SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER	PAGE	OF
REQ-3000-18-0001	1	25

2. CONTRACT NO.	3. AWARD/ EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
			613206180200	07/31/2018

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER (No collect calls)	c. OFFER DUE DATE/LOCAL TIME
	Rudi Johnson	301-504-7028	08/15/2018 1500 ET

9. ISSUED BY	CODE	10. THIS ACQUISITION IS	% FOR:
CONSUMER PRODUCT SAFETY COMMISSION DIV OF PROCUREMENT SERVICES 4330 EAST WEST HWY ROOM 523 BETHESDA MD 20814	EMPS	☒ UNRESTRICTED OR ☐ SET ASIDE ☐ SMALL BUSINESS ☐ HUBZONE SMALL BUSINESS ☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS ☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM ☐ EDWOSB ☐ 8(A)	NAICS: SIZE STANDARD

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b RATING	14 METHOD OF SOLICITATION
☒ SEE SCHEDULE		☐		☒ RFQ ☐ IFB ☐ RFP

15 DELIVER TO	CODE	16. ADMINISTERED BY	CODE
CONSUMER PRODUCT SAFETY COMMISSION OFFICE OF COMPLIANCE 4330 EASTWEST HIGHWAY ROOM 610 BETHESDA MD 20814	EXC	CONSUMER PRODUCT SAFETY COMMISSION DIV OF PROCUREMENT SERVICES 4330 EAST WEST HWY ROOM 523 BETHESDA MD 20814	EMPS

17a. CONTRACTOR/ OFFEROR CODE	FACILITY CODE	18a. PAYMENT WILL BE MADE BY	CODE

TELEPHONE NO.

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

☐ 18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	THIS IS A REQUEST FOR QUOTATION (RFQ) * **THE QUOTER SHALL PROVIDE A FIRM-FIXED PRICE FULLY LOADED RATE FOR THEIR SERVICES DESCRIBE HEREIN AND SHALL ALSO PROVIDE THE FOLLOWING INFORMATION: DUNS# 122452563 TAX IDENTIFICATION # 1716046242A1 *(Use Reverse and/or Attach Additional Sheets as Necessary)*				

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Govt Use Only)*

☒ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4 FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR	31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*

30b. NAME AND TITLE OF SIGNER *(Type or print)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(Type or print)*	31c. DATE SIGNED
Suzanne Alstadt, DPA, CRA Director, Office of Research and Sponsored Programs	8/15/2018	Eddie Ahmad	

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21 QUANTITY	22. UNIT	23 UNIT PRICE	24 AMOUNT
	CAGE CODE # _____				
0001	THE CONTRACTOR SHALL PROVIDE EXPERT SERVICES TO SUPPORT THE U.S. CONSUMER PRODUCT SAFETY COMMISSION, COMPLIANCE AND FIELD OPERATION'S HAZARD INVESTIGATION, STANDARD DEVELOPMENT AND IF NECESSARY, ADMINISTRATIVE PROCEEDINGS OR OTHER LITIGATION RELATED TO INCLINED SLEEP PRODUCTS FOR A PERFORMANCE PERIOD OF ONE (1) YEAR IN ACCORDANCE WITH THE ATTACHED STATEMENT OF WORK AND TERMS AND CONDITIONS.	1	LO		
0002	TRAVEL COST IS HEREBY FUNDED IN THE ESTIMATED AMOUNT "NOT TO EXCEED" $1,000.00. THE CONTRACTOR SHALL NOT EXCEED THIS AMOUNT WITHOUT PRIOR WRITTEN APPROVAL BY THE CONTRACTING OFFICER THROUGH THE ISSUANCE OF A CONTRACT MODIFICATION.				

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED. _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
		32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER ☐ PARTIAL ☐ FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT ☐ COMPLETE ☐ PARTIAL ☐ FINAL	37. CHECK NUMBER
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY (Print)	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT (Location)	
		42c. DATE REC'D (YY/MM/DD)	42d. TOTAL CONTAINERS

VOLUME 1: CONTRACT AND PRICING DOCUMENTS

A detailed budget and budget justification can be found below. The budget includes the time, materials, travel expenses, and indirect costs required to complete the work tasks in Volume 2.

Budget:

PERSONNEL								
Senior/Key Personnel								
First Name	*Last Name*	*Suffix*	*Project Role*	*Base Salary*	*% Effort*	*Requested Salary*	*Fringe*	*Funds Requested*
Erin	Mannen	PhD	PI	$125,000	25%	$31,250	$10,000	$41,250
David	Bumpass	MD	Sub-I	$730,246	2%	$14,605	$4,235	$18,840
Brien	Rabenhorst	MD	Sub-I	$417,466	2%	$8,349	$2,421	$10,771
John	Carroll	MD	Sub-I	$265,317	2%	$5,306	$1,539	$6,845
Brandi	Whitaker	PhD	Sub-I	$100,164	5%	$5,008	$1,452	$6,461
Support Personnel								
First Name	*Last Name*	*Suffix*	*Project Role*	*Base Salary*	*% Effort*	*Requested Salary*	*Fringe*	*Funds Requested*
To be named			Post Doctoral Fellow	$48,434	100%	$48,434	$14,046	$62,480
Janet	Williams		Research Coordinator	$40,000	20%	$8,000	$2,320	$10,320
S. Andrew	Tackett		Laboratory Technician	$36,000	50%	$18,000	$5,220	$23,220
				Total Salary, Wages and Fringe Benefits				**$180,187**

Hourly Rate for 12-month Project for All Personnel = $109/hour

MATERIALS and SUPPLIES		
Lab and testing		
	Inclined Sleep Products	$2,000
	Crib mattress	$150
	Building materials	$150
	Pulse oximeter	$2,000
	Ages & Stages Questionnaire	$300
	Misc research supplies	$250
Computers, Software, and Support		
	Computer	$2,300
	Sofware license - Matlab	$900
	Vicon software support	$2,000
Other		
	Subject compensation	$250
	HipKnee Arkansas Rental Fee	3,000
	Total Materials and Supplies	**$13,300**

Exempt Item

TOTAL BUDGET (no travel)		
	Direct Costs	$197,787
	Indirect Costs (26%)	$50,645
	TOTAL COST	**$248,431**

TRAVEL BUDGET		
	Mileage reimbursement	$300
	CPSC Meeting Travel for PI x 2	$4,000
	Indirect Costs (26%)	$1,118
	Total Travel	$5,418

Budget Justification:

Personnel

- Principal Investigator:
    - *Dr. Erin M. Mannen* has a Ph.D. in mechanical engineering from the University of Kansas and specializes in biomechanics with over nine years of research experience in the field. As Principal Investigator, she will be responsible for oversight of the entire project. Dr. Mannen will lead the design of the biomechanics experiment, oversee data collections, manage data analysis, interpret results, prepare reports, conduct meetings, ensure data quality, and manage all aspects of the project. Dr. Mannen has nine years of experience in biomechanics research, including serving as Principal Investigator on funded projects studying biomechanics of infants in various products. We request 25% salary and fringe support for Dr. Mannen for the 12-month project.

- Sub-Investigators
    - *Dr. John Carroll* is a medical doctor specializing in pediatric pulmonology. He is a graduate of the University of Texas Southwestern Medical School, completed Pediatrics residency at the State University of New York, Upstate Medical Center, and completed Pediatric Pulmonology fellowship at the University of Arizona and McGill University. Dr. Carroll is board certified in Pediatrics and Pediatric Pulmonology and is currently an investigator on several NIH-supported projects. As a Clinical Sub-Investigator, Dr. Carroll will provide clinical guidance on experimental design and data interpretation, focusing on the respiratory aspects of the project. Dr. Carroll has extensive experience in pediatric pulmonary clinical research. We request 2% salary and fringe support for Dr. Carroll for the 12-month project.

    - *Dr. David Bumpass* is a board-certified orthopaedic surgeon specializing in pediatric spine. He is a graduate of the University of Virginia School of Medicine and completed his orthopaedic and spine surgery training at Washington University in St. Louis. He specializes in complex pediatric spinal deformity surgery. As a Clinical Sub-Investigator, Dr. Bumpass will provide clinical insight into experimental design and data interpretation, focusing on understanding an infant's ability to move based on typical motor development milestones. We request 2% salary and fringe support for Dr. Bumpass for the 12-month project.

