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 finding 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 Key Words (page 3)

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Abbreviations: Table of Keywords Within the Report as Added by WUSTL For Report	
ANCHOR	Academic Network of Conservational Hip Outcomes Research
CHEO	The Children's Hospital of Eastern Ontario
CT	Computerized Tomography
DCC	Data Coordinating Center (at WUSTL)
DoD	Department of Defense
FAI	Femoroacetabular impingement
FU	Follow-up
MOP	Manual of Operations
OA	Osteoarthritis
IRB/REB/HRPO	Institutional Review Board/Research Ethic Review Board/Human Research Protections Office
PII	Patient Identifiable Information
PRO/PROs	Patient-Reported Outcomes
PROMIS	Patient-Reported Outcomes Measurement System
REDCap	Research Electronic Data Capture
SAMMC	San Antonio Military Medical Center
SIV	Site Initiation Visit
SOW	Statement of Work
TOH	The Ottawa Hospital
TSRH	Texas Scottish Rite Hospital
USPS	United States Postal Service
WUSTL	Washington University

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, the proposed studies will identify predictors of FAI surgery outcomes. Young patients with symptomatic, pre-arthritic FAI will be 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 studies will be performed by the Academic Network of Conservational Hip Outcomes Research (ANCHOR) study group, and will include two patient cohorts. The first cohort had surgical treatment of FAI between 2008 and 20012 and will be followed at a minimum 8 years. The analysis of this established ANCHOR cohort will have rapid impact on FAI treatment, and we anticipate dissemination of our findings within two years of funding. The second cohort will be new and characterized by novel imaging techniques, standardized arthroscopic procedures and contemporary outcome measures. This second cohort will provide 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. The proposed studies 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:**

Please Refer to: *Abbreviations: Table of Key Words Within the Report* (page 4 above)

3. **ACCOMPLISHMENTS:**

What were the major goals of the project?

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 1 Accomplishments (please refer to **SOW** Table below for additional details)

  - Prepared Regulatory Documents, Research Protocol and Negotiate Contracts/Subawards with DoD and Performance Sites; Subaward Fully Executed at 13/14 Performance Sites
  - ANCHOR FAI-1 Cohort FU: Patient enrollment, disposition and FU initiated for the 8-year minimum dataset.

- **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 2 Accomplishments: (please refer to **SOW** Table below for additional details)

  - Major progress with FAI-2 study standardization of imaging processes and imaging study transfer to the coordinating site. Test CT scans sent by all 14 performance sites; Full software compatibility achieved by twelve (12) sites
  - Prospective study enrollment of the new FAI-2 cohort has initiated at WUSTL and several performance sites.

- **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 3 Accomplishments:

  - ANCHOR FAI-2 study enrollment has initiated. This will be the source for Specific Aim 3 investigations focused on PROMIS.

What was accomplished under these goals?

Answer Below:

Revised SOW Referenced in Formal Award/Contract: Section 10.ii Project Performance Information		
Major Task 1: FAI-1 cohort FU	**Timeline (in Months)**	**Year 1 Completion Status | 14 Performance Sites**
Subtask 1: Prepare Regulatory Documents, Research Protocol and Negotiate Contracts/Subawards with DoD & All Participating Centers		
Negotiate DoD Contract & Site Sub-Award Agreements	1-3	All performance site research contracts offices contacted
Milestone Achieved: Contracts & All Sub-Award Agreements fully executed	3	Subaward Fully Executed: 13/14 Performance Sites One Site Partially Executed, awaiting full: 1. CHU de Quebec
Finalize study protocol/assent & consent documents	1-3	WUSTL Coordinating Center (Nov 2019): Master protocol and consents developed by WUSTL, approved by local and distributed to all performance sites for use.
Coordinate with **ALL** Performance Sites for: A. Submission of protocol and consent documents; B. IRB Review and Approval	1-3	A. Local, Performance site IRB submissions of master protocol and related documents: 13/14 sites submitted One Site Awaiting Local IRB *Submission* 1. BocaCare Orthopedics B. Local Performance Site IRB Approvals: 11/14 sites Two Sites Awaiting Local IRB *Approval* 1. BocaCare Orthopedics 2. CHU de Quebec (provisionally approved) 3. University of Michigan C. Local IRB-Approved Performance site application submitted *to DoD HRPO*: 11/14 sites 1. ***See DoD HRPO Application Updates Table below**

