AWARD NUMBER: W81XWH-19-2-0042

TITLE: Identification of Predictors for Clinical Outcomes in Femoroacetabular Impingement Surgery

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CONTRACTING ORGANIZATION: Washington University, St. Louis, MO

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None

14. ABSTRACT: To date there are no major findings to report.

Femoroacetabular Impingement (FAI) is a complex pre-arthritic hip disorder affecting an increasing number of military personnel and young active individuals in the general population. This disorder has come to the forefront as the most common cause of hip pain, pre-arthritic hip dysfunction and eventual secondary osteoarthritis (OA). FAI can restrict military personnel function during active duty, cause long-term disability, and increase the need for total hip replacement (THR) in our active duty, veteran and general populations. This disorder is characterized by structural deformities of the acetabulum and femur that produce repetitive abutment ("impingement") at the acetabular rim causing intra-articular soft tissue injury (acetabular labrum and articular cartilage), progressive joint degeneration and development of secondary OA over time. FAI is currently the focus of intense interest directed at surgical treatment to relieve pain, enhance function and potentially delay or prevent OA. Despite the surge in diagnosis and enthusiasm for surgical interventions, there is a paucity of clinical evidence to guide treatment. Our grant project specifically seeks to cover the FY2018 PRORP-CTRA surgical care focus area of osteoarthritis. The overarching goal of the proposed investigations is to provide novel clinical evidence to inform future surgical strategies for treating FAI, and improve the clinical outcomes of FAI surgery.

15. SUBJECT TERMS
Femoroacetabular Impingement (FAI); Patient-Reported Outcomes (PRO); see Table of Keywords (page 4)

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Unclassified	Unclassified	Unclassified	Unclassified	26	19b. TELEPHONE NUMBER *(include area code)*

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Abbreviations: Table of Keywords Within the Report (Added by WUSTL For this Report)	
ANCHOR	Academic Network of Conservational Hip Outcomes Research
BCH	Boston Children's Hospital
CHEO	The Children's Hospital of Eastern Ontario
CT	Computerized Tomography
DCC	Data Coordinating Center (at WUSTL)
DoD	Department of Defense
FAI	Femoroacetabular impingement
FE	Fully Executed
Fluoro	Fluoroscopy
FU	Follow-up
HS	Hip Scope Image
IRB/REB/HRPO	Institutional Review Board/Research Ethic Review Board/Human Research Protections Office
MOP	Manual of Operations
OA	Osteoarthritis
QC/QA	Quality Control / Quality Assurance
PI	Principal Investigator
PII	Patient Identifiable Information
PR	Progress Report
PRO/PROs/PROMs	Patient-Reported Outcomes (Measures)
PROMIS	Patient-Reported Outcomes Measurement System
REDCap	Research Electronic Data Capture
SAMMC	San Antonio Military Medical Center
SC	Surgery Completed
SIV	Site Initiation Visit
SOW	Statement of Work
TCO	Twin Cities Orthopedics
TOH	The Ottawa Hospital
TSRH/ SRC	Scottish Rite for Children (previously known as: Texas Scottish Rite Hospital)
USPS	United States Postal Service
UTSW	UT Southwestern Medical Center
WUSTL	Washington University
T8	Minimum 8-year follow-up time point

1. **INTRODUCTION:** FAI is a condition of the hip characterized by abnormalities of the acetabular rim (hip socket) and the femoral head/neck (hip ball) region. With hip motion the femoral head and neck "bump" the acetabular rim and over time, this repetitive contact injures the hip joint, causes pain and leads to secondary osteoarthritis (OA). This disorder commonly affects military personnel and young active individuals in the general population, but also affects middle-aged and elderly patients as the disease progresses and OA develops. In fact, FAI is thought to be the most common cause of hip OA. FAI can restrict military personnel function during active duty, cause long-term disability, and increase the risk for hip OA and total hip replacement in our active duty, veteran and general populations. This condition is currently the focus of intense interest directed at surgical treatment to relieve pain, enhance function and delay or prevent OA. Despite the increase in diagnosis and enthusiasm for surgery, there is a major need to improve FAI treatments. To develop improved FAI treatments, this study will identify predictors of FAI surgery outcomes. Young patients with symptomatic, pre-arthritic FAI are being studied. This patient population is most commonly between 14 and 40 years of age, is highly active and has hip pain and limitations due to FAI. Recent research has shown that 87 percent of active military personnel with hip symptoms have FAI. Our study is being performed by the *Academic Network of Conservational Hip Outcomes Research* (ANCHOR) study group, to include two patient cohorts; FAI-1: This first cohort had surgical treatment of FAI between 2008 and 2012 and has been followed at a minimum 8 years. The analysis of this established ANCHOR cohort will have rapid impact on FAI treatment; FAI-2: This second (new) cohort is characterized by novel imaging techniques, standardized arthroscopic procedures and contemporary outcome measures. It is providing novel clinical evidence to optimize future surgical treatments. The findings from this second cohort will be introduced to the scientific and orthopaedic communities two to four years after study initiation. Given the major disease burden of FAI spanning pre-arthritic disease in young active duty members to endstage disease in veterans and the general population, there is an urgent need to focus on improved FAI treatments. This study will provide novel findings to improve the clinical outcomes of FAI surgery, optimize soldier return to duty, and minimize lifelong FAI disease progression in our career military, veterans and the general population.

2. **KEYWORDS:**

   Answer: Please Refer to *Abbreviations: Table of Key Words Within the Report* on page 4.

3. **ACCOMPLISHMENTS:**

   What were the major goals of the project?
   What was accomplished under these goals?

Answer:

- **Specific Aim 1:** Determine the predictors of mid-term PROs and treatment failures in an established prospective longitudinal cohort of FAI surgeries (ANCHOR FAI-1 cohort).
- **Specific Aim 2:** Determine the impact of three-dimensional femoral and acetabular morphology on PROs at short-term FU in a novel prospective longitudinal cohort of arthroscopic FAI surgery (ANCHOR FAI-2 cohort).
- **Specific Aim 3:** Determine if the new Patient-Reported Outcome Measurement Information System (PROMIS) correlates with legacy PROs in patients undergoing FAI surgery.

Specific Aim 1, 2, and 3 Accomplishments: Please refer to SOW Table below for specific details

Revised SOW Referenced in Formal Award/Contract: Section 10.ii **Project Performance Information**		
Major Task 1: FAI-1 cohort follow-up	**Timeline (in Months)**	**Year 2 PR Completion Status |15 Performance Sites**
Subtask 1: *Prepare Regulatory Documents, Research Protocol & Negotiate Contracts/Subawards with DoD & All Participating Centers*		
Negotiate DoD Contract & Site Sub-Award Agreements	1-3	FE subaward with U of Wisconsin took place on 7/15/2021
Milestone Achieved: Contracts & All Sub-Award Agreements fully executed	3	Milestone Achieved: FE subawards completed at all 15 sites
Finalize study protocol/assent & consent docs	1-3	Completed at all 15 performance sites
Coordinate with **ALL** Performance Sites for: A. Submission of protocol and consent documents; B. IRB Review and Approval	1-3	Complete. Local, IRB approval granted to each performance sites See table below for specifics.
Coordinate with Sites for Military IRB review (ORP/HRPO)	1-3	Complete: USAMRDC HRPO ORP approval granted to all 15 performance sites. See table below for specifics.
Milestone Achieved: IRB Approval granted at each participating site (ANCHOR FAI-1 and ANCHOR FAI-2)	3	**Milestone Achieved: Full Local and DoD HRPO Approval**