    - *Dr. Brien Rabenhorst* is a board-certified pediatric orthopaedic surgeon specializing in pediatric hip development. He is a graduate of Louisiana State University School of Medicine. He completed an orthopaedic residency at Texas Tech Health Science Center, and a pediatric orthopaedic fellowship at the Children's Hospital of Colorado. As a Clinical Sub-Investigator, Dr. Rabenhorst will contribute to the experimental design and data interpretation, focusing on the strength and coordination required of infants to move from compromised positions. We request 2% salary and fringe support for Dr. Rabenhorst for the 12-month project.

    - *Dr. Brandi Whitaker* is a psychologist working extensively over the past seven in the areas of psychological assessment and treatment of infants and young children. She earned her Ph.D. in the Psychology from Washington State University and completed a Post-Doctoral Fellowship in Pediatric Psychology. As a Sub-Investigator, Dr.

Whitaker will provide guidance on administration of a developmental measure for our subjects. She will lead the effort in analyzing and interpreting the developmental data. We request 5% salary and fringe support for Dr. Whitaker for the 12-month project.

- Project Support:

  - *Postdoctoral Fellow – To Be Named* will have a Ph.D. from an ABET-accredited institution in mechanical engineering, biomedical engineering, kinesiology, exercise science, or a related field, with at least two years of biomechanical research experience focusing in human motion data collections and analysis. He/she will assist with technical support through IRB adherence, participant recruitment, data collections, data processing, data analysis, and will assist with report preparation and data quality control. We request 100% salary and fringe support for the Postdoctoral Fellow for the 12-month project.

  - *S. Andrew Tackett, Research Assistant* has a Bachelor of Science degree in exercise science. He has two years of experience in data collecting and processing in a human motion biomechanics laboratory. Mr. Tackett will aid in administrative support, and technical support including patient recruitment, IRB compliance, data collections, and data processing. We request 20% salary and fringe support for S. Andrew Tackett for the 12-month project.

  - *Janet Williams, Research Coordinator* has 20+ years of experience in purchasing and administrative support at UAMS. She will handle administrative support including purchasing and administrative duties for the project. We request 50% salary and fringe support for Janet Williams for the 12-month project.

Materials and Supplies

According to our current cost for supplies and the anticipated usages from our planned study for this project, we request $10,300 for Materials and Supplies.

- Lab and testing supplies
  - *Infant Inclined Sleep Products* will be purchased based on the CPSC's product(s) of interest for the Inclined Sleep Product(s) testing condition(s). We request $2,000.
  - *A crib mattress* will be used in for the Flat Surface testing condition. We request $150.
  - *Supplies to build inclines* will be used to incline the crib mattress to 10, 20, and 30 degree inclines for use in the Inclined Surface testing conditions. We request $150.
  - A *pulse oximeter* will be used to monitor the heartrate and oxygen saturation. $2,000
  - A license for *Ages and Stages Questionnaire* is required to enable to us administer the developmental questionnaire to the participants. We request $300.
  - *Miscellaneous research supplies* are consumable testing materials such as EMG adhesives, coflex bandage, additional retro-reflective markers, medical grade tape, and infant product cleaning supplies. We request $250.

- Computers, Software and Support
  - *Computer and monitor for Postdoctoral Fellow* will be the main workstation for data analysis for the project. We request $2,300.
  - *A Matlab software license* is needed for data analysis. We request $900.

  - *Vicon support* will provide technical support for the motion capture and processing system. We request $2,000.

- Subject compensation
  - Each participant's caregiver will be compensated with a $25 Kroger gift card. We request funds for 10 participants x $25= $250.

- HipKnee Arkansas Rental Feel
  - Annual project rental fee for space and equipment use at HipKnee Arkansas Foundation. We request $3,000.

Travel

- The project team will drive within a 30 mile radius of Little Rock, Arkansas, to advertise for the study. Notes will be kept in a travel log including date and time, purpose of travel, traveler, and miles traveled. We are requesting $300.
- The PI will travel to the CPSC for meetings two times for a maximum of two business days each over the course of the project. We are requesting 2 x $2,000 = $4,000.

Indirect Costs

- The indirect cost rate for a UAMS project conducted off-campus is 26%.

VOLUME 2: TECHNICAL PROPOSAL

A. Proposed Overall Methodology and Demonstrated Ability to Perform the Work

(A1) Background, Objectives, and Work Requirements

Since 1992, the American Academy of Pediatrics (AAP) has recommended that infants under age one should be placed for sleep on a flat and firm surface in the supine position to reduce the incidence of Sudden Infant Death Syndrome (SIDS). The rate of SIDS deaths has decreased by 70% since the National Institute of Child Health and Development (NICHD) "Safe-to-Sleep" campaign (formerly "Back-to-Sleep") was implemented in 1992. However, some infants are currently placed to sleep in Inclined Sleep Products, designed to keep an infant supine at a 10 to 30 degree incline, and do not meet safe sleep guidelines set forth by the NICHD, Consumer Product Safety Commission (CPSC), and AAP. Parents are advised to always use restraints in the products and to discontinue use once an infant has the ability to roll over. However, several infant deaths have been reported in Inclined Sleep Products with the deceased infants often found in the prone position, with suffocation as the apparent cause of death.[1] It is, therefore, imperative to understand if the *design* of the Inclined Sleep Products contribute directly to an increased rate of infant deaths by either making it easier to roll from the supine to the prone position or making it more difficult to self-correct from the prone to the supine position when infants are placed in the product. We hypothesize that the position in which an infant is placed is related to the infant's ability to perform a head lift or a roll from supine to prone or prone to supine.

We propose the following non-invasive *in vivo* study to begin answering these questions. The purpose of this biomechanics study of infants 2 to 5 months of age is to determine:

> (a) the strength and space requirements for infants to move their heads and/or roll from the supine to the prone position in Inclined Sleep Products with and without restraints compared to a Flat Sleep Product,
> (b) the strength and space requirements for infants to lift their heads and/or roll from the prone to the supine position in Inclined Sleep Products with and without restraints compared to a Flat Sleep Product, and
> (c) the impact of the tightness of restraints in Inclined Sleep Products to prevent an infant from rolling from the supine to the side or prone position.

The outcomes of this study will inform the CPSC on how and to what extent the design of the Inclined Sleep Products may have on an infant's ability to move within the product. Based on the results of the biomechanics study, we will review the design of other Inclined Sleep Products, incident reports provided by the CPSC, and the current American Society for Testing and Materials (ASTM) standard to make recommendations to mitigate hazards from this class of products.

(A2) Methods and Techniques

Participants

A two-sample power analysis performed on normalized mean electromyography (EMG) data collected in an ongoing study of healthy infants indicated a sample size of nine participants would be sufficient to produce significant results ($1-\beta = 0.8$; $\alpha = 0.05$). To exceed this minimum

suggested sample size and to align with most human motion pilot study designs, ten infants (even gender distribution within 20%) ages two to five months old will be recruited in this IRB-approved study (IRB# 228457 Biomechanical Evaluation of Infants in Inclined Sleep Products, *under review*).

We will advertise for the study by word-of-mouth and flyers placed near the University of Arkansas for Medical Sciences in Little Rock, Arkansas. Race and ethnicity will be recorded, and efforts will be made to represent the racial and ethnic make-up of the United States within our cohort (approximately 70% Caucasian, 20% Hispanic, 10% African American).

Inclusion criteria include:

- healthy infants born >37 weeks gestation,
- currently between 5 and 95% height and weight for age according to the CDC,
- between the ages of two and five months on the date of testing.

Exclusion criteria include:

- infants born at low birth-weight (<5 lbs 8 oz),
- previous or current diagnosed orthopaedic or neurologic conditions,
- sickness or vaccinations within two-weeks of scheduled data collection.

One legal guardian of each infant participant will sign an IRB-approved consent form and HIPPA agreement to allow their infant to be in the study. The legal guardian will receive a $25 gift card if their infant participates in the study.