*All Performance Sites: Local IRB | DoD HRPO Application Status		
Performance Site	**Local IRB/REB/HRPO Status**	**DoD HRPO Status**
1. WUSTL	Approved	Approved
2. Beaumont	Approved	Approved
3. Boca Care	COVID-19 restriction: No NEW HRPO projects may be submitted	Not Yet Submitted for Review
4. Boston Children's	Approved	Approved
5. CHEO (combined application with Ottawa) 6. Ottawa (combined application with CHEO)	Approved	Two Sites |One REB Application Submitted 8/31/2020: Review In Process
7. CHU de Quebec	Partially Approved; Awaiting FULL	Not Yet Submitted for Review
8. Mayo Clinic	Approved	Approved
9. SAMMC	Approved	Approved
10. Texas Scottish Rite Hospital	Approved	Approved
11. Twin Cities Orthopedics	Approved	Approved (prospective arm)
12. U of Colorado	Approved	Approved
13. U of Iowa	Approved	Approved
14. U of Michigan	Submitted 8/22/2020	Not Yet Submitted for Review

Major Task 1: FAI-1 cohort FU (cont.)	**Timeline (in Months)**	**Year 1 Completion Status | 14 Performance Sites**
Coordinate with Sites for Military IRB review (ORP/HRPO)	1-3	11/14 Sites submitted for DoD HRPO Approval **See DoD HRPO Application Updates Table above*
Milestone Achieved: IRB approval granted at each participating site (ANCHOR FAI-1 and ANCHOR FAI-2)	3	DoD HPRO grants initial approval to 9/14 performance sites. Two Sites (with one [1] combined REB Application) currently under DoD HRPO Review: 1. Ottawa 2. CHEO Three Other Sites Still Require DoD HRPO Review 1. BocaCare Orthopedics 2. CHU de Quebec 3. U of Michigan
Submit amendments, adverse events and protocol deviations as needed	As Needed	COVID-19 Consent Alterations From Local/DoD HRPO Approved Inital Procedures: The following sites received DoD HRPO approved to modify their approved, verbal consenting processes: 1. Washington University 2. Texas Scottish Rite Hospital 3. Twin Cities Orthopedics Please refer to p. 16 **(Q.5 CHANGES | PROBLEMS)** for further details regarding these submitted & approved modifications.
Coordinate with Sites for annual IRB report for continuing review (from all sites)	Annually	Ongoing, Annual Process with Performance Site Local IRBs
Milestone Achieved: Continuing Review, local IRB approval granted at each participating site	Annually	Ongoing, Annual Process with Performance Site Local IRBs

Revised *Statement of Work* Referenced in Award/Contract: Section 10.ii Project Performance Information (con't)

Major Task 1: FAI-1 cohort FU (cont.)	Timeline (in Months)	Year 1 Completion Status | 14 Performance Sites
Subtask 2: *ANCHOR FAI-1 cohort clinical FU*		
Determination of patients with active 7-10 yr. clinical f/u	1-3	WUSTL finalized full list of retrospective ANCHOR FAI-1 participants -meeting minimum 8-yr FU criteria- and distributed individual list of site participants to each performance site.
Identification of patients reaching endpoints	1-3	
Milestone Achieved: List of eligible ANCHOR FAI-1 patients developed	3	**ANCHOR FAI-1 Cohort: Minimum 8-yr Follow Up**

Performance Site	Total Cases	# of Cases Reaching End Point	% Reaching End Point
1. WUSTL	**357**	**18**	**5%**
2. Beaumont	155	9	6%
3. Boston Children's	35	1	3%
4. Colorado	32	1	3%
5. TSRH	33	0	0%
6. Mayo Clinic	41	3	7%
7. Twin Cities Orthopedics	57	0	0%
8. Ottawa	50	9	18%
Total	**760**	**41**	**5.4%**

Subtask 3: *Central site FU (if treating site unable to track patient)*		
Phone contact	4-24	Performance sites, with ANCHOR FAI-1 participants, continue to track their own participants for: 1. Possible enrollment in DoD through "sharing" of minimum 8-year PRO data, and 2. Re-consenting to allow WUSTL to become centralized FU center. When re-consented, WUSTL will be ready to assist with FU, if activated.
Mail and email contact	4-24	
Advanced patient search strategies	4-24	
Milestone Achieved: Eligible, locatable, & willing ANCHOR FAI-1 patients complete T8 FU	24	100% Achieved: Min T8 Eligibility determination In process: Locatability and contact with ANCHOR FAI-1 subjects. Per site specifics are listed below:

ANCHOR FAI-1 Cohort: DoD Enrollment to Date

Performance Site	# of Cases to Call (minus endpoints)	# Enrolled in DoD to Date	
		Patients	Hips
1. WUSTL	339	61	72
2. Beaumont	146		
3. Boston	34		
4. Colorado	31		
5. TSRH	33		
6. Mayo Clinic	38		
7. Twin Cities	57	Awaiting DoD HPRO Approval to enroll this arm of project	
8. Ottawa	50		