Performance Site	Local IRB	USAMRDC HRPO ORP
1. WUSTL	Approved	Approved
2. Beaumont	Approved	Approved
3. Boca Care	Approved	Approved
4. BCH	Approved	Approved
5. CHEO & 6. TOH (combined REB)	Approved	Approved
7. CHU de Quebec	Approved	Approved
8. Mayo Clinic	Approved	Approved
9. SAMMC	Approved	Approved
10. TSRH	Approved	Approved
11. TCO	Approved	Approved
12. U of Colorado	Approved	Approved
13. U of Iowa	Approved	Approved
14. U of Michigan	Approved	Approved
15. U of Wisconsin	Approved	Approved

Submit amendments, adverse events and protocol deviations as needed	As Needed	Since submission of our YR1 PR, no additional performance site consent alterations, or adverse events *directly related to study procedures*, have been reported. Protocol deviations, in the form of PRO non-completion at our various study time points, is tracked by DCC's robust weekly report generation.
Coordinate with Sites for annual IRB report for continuing review (from all sites)	Annually	For sites not operating under the *2018 Common Rule*, annual IRB approval (local and USAMRDC HRPO ORP) is an ongoing process.
Milestone Ongoing: Continuing Review, local IRB approval granted at <u>each</u> participating site	Annually	Milestone Ongoing: For sites not operating under the 2018 Common Rule, annual IRB approval is an ongoing process
Subtask 2: *ANCHOR FAI-1 cohort clinical FU (minimum 8-yr FU PRO data)*		
Determination of patients with active 7-10 yr. clinical f/u	1-3	Milestone Complete: Minimum 8-year FU eligibility determined by WUSTL and per site reports provided to Site PI/Coordinator in YR 1
Identification of patients reaching endpoints	1-3	In process: Sites continue collection of T8 FU PRO data while identifying subjects reaching study endpoints. See table below.

<table>
<tr><th>Major Task 1: FAI-1 cohort FU (cont.)</th><th>Timeline (in Months)</th><th>Year 2 PR Completion Status |15 Performance Sites</th></tr>
<tr><td rowspan="10">Milestone Achieved: List of eligible ANCHOR FAI-1 patients developed and disseminated to each site</td><td rowspan="10">3</td><td>
Milestone In Process:
ANCHOR FAI-1 Cohort: T8 Follow Up As of 9/30/2021
<table>
<tr><th>Performance Site</th><th>Total Hips</th><th># of Hips Reaching an End Point</th><th>% Reaching End Point</th></tr>
<tr><td>1. WUSTL</td><td>357</td><td>29</td><td>8%</td></tr>
<tr><td>2. Beaumont</td><td>155</td><td>9</td><td>6%</td></tr>
<tr><td>3. BCH</td><td>35</td><td>1</td><td>3%</td></tr>
<tr><td>4. Colorado</td><td>32</td><td>1</td><td>3%</td></tr>
<tr><td>5. Mayo Clinic</td><td>41</td><td>9</td><td>22%</td></tr>
<tr><td>6. TSRH</td><td>33</td><td>0</td><td>0%</td></tr>
<tr><td>7. TCO</td><td>57</td><td>0</td><td>0%</td></tr>
<tr><td>8. Ottawa</td><td>50</td><td>11</td><td>22%</td></tr>
<tr><td>Total</td><td>760</td><td>60</td><td>8%</td></tr>
</table>
</td></tr>
<tr><td colspan="2">Subtask 3: Central site FU (if treating site unable to track patient)</td></tr>
<tr><td>Phone contact</td><td>4-24</td><td rowspan="3">Performance sites continue to track/re-contact their ANCHOR FAI-1 participants for possible: 1. Enrollment in DoD through consent “sharing” of T8 FU PRO data, and 2. Re-consenting to allow WUSTL to become centralized FU site.</td></tr>
<tr><td>Mail and email contact</td><td>4-24</td></tr>
<tr><td>Advanced patient search strategies</td><td>4-24</td></tr>
<tr><td rowspan="2">Milestone Achieved: Eligible, locatable, & willing ANCHOR FAI-1 patients complete T8 FU</td><td rowspan="2">24</td><td>Milestone In process: <u>Impact of COVID-19 on ANCHOR FAI-1 enrollment</u>: Widespread economic challenges experienced have impacted the completion of this milestone by month 24. Research staff layoffs, furloughs, job eliminations, and/or salary reductions have decreased staff hours and/or increased Coordinator turnover rates at many sites. For current enrollment, See table below for specifics.</td></tr>
<tr><td>
ANCHOR FAI-1 Cohort Enrollment as of 9/30/21
<table>
<tr><th>Performance Site</th><th># of Hips (<u>minus endpoints</u>)</th><th># of Hips Being Shared with DoD (% of total at each site)</th><th># of Remaining, Eligible Participants</th></tr>
<tr><td>1. WUSTL</td><td>328</td><td>194 (59%)</td><td>134</td></tr>
<tr><td>2. Beaumont</td><td>146</td><td>19 (13%)</td><td>127</td></tr>
<tr><td>3. BCH</td><td>34</td><td>16 (47%)</td><td>18</td></tr>
<tr><td>4. Colorado</td><td>31</td><td>6 (19%)</td><td>25</td></tr>
<tr><td>5. Mayo Clinic</td><td>32</td><td>1 (3%)</td><td>31</td></tr>
<tr><td>6. TRSH</td><td>33</td><td>6 (18%)</td><td>27</td></tr>
<tr><td>7. TCO</td><td>57</td><td>9 (16%)</td><td>48</td></tr>
<tr><td>8. Ottawa</td><td>39</td><td>11 (28%)</td><td>28</td></tr>
<tr><td>Total</td><td>700</td><td>262 (37%)</td><td>438</td></tr>
</table>
</td></tr>
<tr><td colspan="3">Major Task 2: FAI-1 Data Analysis</td></tr>
<tr><td>Data cleaning and quality checks</td><td>4-36</td><td>Ongoing Process: As additional T8 FU legacy PRO data is collected and entered into REDCap, quality control checks continue to support data cleaning procedures.</td></tr>
<tr><td>Univariate data analysis</td><td>36-42</td><td rowspan="3">These milestones represent efforts during Months 36-48 that have not yet begun. Accordingly, their discussion will be included in later, technical progress reports.</td></tr>
<tr><td>Multivariate data analysis</td><td>36-42</td></tr>
<tr><td>Milestone Achieved: Report Results of Data Analysis</td><td>42-48</td></tr>
</table>

