j.healun.2020.01.825

4. Daly KP, Sleeper LA, Addonizio LJ, Alejos JC, Auerbach S, Bock MJ, Butto A, Carlo WF, Castleberry C, Dreyer WJ, Feingold B, Lamour JM, Albers EL, Hollander SA, Klein GL, Lal A, Pahl E, Peng D, Punnoose AR, Rossano JW, Ryan TD, Su J, Sutcliffe DL, Zangwill S, Almond CS. Recruitment in the Pediatric Heart Transplant TEAMMATE Trial: Observed vs. Expected [abstract]. *Am J Transplant*. 2020; 20 (suppl. 3). https://atcmeetingabstracts.com/abstract/recruitment-in-the-pediatric-heart-transplant-teammate-trial-observed-vs-expected/. Accessed June 18, 2020.

See Appendix for published abstracts reported in prior Annual Reports.

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)

The following website went live in October 2018. Its purpose was to promote TEAMMATE Trial visibility and serve as an informational resource to patient families and study centers:

http://med.stanford.edu/teammate.html

- **Technologies or techniques**

Nothing to report.

- **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.

Nothing to report.

- **Other Products (presented in past Annual Report)**

  - **A Spanish language version informed consent video** was produced as an informational tool for families: : https://www.youtube.com/watch?v=KnWwkHUZCv8

  - **An instructional video on Preparation of Liquid Everolimus** was produced for use by families participating in the trial:

    https://www.youtube.com/watch?v=CO7VtATeofU&feature=youtu.be

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project? Annual effort

Name:	Lynn Sleeper, ScD
Project Role:	PD/PI, PI of DCC
Researcher Identifier (e.g. ORCID ID):	0000-0002-8055-768X
Nearest person month worked:	3
Contribution to Project:	No change.
Name:	Kevin Daly, MD
Project Role:	Co-Investigator, Co-PI of CCC
Researcher Identifier (e.g. ORCID ID):	0000-0003-4327-1532
Nearest person month worked:	3
Contribution to Project:	No change.
Name:	Christopher Almond, MD, MPH
Project Role:	Co-Investigator, Co-PI of CCC
Researcher Identifier (e.g. ORCID ID):	0000-0001-7136-8337
Nearest person month worked:	3
Contribution to Project:	No change.
Name:	Tajinder Pal Singh, MD, MSc
Project Role:	Co-Investigator/Medical Monitor
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	1,2
Contribution to Project:	No change.
Name:	Shelley Miyamoto, MD
Project Role:	Co-Investigator/Director of Angiography Core Laboratory
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	0.33
Contribution to Project:	No change.

Name:	Mary McGarigle
Project Role:	Senior Data Manager
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	12
Contribution to Project:	Replaced Linda Massey.

Name:	Adrianna Twombly
Project Role:	Assistant Project Director
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	0.5
Contribution to Project:	Ms. Twombly has left Boston Children's Hospital at the end of September 2019.

Name:	Gloria Klein, MS, RD
Project Role:	Project Director of DCC
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	7.2
Contribution to Project:	No change.

Name:	Kendra Lagerborg
Project Role:	Administrative Coordinator of DCC
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	6
Contribution to Project:	Ms. Lagerborg provides administrative and research support for the Data Coordinating Center.

Name:	Matthew MacLean
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	0
Contribution to Project:	Mr. McLean is no longer working on this project.

Name:	Jared Wilber
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	6
Contribution to Project:	No change.

Name:	Minmin Lu, MS
Project Role:	Statistical Programmer
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	1.2
Contribution to Project:	No change.

Name:	Jane Messere, RN
Project Role:	Clinical Research Associate
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	1.44
Contribution to Project:	No change.

Name:	Joanne Lee, PharmD
Project Role:	Pharmacist
Researcher Identifier (e.g. ORCID ID):	0000-0002-8008-6910
Nearest person month worked:	1.2
Contribution to Project:	No change.

Name:	Selena Gonzales, MPH
Project Role:	Project Manager of the CCC
Researcher Identifier (e.g. ORCID ID):	0000-0003-3744-111X
Nearest person month worked:	12
Contribution to Project:	No change.

Name:	Joseph Rossano, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	0.9
Contribution to Project:	No change.

Name:	Scott Auerbach, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-2341-0913
Nearest person month worked:	0.9
Contribution to Project:	No change.

Name:	Seth Hollander, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-0818-3150
Nearest person month worked:	0.9
Contribution to Project:	No change.

Name:	Matthew Bock, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-1357-4698
Nearest person month worked:	0.9
Contribution to Project:	No change.

Name:	Chesney Castleberry, MD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-9052-2333
Nearest person month worked:	0
Contribution to Project:	No change

Name:	Elfriede Pahl, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	0.9
Contribution to Project:	No change for Yr 3. Dr. Anna Joong will be taking on the site responsibilities as of 9/15/20.

Name:	Ashwin Lal, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-0935-6858
Nearest person month worked:	0.9
Contribution to Project:	No change.

Name:	Aecha Marion Ybarra, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	0.9
Contribution to Project:	No change.

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

Nothing to Report.

What other organizations were involved as partners?

Nothing to Report.

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.*

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

9. APPENDICES:

Previously published/listed in past Annual Report:

1. Bock MJ, Chau P, Kuhn MA, Martens T, Razzouk A, Chinnock RE. The Major Adverse Transplant Events (MATE) Score Applied to a Cohort of Pediatric Heart Transplant Recipients. *J Heart Lung Transpl* April 2019; 38(4), Supplement, S471-S472. DOI: https://doi.org/10.1016/j.healun.2019.01.1199

2. Sleeper LA, Daly KP, Rossano JW, Desai M, Auerbach S, Bock MJ, Castleberry CD, Fenton M, Hollander SA, Lal A, Pahl E, Almond CS. Design of the TEAMMATE Trial for children with heart transplant and development of a novel efficient endpoint. *Clinical Trials* 2018; 15:2 suppl. P79; p.183