Data Collection

Biomechanical testing will take place at the HipKnee Arkansas Foundation human motion laboratory under the direction of the PI. Height, weight, head circumference, head weight, birth date, birth weight, gestational age at birth, race, and ethnicity will be recorded. The Ages and Stages Questionnaire Third Edition (ASQ-3) developmental screening tool will be used to assess early development gross motor and fine motor skills.[2,3] Retro-reflective markers will be placed on anatomical landmarks [head, shoulders, elbows, hands, back, pelvis, knees, ankles, feet, philtrum] on the infant's body while ten motion capture cameras (Vicon Motion Systems Ltd, Oxford, UK) record the spatial coordinates of each marker (100 Hz). EMG sensors (Delsys, Natick, MA, USA) will be placed bilaterally on muscle groups [cervical paraspinals, erector spinea, abdominals, pectoralis majors, and triceps] to record muscle activity (1000 Hz). The Owlet Smart Sock (Owlet, Lehi, UT, USA) will be secured to one randomly assigned foot, while a medical-grade pulse oximeter will be secured on the other foot to monitor heart rate and oxygen saturation levels. A pressure mapping surface sensor (Novel, Munich, GER) will be placed between the infant's upper extremities and the surface to record the pressure the infant is applying to the surface to achieve a head lift or roll (100 Hz). A high-speed video camera (240 Hz) will be used to video record the testing (GoPro, Inc., San Mateo, CA, USA).

Participants will be placed both supine and prone in the following positions for at least 30 second durations, occurring in a random order: Flat Sleep Surface (control condition), Inclined Sleep Product(s) with and without restraints, and on an Inclined Sleep Surface (10°, 20°, 30°). In each position, the infant will be encouraged by his/her caregiver to lift his/her head and roll over. Based on previous experimental studies, we expect that of the infants who have rolled previously, 50% will roll during experimentation. While rolling is desirable and will be encouraged, it will not be

considered necessary for successful completion of each testing condition. Caregivers will be encouraged to tend to their infants if infants are visibly upset during testing. Ample time will be given to the caregiver to calm the infant so the infant will not experience undue stress during experimentation. Figure 1 shows an experimental setup used in the PI's lab on a previous project; similar experimental techniques will be utilized in this proposed work.

Figure 1: Experimental setup from a previous infant biomechanics study showing the reflective motion capture markers and EMG sensors on a five-month old participant.

Data and Statistical Analysis

The following parameters will be extracted from the experimental data in all testing conditions via custom code (Matlab, Natick, NJ):

- Motion Capture
  - Head, neck, trunk, pelvis, leg, and arm positioning,
  - Distance nose/mouth from surface,
  - Horizontal space required to roll;
- EMG, muscle activity required to:
  - lift and move head,
  - roll from supine to prone,
  - roll from prone to supine;
- Pressure Sensor
  - Force required of the upper limbs to lift the head during prone positioning;
- Pulse oximeter and Owlet
  - Heart rate,
  - Oxygen saturation level.
- Video recording

EMG and force data will be normalized to the recommended Flat Sleeping Surface condition and reported as a percentage with respect to that condition. Paired t-tests ($p<0.05$) will be used to compare data to the Flat Sleeping Surface conditions.

Motion capture data will inform us on how babies are able to move within the various conditions, which can indicate if the product design promotes or inhibits certain movements. We will also quantify how the space between the mouth/nose and the product surface may differ between conditions, which may be linked to rebreathing or suffocation risks. EMG data will inform us on the relative muscle activity that infants use to keep their heads lifted or to roll in each condition. We can quantify from EMG data how much more or less muscle activity infants use to perform a movement based on the condition. The pressure data will give us a direct measurement of how much force the infant must exert to achieve a head lift in each condition, which can be directly linked to strength and work required to perform the task. The heart rate data will be compared between conditions and can be linked to the infants' level of distress. The oxygen saturation levels will be compared between conditions and can be linked to risk of rebreathing or suffocation. Video recording of the data collection will be used to make observational analyses on the infants' motion in each condition. While each of these measurements tell a piece the overall story, the project team will consider all outcomes to evaluate the safety of the design of the Inclined Sleep Products.

Review of Product Safety

With the guidance of the CPSC and the findings of the proposed biomechanical study, the team will review, analyze, and interpret the safety and design of products as requested by CPSC. We will generate written Microsoft Word reports based on our data analyses and interpretations that may help the CPSC assess the safety of the Inclined Sleep Products in question.

The PI will be prepared to attend and testify as an expert witness regarding this proposed study and the recommendations put forth based on the results at a daily rate to be negotiated by the CPSC and the PI for up to five business days.

Support Inclined Sleep Product Standard Development Work

Based on the findings of the biomechanical research, the project team will examine other Inclined Sleep Products per the CPSC's requests to determine whether the design specifications in ASTM F3118-17a are appropriate to prevent accidental deaths. The team will review the incident data provided by the CPSC and examine other Inclined Sleep Products of interest to assess safety based on the results of the experimental data collection and expert analysis. Particular attention will be paid to the following design requirements: seatback incline angle, minimum side barrier height, maximum width, and maximum length. The team will generate a written report in Microsoft Word that specifically addresses: (a) the safety or hazard presented by a 30 degree incline, (b) the characteristics of Inclined Sleep Products that may diminish respiration and ways to minimize the hazard, and (c) recommendations to improve the ASTM standard to minimize injuries and deaths in Inclined Sleep Products

Data Storage and Reporting

All raw and processed data will be de-identified and stored in password-protected and HIPPA-approved secured storage space provided by the University of Arkansas for Medical Sciences (UAMS). Processed data will be converted to Microsoft Excel file formats. A narrative report of the overall project will be prepared in Microsoft Word, and the data will be presented both graphically and tabularly. The project team will hold at least two joint meetings after data analysis has been completed to discuss the implications of the results, and the data interpretations will be written in the report.

Timeline and Deliverables

Review of the IRB application is in progress and is expected to be approved before September 1, 2018. Figure 2 represents an estimated timeline for the project.

The team will work closely with the CPSC to modify experimental design, focus of data analysis, and other aspects of the project as needed both before and throughout the project. Consistent with the nature of biomechanical experimentation, we expect to be flexible in our proposal and timeline as requested by the CPSC. We expect to have data collections completed by March 31, 2019 and a report of our findings with implications of those findings by June 30, 2019. The final three months of the project will focus on applying the results and implications of our biomechanics

study to other Inclined Sleep Products and to provide technical analysis and recommendations for revisions of ASTM F3118-17a. A final report will be delivered by September 30, 2019.

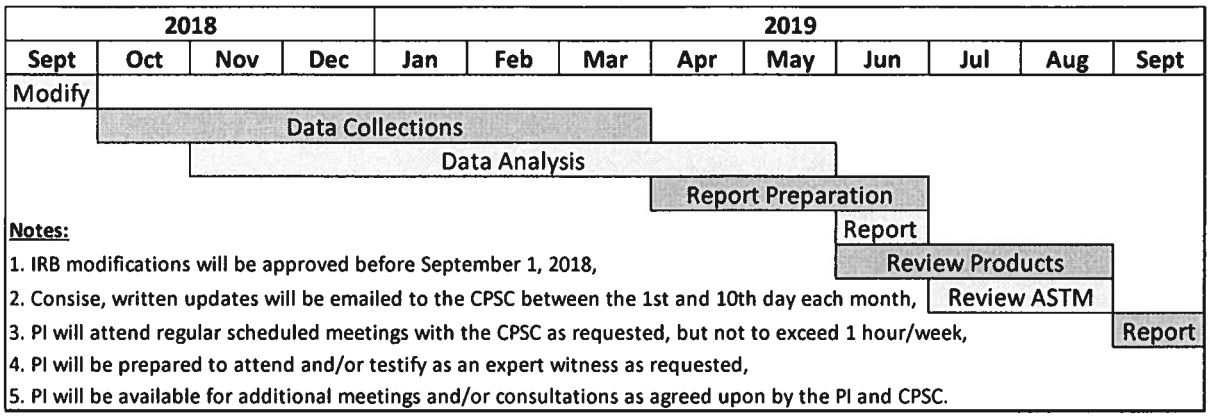

Figure 2: Project Timeline from September 2018 to September 2019.

References

1. United States Consumer Product Safety Commission. *Proposed Rule: Safety Standard for Infant Inclined Sleep Products*. Bethseda, MD; 2017. http://www.cpsc.gov.
2. Valleley RJ, Roane BM. Review of Ages & Stages Questionnaires: A Parent-Completed Child Monitoring System, Third Edition. In: Spies RA, Carlson JF, Geisinger KF, eds. *The Eighteenth Mental Measurements Yearbook*. Lincoln, NE: Buros Institute of Mental Measurements; 2010:13-15.
3. American Academy of Pediatrics Policy Statement: Identifying Infants and Young Children with Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening. *Pediatrics*. 2006;118:405-420.