Revised *Statement of Work* Referenced in Award/Contract: Section 10.ii Project Performance Information (cont.)		
Major Task 3: FAI-2 Study Planning & Coordination	**Timeline (in Months)**	**Year 2 PR Completion Status |15 Performance Sites**
Subtask 1: FAI-2 Study Plan Refinement and Completion		
Central Site imaging review protocols	1-3	Completed by WUSTL in YR1: Standardization of pre-op, intra and post-surgical imaging protocol & transfer processes; Final beta-testing of study's imaging software (Dyonics) employed to visualize pre-surgical low-dose CT images.
Surgeon & research coordinator standardization, education, & in-person pre-study meeting	1-3	Completed in YR1 (Nov. 2019): Initial Standardization & Education: Pre-study launch took place during in-person start-up meeting attended by Site PIs and Study Coordinators to help ensure shared understanding of project goals, site deliverables and efficient workflows.
Imaging Repository Testing at each site	1-3	Completed: Low dose test CTs (transferred from each site to WUSTL prior to launch approval) each determined to be Dyonics compatible.
Milestone Achieved: FAI-2 study plan & implementation process finalized	3	Milestone Achieved
Major Task 4: FAI-2 Study Enrollment	**Timeline (in Months)**	**Year 2 PR Completion Status |15 Performance Sites**
Active patient enrollment and FU	4-42	Prospective ANCHOR FAI-2 enrollment initiated at 13/15 sites: **1. WUSTL** – Launched Feb 2020 2. Beaumont – Launched August 2020 3. BCH – Launched September 2020 4. SAMMC – Launched September 2020 5. TSRH - Launched Sept. 2020 / Full launch Feb '21 6. U of Colorado – September 2020 7. U of Iowa – Launched August 2020 8. Mayo Clinic – Launched October 2020 9. Colorado – Launched February 2021 10. CHU de Quebec – Launched February 2021 11. TCO – Full Launch March 2021 12. CHEO | TOH – Launched August 2021 13. U of Wisconsin – Launched September 2021 14. To Be Launched After SIV: Boca Care Orthopedics 15. To Be Launched After SIV: U of Michigan
Data quality checks (ongoing)	4-42	In April 2021, Dr. Amber Salter accepted a faculty position at UT Southwestern Medical Center. To retain Dr. Salter's scientific guidance of DCC while continuing her expert direction of REDCap's design improvements, WUSTL fully executed a subaward with Dr. Salter/UTSW after prior approval was provided by our Grants Officer, Teresa Parker-Reeser and Grants Specialist, Jennifer Shankle. As defined within her SOW, Dr. Salter will continue to guide the scientific direction for the project's robust statistical planning, analysis, and coordination. Additionally, Dr. Salter will continue to: 1. Provide oversight of the study's established electronic database, REDCap, through on-going development, testing, and implementation of programming activities necessary to maximize the accuracy and completeness of the captured data. 2. Provide expert consultations with on-site WUSTL REDCap Data Manager, Tanner Thornton, regarding: • QA/QC activities through report generation and refinement (e.g., Random Data Audit Report, REDCap Summary Report; Automated SAS-based query system). 3. Assist PI and Site PIs with data, correlation, power, and subgroup

		stratification analysis; Statistical and strategic input in the writing and planning of manuscripts derived from this research project; Perform and/or supervise complex statistical analyses and create or provide input to statistical reports; Provide internal statistical review and technical guidance as requested by the PI and Site PIs; Perform analyses to support programmatic activities; Provide expertise in managing and/or analyzing large complex datasets. 4. Participate & provide expertise and guidance on the monthly Executive Committee and Data Management. Specific YR 2 data management and QC efforts completed include: **1. Ongoing QC | Data Management of REDCap:** The REDCap project is currently in production and real-time data continues to be entered at all launched sites. Implementation of specific QC measures include: **1A. Ongoing analysis of data accuracy and completeness**: REDCap has a number of built-in quality control features to help ensure accurate and complete data. The system keeps a log of who entered or changed all data, a feature that permits DCC to discuss -with the data enterer- any concerns regarding a particular data item. <u>Other QC measures include</u>: 1. Range checks that flag values outside a pre-defined acceptable range. 2. Accepting only a predefined set of values for categorical measures. 3. All data forms contain the identification number of the person who completed the form, facilitating easy access to the source if there are problems with a form. 4. Site Investigators & Coordinators visual checks of completed forms to confirm completeness and reasonableness after each form is filled out. **1B. Ongoing Data audits**: DCC conducts annual item-by-item random audits of 10% of data. Randomly selected forms will be requested by the DCC and every item on the requested forms will be reviewed for completeness and logical consistency. Clinic specific error rates will be recorded so we can identify any clinic that may be performing inadequately. Following each audit, a detailed report will be distributed to each participating ANCHOR site and to the Steering Committee. **1C**. **Ongoing Training and Certification of New Personnel:** 1. A central feature data QC is ensuring all new, performance site staff are collecting data in accordance with REDCap system requirements. With an increasing level of Coordinator turnover, standardized and ongoing training has been a key focus for DCC over the past year where DCC works closely with all existing and new study personnel to ensure training & certification to perform data entry and manage tasks. In addition, current DCC workflows continue to ensure that: • Site Investigators and coordinators have gained appropriate familiarity with MOP details; and relevant site personnel are comfortable with data entry and management procedures. To accomplish these goals, the following procedures are in place: 2. DCC staff participate in all SIVs to discuss date-entry details & standardization of data collection procedures. During each performance site ZOOM SIV call, DCC reviews the protocol and provides hands on experience with data collection procedures. 3. Following each SIV, DCC certifies new site staff on: Familiarity with REDCap; Required competencies and knowledge to use the "live" project for both data entry and collection of subject data. 4. User IDs are included on each electronic data form to facilitate data

		entry corrections and/or inappropriately missing data are detected by the DCC query system. 5. Using a DCC maintained list of certified personnel, they routinely confirm that only certified staff perform REDCap data processes. 6. REDCap data modifications tagged with timestamp & User ID. **1D. YR2 Newly Programmed Data Summary Reports:** As part of DCC's QA/QC responsibilities (and data summary and reporting requirements) they have developed a series of weekly reports shared with each Site Investigator and Coordinator to better focus workflow efficiencies in pre-op and follow-up data collection. <u>Specific Reports include the following:</u> 1. **Enrollment and Data Collection PR** 2. **Average Enrollments Per Month**: Uses Enrollment data for last three months (hard start at beginning of 1st month, hard stop at end of third month) to calculate recent enrollment rate. 3. **PROs Nearing End of 3M, 6M, 1YR Window:** Once patients are within 1 month of the surveys closing, and they have not completed data collection for the event, they are added to the appropriate "nearing out of window" list. 4. **PROs Out of 3M, 6M, 1YR Window** 5. **Enrollment Period Projections**: Based on most recent 3month average enrollment, projected total enrollment by month until end of study 6. **Projections By Month:** Projected enrollment applied per month 7. **Historical Monthly Enrollment:** Table of actual enrollment, months where no site enrolled patients are not included. 8. **Monthly Projections Chart:** Visualization of projected remaining enrollment based on most recent 3 month average. 9. **Quarterly Site Remuneration Report:** Using specific and required data points – and their completion dates, this report determines when a site should be reimbursed for each consented participant 10 **FAI-1 Per site Productivity**
Enrollment audit – Months into enrollment	8, 12, 16, 18	Please see Table below for current FAI-2 enrollment numbers.

ANCHOR DoD FAI-2: Enrollment and Data Collection Progress Report Through September 30, 2021

Site (Target Enrollment)	On Study	Pre-op Baseline Data	# Completed Surgeries	Surgical Day Data	Post-Op 3M Eligible	Post-Op 3M Data Collected	Post-Op 6M Eligible	Post-Op 6M Data Collected	Post-Op Y1 Eligible	Post-Op Y1 Collected
Beaumont	0	0	0	0	0	0	0	0	0	0
Boca (30)	0	0	0	0	0	0	0	0	0	0
BCH (80)	40	39	37	37	28	21 (75%)	23	12 (52%)	0	0
Quebec (30)	2	0	0	0	0	0	0	0	0	0
Mayo (100)	68	63	67	66	49	35 (71%)	31	12 (39%)	0	0
TOH (15)	2	2	2	2	0	0	0	0	0	0
CHEO (15)	5	3	4	3	0	0	0	0	0	0
SAMMC (30)	17	17	17	17	11	7 (64%)	7	2 (29%)	0	0
TSRH (30)	10	10	8	8	8	7 (88%)	8	7 (88%)	1	1 (100%)
TCO (100)	20	18	14	13	3	1 (33%)	0	0	0	0
Colorado (30)	7	4	5	5	5	4 (80%)	3	1 (33%)	0	0