Major Task 2: FAI-1 Data Analysis		
Data cleaning and quality checks	4-36	Ongoing Process: As new ANCHOR FAI-1 legacy PRO data is entered into REDCap, quality checks assist with ongoing data cleaning procedures.
Univariate data analysis	36-42	These milestones represent efforts during Months 36-48 that have not begun. Accordingly, their discussion will be included in later, technical progress reports.
Multivariate data analysis	36-42	
Milestone Achieved: Report Results of Data Analysis	42-48	

<table>
<tr><th colspan="3">Revised Statement of Work Referenced in Award/Contract: Section 10.ii Project Performance Information (con't)</th></tr>
<tr><th>Major Task 3: FAI-2 study planning & Coordination</th><th>Timeline (in Months)</th><th>Year 1 Completion Status | 14 Performance Sites</th></tr>
<tr><td colspan="3">Subtask 1: FAI-2 Study Plan Refinement and Completion</td></tr>
<tr><td>Central Site imaging review protocols</td><td>1-3</td><td>Completed: In addition to standardizing the intra and post-surgical imaging protocol & transfer processes, WUSTL completed their testing of the study's imaging software (Dyonics) employed to visualize pre-surgical low-dose CT images. This software will allow the study to visualize FAI and identify the degree of hip impingement based on the participant's unique morphology.</td></tr>
<tr><td>Surgeon & research coordinator standardization, education, & in-person pre-study meeting</td><td>1-3</td><td>Initial Standardization & Education Completed (Nov 2019): Pre-launch, in-person start-up meeting attended by Site PIs and Study Coordinators and held in conjunction with Annual ANCHOR meeting. Pre-launch discussions, moderated by WUSTL Investigators and Research Team Members, included:
1. Specific Aims Review; 2. Recruitment Plans For: Retrospective ANCHOR FAI-1 and Prospective ANCHOR FAI-2 participants; 3. Study Site Enrollment Targets; 4. Inclusion/Exclusion Criteria; 5. Study Visit Windows; 6. Study PRO Form completion (surgeon and participant); 7. Study & Central Imaging Protocols; 8. Strategic Timeline Specifics (per grant month); 9. Consenting Overview including role of WUSTL as Centralized FU center; 10. Statement of Work Deliverables for Performance Sites & Coordinating Center; 11. Participant reimbursement; 12. Data collection, Management, & Monitoring; 12. Question & Answer Sessions.</td></tr>
<tr><td>Imaging repository testing at each site</td><td>1-3</td><td>
<table>
<tr><th colspan="2">Image Repository Testing & Compatibility Standardization</th></tr>
<tr><th>Site</th><th>Results | Notes</th></tr>
<tr><td>1. WUSTL</td><td>Compatible</td></tr>
<tr><td>2. Beaumont</td><td>Compatible</td></tr>
<tr><td>3. BocaCare</td><td>Compatible</td></tr>
<tr><td>4. Boston Children's</td><td>Compatible</td></tr>
<tr><td>5. CHEO</td><td>Only minor adjustments needed</td></tr>
<tr><td>6. CHU de Quebec</td><td>Compatible</td></tr>
<tr><td>7. Mayo Clinic</td><td>Compatible</td></tr>
<tr><td>8. Ottawa</td><td>Compatible</td></tr>
<tr><td>9. SAMMC</td><td>Compatible</td></tr>
<tr><td>10. TSRH</td><td>Compatible</td></tr>
<tr><td>11. Twin Cities</td><td>Compatible</td></tr>
<tr><td>12. U of Colorado</td><td>Compatible</td></tr>
<tr><td>13. U of Iowa</td><td>Compatible</td></tr>
<tr><td>14. U of Michigan</td><td>Compatible</td></tr>
</table>
</td></tr>
<tr><td>Milestone Achieved: FAI-2 study plan & implementation process finalized</td><td>3</td><td>100% Achieved: FAI-2 Study Plan & Implementation Process Finalized
93% Achieved: CT Testing and Compatibility per Dyonics Program</td></tr>
<tr><th>Major Task 4: FAI-2 Study Enrollment</th><th>Timeline (in Months)</th><th>Year 1 Completion Status | 14 Performance Sites</th></tr>
<tr><td>Active patient enrollment and FU</td><td>4-42</td><td>Prospective study enrollment of the new ANCHOR FAI-2 cohort has initiated at the following performance sites:
1. WUSTL – Launched Feb 2020
2. Beaumont – Launched August 2020
3. Boston Children's – Launched September 2020
4. SAMMC – Launched September 2020
5. TSRH – Launched September 2020
6. U of Colorado – September 2020
7. U of Iowa – Launched August 2020
8. Mayo Clinic – Launched in October 2020</td></tr>
</table>