(A3) Quality Control

Calibration of the experimental equipment will be conducted prior to each testing session to ensure measurements are accurate. Both the PI and the Post-Doctoral Fellow will review the analysis of every data set for accuracy and completeness. EMG measurements from the prone and supine positions on the Flat Sleeping Surface in this study will be compared to a previously collected healthy infant cohort which includes prone and supine positions to ensure reasonableness. If all data from a participant's testing session is found to be errant, we will exclude the data from the analysis and recruit another participant.

(A4) Potential Problems and Proposed Solutions

What if the infants do not complete all conditions?

- It is expected that not every infant enrolled in the study will successfully complete every activity. We expect each infant will complete at least 70% of the planned conditions. By randomizing the order of activities, we believe we will capture enough data from the cohort

to make a complete data set. If fewer than seven infants have completed a single activity after the collection of ten participants, we will enroll more subjects in the study.

What if no caregivers enroll their babies in the study?

- Participant recruitment is sometimes a concern in human subject research. If the word-of-mouth and flyer recruitment strategy is unsuccessful, we will solicit the help of the UAMS Translational Research Institute to aid in subject recruitment. We will also reach out to local pediatricians who may refer healthy babies to our study. Based on previous research, we do not expect to have trouble reaching our enrollment goal of ten infants over the course of the study.

What if the Clinical Sub-Investigators leave UAMS?

- Although these collaborators were specifically asked to take part in this project based on their expertise and interest in the project, because UAMS is an academic hospital, we have several other clinicians within the same specialties who we would ask to take part in the study if our clinical Sub-Investigators were to leave the institution.

What if members of the Research Support team leave UAMS?

- We will recruit an alternative Postdoctoral Research Fellow with the same skillset. We have personnel in place who can step in to this project to provide support for data collections and administrative duties if the support personnel on this proposal leave the institution.

What if the experimental research equipment malfunctions?

- By calibrating prior to each data collection, we hope to avoid mishaps of failed research equipment. However, if equipment does not function appropriately, we have the following solutions in place:
    - Vicon cameras: we can collect data with only 8 functioning cameras (we have 10) and have a service plan in place to replace all broken hardware or software.
    - Electromyography sensors: we have a total of 24 sensors, and only 10 are required for this project.
    - Pressure sensors: we have two functional pressure sensors, and only one is required for this project.
    - Owlet and pulse oximetry: we will purchase new devices if these stop functioning appropriately.

(A5) Logistical Considerations

- Laboratory: The HipKnee Arkansas motion laboratory at which testing will take place is equipped with state-of-the art validated experimental equipment costing over $250,000. Service contracts are in place to ensure all equipment is functional.

- Environment: UAMS is a research and teaching institution, fostering this collaborative team of engineers, researchers, and clinicians in a variety of specialties. As faculty, both research and clinical, we are encouraged and expected to participate in translational, meaningful projects. We are supported by a team of professionals in the UAMS Office of Research and Sponsored Programs to aid in the administrative requirements of a government contract.

- IT: UAMS has a team of professionals to handle all technical issues that may arise relating to internet connectivity, computers, telephones, video-conferencing, email, and HIPPA-secured cloud storage space.

- Office Space: The PI and Sub-Investigators have their own computers and private offices. Members of the Project Support Team each has their own personal workspace and computer. There are private meeting rooms available to use as needed.

B. Qualified Personnel

Organizational Structure:

The multi-disciplinary project team consists of investigators with doctoral degrees in mechanical engineering specializing in biomechanics and psychology specializing in pediatrics, and medical doctors in the fields of pediatric pulmonology and pediatric orthopaedics. Our team has the technical ability to carefully design and execute the proposed work and interpret the results from both an engineering and a medical viewpoint. Figure 3 shows the organizational structure for the project, with detailed descriptions of the qualifications and duties of each team member below.

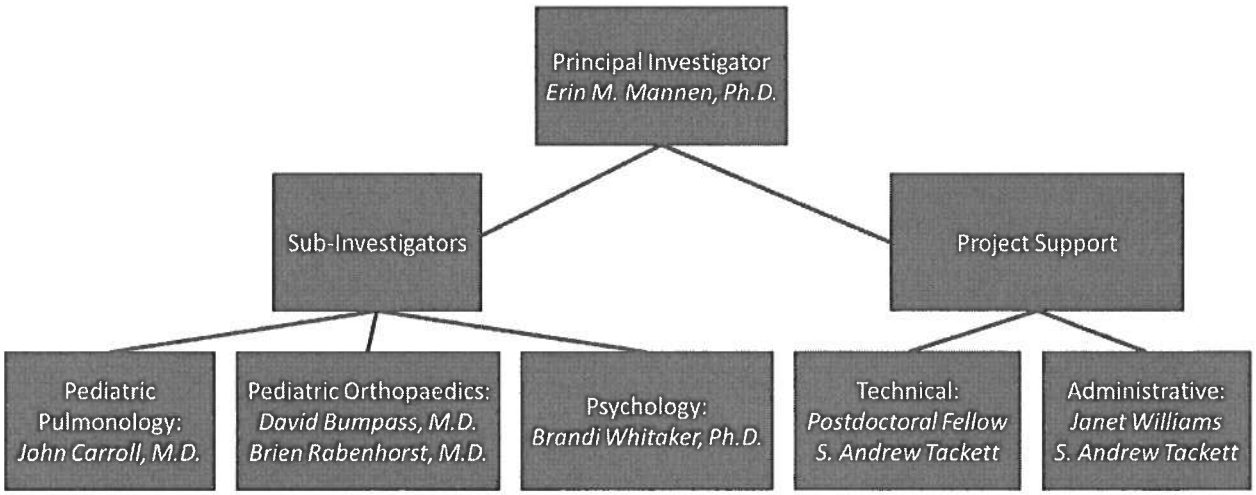

Figure 3: Organizational structure of the Project Team.

Roles, Responsibilities, and Skill Sets

Principal Investigator:

Dr. Erin M. Mannen has a Ph.D. in mechanical engineering from the University of Kansas and specializes in biomechanics with over nine years of research experience in the field. As Principal Investigator, she will be responsible for oversight of the entire project. Dr. Mannen will lead the design of the biomechanics experiment, oversee data collections, manage data analysis, interpret results, prepare reports, conduct meetings, ensure data quality, and manage all aspects of the project. Dr. Mannen has over nine years of experience in biomechanics research, including

serving as Principal Investigator on a similar industry-funded projects studying biomechanics of infants in various infant products.

Sub-Investigators:

Dr. John Carroll is a medical doctor specializing in pediatric pulmonology. He is a graduate of the University of Texas Southwestern Medical School, completed Pediatrics residency at the State University of New York, Upstate Medical Center, and completed Pediatric Pulmonology fellowship at the University of Arizona and McGill University. Dr. Carroll is board certified in Pediatrics and Pediatric Pulmonology and is currently an investigator on several NIH-supported projects. As a Clinical Sub-Investigator, Dr. Carroll will provide clinical guidance on experimental design and data interpretation, focusing on the respiratory aspects of the project. Dr. Carroll has extensive experience in pediatric pulmonary clinical research.

Dr. David Bumpass is a board-certified orthopaedic surgeon specializing in pediatric spine. He is a graduate of the University of Virginia School of Medicine and completed his orthopaedic and spine surgery training at Washington University in St. Louis. He specializes in complex pediatric spinal deformity surgery. As a Clinical Sub-Investigator, Dr. Bumpass will provide clinical insight into experimental design and data interpretation, focusing on understanding an infant's ability to move based on typical motor development milestones.

Dr. Brien Rabenhorst is a board-certified pediatric orthopaedic surgeon specializing in pediatric hip development. He is a graduate of Louisiana State University School of Medicine. He completed an orthopaedic residency at Texas Tech Health Science Center, and a pediatric orthopaedic fellowship at the Children's Hospital of Colorado. As a Clinical Sub-Investigator, Dr. Rabenhorst will contribute to the experimental design and data interpretation, focusing on the strength and coordination required of infants to move from compromised positions.

Dr. Brandi Whitaker is a psychologist working extensively over the past seven in the areas of psychological assessment and treatment of infants and young children. She earned her Ph.D. in the Psychology from Washington State University and completed a Post-Doctoral Fellowship in Pediatric Psychology. As a Sub-Investigator, Dr. Whitaker will provide guidance on proper selection of a developmental measure for our subjects. She will lead the effort in analyzing and interpreting the developmental data.