ANCHOR DoD FAI-2: Enrollment and Data Collection Progress Report Through September 30, 2021										
Site (Target Enrollment)	**On Study**	**Pre-op Baseline Data**	**# Completed Surgeries**	**Surgical Day Data**	**Post-Op 3M Eligible**	**Post-Op 3M Data Collected**	**Post-Op 6M Eligible**	**Post-Op 6M Data Collected**	**Post-Op Y1 Eligible**	**Post-Op Y1 Collected**
Iowa (100)	78	75	71	60	59	53 (90%)	52	41 (79%)	8	6 (75%)
Michigan (65)	0	0	0	0	0	0	0	0	0	0
WUSTL (125)	73	68	62	56	57	42 (74%)	50	35 (70%)	20	12 (60%)
Wisconsin (50)	2	1	0	0	0	0	0	0	0	0
Total (800)	**324**	**300**	**287**	**267**	**220**	**170 (77%)**	**174**	**110 (63%)**	**29**	**19 (66%)**

Milestone Achieved: Report initial, per site FAI-2 Enrollment	18	In process: As stated earlier in this report, prospective ANCHOR FAI-2 enrollment has successfully initiated at 13/15 performance sites (the final two (2) sites are only awaiting the completion of respective SIVs (BocaCare Orthopedics and the University. of Michigan). Ongoing Enrollment and Impact of COVID-19: (1) The emergence of this novel coronavirus, and its infection resurgence through the delta variant, has significantly impacted orthopedic surgery practice and in-person clinic visits at all performance sites. For many regions in the United States and Canada, the initial impact to clinical research came between March and May-June 2020 when all elective surgical procedures and in-person clinic visits were completely halted. The effects of the economic impact (e.g., staff layoffs, furloughs, job eliminations, salary reductions, staff turnover) continues to have an economic and staff impact at several sites due to reduced procedural volumes; (2) At the inception of the pandemic, enrolling sites rapidly deployed workflow modifications to enable verbal, virtual and/or REDCap-enabled consenting, clinic prep, and virtual (telemedicine) follow-up monitoring to minimize participant/staff risk to COVID-19 infection and to minimize disruptions based on diversion of healthcare resources; (3) While surgery plan management has continued to adapt in order to respond more effectively to resurgent infection rates, nonetheless, elective surgeries have continued to be reduced and/or postponed at several performance site where infection rates have surged in their geographic regions. In order to better elucidate COVID-19's impact on each performance site since submission of our YR1 PR, please see the following table and section for details: *COVID-19/Delta Variant Impact on Operating Room and/or In-Person Clinic Capacity & Action-Plans to Resolve the delays in recruitment/enrollment caused by the pandemic* on pages 16-18.
Major Task 5: FAI-2 cohort baseline & follow-up data	**Timeline (in Months)**	**Year 2 Completion Status | 15 Performance Sites**
Subtask 1: ANCHOR site clinical Follow Up		
Phone contact	4-42	REDCap Automated Survey Invitation Function – 3M, 6M, 1YR, 2YR PRO collection): When a specific study window is ready to open, an automated PRO survey invitation is sent to each participant's master email address. Then, a *survey reminder* is sent to the participant every 5 days if s/he does not complete the PROs in a specific amount of time. At present, 5 reminders are delivered every 5 days. This automated REDCAp survey invitation process continues throughout the course of each subject's longitudinal participation. In addition, if a participant fails to fully complete their PROs before a study window is about to close, a Coordinator will contact the subject directly and request timely completion of the unfinished PROs. The effectiveness of this process has significantly improved with DCC's automation of weekly progress reports produced every Monday morning.
Mail and email contact	4-42	

		Specifically, the *PROs Nearing End of 3M, PROs Nearing End of 6M, and PROs Nearing End of 1YR Window* reports list the site-specific participants who have not completed their PROs and are nearing the end of a specific time point window. WUSTL disseminates these weekly reports to all performance Site PIs/Coordinators in order to focus their efforts to the exact participants who need additional follow-up in order to facilitate PRO completion.
Subtask 2: Central site Follow Up		
Phone contact	4-42	To date, no subjects at any of our performance sites have required WUSTL central site FU/advance search strategies to re-locate and/or re-contact. WUSTL remains ready to assist each performance site with this task, if activated.
Mail and email contact	4-42	
Advanced patient search strategies	4-42	
Milestone Achieved: If activated to assist participating site with centralized FU, report clinical outcome metrics assessed at postoperative time points	4-42	To date, no subjects at any of our performance sites have required WUSTL central site FU/advance search strategies to re-locate and/or re-contact. WUSTL remains ready to assist each performance site with this task, if activated.
Radiographic & CT transfer to central site (WU)	4-42	Per Participant, Per Site: Study required pre-op/post-op radiographic, CT, and intraoperative fluoroscopy assessments continue their successful transfer to WUSTL. Per each site's SOW, pre-op and intra-op imaging data is transferred to WUSTL BOX (a cloud-based storage system that meets higher education security and regulatory requirements) within 10 days of surgery completion.
Radiographic and CT analysis for all site data	4-42	Ongoing Process of Analysis: Per study deliverable, all newly transferred preoperative low-dose CTs are reviewed at WUSTL in order to ensure timely FAI hip impingement evaluation. Dyonics, a software application developed specifically for CT orthopedic analysis of the Hip and Pelvis, is employed for this evaluation. At the end of each month, WUSTL provides each Site PI and Coordinator their monthly "imaging report" defining all transferred/missing images per enrolled subject.
Milestone Achieved: Report Results of CT transfer and analysis (by sites)	20	Ongoing: This milestone represents continuous, ongoing, and time-sensitive study procedures relating to image transfers and QC analysis where work efforts continue in accordance with site deliverables included in each site's SOW. Please refer to two (2) imaging tables below.

Preoperative/Intraoperative Imaging Report Through September 30, 2021

Site Name	Cases Enrolled	Surgery Completed (SC)	N = % of *Surgery Complete* Images received			
			X-Rays Rec'd	Low Dose CT Rec'd	Hip Scope Rec'd	Fluoro Rec'd
Colorado	6	5	5	5	5	5
Boston	40	40	35	33	33	35
Mayo Clinic	67	66	66	66	65	65
Iowa	78	71	69	69	69	69
SAMMC	18	17	12	12	17	10
TSRH	10	8	10	10	8	8
TWO	20	15	18	16	13	13
WUSTL	73	62	73	62	61	61
Quebec	3	2	2	2	0	2
CHEO	6	5	5	5	4	4
TOH	3	2	2	2	2	0
Wisconsin	2	0	0	0	0	0
Total	**326**	**293**	**297 (n =101%)**	**282 (n =96%)**	**277 (95%)**	**272 (93%)**

Overall Preoperative CT Protocol Compliance Report Through September 30, 2021						
Site Name	**Cases Enrolled**	**Surgery Completed**	**CT Complete**	**Protocol Complaint n (%)**	**Protocol Non-Compliant or Not Performed Prior to Surgery n (%)**	**CT Not Centralized, Reviewed, or Not Yet Ordered (n)**
Colorado	6	5	5	5 (100)	0 (0)	1
Boston	40	40	33	33 (83)	1 (2) - ND	6
Mayo Clinic	67	66	66	62 (94)	4 (6) - PNC	1
Iowa	78	71	69	68 (96)	1 (1) - PNC	9
SAMMC	18	17	12	12 (71)	0 (0)	6
TSRH	10	8	10	9 (90)	1 (10) - PNC	0
TWO	20	15	16	14 (88)	1 (6) – ND | 1 (6) - PNC	3
WUSTL	73	62	62	60 (97)	2 (3) - PNC	11
CHU de Quebec	3	2	2	2 (100)	0	1
CHEO	6	5	5	5 (100)	0	1
TOH	3	2	2	2 (100)	0	1
Wisconsin	2	0	0	0	0	2
Total	**326**	**293**	**282**	**272 (96)**	**8 PNC (3) | 2 ND (1)**	**42**

Major Task 6: FAI-2 Data Analysis	**Timeline (in Months)**	**Year 2 Completion Status | 15 Performance Sites**
Data cleaning and quality checks	42-48	These milestones represent efforts that have not begun. Accordingly, their discussion will be included in later, technical progress reports.
Univariate data analysis	42-48	
Multivariate data analysis	42-48	
Milestone Achieved: Report Results of Data Analysis	42-48	These milestones represent efforts that have not begun. Accordingly, their discussion will be included in later, technical progress reports.

