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

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Identification of Predictors for Clinical Outcomes in Femoroacetabular Impingement Surgery

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Not needed per Dr. Yadav in 2020

**12. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**
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 |
|---|---|---|---|---|---|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | USAMRDC |
| Unclassified | Unclassified | Unclassified | Unclassified | 27 | 19b. TELEPHONE NUMBER *(include area code)* |

## TABLE OF CONTENTS

| **Table 1. Abbreviations and Keywords Within the Report (Added by WUSTL For Report)** | |
|---|---|
| ANCHOR | Academic Network of Conservational Hip Outcomes Research |
| CHEO | The Children's Hospital of Eastern Ontario |
| CR | Continuing Review |
| CT | Computerized Tomography |
| DCC | Data Coordinating Center/Data Management Center (located at WUSTL) |
| DoD | Department of Defense |
| FAI | Femoroacetabular impingement |
| FERPA | Family Educational Rights and Privacy Act |
| FU | Follow-up |
| HIPPA | Health Insurance Portability and Accountability Act |
| ICD | Informed Consent Document(s) |
| IRB/REB/HRPO | Institutional Review Board/Research Ethic Review Board/Human Research Protections Office |
| MOP | Manual of Operations |
| PR | Progress Report |
| PRO/PROs/PROMs | Patient-Reported Outcomes |
| PROMIS | Patient-Reported Outcomes Measurement Information System |
| QA/QC | Quality Assurance Quality Control |
| REDCap | Research Electronic Data Capture |
| REDCap FR | Research Electronic Data Capture, French Version |
| SAMMC | San Antonio Military Medical Center |
| SIV | Site Initiation Visit |
| SOW | Statement of Work |
| T8 | Minimum 8-year time point |
| TOH | The Ottawa Hospital |
| TSRH | Texas Scottish Rite Hospital |
| UM | University of Michigan |
| UW | University of Wisconsin - Madison |
| USAMRDC ORP HRPO | U.S. Army Medical Research and Development Command Office of Research Protections Human Research Protection Office |
| WUSTL | Washington University \| Washington University School of Medicine |

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 for YR 3 Annual:** 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 for YR 3 Annual:**
   - **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.

<table>
<tr><th colspan="3">Revised SOW Referenced in Formal Award/Contract: Section 10.ii <u>Project Performance Information</u></th></tr>
<tr><th>Major Task 1: FAI-1 cohort follow-up</th><th>Timeline (in Months)</th><th>Year 3 PR Completion Status</th></tr>
<tr><td colspan="3">Subtask 1: Prepare Regulatory Documents, Research Protocol & Negotiate Contracts/Subawards with DoD & All Participating Centers</td></tr>
<tr><td>Negotiate DoD Contract & Site Sub-Award Agreements</td><td>1-3</td><td>Milestone achieved with all performance centers</td></tr>
<tr><td>Milestone Achieved: Contracts & All Sub-Award Agreements fully executed</td><td>3</td><td>Milestone Achieved: FE subawards completed at all 15 sites</td></tr>
<tr><td>Finalize study protocol/assent & consent docs</td><td>1-3</td><td>Completed at all 15 performance sites</td></tr>
<tr><td>Coordinate with ALL Performance Sites for:<br>A. Submission of protocol and consent documents; B. IRB Review & Approval</td><td>1-3</td><td>Complete. Local, IRB approval granted to each performance sites<br>See Table 2 below for specifics.</td></tr>
<tr><td>Coordinate with Sites for Military IRB review (ORP/HRPO)</td><td>1-3</td><td>Complete: USAMRDC HRPO ORP approval granted to all 15 performance sites. See Table 2 below for specifics.</td></tr>
<tr><td>Milestone Achieved: IRB Approval granted at each participating site (ANCHOR FAI-1 and ANCHOR FAI-2)</td><td>3</td><td>
Table 2. Milestone Achieved: Full Local and DoD HRPO Approval
<table>
<tr><th>Performance Site</th><th>Local IRB</th><th>USAMRDC HRPO ORP</th></tr>
<tr><td>1. WUSTL</td><td>Approved</td><td>Approved</td></tr>
<tr><td>2. Beaumont</td><td>Approved</td><td>Approved</td></tr>
<tr><td>3. Boca Care</td><td>Approved</td><td>Approved</td></tr>
<tr><td>4. BCH</td><td>Approved</td><td>Approved</td></tr>
<tr><td>5. CHEO &<br>6. TOH (combined REB)</td><td>Approved</td><td>Approved</td></tr>
<tr><td>7. CHU de Quebec</td><td>Approved</td><td>Approved</td></tr>
<tr><td>8. Mayo Clinic</td><td>Approved</td><td>Approved</td></tr>
<tr><td>9. SAMMC</td><td>Approved</td><td>Approved</td></tr>
<tr><td>10. TSRH</td><td>Approved</td><td>Approved</td></tr>
<tr><td>11. TCO</td><td>Approved</td><td>Approved</td></tr>
<tr><td>12. U of Colorado</td><td>Approved</td><td>Approved</td></tr>
<tr><td>13. U of Iowa</td><td>Approved</td><td>Approved</td></tr>
<tr><td>14. U of Michigan</td><td>Approved</td><td>Approved</td></tr>
<tr><td>15. U of Wisconsin</td><td>Approved</td><td>Approved</td></tr>
</table>
</td></tr>
<tr><td>Submit amendments, adverse events and protocol deviations as needed</td><td>As Needed</td><td>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.</td></tr>
<tr><td>Coordinate with Sites for annual IRB report for CR review (from all sites)</td><td>Annually</td><td>For sites not operating under the 2018 Common Rule, annual CR approval (local and USAMRDC HRPO ORP) is ongoing.</td></tr>
<tr><td>Milestone Ongoing: Continuing Review, local IRB approval granted at <u>each</u> participating site</td><td>Annually</td><td>Milestone Ongoing: For sites not operating under the 2018 Common Rule, annual CR approval (local and USAMRDC HRPO ORP) is ongoing.</td></tr>
<tr><td colspan="3">Subtask 2: ANCHOR FAI-1 cohort clinical FU (minimum 8-yr FU PRO data)</td></tr>
<tr><td>Determination of patients with active 7-10 yr. clinical f/u</td><td>1-3</td><td>Milestone Achieved: Minimum T8 FU eligibility was determined by WUSTL, per site reports, provided in YR 1 to Site PI/Coordinators</td></tr>
<tr><td>Identification of patients reaching endpoints</td><td>1-3</td><td>Milestone Achieved: ANCHOR FAI-1 sites have completed their collection of T8 FU PRO data being shared with DoD. Please see Table 3 below.</td></tr>
</table>