Project Support:

Postdoctoral Research Fellow – To Be Named will have a Ph.D. from an ABET-accredited institution in mechanical engineering, biomedical engineering, kinesiology, exercise science, or a related field, with at least two years of biomechanical research experience focusing in human motion data collections and analysis. He/she will assist with technical support through IRB adherence, participant recruitment, data collections, data processing, data analysis, and will assist with report preparation and data quality control.

S. Andrew Tackett, Research Assistant has a Bachelor of Science degree in exercise science. He has two years of experience in data collecting and processing in a human motion biomechanics laboratory. Mr. Tackett will aid in administrative support, and technical support including patient recruitment, IRB compliance, data collections, and data processing.

Janet Williams, Research Coordinator has 20+ years of experience in purchasing and administrative support at UAMS. She will handle administrative support including purchasing and administrative duties for the project.

Resource planning processes and procedures to support the changing needs of the environment

It is understood that the project direction, goals, outcome measures, and timeline may be changed as agreed upon by both the CPSC and the PI. Reasonable modifications in experimental design, data analysis techniques, and report formatting will be discussed and agreed upon during the monthly meetings of the PI and CPSC. All efforts will be made to inform the CPSC of any necessary changes in the project as soon as possible.

Management and status reporting approaches

The PI will meet weekly with the Technical Support team, and the Postdoctoral Fellow will provide a written update each week. The PI will meet with the Sub-Investigators prior to the first data collection and quarterly thereafter to discuss implications of results. The PI will provide the team and the CPSC with written monthly updates on the project.

VOLUME 3: PAST PERFORMANCE

The following projects represent relevant biomechanics research that Dr. Mannen has undertaken in the past five years. Items 1 and 2 represent current funded research projects focused on infant biomechanics utilizing the same experimental methodology as the proposed study. These projects include collaboration with both Dr. Rabenhorst and Dr. Bumpass, two Sub-Investigators on the proposed study. Items 3 and 4 represent adult human motion studies utilizing similar experimental motion capture and electromyography methodology to the proposed study. Items 5 and 6 represent cadaveric biomechanics studies utilizing motion capture, a main component in the proposed study. These examples represent the ability of the team to design, execute, analyze and interpret data, and present findings at academic conferences and in peer-reviewed journals. We are well-prepared to undertake the proposed infant biomechanics study.

1. *Title:* Infant Biomechanics in Various Positions

PI: Erin Mannen, *Relevant Sub-Is:* David Bumpass, Brien Rabenhorst

Funding: International Hip Dysplasia Institute ($10,160 Direct) and Boba, Inc. ($31,722 Direct), UAMS Start-up funding, NIH COBRE Award Number P20GM125503 ($75,000 Direct).

Dates: October 2017 to October 2019.

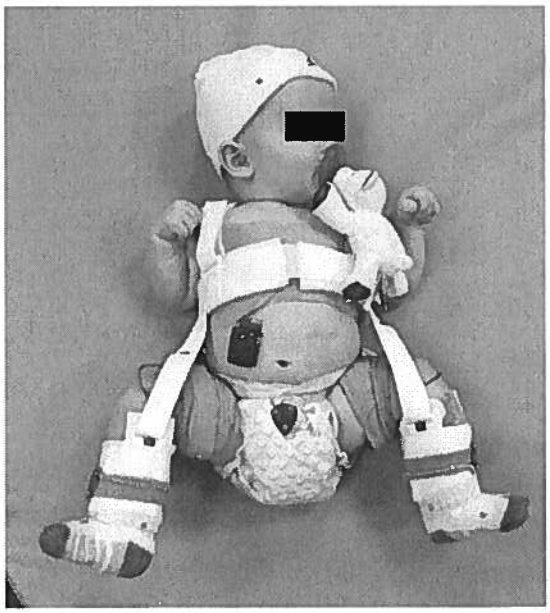

Figure 1: Experimental setup; Pavlik harness testing condition on a 4 month old infant.

Description: The goal of this project is to understand how babies are using their muscles and moving their bodies in several common positions. Parents are bombarded with options for baby gear, yet little is understood about how positioning babies within various types of baby gear may impact their ability to move and use their muscles. However, it is known that movement and muscle use contribute to proper musculoskeletal and motor development. *This study aims to understand: (1) neck and back muscle activity of infants in common positions, and (2) lower extremity muscle activity and hip positioning in common positions.* In this pilot study, we are examining 25 healthy babies ages 2 to 6 months to gain a better understanding of how babies are or are not using their muscles and moving in common positions: lying supine, lying prone, in a car seat, held in arms, in a Boba babycarrier, and in Pavlik harness (Figure 1) and Rhino cruiser devices which are common used for babies with developmental dysplasia of the hip. Marker-based motion capture and surface electromyography are being used to measure hip motion and neck, back, and lower extremity muscle activity of the infants in each position. The results of this research will inform caregivers and medical professionals on the potential impact that positioning and use of baby gear may have on neck, back, and hip development.

Status: In progress. Fourteen infants have been enrolled and tested in the study, and enrollment and testing are ongoing. The expected completion date is December 2018, with a goal of February 2019 for manuscript submission. Preliminary results of our study (n=14) have been accepted as abstracts and selected for oral presentations at the American Society of Biomechanics Annual Meeting (August 2018, Mayo Clinic, Rochester, MN) and the North American Spine Society Annual Meeting (September 2018, Los Angeles, CA). *Figure* 2 shows the mean muscle activity of the right hamstrings (HamR) and right gluteus maximus (GluteR) for the fourteen subjects in all positions. Data is normalized to the Pavlik harness condition, positioning that is known to benefit infant hip development. The preliminary results of this study confirm how babies use their muscles based on the position in which they are placed. Data analysis of hip position in the various conditions is ongoing.

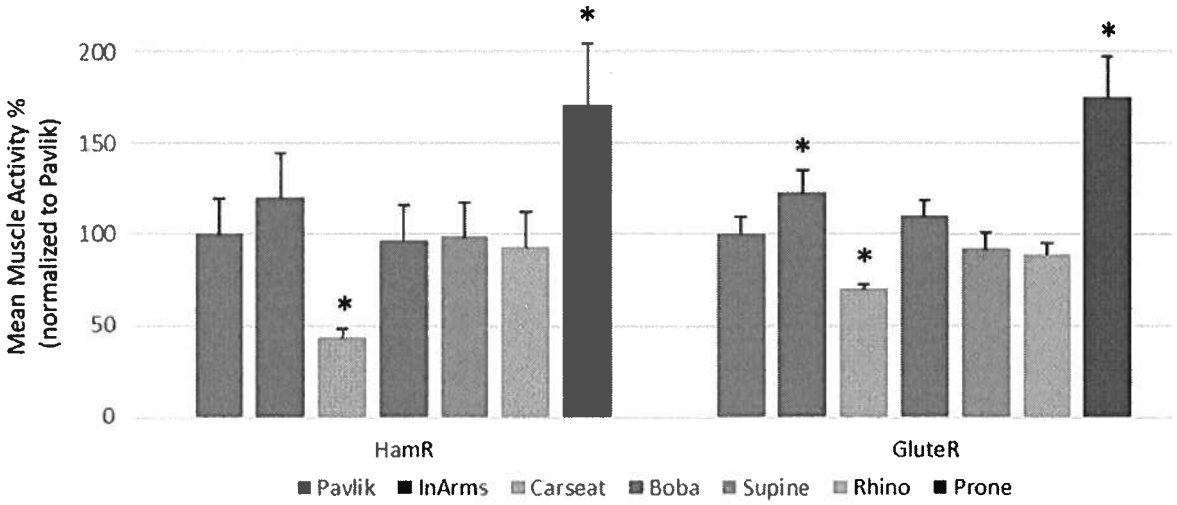

Figure 2: Mean muscle activity (%, normalized to Pavlik condition) for two of the muscle groups measured [right hamstrings (HamR) and right gluteus medius (GluteR)]. *p<0.05 with respect to the Pavlik condition.

Relevance: Through this study, we have developed non-invasive biomechanical testing methods for infants aged 2 to 6 months old by adapting methods commonly used in adults. We have learned best methods for testing infants to obtain the cleanest and most reliable biomechanics data possible. Additionally, we have implemented methods to easily compare mean muscle activity and positioning between specific positions of interest. The methods developed in this study will be applied directly to the proposed work. This healthy data set will also serve to confirm the quality of the proposed study since two conditions (supine and prone) will be collected in both studies and therefore the data is expected to be comparable. In addition, the PI and two Sub-Is on the proposed project have been collaborating on this project for the past year.