Major Task 7: Data Analysis of PROMIS vs. Legacy PROs	**Timeline (in Months)**	**Year 2 Completion Status | 15 Performance Sites**
Data cleaning and quality checks	7-42	As stated above, COVID-19 and its delta variant have had a significant impact on orthopedic surgery practice and in-person clinic visits resulting in a slower rate of enrollment than planned within the funded application. Once full enrollment is achieved, this new cohort will be the source for Specific Aim 3 investigations focused on PROMIS. Ongoing Process: As additional legacy PRO and PROMIS data are to REDCap entered, QC checks assist with data cleaning procedures.
Correlation analysis for PROMIS subdomains vs legacy PROs	30-48	These milestones represent efforts that have not begun. Accordingly, their discussion will be included in later, technical progress reports
Subgroup stratification analysis	30-48	
Milestone Achieved: Report Results of Correlation & Subgroup Stratification Analysis	30-48	This milestone represents efforts that have not begun. Accordingly, its discussion will be included in later, technical progress reports.
Data reporting; Manuscript preparation	30-48	This milestone represents efforts that have not begun. Accordingly, its discussion will be included in later, technical progress reports
Milestone Achieved: Report Manuscript Preparation Results	24-48	This milestone represents efforts that have not begun. Accordingly, its discussion will be included in later, technical progress reports.

Other, Ongoing Achievements since our last quarterly PR (Y2 Q3):

- **Site Initiation Visits (SIV):** To help ensure that all Site Investigators and Research staff are fully aware of their responsibilities with the study protocol and documentation, electronic data capture platform (REDCap), correct Image transfer procedures, and all study and administrative deliverables, WUSTL hosts an SIV ZOOM call with each performance site *prior to site launch and enrollment of their first participant*. Since last year's annual report, we have completed the following SIVs:
    - SIV with new TRSH Site Coordinator (Part 1: 7/30/2021 and Part 2: 9/23/2021)
    - SIV with University of Wisconsin (8/16/2021 with their full activation and launch approval on 9/21/2021)
    - SIV with new U of Colorado Coordinator (Part 1: 8/19/21 and Part 2: 9/8/2021)
- **Monthly Meetings:** WUSTL continues to organize and host the following ZOOM study meetings:
    - DoD Executive Steering Committee: The 1st Thursday of every month
    - DoD Data Management: The 1st Thursday of every month
    - DoD Study-Wide Coordinator: The 3rd Friday of every month

  For each of the three (3) monthly DoD meetings, WUSTL: (1) Drafts and distributes agendas prior to call, (2) Writes and distributes all meeting minutes, and (3) hosts each ZOOM audio/video recording on WUSTL BOX for viewing by all Site PIs and Coordinators.
- Fully Executed Subaward with Dr. Amber Salter/UT Southwestern Medical School (8/10/2021) following approval by Jennifer Shankle and Teresa Parker-Reece on 7/30/2021.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Answer: Nothing to Report at this time

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Answer: Nothing to Report at this time

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Answer: By the end of YR3 Q1 (our next reporting period), we plan to:

- Complete SIV and launch of BocaCare Orthopedics
- Complete SIV and launch of University of Michigan
- Intensify follow- up efforts to enroll ANCHOR FAI-1 participants at sites with this retrospective cohort of patients

- Increase enrollment of ANCHOR FAI-2 cohort at all launched sites. Continue ongoing, monthly Executive Committee Meetings to strategize ways to accelerate recruitment and maximize enrollment
- Expand QC procedures (data cleaning and quality checks)
- Advance PRO data collection from: 1. Newly enrolled participants; 2. Established participants reaching follow-up study time points
- Continue ongoing IRB Continuing Review approvals at each performance site

4. **IMPACT:**

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

Answer: Nothing to Report at this time

What was the impact on other disciplines?

Answer: Nothing to Report at this time

What was the impact on technology transfer?

Answer: Nothing to Report at this time

What was the impact on society beyond science and technology?

Answer: Nothing to Report at this time

5. **CHANGES/PROBLEMS:**

Answer: As noted in our ***YR2 Q2 report***, we have added a new performance site to our study's organizational structure; University of Wisconsin [Andrea Spiker, MD Site PI]. By accessing Dr. Spiker's clinic and elective surgical capacity, we are able to leverage her resources to expand patient screening and enrollment.

On 3/9/2021, Dr. Prem Yadav (Scientific Officer) and Jennifer Shankle (Grants Officer) provided prior approval for WUSTL to engage the University of Wisconsin as a performance site/subrecipient.

Benefit to the Project: The addition of the University of Wisconsin will help to enhance patient recruitment and improve the representative sample of enrolled patients.

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

Answer: No changes in objectives or scope have occurred since our YR 1 PR.

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

Answer: Please see table below for specific *COVID-19/Delta Variant Impact on Operating Room and/or In-Person Clinic Capacity* during YR2 at each of our launched, enrolling performance centers.

YR2 COVID-19/Delta Variant Impact on Operating Room and/or In-Person Clinic Capacity	
BCH	Enrolling surgeons are still operating under reduced COVID schedules where only 3-4 OR days are available (per month) instead of 6-8 pre-COVID.
CHEO **TOH**	The COVID-19 pandemic has put a strain on medical resources, especially in the province of Ontario, Canada. **At CHEO:** Between March 2020 and the end of 2020, there were no hip arthroscopy surgeries being performed due to operating room (OR) closures. Since the start of 2021, they have resumed more "normal" volumes and are effectively playing catch-up now. There were minimal impacts from Ontario's 3rd wave, but the 4th wave driven by the Delta Variant have led to OR cancellations in August and September 2021 due primarily to OR staffing issues. While Ontario remains in the midst of high pressure, and threats/risks of cancellations, CHEO is still currently running at 100%. **At TOH:** Between March 2020 and the end of 2020, there were very low volumes of surgeries being completed. In January 2021 through to early April 2021 hip arthroscopy surgeries resumed at a relatively "normal" volume. The 3rd wave of COVID greatly impacted the surgery volume at TOH. As we continue into the 4th wave driven by the Delta variant, the surgery volumes have not yet recovered, and current pressures on the hospital continue to severely limit hip arthroscopy OR availability for Dr. Carsen.
Colorado	During the past year, Dr. Mayer has been able to have full in-clinic capacity. At their inpatient surgery sites, however, they have experienced three (3) shutdown periods which has limited capacity to perform inpatient surgery (including currently) and one period which affected outpatient surgery.
Iowa	During the past three months, Dr. Westermann experienced a 10% reduction in operating room time. And, he has also experienced a 10% reduction in operating room time last November- December 2020.
Mayo	Since the beginning of the year, their joint preservation practice has been slightly impacted by COVID-19. Recently, the enrolling surgeons have been asked to postpone certain cases (those requiring nursing home care after surgery) which usually does not apply to their elective hip preservation practice.
Quebec	Over the past 18 months, the COVID-19 pandemic has dramatically slowed Dr. Belzile's access to the operating room. Patient access (to first consultation) has also slowed creating a longer waitlist for surgery. As a result, he has delayed the recruitment of patients into the study in order to secure a guaranteed surgical date before enrollment. With the rise of the Delta variant, there is uncertainty surrounding the speed of recovery of operating room access.