<table>
<tr><th>Major Task 1: FAI-1 cohort FU (cont.)</th><th>Timeline (in Months)</th><th>Year 3 PR Completion Status</th></tr>
<tr><td>Milestone Achieved: List of eligible ANCHOR FAI-1 patients developed and disseminated to each site</td><td>3</td><td>
Table 3. ANCHOR FAI-1 Cohort Milestone Achievement<br>T8 Follow Up At Closure of Enrollment on 3/7/2022
<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>293</td><td>82.07%</td></tr>
<tr><td>2. Beaumont</td><td>155</td><td>47</td><td>30.32%</td></tr>
<tr><td>3. BCH*</td><td>35</td><td>29</td><td>82.86%</td></tr>
<tr><td>4. Colorado*</td><td>32</td><td>17</td><td>53.13%</td></tr>
<tr><td>5. Mayo Clinic*</td><td>41</td><td>34</td><td>82.93%</td></tr>
<tr><td>6. TSRH</td><td>33</td><td>9</td><td>27.27%</td></tr>
<tr><td>7. TCO</td><td>57</td><td>20</td><td>35.09%</td></tr>
<tr><td>8. Ottawa*</td><td>50</td><td>40</td><td>80%</td></tr>
<tr><td>All Site Total</td><td>760</td><td>489</td><td>64.34%</td></tr>
<tr><td>*Total for Top 5 Sites being Used In Analysis</td><td>515</td><td>413</td><td>80.12%</td></tr>
</table>
</td></tr>
<tr><td colspan="3">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">Enrollment in DoD - through consent “sharing” of T8 FU PRO data - has been completed.</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>Milestone Achieved: Eligible, locatable, & willing ANCHOR FAI-1 patients complete T8 FU</td><td>24</td><td>Milestone Achieved: <u>Impact of COVID-19 on ANCHOR FAI-1 enrollment</u>: Widespread economic challenges greatly impacted our ability to complete this milestone by month 24. However, enrollment in DoD, through consent “sharing” of T8 FU PRO data, has now been completed. For final enrollment numbers and specifics, please see Table 3 above.</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: The cleaning of collected T8 FU PRO data continues.</td></tr>
<tr><td>Univariate data analysis</td><td>36-42</td><td rowspan="3">The Executive and Data Coordinating/Management Committee members are developing and refining a statistical plan to optimize the analytical models and subgroup analysis that will be used to determine the predictors of mid-term PROs and treatment failures in the established ANCHOR FAI-1 cohort.</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>
<tr><td colspan="3">Revised Statement of Work Referenced in Award/Contract: Section 10.ii <u>Project Performance Information</u> (cont.)</td></tr>
<tr><th>Major Task 3: FAI-2 Study Planning & Coordination</th><th>Timeline (in Months)</th><th>Year 3 PR Completion Status</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><u>Completed by WUSTL in YR1:</u> Standardization of pre-op, intra and post-surgical imaging protocol & transfer processes; Testing of the study’s imaging software (Dyonics) employed to visualize pre-surgical low-dose CT images.</td></tr>
<tr><td>Surgeon & research coordinator standardization, education, & in-person pre-study meeting</td><td>1-3</td><td><u>Completed in YR1 (Nov. 2019): Initial Standardization & Education:</u> Pre-study launch occurred during in-person start-up meeting attended by Site PIs and Study Coordinators. This process helped ensure a shared understanding of project goals, site deliverables and efficient workflows.</td></tr>
<tr><td>Imaging Repository Testing at each site</td><td>1-3</td><td><u>Completed:</u> Low dose CT testing/Dyonics compatibility complete at all sites.</td></tr>
<tr><td>Milestone Achieved: FAI-2 study plan & implementation process finalized</td><td>3</td><td>Milestone Achieved</td></tr>
</table>