Revised *Statement of Work* Referenced in Award/Contract: Section 10.ii Project Performance Information (con't)		
Major Task 4: FAI-2 Study Enrollment (con't)	**Timeline (in Months)**	**Year 1 Completion Status | 14 Performance Sites**
Data quality checks (ongoing)	4-42	Dr. Amber Salter, in the Division of Biostatistics at WUSTL, is directing the DCC's quality control activities and Director of our Data Management Center. She has a broad view of data management that includes the development, testing, and implementation of a data management system in conjunction with all activities that are necessary to maximize the accuracy and completeness of the data that are captured by that system. Specific data management and quality control efforts during YR1 include: **1. Quality control | Data Management of REDCap:** As the standard data entry and management tool for the Division of Biostatistics, the study's REDCap project is currently in production for real-time data entry of all enrolled ANCHOR FAI-2 subjects. The development of the study's REDCap MOP, provided to all launched performance sites, serves as both a reference and guidance document for accurate data-entry. Implementation of specific quality control measures include: **1A. Ensuring data accuracy and completeness**: REDCap has a number of built-in quality control features to help ensure accurate and complete data. Other quality control measures involve actions taken at the DCC, features of the data forms that help facilitate high quality data, and steps take as data forms are completed. The system keeps a log of who entered or changed all data, a feature that permits us to discuss with the data enterer any concerns we have about a particular data item. Other quality control measures include: • Range checks flag values that are outside a predefined acceptable range. • Accept only a predefined set of values for categorical measures. • 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. • Investigators and coordinators will do visual checks of completed forms to confirm completeness and reasonableness after each form is filled out. **1B. Data audits**: The DCC will conduct 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**. **Training and certifying personnel:** A central feature of the quality control of data is ensuring performance site staff are collecting data in accordance with the REDCap system requirements. DCC is working closely with all study teams to ensure their training & certification to perform data entry and manage tasks. In addition, current DCC workflows ensure that (1) investigators and coordinators have gained appropriate familiarity with MOP details; (2) all evaluations are carried out by certified individuals; and (3) relevant personnel are comfortable with data entry and management procedures. To accomplish these goals, the following procedures have been carried out: • DCC staff participate in all Site Initiation Visits to discuss date-entry details & standardization of data collection procedures. During each performance site ZOOM SIV call

		DCC reviews the protocol, MOP, and provides hands on experience with data collection procedures. • Following the SIV, DCC certifies all performance site staff on data entry, familiarity with the system (by entering data from at least two sets of completed forms) and required competencies and knowledge to use the "live" data entry system for collection of subject data. • ID numbers, of staff performing date collection, is included on data forms to facilitate corrections when errors or inappropriately missing data are detected by the DCC query system • Using a DCC maintained list of certified personnel, the Center routinely confirms that only certified staff perform REDCap data processes. • Data modifications - within REDCap - are tagged with a timestamp and information on the user who made the modification. • When new personnel are hired during the study, individual clinics will be empowered to certify the new person as a frequently necessary alternative to less efficient centralized efforts. **1D. Summary Reports:** The DCC will regularly prepare summary reports. Using automated features built into our SAS database, these reports will consider such issues as (1) recruitment rates for the prospective component of the study, (2) the proportion of screened subjects who are eligible, (3) missing form and data rates, and (4) adverse event rates.
Major Task 4: FAI-2 Study Enrollment	**Timeline (in Months)**	**Year 1 Completion Status | 14 Performance Sites**
Enrollment audit – 4 months into enrollment	8	To reduce the risk of COVID-19 transmission across the United States and Canada, and based on recommendations from Center for Medicare & Medicaid Services, the U.S. Surgeon General, the American College of Surgeons (ACS) and/or the medical institute governing each performance site, the following guidance policies were and/or continue to be followed: 1. Cancellation of all elective surgeries and non-essential medical, surgical procedures from March - May 2020. Due to a resurgence of cases in Texas, elective surgeries were cancelled for two additional months at SAMMC (end of June-end of August). 2. Clinical research categorized as *non-essential* (e.g., research that does not explicitly improve or protect the lives of its participants, by providing treatment or otherwise providing medical care) and clinical research staff working on research *unrelated* to COVID-19, have not been permitted to conduct face-to-face research activities with patients/subjects, including enrollment and data collection. This face-to-face ban continues until the present at WUSTL and most of our performance sites. • Because WUSTL launched the project (in February 2020) before pandemic restrictions took effect, our already-enrolled patients were able to complete their Pre-op/Baseline & 3-month/6-month/Post-op PRO questionnaire packets via link sent from REDCap to their preferred email address. 4. Please see page 19, section ***Actions | Plans to Resolve the delays in recruitment/enrollment caused by the pandemic*** for further details surrounding study plans to increase enrollment shutdowns and delays due to COVID-19 * *Please refer to table below for current FAI-2 enrollment numbers.*