YR2 COVID-19/Delta Variant Impact on Operating Room and/or In-Person Clinic Capacity	
SAMMC	At Dr. Schmitz's military site, located in the State of Texas, he has had to shut down all elective surgical cases from Mid Dec 2020 until March 2021. Then, starting on August 23, 2021 he again had to shut down all elective surgeries until just recently where he's been allowed to open up elective cases at only 50% capacity.
TCO	As of now there haven't been any additional adjustments to the clinic and surgery schedule due to the delta variant specifically. The new, full volume is approx. 80% of what pre-COVID full volumes were and it has been decided that Dr. Larson's schedule will remain at this new scheduling volume going forward. All COVID-19 protocols remain in place which includes: limiting staff attendance at in-person clinic, requiring masks in all patient areas, surgical patients required to have proof of vaccination or a negative COVID test within 72hrs of surgery.
TSRH	With the new wave of COVID positive (delta variant), in Texas, Dr. Ellis reports that they have not seen a significant effect on our acute injuries in terms of case volume or clinical referrals. This is in part because youth sports has maintained participation without restrictions. Chronic conditions, at least anecdotally, have declined in the last 6 months which include conditions such as hip impingement. For the last 3 weeks, our asymptomatic positive rate for surgical patients has reached close to 10%. This is always an evolving situation.
Wisconsin	There has been a noted and significant increase in the number of COVID-19 positive patients admitted to our hospital over the past 6 months coinciding with the emergence of the Delta variant. While their outpatient surgeries have thus far not been paused, Dr. Spiker has had to decrease our scheduled inpatient procedures to accommodate for the increased admissions due to COVID. In addition, they have seen an increase in the number of surgery cancellations as patients are falling ill with COVID in close proximity to their scheduled procedures, and due to the implemented COVID pre-surgical standards (including pre-operative COVID testing), they have not been able to fill those empty surgical spots on short notice. So overall, Dr. Spiker has noted a decrease in the number of outpatient hip procedures as well.
WUSTL	Due to a dramatic increase in COVID – delta variant infection rates in St. Louis City and County (within the first 6 months of 2021) the medical school reinstated many of its COVID-19 response polices: Indoor mask and physical distancing requirements coupled with staff restrictions within in-person clinic settings and medical office space. During late Spring/early Summer, elective surgeries were postponed for several weeks at several of our surgical centers in order to allow nurses and other vital staff/resources to be shifted to front-line COVID patient care units.

Answer: **Actions | Plans to Resolve the delays in recruitment/enrollment caused by the pandemic:**

- NEW: Increased use of technology to drive efficiency, transparency and maintain remote, team communication (WUSTL BOX, ZOOM; REDCap); Ongoing use of telemedicine visits
- Expansion of consent procedures to allow verbal consenting through multiple methods not reliant on traditional, in-person/in-clinic/face-to-face interactions with patients
- Realignment of block enrollment to support performance sites whose FAI surgical procedures support expansion from initially proposed targets
- NEW: Continue leveraging the ongoing use of efficient, technology-based communication systems to stay connected with Site PIs and all Coordinators (e.g., use of Tele- or video conferences; ongoing use of secure, cloud-based WUSTL storage platform where Site PIs and Coordinators may access study protocols and other important documents 24/7).
- NEW: Ongoing and timely use of email and ListServ messages to communicate and/or disseminate updates, answer project question, provide data reports, and share ideas between Coordinators, the DCC, and leadership.
- NEW: Leveraging the expanded use of Site PI telemedicine follow-up visits with their patient participants as a safe and remote means to gather follow-up study data
- Ongoing, monthly study-wide Coordinator ZOOM conference calls
- NEW: Continue to navigate COVID-19's impact on enrollment with agility and transparency (e.g. shifting between-individual enrollment targets to accommodate shut/slow-downs caused by infection rate increases.

- Performance sites with multiple, enrolling surgeons: Centralization of patient identification and screening procedures according to the project's inclusion and exclusion criteria
- Movement towards virtual data collection and away from paper forms: For the legacy PRO data collection of all ANCHOR FAI-1 participants, WUSTL has developed a REDCAp data entry program to be shared with all DoD performance sites who have ANCHOR FAI-1 participants to contact at their minimum 8-year time follow-up time point.
    - A separate REDCap payment database has been developed for the collection of PII (including SSN) in lieu of the paper, payment form that used to accompany the paper PRO packet sent to ANCHOR FAI-1 participants for completion and return via USPS.
    - WUSTL continues to maintain regular, on-going communication with all Site PIs and Study Personnel through weekly emails and monthly conference calls, which are video-recorded and securely saved, along with all study documents, to our secure cloud-based storage, BOX.
- Modify specific REDCap data entry points to accommodate telemedicine data collection at follow-up study timepoint/clinic visits with enrolled participants.

Changes that had a significant impact on expenditures

Answer: Nothing to Report at this time

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

Significant changes in use or care of human subjects

Answer: Nothing to Report at this time

Significant changes in use or care of vertebrate animals

Answer: Not Applicable

Significant changes in use of biohazards and/or select agents

Answer: Not Applicable

6. **PRODUCTS:**

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

Journal publications.

Answer: Nothing to Report at this time

Books or other non-periodical, one-time publications.

Answer: Nothing to Report at this time

Other publications, conference papers and presentations.

Answer: Nothing to Report at this time

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

  Answer: Nothing to Report at this time

- **Technologies or techniques**

  Answer: Nothing to Report at this time

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

  Answer: Nothing to Report at this time

- **Other Products**

Answer: Nothing to Report at this time

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Answer: *Please refer to table that starts on next page.*