Abstracts and Manuscripts:

a. Mannen EM, Krishnan A, Sachleben BC. "Lower extremity muscle activity of healthy infants: Implications for hip dysplasia patients." *American Society of Biomechanics Annual Conference*, 2018; Rochester, MN. Oral presentation given by EM Mannen.
b. Mannen EM, Krishnan AR, Tackett SA, McCarthy RE, Bumpass, DB. "Infant positioning impacts neck and back muscle activity: a pilot study exploring implications for spinal development." *North American Spine Society Annual Conference*, 2018; Los Angeles, CA. Oral presentation given by EM Mannen.

2. ***Title:*** **Biomechanical changes in infants after successful nonsurgical treatment of developmental hip dysplasia.**

   PI: Erin Mannen, *Relevant Sub-Is:* Brien Rabenhorst

   Funding: NIH COBRE Pilot Project Award Number P20GM125503 ($65,000 Direct)

   Dates: August 2018 to August 2019.

   Description: Hip instability or developmental dysplasia of the hip (DDH) requires medical treatment for 2/1000 newborns and is typically diagnosed before 6 months of age. Untreated, the condition may progress to cause a lifetime of pain and disability. Early diagnosis and treatment with a Pavlik harness, a 70 year old solution that holds the baby's hips in a flexed and abducted position, are key to reducing the hip and solving the DDH problem. However, the baby must wear the harness for 24 hours/day for several weeks, resulting in a unique burden for the motion/caregiver and the infant. While the Pavlik harness is effective in reducing hips in nearly 80% of cases, the biomechanical change that the harness induces is not well understood. Without a clear idea of why and how the brace works to reduce hips, it is impossible to improve upon this time-honored yet basic treatment device. *The purpose of this study is to understand the muscle activity and hip positioning changes of DDH infants from successful Pavlik harness treatment and to compare DDH biomechanics with healthy controls to lead to the development of improved DDH therapies.* We will quantify the lower-extremity muscle and hip motion changes that infants who have been successfully treated for DDH with the Pavlik harness undergo, with the ultimate goal of using the information to develop better therapies. Ten infants newly diagnosed with DDH will undergo two test sessions in the HipKnee Arkansas Foundation motion laboratory (1) shortly after diagnosis and (2) after successful Pavlik harness treatment. Using novel methods developed in a preliminary study on healthy infants, biomechanical data will be collected on this DDH cohort pre- and post-Pavlik harness treatment and will be compared to the previously collected healthy infant cohort. Electromyography will be used to measure mean, peak, and duration of lower extremity muscle activations and reflective markers will capture the hip flexion and abduction positions of the babies in five common positions: Pavlik harness, prone, supine, in a baby carrier, and in a car seat. The quantified changes induced by the Pavlik harness will better enable the development of innovative therapies that could reduce the time or burden on the caregivers and DDH infants.

   Status: In progress. We recently received funding and IRB approval for this project and are currently seeking to enroll patients from our clinical Sub-Investigator's practices.

   Relevance: Through this study, we will utilize similar biomechanical testing methods proposed in the current quotation. This proposal has undergone NIH-style reviews from four senior investigators, receiving high scores and resulting in funding of the project. In addition, the PI and one Sub-Is on the proposed project will continue collaborating on this research.

3. ***Title:*** **Biomechanical considerations of child-carrying methods**

   PI: Erin Mannen

   Funding: Ergobaby, Inc. ($20,000; $16,667 direct)

Dates: October 2016 to June 2017.

Description: The PI conducted independent human-motion research during her postdoctoral fellowship examining the biomechanics of caregivers during different infant-carrying methods. Infant/mother proximity has been shown to have positive emotional, physiological, and mental impacts on the infants, but no studies have examined the biomechanical impact of hold an infant on the caregiver's body. This biomechanics study examined the kinematics, kinetics, postural sway, muscle fatigue, and self-reported pain of ten women during prolonged standing, gait, and retrieval tasks while carrying infant mannequins in-arms v. in a baby carrier. Marker-based motion capture and electromyography research tools were used to collect the data. The PI conceptualized the study, obtained industry funding, performed the experiments, conducted the analyses, and prepared the abstracts and manuscripts. Three conference abstracts have been accepted from this study, and two manuscripts are in preparation to submit in 2018. The results of this study will inform caregivers of the biomechanical impact of infant-carrying methods.

Relevance: This project examined the biomechanics of adult women using the same tools proposed in the current study (marker-based motion capture and electromyography). The methods used in this study have been adapted to work within the infant population of the proposed study. All data analysis programming codes developed for this study will be directly translatable to the proposed project.

Abstracts and Manuscripts:

a. Havens KL, Kahney A, Mannen EM. "Asymmetrical stance during child carrying: Implications for back pain." American Society of Biomechanics Annual Conference, 2018; Rochester, MN..
b. Mannen EM, Kahney A. "Impact of baby carrying method on postural sway in prolonged standing." American Society of Biomechanics, 2017; Boulder, CO.
c. Kahney A, Mannen EM. "Baby carrying method impacts upper extremity muscle activity in prolonged standing." Rocky Mountain American Society of Biomechanics, 2017; Estes Park, CO.

4. ***Title:*** **In vivo mechanics of the patellofemoral joint in natural and implanted knees.**

Post-Doctoral Fellow: Erin Mannen

Dates: September 2015 to June 2017.

Description: Dr. Mannen's postdoctoral research with Drs. Paul Rullkoetter and Kevin Shelburne focused on understanding the in vivo mechanics of the patellofemoral joint in natural and implanted knees. One of the most common complaints of patients who undergo total-knee arthroplasty is patellofemoral pain, yet little has been done to compare the mechanics of natural and implanted knees. Healthy adults and patients implanted with two different patellar geometries performed several activities of daily living while traditional motion-capture, electromyography, and high-speed stereo-radiography recorded the motion of their knees. Dr. Mannen led the data collection and analysis of over 50 patients. The results of this study are being used to understand natural patellofemoral motion for the purpose of informing and improving implant design for patients with total-knee arthroplasty. Five abstracts have

been presented, one manuscript has been accepted, and three manuscripts are in preparation from this work.

Relevance: This project examined the biomechanics of over 50 adult men and women using the same tools proposed in the current study (marker-based motion capture and electromyography). The methods used in this study have been adapted to work within the infant population of the proposed study. All data analysis programming codes developed for this study will be directly translatable to the proposed project.

Abstracts and Manuscripts:

a. Ali AA, Mannen EM, Rullkoetter PJ, Shelburne KB. In vivo comparison of medialized dome and anatomic patellofemoral geometries using subject-specific computational modeling. J Orthop Res. 2018 Feb 7. doi: 10.1002/jor.23865. [Epub ahead of print] PubMed PMID: 29411900.
b. Mannen EM, Kefala V, Ali AA, Walter JP, Reilly KR, Jackels MK, Liu X, Schmidt W, Rullkoetter PJ, Shelburne KB. "Tibiofemoral Kinematics of Healthy Older Adults during Dynamic Seiza-Style Kneeling:A Pilot Study,"Orthopaedic Research Society:Late-Breaking Abstract,2017;San Diego,CA.
c. Mannen EM, Ali AA, Walden S, Dennis DA, Haas B, Rullkoetter PJ, Shelburne KB. "Influence of implant design on knee mechanics in posterior-stabilized rotating platform TKA." Orthopaedic Research Society, 2017; San Diego, CA.
d. Kefala VK, Ali AA, Mannen EM, Kim RH, Rullkoetter PJ, Shelburne KB. "Assessment of patellar kinematics in healthy older adults." Orthopaedic Research Society, 2017; San Diego, CA.

5. ***Title: Biomechanical changes in the thoracic spine with a follower load***

Postdoctoral Research Consultant: Erin Mannen

Funding: NIH Subcontract K99AG042458 ($40,000).

Dates: January 2015 to August 2015.

Description: As a consultant with Drs. Dennis Anderson and Mary Bouxsein's research group at Harvard Medical School with the collaboration of her Ph.D. mentor Dr. Lisa Friis, Dr. Mannen led the experimental design, implementation, and data analysis of a cadaveric thoracic spine study which aimed to incorporate physiological loading of the thoracic spine by implementing a novel follower load technique for understanding loading and stiffness of the thoracic spine and rib cage. The improved mechanical testing cadaveric model has been used to quantify the mechanical impact of a growth-friendly rod construct used in scoliosis surgery and to inform musculoskeletal models of the thoracic spine. Ten conference abstracts have been presented and five manuscripts have been published in peer-reviewed journals.