ANCHOR DoD FAI-2: Current Enrollment and Data Collection Progress Report								
Site	**Participants Enrolled**		**Collected Research Data at Defined Study Time Points**					
	# Consented	**Pre-Op Baseline Data**	**# completed surgery**	**Surgical Day Data**	**Post-op 3M Eligible**	**Post-op 3M Data Collected**	**Post-op 6M Eligible**	**Post-op 6M Data Collected**
WUSTL	23	22	20	19	16	13	7	6
Iowa	14	14	11	10	0	0	0	0
TSRH	2	2	1	1	0	0	0	0
Beaumont	0	0	0	0	0	0	0	0
Colorado	1	0	0	0	0	0	0	0
SAMMC	0	0	0	0	0	0	0	0
BCH	4	4	4	4	0	0	0	0
Mayo	0	0	0	0	0	0	0	0
Totals	44	42	36	34	16	13	7	6

Enrollment audit – 8 months into enrollment	12	* *Please refer to table above for current enrollment numbers*.
Major Task 4: FAI-2 Study Enrollment	**Timeline (in Months)**	**Year 1 Completion Status | 14 Performance Sites**
Enrollment audit – 12 months into enrollment	16	These 16 & 18-milestones represent efforts that have not begun. Accordingly, its discussion will be included in later, technical progress reports.
Enrollment audit – 14 months into enrollment	18	
Milestone Achieved: Report initial, per site FAI-2 Enrollment	18	This 18-month milestone represents efforts that have not begun. Accordingly, its discussion will be included in later, technical progress reports.
Major Task 5: FAI-2 cohort baseline & FU data	**Timeline (in Months)**	**Year 1 Completion Status | 14 Performance Sites**
Subtask 1: ANCHOR site clinical Follow Up		
Phone contact	4-42	When a specific study window is about to open, each consented subject receives a REDCap survey link to their preferred email address delivers an electronic version of all PROs for completion at that specific time point. This automated REDCAp survey queue process continues throughout the course of each subject's longitudinal participation. In addition, if a study window is about to expire before a participant's full completion of PROs, a research team member contacts the subject directly and requests timely completion of unfinished PROs.
Mail and email contact	4-42	
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 or 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 launched and enrolling performance sites have required WUSTL central site FU or 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 at Enrolling Sites: All study required preop/post-op radiographic, CT, and intraoperative fluoroscopy assessments continue successful transference/upload to WUSTL. Within 10 days post-surgery, performance sites transfer all pre-op and intraop imaging data to WUSTL BOX, a cloud-based storage system that meets higher education security and regulatory requirements.

Revised *Statement of Work* Referenced in Award/Contract: Section 10.ii Project Performance Information (con't)		
Radiographic and CT analysis for all site data	4-42	For each scheduled imaging event, the radiographs are uploaded to WUSTL and reviewed for QC. Orthopedic Studio, a plugin developed specifically for Hip and Pelvis X-rays, is used within Macintosh based OsiriX software. The X-ray measurements and assessment data are stored in WUSTL's REDCap and BOX platforms dedicated to the DoD study. According to established SOW site deliverable time lines, all preoperative low-dose CTs are reviewed at WUSTL upon receipt 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 within a Windows based operating system. The CT analysis data are stored in the REDCap project dedicated to the DoD study.
Milestone Achieved: Report Results of CT transfer and analysis (by sites)	20	Per Participant | 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 SOW.
Major Task 6: FAI-2 Data Analysis	**Timeline (in Months)**	**Year 1 Completion Status | 14 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 1 Completion Status | 14 Performance Sites**
Data cleaning and quality checks	7-42	Ongoing Process: As new legacy PRO and PROMIS data are entered into REDCap, quality checks assist with ongoing 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:

- **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), 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*. To date, we have completed the following SIVs:
    - Beaumont –Completed 8/27/2020
    - Boston Children's Hospital – Completed on 8/7/2020
    - CHEO – Completed 9/22/2020
    - Mayo Clinic – Completed 9/14/2020
    - Ottawa – Completed 9/22/2020
    - SAMMC – Completed on 7/24/2020
    - TSRH- Completed on 7/31/2020

- Twin Cities Orthopedics – Completed 9/25/2020
- University of Iowa – Completed on 7/14/2020
- University of Colorado/Colorado Children's Hospital – Completed on 8/3/2020

- **Monthly Meetings:** WUSTL organizes and hosts the following:
  - 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 all DoD Monthly Meeting: Prior to each meeting, WUSTL drafts and distributes agendas. Following each meeting, WUSTL writes and distributes all minutes (and ZOOM call audio/video recordings) to all committee and/or team members.

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

Answer: Nothing to Report

How were the results disseminated to communities of interest?