DoD Quarterly Technical Progress Report for Period Covering: 7. Participant and Other Collaborating Organizations | What individuals have worked on the project?					
Performance Site	**Name**	**Project Role**	**Research Identifier ORCID ID**	**Nearest person month worked (see calculator worksheet)**	**Contribution to the project**
Washington University	John Clohisy	Project Director Principal Investigator	0000-0001-7040-616X	1.2 PM	Dr. Clohisy directs the Clinical Coordinating Center, the Executive Committee and is a significant contributor to the scientific development, execution and clinical conduct and integrity of the investigation. He is responsible for leading the project intellectually and logistically. Dr. Clohisy collaborates and work closely with the other investigators regarding the studies progress, identify problems, and seek and implement solutions.
	Jeffrey Nepple	Co-Investigator	0000-0002-7582-1415	0.6 PM	Dr. Nepple serves on the Executive Committee and is involved in all aspects of the project including patient enrollment, surgical treatment, study design, and study oversight. He collaborates and works closely with Dr. Clohisy and the other investigators regarding the studies progress, problem identification, and solutions implementation.
	Cecilia Pascual-Garrido	Collaborator	0000-0001-7487-4753	0.36 PM	Dr. Pascual-Garrido will be an enrolling surgeon and will be involved in all aspects of the studies at the clinical coordinating center including patient enrollment, data analysis and data reporting.
	Liz Yanik	Research Team Member	0000-0002-5835-0201	0.36 PM	Dr. Yanik serves on the Executive Committee participates in all activities of the executive and steering committees. She is involved in all statistical activities of the investigations and will be involved in all study design, data analysis and data reporting activities.
	Tanner Thornton	Research Team Member	NA	12.00 PM	Mr. Thornton serves as both a Data Analyst and REDCap Data Manager for the project. In this role, he closely works with Drs. Salter and Clohisy in the development of the data management plan (REDCap) and analysis of data.
	Caroline E. Drain	Research Team Member	NA	6.00 PM	Ms. Drain serves on the Executive Committee. She is a Clinical Research Specialist assisting with the management and oversight of all grant activities between WUSTL, the DoD, & each performance site. She answers site queries regarding patient enrollment, follow-up, tracking, data acquisition and interaction with the clinical coordinating center for all aspects of the studies.
	Zak Robben	Research Team Member	NA	6.00 PM	Mr. Robben serves on the Executive Committee and assists in management and oversight of the day-to-day operations of the project for the entire study. In addition, he supports the enrollment of patients for WUSTL and assists with the patient remunerations for all sites.
	Sean Akers	Research Team Member	NA	6.00 PM	Mr. Akers serves on the Executive Committee and manages all imaging collection efforts for the entire project. This includes, but is not limited to: creating image transfer and creation protocols that govern all performance sites; QA/QC images for archiving and analysis of all CT images, X-rays etc.
UTSW	Amber Salter	Associate Professor Section Head, Statistical Planning and Analysis	0000-0002-1088-110X	3.00PM	Dr. Salter serves on the Executive Committee and provides expert, scientific guidance to data management/data coordinating center and to Principle Investigator and Site PIs with: Data, correlation, power, and subgroup stratification analysis; Provide statistical and strategic input in the writing and planning of manuscripts derived from this research project; Perform and/or supervise complex statistical analyses and create or provide input to statistical reports; Provide internal statistical review and technical guidance as requested by the Principal Investigator and Site PIs. Dr. Salter is now a faculty member at the University of Texas Southwest where a subrecipient award mechanism allows her to continue to provide expert guidance to the project.

DoD Quarterly Technical Progress Report for Period Covering: 7. Participant and Other Collaborating Organizations | What individuals have worked on the project?					
Performance Site	**Name**	**Project Role**	**Research Identifier ORCID ID**	**Nearest person month worked (see calculator worksheet)**	**Contribution to the project**
The Ottawa Hospital Research Institute **Children's Hospital of Eastern Ontario (CHEO)**	Paul Beaule	Site PI/Collaborator	0000-0001-7667-9994	0.24 PM	Dr. Beaule' will lead the team at The Ottawa Hospital Research Institute as the nominated site PI. He is responsible for overseeing the trial at The Ottawa Hospital Research Institute and ensuring adequate resources are available to support the work.
	Sasha Carsen	Site PI/Collaborator	0000-0002-8180-9770	0.24 PM	Dr. Carsen will be a key enrolling surgeon at The Ottawa Hospital Research Institute/The Children's Hospital of Eastern Ontario.
	Cheryl Kreviazuk	Research Team Member	0000-0002-5778-6943	2.25PM	Ms. Kreviazuk is a Clinical Research Coordinator assisting with the ethics submission and study-start up locally at The Ottawa Hospital Research Institute. Once enrollment starts, she will support the local enrollment and data collection for participants.
	Holly Livock	Research Team Member	0000-0003-3171-4447	1.2 PM	Ms. Livock is a Clinical Research Coordinator assisting with the ethics submission and study-start up locally at The Ottawa Hospital Research Institute/Children's Hospital of Eastern Ontario. Once enrollment starts, she will support the local enrollment and data collection for participants.
	Patrick Sachsalber	Clinical Research Assistant	NA	1.2 PM	Mr. Sachsalber is a Clinical Research Assistant at the Children's Hospital of Eastern Ontario. Patrick assists with patient screening, consenting, and follow-up and data collection for FAI-2 at CHEO.
Mayo Clinic	Rafael Sierra	Site PI/Collaborator	0000-0002-8513-1477	0.24PM	Dr. Sierra is the Principal Investigator for Mayo Clinic's portion of the DoD and JP2 Grants. He will be an enrolling surgeon and will be involved in all aspects of the study for Mayo patients that includes enrollment, data analysis, and data reporting.
	Aaron Krych	Collaborator	0000-0003-3248-8007	0.12	Dr. Krych will be an enrolling surgeon and will be involved in all aspects of the study for Mayo patients that includes enrollment, data analysis, and data reporting.
	Bruce Levy	Collaborator	0000-0002-7694-1814	0.12	Dr. Levy will be an enrolling surgeon and will be involved in all aspects of the study for Mayo patients that includes enrollment, data analysis, and data reporting.
	Karina Gonzalez-Carta	Research Associate and Instructor of Medicine	0000-0003-2383-3868	0.06PM	Dr. Gonzalez Carta recently joined the Mayo team as their Research Associate. She will oversee staff and assist the enrolling surgeons with project management and oversight of patient enrollment at the Mayo Clinic.
	Riley Voll	Research Coordinator	NA	0.96PM	Mr. Voll is Mayo Clinic's new Research Coordinator assisting with patient screening, consenting, and follow-up and data collection for all enrollees.
University of Michigan	Asheesh Bedi	Site PI/Collaborator	0000-0001-8926-7139	0.12PM	Dr. Bedi is the Site PI and key enrolling surgeon at University of Michigan. He will be involved in all aspects of the studies including patient enrollment, data analysis and data reporting.
	Jaimee Gauthier	Research Team Member	NA	0.12PM	Mrs. Gauthier is a project manager for University of Michigan Orthopaedics. She will ensure that the MedSport program has the resources, personnel and support needed to effectively execute this protocol.

DoD Quarterly Technical Progress Report for Period Covering: 7. Participant and Other Collaborating Organizations | What individuals have worked on the project?					
Performance Site	**Name**	**Project Role**	**Research Identifier ORCID ID**	**Nearest person month worked (see calculator worksheet)**	**Contribution to the project**
Beaumont Hospital	Ira Zaltz	Site PI/Collaborator	0000-0003-4036-6149	.36 PM	Dr. Zaltz is the site PI and key enrolling surgeon. He will be involved in all aspects of the studies including patient enrollment, data analysis and data reporting.
	Lisa Motowski	Clinical Research Nurse Manager	NA	0.60PM	Ms. Motowski left the project in May 2021. Until May, she developed and implemented research protocols, prepared reports, developed timelines and budgets. Planned and monitored all activities related to research protocols to ensure the ethical conduct of research.
	Shalinee Mylvaganam	Research Team Member	NA	3.0PM	Ms. Mylvaganam is a Clinical Research Coordinator assisting with the study-start up and submission at William Beaumont Hospital. Once enrollment starts, she will support with enrollment, follow-up & data collection for Beaumont Hospital.
CHU Quebec	Etienne Belzile	Site PI/Collaborator	0000-0003-2837-981X	.24PM	Dr. Belzile will be an enrolling surgeon and will be involved in all aspects of the studies at the CHU de Quebec-University Laval site. He collaborates and work closely with Dr. Clohisy and with the other investigators regarding the studies progress, identify problems, and seek and implement solutions.
	Sylvie Turmel	Research Team Member	0000-0002-3200-356X	3.0PM	Ms. Turmel is a Clinical Research Specialist assisting with the ethics approval and project preparation at the local site. Once enrollment commences, she will support the enrollment of patients and data reporting for the CHU de Quebec.
Univ of Iowa	Robert Westermann	Site PI/Collaborator	0000-0002-5289-4689	0.6 PM	Dr Westermann is Site PI and a collaborator/ enrolling surgeon and will be involved in all aspects of the studies at his performance site including patient enrollment, data analysis and data reporting.
	John Gentile	Research Team Member	NA	1.8 PM	Mr. Gentile will be an enrolling Research team member involved in all aspects of the study at the University of Iowa including patient enrollment and data reporting.
SAMMC	Matthew Schmitz	Site PI/Collaborator	0000-0002-4156-5177	0.5 PM	Dr. Schmitz is involved in all aspects of the project including patient enrollment, surgical treatment, study design, and study oversight. He participates on the Executive Committee for Grant management. He is the site PI at SAMMC and enrolling surgeon.
	Liz Summerfield	Research Team Member	NA	0.05 PM	Mrs. Summerfield manages the Regulatory lifecycle of research study applications to ensure compliance with ICH, GCP and all other regulatory bodies. Coordinates and maintain the tracking and reviewing of regulatory submissions including annual reports, informed consent forms, protocol reviews & review for accuracy & completeness.
	Cornell Richardson	Administrative Assistant	NA	0.12PM	Mr. Richardson is assisting Dr. Schmitz with enrollment of patients and REDCAp data entry.
TCO	Christopher Larson	Site PI/Collaborator	0000-0002-9910-0145	0.6 PM	Dr. Larson is involved in all aspects of the project including patient enrollment, surgical treatment, and study oversight. He collaborates and works closely with Washington University Physician Investigators and with the other investigators regarding the studies progress.
	Kayla Seiffert	Research Team Member	NA	3.0 PM	Ms. Seiffert assists in management and oversight of the day-to-day operations of the project. Once enrollment commences, she will support the enrollment of patients.