Relevance: Through this project, we utilized motion-capture methods and wrote novel Matlab code to determine motion of vertebral bodies during loading. Similar methodology will be used in the data analysis of the motion capture data in the proposed study. This project also shows the PI's ability to work with a team of individuals (eleven co-authors) to produce high-quality, peer-reviewed research products in the form of five publications in Medline-indexed journals.

Manuscripts:

a. Mannen EM, Friis EA, Sis HL, Wong BM, Cadel ES, Anderson DE. "The rib cage stiffens the thoracic spine in a cadaveric model with body weight load under dynamic moments," Journal of the Mechanical Behavior of Biomedical Materials. 2018;84:258-64. doi: 10.1016/j.jmbbm.2018.05.019.
b. Anderson DE, Mannen EM, Tromp R, Wong BM, Sis HL, Cadel ES, Friis EA, Bouxsein ML. "The rib cage reduces intervertebral disc pressures in cadaveric thoracic spines under applied dynamic loads," Journal of Biomechanics. 2018 Mar 21;70:262-266. doi: 10.1016/j.jbiomech.2017.10.005. Epub 2017 Oct 12. PubMed PMID: 29106896.
c. Galvis SN, Arnold JA, Mannen EM, Wong BM, Sis HL, Cadel ES, Anderson DE, Arnold PA, Friis EA. "Biomechanical evaluation of a growth-friendly rod construct," Spine Deformity. 2017;5:11-17. PMID: 28038688, PMCID: PMC5621639.
d. Sis HL, Mannen EM, Wong BM, Cadel ES, Bouxsein ML, Anderson DE, Friis EA. "Effect of Follower Load on Motion and Stiffness of the Human Thoracic Spine with Intact Rib Cage," The Journal of Biomechanics. 2016;49(14):3252-3259. PMID: 27545081; PMCID: PMC5702885.
e. Anderson DE, Mannen EM, Tromp R, Wong BM, Sis HL, Cadel ES, Friis EA, Bouxsein ML. "The rib cage reduces intervertebral disc pressures in cadaveric thoracic spines under applied dynamic loads," Journal of Biomechanics. 2018;70:262-266. doi: 10.1016/j.jbiomech.2017.10.005. PMID: 29106896.

6. ***Title:*** **Biomechanics of the thoracic spine and rib cage.**

Ph.D. Candidate: Erin Mannen

Funding: Madison and Lila Self Graduate Fellowship ($164,000), University of Kansas

Dates: August 2009 to September 2014.

Description: During her Ph.D. training, Dr. Mannen developed and used a novel technique of testing the cadaveric thoracic spine with intact rib cage. Previously, the rib cage was not included in full thoracic spine testing, leaving questions regarding the clinical applicability of mechanical testing of the thoracic spine. Through this work, Dr. Mannen validated a novel spine-testing machine, examined the mechanics of the thoracic spine with rib cage, quantified the mechanical contribution of the rib cage, and used the cadaveric model to determine the mechanical influence of a surgical procedure. She led the experimental design, implementation, and data analysis. The results show the importance of utilizing the rib cage to enhance clinical applicability in cadaveric spine mechanical testing. Five abstracts have been presented and four peer-reviewed manuscripts have been published.

Relevance: This project represented the validation and testing of a new experimental protocol which included novel motion capture methodology and data analysis. For the proposed infant biomechanics project, similar data analysis methodology will be used. Further, this project shows the collaboration of Dr. Mannen with both biomechanics researchers (EA Friis, S Ranu) and clinicians (PM Arnold, JA Anderson).

Manuscripts:

a. Mannen EM, Arnold PM, Anderson JT, and Friis EA. "Influence of sequential Ponte osteotomies on the human thoracic spine with a rib cage," Spine Deformity, 2017 Mar,5(2):91-96. PMID: 28259271.
b. Mannen EM, Anderson JT, Arnold PM, and Friis EA. "Mechanical Contribution of the Rib Cage in the Human Cadaveric Thoracic Spine," Spine. 2015;40(13), pp. E760-766. PMID: 25768687.
c. Mannen EM, Anderson JT, Arnold PM, and Friis EA. "Mechanical Analysis of a Human Cadaveric Thoracic Spine with Intact Rib Cage," Journal of Biomechanics. 2015;48(10), pp. 2060-2066. PMID: 25912664.
d. Mannen EM, Ranu SS, Villanueva AM, Friis EA. "Validation of a Novel Spine Test Machine." ASME: Journal of Medical Devices. 2015;9(1):011002-011002-8.

ATTACHMENT C

52.212-3 Offeror Representations and Certifications—Commercial Items. (Nov 2017)

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) website located at https://www.sam.gov/portal. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (u) of this provision.

(a) *Definitions.* As used in this provision—

"Economically disadvantaged women-owned small business (EDWOSB) concern" means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business eligible under the WOSB Program.

"Highest-level owner" means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest level owner.

"Immediate owner" means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

"Inverted domestic corporation", means a foreign incorporated entity that meets the definition of an inverted domestic corporation under 6 U.S.C. 395(b), applied in accordance with the rules and definitions of 6 U.S.C. 395(c).

"Manufactured end product" means any end product in product and service codes (PSCs) 1000-9999, except—

(1) PSC 5510, Lumber and Related Basic Wood Materials;

(2) Product or Service Group (PSG) 87, Agricultural Supplies;

(3) PSG 88, Live Animals;

(4) PSG 89, Subsistence;

(5) PSC 9410, Crude Grades of Plant Materials;

(6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;

(7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;

(8) PSC 9610, Ores;

(9) PSC 9620, Minerals, Natural and Synthetic; and

(10) PSC 9630, Additive Metal Materials.

"Place of manufacture" means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

"Predecessor" means an entity that is replaced by a successor and includes any predecessors of the predecessor.

"Restricted business operations" means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

(1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;

(2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended.

"Sensitive technology"—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

"Service-disabled veteran-owned small business concern"—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern" means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.

"Small disadvantaged business concern", consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13.CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

"Subsidiary" means an entity in which more than 50 percent of the entity is owned—

(1) Directly by a parent corporation; or

(2) Through another subsidiary of a parent corporation.

"Veteran-owned small business concern" means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Successor" means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term "successor" does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

"Women-owned business concern" means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

"Women-owned small business concern" means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

"Women-owned small business (WOSB) concern eligible under the WOSB Program" (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)(1) *Annual Representations and Certifications.* Any changes provided by the offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications posted on the SAM website.

(2) The offeror has completed the annual representations and certifications electronically via the SAM website accessed through http://www.acquisition.gov. After reviewing the SAM database information, the offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror

Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs _____.

[*Offeror to identify the applicable paragraphs at (c) through (t) of this provision that the offeror has completed for the purposes of this solicitation only, if any.*

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted electronically on SAM.]

(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply.

(1) *Small business concern.* The offeror represents as part of its offer that it □ is, □ is not a small business concern.

(2) *Veteran-owned small business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents as part of its offer that it □ is, □ is not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern.* [*Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.*] The offeror represents as part of its offer that it □ is, □ is not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents, that it □ is, □ is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(5) *Women-owned small business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents that it □ is, □ is not a women-owned small business concern.

(6) WOSB concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(5) of this provision.] The offeror represents that—

(i) It □ is,□ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(6)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(7) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a WOSB concern eligible under the WOSB Program in (c)(6) of this provision.] The offeror represents that—

(i) It □ is, □ is not an EDWOSB concern, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(7)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [*The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture:* _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

Note: Complete paragraphs (c)(8) and (c)(9) only if this solicitation is expected to exceed the simplified acquisition threshold.

(8) *Women-owned business concern (other than small business concern).* [*Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents that it □ is a women-owned business concern.

(9) *Tie bid priority for labor surplus area concerns.* If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:_____

(10) *HUBZone small business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents, as part of its offer, that—

(i) It □ is, □ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It □ is, □ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order 11246—

(1) Previous contracts and compliance. The offeror represents that—

(i) It □ has, □ has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It □ has, □ has not filed all required compliance reports.

(2) *Affirmative Action Compliance.* The offeror represents that—

(i) It □ has developed and has on file, □ has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 cfr parts 60-1 and 60-2), or

(ii) It □ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions (31 U.S.C. 1352).* (Applies only if the contract is expected to exceed $150,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract. If any registrants under the Lobbying

Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(f) *Buy American Certificate.* (Applies only if the clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American—Supplies, is included in this solicitation.)