Answer: Nothing to Report at this time

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

Answer:

December 2020: By the end of YR2 Q1 (our next reporting period), we plan to have the following goals accomplished:

- Initial, New Project submission to local IRB: BocaCare Orthopedics
- Initial DoD HRPO submission of local IRB-approved applications: 1. CHU de Quebec; 2. University of Michigan
- Submission of all French-translated study documents, certified translation accuracy letter, and Internation al Research Study Information Form required for completion of DoD HRPOs initial application review of 1. CHEO, and 2. The Ottawa Hospital

- Submission of all local, IRB-approved documents allowing inclusion of the ANCHOR FAI-1 retrospective cohort into project. These requested documents will allow DoD HRPO to complete their initial review of this arm of the project: 1. Twin Cities Orthopedics
- Completion of SIVs with: 1. BocaCare Orthopedics; 2. CHU de Quebec; 3. University of Michigan
- Launch of retrospective ANCHOR FAI-1 enrollment at centers with this established cohort
- Continued ANCHOR FAI-1 enrollment at WUSTL
- Launch and/or continued enrollment of ANCHOR FAI-2 cohort at all DoD HRPO approved sites
- Continued ANCHOR FAI-2 enrollment at approved and launched performance sites
- Ongoing communication with Site PIs and Coordinators through monthly ZOOM conference calls
- Ongoing, monthly Executive Committee Meetings with leadership
- Ongoing Quality Control procedures (data cleaning and quality checks) through the DCC
- Ongoing PRO data collection from: 1. Newly enrolled participants; 2. Established participants reaching follow-up study time points
- Ongoing Enrollment Auditing at each performance site.
- Ongoing IRB Continuing Review audits 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:

A. As noted in our ***YR1 Q3 report***, we added a new performance site to our study's organizational structure: The Children's Hospital of Eastern Ontario [CHEO]:

In the course of working with *The Ottawa Hospita*l to execute their sub-agreement, it became known that the affiliation mechanism between their adult and children's hospitals required separate IRB applications and sub-agreements; one for TOH (adult) and one for CHEO. Because enrolled participants will come from both hospitals, we requested formal DoD approval to add Children's Hospital of Eastern Ontario (CHEO) as a performance site.

On 5/1/2020, Jennifer Shankle (Grants Officer) provided prior approval for WUSM to engage the Children's Hospital of Eastern Ontario as a performance site/subrecipient.

Benefit to the Project: The addition of the CHEO site will help to optimize patient enrollment to meet site targets for Dr. Sasha Carsen, as well as improve the representative sample of patients of all eligible ages enrolled by Dr. Carsen across the TOH and CHEO sites.

B. In the most recent Executive Committee Meeting, members voted to remove UH Cleveland (Dr. Michael Salata, Site PI) as a study site based on failure to progress towards IRB approval and inadequate communication on the part of the Site PI on ability to fulfill the needs of the study. The study's enrollment adjustments created by this removal are in line with the block-enrollment guidelines in the grant.

C: In YR1 Q2, we added the University of Colorado as a full performance site. Their addition will help to ensure generalizability across moderate to high volume arthroscopists without weighing the cohort towards high volume surgeons. The addition of this site did not require any re-budgeting of funds since overall enrollment is competitive. The study's enrollment adjustments created by this addition are in line with the block-enrollment guidelines in the grant. Per Dr. Prem Yadav's request, this information was emailed to him on 3/9/2020 by Caroline E. Drain.

Changes in approach and reasons for change

Answer:

Because of COVID-19's required curtailment to elective surgeries and in-clinic, face-to-face clinical research activities, several performance sites re-submitted approved study applications to their local IRB to secure additional approval to alter consent procedures to include verbal consenting through REDCap e-consenting, telehealth methods and/or telephone & web-conferencing platforms like ZOOM. Once local

IRB approval was received, each application was re-submitted for additional DoD HRPO approval so that study presentations, to in-clinic patient populations, could take place via remote interactions.

Consent Alteration Submissions: Approved by Local IRB, followed by DoD HRPO:

1. WUSTL – Submitted 6-10-2020 | Approved 7-7-2020
2. Texas Scottish Rite Hospital – Submitted 8-3-2020 | Approved 8-7-2020
3. Twin Cities Orthopedics – Submitted on 8-28-2020 | Approved on 9-9-2020

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

Answer:

As noted in our ***YR1 Q2 report,*** WUSTL formally submitted the following communication to usarmy.detrick.medcom-usamrmc.mbx.COVID-19@mail.mil and various DoD and WUSTL representatives discussing the study-wide COVID-19 postponement of all non-essential surgeries and in-person/face-to-face patient office visits at all performance sites for a period of three months.