DoD Quarterly Technical Progress Report for Period Covering: 7. Participant and Other Collaborating Organizations | What individuals have worked on the project?					
Performance Site	**Name**	**Project Role**	**Research Identifier ORCID ID**	**Nearest person month worked (see calculator worksheet)**	**Contribution to the project**
SCH (formally TSRH)	Henry Ellis	Site PI/Collaborator	0000-0001-5444-094X	.12 PM	Dr. Ellis is involved in all aspects of the project at Texas Scottish Rite including patient enrollment, surgical treatment, study implementation, and study oversight.
	Daniel Sucato	Collaborator	0000-0003-3352-5551	.06 PM	Dr. Sucato is involved in study implementation and is assisting with the retrospective arm of the study.
	David Podeszwa	Collaborator	0000-0002-2367-2657	.06 PM	Dr. Podeszwa is involved in study implementation and is assisting with the retrospective arm of the study.
	Savannah Cooper	Clinical Research Coordinator	NA	2.4 PM	Ms. Cooper assists in management and oversight of the day-to-day operations of the project (e.g. patient enrollment, study implementation, consenting).
	Lauren Osborne	Hip Research Coordinator	NA	2.4PM	Ms. Osborne assists in management and oversight of the day-to-day operations of the project (e.g. patient enrollment, study implementation, consenting).
	Hannah Worrall	Clinical Research Coordinator	NA	0.12PM	Ms. Osborne assists in management and oversight of the day-to-day operations of the project (e.g. patient enrollment, study implementation, consenting).
Boston Children's Hospital	Eduardo Novais	Collaborator	0000-0002-9187-3100	0.1 PM	Dr. Novais is an enrolling surgeon who is involved in all aspects of the project at Boston Children's Hospital including patient enrollment, surgical treatment, study implementation, and study oversight.
	Young-Jo Kim	Collaborator	0000-0002-0855-0168	0.6 PM	Dr. Kim is an enrolling surgeon who is involved in all aspects of the project at Boston Children's Hospital including patient enrollment, surgical treatment, study implementation, and study oversight.
	Yi-Meng Yen	Site PI/Collaborator	0000-0002-1306-4201	0.6 PM	Dr. Yen is Site PI, and an enrolling surgeon who is involved in all aspects of the project at Boston Children's Hospital including patient enrollment, surgical treatment, study implementation, and study oversight.
	Michael Millis	Collaborator	0000-0002-1380-5495	0.1 PM	Dr. Millis will work closely with his Boston colleagues to implement data collection. He will oversee the overall implementation of the study and focus efforts on the retrospective collection of their ANCHOR FAI-1 cohort.
	Lauren Hutchinson	Research Team Member	NA	1.2 PM	Mrs. Hutchinson is involved in study administration, implementation, management, and study oversight of all newly hired staff at BCH.
	Samantha Ferraro	Research Team Member	NA	6.0PM	Ms. Ferraro is involved with patient enrollment, data collection, data entry and imaging uploads, data cleaning.
	Madison Earle	Research Team Member	NA	6.0PM	Ms. Earle is involved with patient enrollment, data collection, data entry and imaging uploads, data cleaning.

DoD Quarterly Technical Progress Report for Period Covering: 7. Participant and Other Collaborating Organizations | What individuals have worked on the project?					
Performance Site	**Name**	**Project Role**	**Research Identifier ORCID ID**	**Nearest person month worked (see calculator worksheet)**	**Contribution to the project**
Boca Raton Regional Hospital	James Ross	Site PI/Collaborator	0000-0002-8465-8250	.12PM	Dr. Ross is the Site PI and enrolling surgeon who is involved in all aspects of the project at BocaCare Orthopedics including patient enrollment, surgical treatment, study implementation, and study oversight.
	Ileana Vargas	Research Team Member	NA	0.6	Ms. Vargas is the Regulatory Coordinator at Boca Raton Regional Hospital/Baptist Health South Florida (IRB of record for BocaCare Orthopedics). Ms. Vargas has prepared the DoD application for local submission. However, since the start of the COVID-19 pandemic in March 2020, their IRB has temporarily closed NEW application submissions for all non_COVID-19 applications.
Univ of Colorado Children's Hospital of Colorado	Stephanie Mayer	Site PI/Collaborator	0000-0002-9432-8191	.04 PM	Dr. Mayer is involved with all aspects of the research study at the University of Colorado and Children's Hospital Colorado from study implementation, oversight, enrollment, surgical treatment, and study follow-ups.
	Sierra Imoe	Clinical Research Assistant	NA	0.09 PM	Ms. Imoe assists in management and oversight of day-to-day operations of the project. She supports the enrollment of patients from Colorado.
U of Wisconsin	Andrea Spiker	Site PI/Collaborator	0000-0003-1243-9726	0.60PM	Dr. Spiker is involved in all aspects of the project including patient enrollment, surgical treatment, and study oversight. He collaborates and works closely with Washington University Physician Investigators and with the other investigators regarding the studies progress.
	Jennifer Wang	Regulatory Manager	NA	0.12PM	Ms. Wang is the Regulatory Manager at the University of Wisconsin – Madison. She will work closely with WUSTL of consent form development and all regulatory aspects of their DoD application for local IRB submission.
	Katie Schjei	Clinical Research Manager	NA	0.60PM	Ms. Schjei is consenting patients from Dr. Spiker's clinic. Her efforts will support the enrollment of patients and follow up with each so that PROs are completed.

Has there been a change in the active, other support of the PD/PI(s) or Senior/Key Personnel since the Last Reporting Period?

Answer: Nothing to Report at this time

What other organizations were involved as partners?

Answer: Nothing to Report at this time

8. **SPECIAL REPORTING REQUIREMENTS**

   COLLABORATIVE AWARDS:

   QUAD CHARTS:

   Answer: We have uploaded our updated QUAD chart to our eBRAPS submission page.

9. **APPENDICES:**

   Answer: Nothing to Report at this time