| Major Task 4: FAI-2 Study Enrollment | Timeline (in Months) | Year 3 PR Completion Status |
|---|---|---|
| Active patient enrollment and FU | 4-42 | Prospective **ANCHOR FAI-2** enrollment initiated at 13/15 sites:<br>1. WUSTL – Launched Feb 2020<br>2. Beaumont (FU of T8 FAI-1 cohort only) Local IRB closure on 8/31/22<br>3. BCH – Launched September 2020<br>4. <u>On HOLD</u>: Boca Care Orthopedics<br>5. SAMMC – Launched September 2020<br>6. TSRH - Launched Sept. 2020 / Full launch Feb '21<br>7. U of Colorado – September 2020<br>8. U of Iowa – Launched August 2020<br>9. Mayo Clinic – Launched October 2020<br>10. Colorado – Launched February 2021<br>11. CHU de Quebec – Launched February 2021<br>12. TCO – Full Launch March 2021<br>13. CHEO \| TOH – Launched August 2021<br>14. U of Wisconsin – Launched September 2021<br>15. U of Michigan: Launched November 2021 \| Site being closed due to Site PI transfer to a new institution |
| 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.<br>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:<br>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.<br>2. Provide expert consultations with on-site WUSTL REDCap Data Manager, Tanner Thornton, regarding:<br>• QA/QC activities through report generation and refinement (e.g., Random Data Audit Report, REDCap Summary Report; Automated SAS-based query system).<br>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.<br>4. Participate & provide expertise and guidance on the monthly Executive Committee and Data Management. |

| | | |
|---|---|---|
| | | Specific YR 3 data management and QC efforts in process or completed include:<br>**1. Ongoing QC \| Data Management of REDCap:** The project remains in production with real-time data being entered at each performance site.<br>Implementation of specific QC measures include:<br>**1A. Ongoing analysis of data accuracy and completeness**: REDCap's built-in quality control features help ensure accurate and complete data. The system keeps a log of who entered and/or changed all data, a feature that permits DCC to discuss -with the data enterer- any concerns regarding a particular data item.<br><u>Other QC measures that continue in place include</u>:<br>1. Range checks that flag values outside a pre-defined acceptable range.<br>2. Accepting only a predefined set of values for categorical measures.<br>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.<br>4. Site Investigators & Coordinators visual checks of completed forms to confirm completeness and reasonableness after each form is filled out.<br>**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.<br>**1C**. **Ongoing Training and Certification of New Personnel:**<br>1. A central feature data QC is ensuring all new, performance site staff are collecting data in accordance with REDCap system requirements. With the ongoing level of Coordinator turnover, standardized training has been a key focus for DCC who works closely with all existing and new study personnel to ensure continuous training & certification in performing data entry. DCC workflows continue to ensure that:<br>Site Investigators and Coordinators have gained appropriate familiarity with REDCap and its MOP; Relevant site personnel are comfortable and competent with data entry procedures.<br>To further the accomplishment of these goals:<br>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 provides visual aids (power point slides) that cover data collection procedures.<br>3. Following each SIV, DCC certifies new site staff on: Familiarity with REDCap; Required data-entry competencies and knowledge within our "practice" database environment before access to the "live" project is granted.<br>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.<br>5. Using a DCC maintained list of certified personnel, WUSTL leadership and DCC leadership routinely confirm that only current, active, and certified staff have access to REDCap through each site's data access group (DAG).<br>6. REDCap data modifications are tagged with timestamp & User ID for ease of identification.<br>**1D. YR3: Continuation of all Programmed Data Summary Reports:** Based on their QA/QC responsibilities, the DCC has developed a series of weekly "data query" reports shared with each Site Investigator and Coordinator to better focus data-entry error corrections in pre-op and follow-up data collection time points. |