> "As the COVID-19 pandemic continues to unfold across the U.S., the leadership at Washington University School of Medicine has taken deliberate steps to curtail its spread. Specifically, our Executive Vice Chancellor for Medical Affairs and Dean, as well as Institutional Deans from each of our performance sites, has made the difficult decision to ramp down all research activities at the medical school including the following:
>
> **COVID-19 Guidance for Clinical and Human Subjects Researchers - Non-Essential Clinical and Human Subjects Research Visits:**
>
> - Research visits that cannot be performed remotely and are not essential to a participant's health and/or well-being should be postponed until further notice.
> - To reduce the risk of COVID-19 transmission and promote social distancing, effective immediately or as soon as possible, all clinical research visits that can be postponed or performed remotely (e.g. by phone, HIPAA-compliant version of Zoom, local lab or other means) should be conducted this way whenever possible. Research that does not explicitly improve or protect the lives of its participants, by providing treatment or otherwise providing medical care, should be regarded as non-essential. For non-essential studies requiring direct participant contact, which do not provide a benefit to the participant, new participant recruitment and in-person research visits must be postponed, unless they can be done remotely, effective March 23 until April 30.
> - For clinical research not related to COVID-19, research staff (PRAs, Sr PRAs, research coordinators) are not permitted to conduct face-to-face research activities with patients/subjects, including enrollment, data collection, and sample collection.
> - Please be assured that we will continue to work with our performance sites to move their IRB applications through to local approval so that each approval packet may be formally submitted to USAMRDC Human Research Protection Office (HRPO) for review and approval.
>
> We will continue to share additional information as updates become available".

To further elucidate COVID-19's impact/restrictions on study-wide enrollment and recruitment, the following table was produced and provided in our YR1 Q2 progress report. The report has been updated to reflect current restrictions:

See "**Per Performance Site Research Activity Directives In Response to COVID-19" on next page**

Per Performance Site Research Activity Directives In Response to COVID-19 Institutional Research Related Responses	
Beaumont Hospital	For first three months of pandemic, all non-essential surgeries were suspended. The following restrictions are still in place: Clinical research staff presence restricted to activities that do not require direct subject contact. Subject contact transitioned to phone, email, etc. whenever possible to limit direct contact. Other study related activities must be done remotely.
BocaCare Orthopedics	All restrictions are still in place: Per hospital directive, site may continue preparing relevant regulatory documentation (i.e. finalize ICF revisions, sponsor approval of site revisions, preparing IRB submission documents) but IRB will not review/approve NEW non-essential research projects until further notice.
Boston Children's Hospital	For first three months of pandemic, all non-essential surgeries were suspended. The following restrictions are still in place: Suspension of all in-person research activities. Clinical Research operations will remain remote. iPads and other touch devices are currently banned from use in all clinics.
CHU de Quebec	For first three months of pandemic, all non-essential surgeries were suspended. The following restrictions are still in place: No recruitment of new subjects via face-to-face interactions; Follow up by phone-only.
Mayo Clinic	For first three months of pandemic, all non-essential surgeries were suspended. The following restrictions are still in place: Restrictions to visitors and non-essential clinical visits. Non-essential research staff working remotely for the time being.
Ottawa Hospital **CHEO**	All elective surgeries cancelled for the three months of the pandemic and elective patient follow-ups are either being cancelled, rescheduled or switched to an e-consult. The following restrictions are still in place: Clinical research staff presence restricted to activities that do not require direct subject contact. Subject contact transitioned to phone, email, etc. whenever possible to limit direct contact. Other study related activities must be done remotely.
SAMMC	After March 23, all non-essential, in-person human subjects research, community-based and clinical research was suspended until further notice. Non-essential recruitment and enrollment of new subjects temporarily halted. Due to a resurgence of COVID-19 cases in Texas, all elective surgeries at SAMMC were again suspended from the end of June through the end of August.
TSRH	Complete suspension of face-to-face enrollment/follow-up for all observational studies, which continues through present.
Twin Cities	For first three months of pandemic, all non-essential surgeries were suspended. Not allowed to conduct direct subject contact, work related activities until further notice. All staff furloughed from March – Beginning of July.
University of Colorado	For first three months of pandemic, all non-essential surgeries were suspended. For clinical research *not related to COVID-19*, research staff are not permitted to conduct face-to-face research activities with patients/subjects, including enrollment, data collection, and sample collection. For clinical research with UCHealth employed research teams, face-to-face research activities with patient/subjects including enrollment, data collection, and sample collection will need to be evaluated & approved on a project-by-project basis with the Regional Director of Research Administration & CMO. Same restrictions are currently in place for clinical research staff and face-to-face patient interactions
University of Iowa	For first three months of pandemic, all non-essential surgeries were suspended. From March – May 2020: Ramping down all on-campus research. Restrictions to visitors and non-essential clinical visits. Non-essential research staff must work remotely. Currently, clinical research staff are back in clinic and allowed to see patients.
University of Michigan	For first three months of pandemic, all non-essential surgeries were suspended. The following restrictions are still in place: Study procedures involving in-person contact with participants or participant travel for research purposes must be paused, effective immediately, if they do not meet the above criteria. Research interactions with participants such as telephone contact, remote monitoring or remote data collection may continue.
WUSM	For first three months of pandemic, all non-essential surgeries were suspended. March through Present: Ramping down of all on-campus, in person, non-essential research where face-to-face interactions take place. Restrictions to visitors and non-essential clinical visits. Non-essential research staff still working remotely. All non-essential clinical research that can be performed remotely should continue remotely. iPads were re-introduced to Orthopedic clinics in October 2020.