(1) The offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products, *i.e.*, an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of "domestic end product." The terms "commercially available off-the-shelf (COTS) item" "component," "domestic end product," "end product," "foreign end product," and "United States" are defined in the clause of this solicitation entitled "Buy American—Supplies."

(2) Foreign End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[*List as necessary*]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(g)(1) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate.* (Applies only if the clause at FAR 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (g)(1)(iii) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms "Bahrainian, Moroccan, Omani, Panamanian, or

Peruvian end product," "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "Israeli end product," and "United States" are defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements–Israeli Trade Act."

(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[*List as necessary*]

(iii) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act." The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products, *i.e.*, an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of "domestic end product."

Other Foreign End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[*List as necessary*]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(2) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate I.* If Alternate I to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Canadian End Products:

Line Item No.

_____

_____

_____

[*List as necessary*]

(3) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate II.* If Alternate II to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Canadian or Israeli End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[*List as necessary*]

(4) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate III.* If Alternate III to the clause at 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end

products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[*List as necessary*]

(5) *Trade Agreements Certificate.* (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(5)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[*List as necessary*]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) *Certification Regarding Responsibility Matters (Executive Order 12689).* (Applies only if the contract value is expected to exceed the simplified

acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals—

(1) □ Are, □ are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) □ Have, □ have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(3) □ Are, □ are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses enumerated in paragraph (h)(2) of this clause; and

(4) □ Have, □ have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,500 for which the liability remains unsatisfied.

(i) Taxes are considered delinquent if both of the following criteria apply:

(A) *The tax liability is finally determined.* The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(B) *The taxpayer is delinquent in making payment.* A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(ii) *Examples.*

(A) The taxpayer has received a statutory notice of deficiency, under I.R.C. §6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(B) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. §6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals

contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(C) The taxpayer has entered into an installment agreement pursuant to I.R.C. §6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(D) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. §362 (the Bankruptcy Code).

(i) Certification Regarding Knowledge of Child Labor for *Listed End Products (Executive Order 13126).* [*The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b).*]

(1) *Listed end products.*

Listed End Product Listed Countries of Origin

_____ _____

_____ _____

(2) *Certification.* [*If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.*]

□ (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

□ (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j) *Place of manufacture.* (Does not apply unless the solicitation is predominantly for the acquisition of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly—

(1) □ In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or

(2) □ Outside the United States.

(k) *Certificates regarding exemptions from the application of the Service Contract Labor Standards* (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services.) [*The contracting officer is to check a box to indicate if paragraph (k)(1) or (k)(2) applies.*]

□ (1) Maintenance, calibration, or repair of certain equipment as described in FAR 22.1003-4(c)(1). The offeror □ does □ does not certify that—

(i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR 22.1003-4(c)(2)(ii)) for the maintenance, calibration, or repair of such equipment; and

(iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

□ (2) Certain services as described in FAR 22.1003-4(d)(1). The offeror □ does □ does not certify that—

(i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR 22.1003-4(d)(2)(iii));

(iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of

less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and

(iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.

(3) If paragraph (k)(1) or (k)(2) of this clause applies—

(i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

(ii) The Contracting Officer may not make an award to the offeror if the offeror fails to execute the certification in paragraph (k)(1) or (k)(2) of this clause or to contact the Contracting Officer as required in paragraph (k)(3)(i) of this clause.

(l) *Taxpayer Identification Number (TIN) (*26 U.S.C. 6109, *31 U.S.C. 7701).* (Not applicable if the offeror is required to provide this information to the SAM database to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (l)(3) through (l)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) *Taxpayer Identification Number (TIN).*

□ TIN: _____.

□ TIN has been applied for.

□ TIN is not required because:

□ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

□ Offeror is an agency or instrumentality of a foreign government;

□ Offeror is an agency or instrumentality of the Federal Government.

(4) *Type of organization.*

□ Sole proprietorship;

□ Partnership;

□ Corporate entity (not tax-exempt);

□ Corporate entity (tax-exempt);

□ Government entity (Federal, State, or local);

□ Foreign government;

□ International organization per 26 CFR 1.6049-4;

□ Other _____.

(5) *Common parent.*

□ Offeror is not owned or controlled by a common parent;

□ Name and TIN of common parent:

Name _____.

TIN _____.

(m) *Restricted business operations in Sudan.* By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(n) Prohibition on Contracting with Inverted Domestic Corporations.

(1) Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of an inverted domestic corporation, unless the exception at 9.108-2(b) applies or the requirement is waived in accordance with the procedures at 9.108-4.

(2) *Representation.* The Offeror represents that—

(i) It □ is, □ is not an inverted domestic corporation; and

(ii) It □ is, □ is not a subsidiary of an inverted domestic corporation.

(o) Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.

(1) The offeror shall e-mail questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(2) *Representation and Certifications.* Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror—

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds $3,500 with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) (see OFAC's Specially Designated Nationals and Blocked Persons List at http://www.treasury.gov/ofac/downloads/t11sdn.pdf).

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if—

(i) This solicitation includes a trade agreements certification (*e.g.*, 52.212-3(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products.

(p) Ownership or Control of Offeror. (Applies in all solicitations when there is a requirement to be registered in SAM or a requirement to have a unique entity identifier in the solicitation.

(1) The Offeror represents that it □ has or □ does not have an immediate owner. If the Offeror has more than one immediate owner (such as a joint venture), then the Offeror shall respond to paragraph (2) and if applicable, paragraph (3) of this provision for each participant in the joint venture.

(2) If the Offeror indicates "has" in paragraph (p)(1) of this provision, enter the following information:

Immediate owner CAGE code: _____.

Immediate owner legal name: _____.

(Do not use a "doing business as" name)

Is the immediate owner owned or controlled by another entity: □ Yes or □ No.

(3) If the Offeror indicates "yes" in paragraph (p)(2) of this provision, indicating that the immediate owner is owned or controlled by another entity, then enter the following information:

Highest-level owner CAGE code: _____.

Highest-level owner legal name: _____.

(Do not use a "doing business as" name)

(q) *Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law.*

(1) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, The Government will not enter into a contract with any corporation that—

(i) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(ii) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(2) The Offeror represents that—

(i) It is □ is not □ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and

(ii) It is □ is not □ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(r) *Predecessor of Offeror.* (Applies in all solicitations that include the provision at 52.204-16, Commercial and Government Entity Code Reporting.)

(1) The Offeror represents that it □ is or □ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(2) If the Offeror has indicated "is" in paragraph (r)(1) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: _____ (or mark "Unknown")

Predecessor legal name: _____

(Do not use a "doing business as" name)

(s) [Reserved].

(t) *Public Disclosure of Greenhouse Gas Emissions and Reduction Goals.* Applies in all solicitations that require offerors to register in SAM (52.212-1(k)).

(1) This representation shall be completed if the Offeror received $7.5 million or more in contract awards in the prior Federal fiscal year. The representation is optional if the Offeror received less than $7.5 million in Federal contract awards in the prior Federal fiscal year.

(2) *Representation.* [*Offeror to check applicable block(s) in paragraph (t)(2)(i) and (ii)*].

(i) The Offeror (itself or through its immediate owner or highest-level owner) □ does, □ does not publicly disclose greenhouse gas emissions, *i.e.*, makes available on a publicly accessible website the results of a greenhouse gas inventory, performed in accordance with an accounting standard with publicly available and consistently applied criteria, such as the Greenhouse Gas Protocol Corporate Standard.

(ii) The Offeror (itself or through its immediate owner or highest-level owner) □ does, □ does not publicly disclose a quantitative greenhouse gas emissions reduction goal, *i.e.*, make available on a publicly accessible website a target to reduce absolute emissions or emissions intensity by a specific quantity or percentage.

(iii) A publicly accessible website includes the Offeror's own website or a recognized, third-party greenhouse gas emissions reporting program.

(3) If the Offeror checked "does" in paragraphs (t)(2)(i) or (t)(2)(ii) of this provision, respectively, the Offeror shall provide the publicly accessible website(s) where greenhouse gas emissions and/or reduction goals are reported:_____.

(u)(1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(2) The prohibition in paragraph (u)(1) of this provision does not contravene requirements applicable to Standard Form 312 (Classified Information

Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(3) *Representation.* By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.*, agency Office of the Inspector General).