Answer: As noted in our ***YR1 Q3 report:***

For WUSTL's orthopaedic department, our ongoing and documented reductions were emblematic of trends experienced at each performance site and included significant patient/surgical reduction (through June):

- **Clinic Volume**: At 90% of pre-COVID average daily patient visits. Significant workflow modifications are still required including: Socially distanced waiting rooms (or empty waiting room), telehealth visits, staffing changes, etc.
- **Clinical research staff,** working on non-emergency research projects, are still prohibited from attending in-person clinics and waiting rooms.
- **Operating Room Volume:** While orthopaedic operating rooms are increasing their capacity, completed case numbers were not back to normal.

Answer: **Ongoing slowdowns and shutdowns in *YR1 Q4***

- SAMMC required resuspension of all elective surgeries due to resurgence of COVID-19 in their Texas County. Resumption of surgeries did not take place until August 31, 2020.
- BocaCare Orthopedics/Boca Raton Regional Hospital/Baptist Health South Florida: Due to COVID-19 restrictions, their IRB continues to restrict NEW PROJECT start-up activities including submission for initial IRB Review and Site Initiation Visit scheduling.

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

- 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
- 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.

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?

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.
	Amber Salter	Research Team Member	0000-0002-1088-110X	3.00 PM	Dr. Salter serves on the Executive Committee and is the Director of the Data Coordinating Center (DCC) for the entire project. In addition, Dr. Salter directs all data management, quality control activities, and database manual creation. Dr. Salter, in consultation with Dr. Clohisy, will design and manage all statistical activities. She will lead 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.

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. Beaulé 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	NA	1.2 PM	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	NA	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.
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.
	Elizabeth Smith	Regulatory Coordinator	NA	1.2PM	Ms. Smith 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 and review for accuracy and completeness.
	Jonathan Furuseth	Research Team Member	NA	0.06PM	Mr. Furuseth recently joined the research team and is a Clinical Research Coordinator who assists in management and oversight of the project and supports the enrollment of patients for Mayo Clinic.
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.
	Bethany Ruffino	Research Team Member	NA	0.06PM	Mrs. Ruffino is a certified clinical research professional she will directly manage and oversee the entire lifecycle of this study. This will include the IRB applications process, patient enrollment, data collection and reporting.

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	Leads project teams to develop and implement research protocols, and prepare reports, develops timelines and budgets. Plans and monitors all activities related to research protocols to ensure the ethical conduct of research. Effectively collaborate with external partners, regulators, and diverse internal stakeholders and collaborators.
	Shalinee Mylvaganam	Research Team Member	NA	2.4PM	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	1.8PM	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.
Twin Cities Orthopedics	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.
	Becky Stone	Research Team Member	0000-0001-9614-5383	1.2 PM	Mrs. Stone assists in management and oversight of the day-to-day operations of the project. Once enrollment commences, she will support Dr Larson and Kayla with enrollment of patients for Twin Cities Orthopedics.
	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 for Twin Cities Orthopedics.

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.
	Kenny Halloran	Research Team Member	NA	.6 PM	Mr. Halloran is involved with operational and regulatory management at TSRH as well was patient enrollment and oversight
	Sean Hines	Research Team Member	NA	2.4 PM	Mr. Hines is a research associate who is responsible for patient contract and recruitment for the FAI-1 follow up study
	Savannah Cooper	Research Team Member	NA	2.4 PM	Ms. Cooper is involved with patient enrollment, study implementation, and oversight.
Boston Children's Hospital	Eduardo Novais	Collaborator	0000-0002-9187-3100	0.1 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.
	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. Kim 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 Dr. Clohisy in the development of the protocol, data collection forms, and data collection implementation. He will also oversee the overall implementation of the study at his site.
	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.
Boca Raton Regional Hospital	James Ross	Site PI/Collaborator		.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	.60 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.
	Whitney Hovater	Research Team Member	0000-0002-7345-3970	1.20 PM	Ms. Hovater assists in management and oversight of the day-to-day operations of the project. Once enrollment commences, she will support the enrollment of patients from Colorado

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