| | | |
|---|---|---|
| | | Specific Reports include the following:<br>1. **Enrollment and Data Progress Collection Report: Enrollment and Data Progress Collection Report:** This report is generated every Monday morning and immediately emailed to all Site Coordinators/PIs to focus their FU efforts in contacting participants who are about to "exit" each study window. After the full report is emailed, WUSTL staff sends a separate email alerting the Site PI/Coordinator of all participants who will "exit" a window within the next 7 days. This added attention is meant to increase study time point FU rates to 80% or higher, at each performance site.<br>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.<br>3. **Notification Report: PROs When Entering 3M, 6M, 1YR, 2YR Windows:** When a participant enters a study window, their ID appears on this report so that sites have sufficient time to notify said participant to request timely completion of that time point's PROs. Report is generated and sent to Site Coordinators every Monday<br>4. **Notification Report: PROs Nearing End of 3M, 6M, 1YR, 2YR Windows:** If a participant has not completed their PROs within 1M of a study window closing, they are added to the appropriate "nearing out of window" list generated and sent to Site Coordinators every Monday.<br>5. **PROs Out of 3M, 6M, 1YR 2YR Windows**<br>6. **Enrollment Period Projections**: Based on most recent 3M average enrollment, report projects total enrollment by month until end of study<br>7. **Projections By Month:** Projected enrollment applied per month<br>8. **Historical Monthly Enrollment:** Table of actual enrollment; months where no site enrolled patients are not included.<br>9. **Monthly Projections Chart:** Visualization of projected remaining enrollment based on most recent 3M average.<br>10. **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.<br>11. **FAI-1 Per site Productivity:** Last report generated in March 2022 when T8 FU PRO enrollment concluded. |
| Enrollment audit – Months into enrollment | 8, 12, 16, 18 | Please see **Table 4** below for current FAI-2 enrollment numbers. |

**Table 4. ANCHOR DoD FAI-2: Enrollment and Data Collection Progress Report Through September 30, 2022**

| Site - Target Enrollment | Consented | Pre-op Baseline data | # Surgeries Complete | Surgical day data | Post-Op 3M Eligible | Post-Op 3M Data Collected | Post-Op 6M Eligible | Post-Op 6M Data Collected | Post-Op 1Y Eligible | Post-Op 1Y Data Collected | Post-Op 2Y Eligible | Post-op 2Y Data Collected |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **BCH - 80** | 66 | 65 | 66 | 64 | 57 | 37 (65%) | 50 | 30 (60%) | 40 | 19 (48%) | 0 | 0 |
| **Quebec - 30** | 21 | 20 | 19 | 19 | 19 | 16 (84%) | 12 | 12 (100%) | 2 | 0 | 0 | 0 |
| **Mayo - 100** | 110 | 107 | 109 | 103 | 100 | 82 (82%) | 96 | 62 (65%) | 64 | 40 (63%) | 0 | 0 |
| **TOH - 15** | 15 | 15 | 15 | 15 | 12 | 9 (75%) | 6 | 5 (83%) | 2 | 0 | 0 | 0 |
| **CHEO - 15** | 18 | 17 | 18 | 17 | 18 | 12 (67%) | 11 | 7 (64%) | 4 | 0 | 0 | 0 |
| **SAMMC -30** | 25 | 25 | 25 | 25 | 20 | 18 (90%) | 17 | 15 (88%) | 10 | 8 (80%) | 0 | 0 |
| **TSRH - 30** | 12 | 11 | 11 | 11 | 10 | 9 (90%) | 10 | 10 (100%) | 8 | 7 (88%) | 1 | 0 |
| **TCO - 100** | 66 | 64 | 63 | 62 | 52 | 49 (94%) | 40 | 30 (75%) | 14 | 8 (57%) | 0 | 0 |

**Table 4. ANCHOR DoD FAI-2: Enrollment and Data Collection Progress Report Through September 30, 2022**

| Site - Target Enrollment | Consented | Pre-op Baseline data | # Surgeries Complete | Surgical day data | Post-Op 3M Eligible | Post-Op 3M Data Collected | Post-Op 6M Eligible | Post-Op 6M Data Collected | Post-Op 1Y Eligible | Post-Op 1Y Data Collected | Post-Op 2Y Eligible | Post-op 2Y Data Collected |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Colorado-30** | 30 | 22 | 28 | 25 | 25 | 13 (52%) | 18 | 6 (33%) | 5 | 2 (40%) | 0 | 0 |
| **Iowa -150** | 121 | 118 | 116 | 96 | 104 | 97 (93%) | 97 | 88 (91%) | 71 | 58 (82%) | 8 | 4 (50%) |
| **Michigan -0** | 1 | 1 | 1 | 1 | 1 | 1 (100%) | 1 | 1 (100%) | 0 | 0 | 0 | 0 |
| **WUSM-125** | 116 | 111 | 107 | 78 | 98 | 79 (81%) | 85 | 66 (78%) | 62 | 48 (77%) | 19 | 12 (63%) |
| **WISC - 65** | 77 | 69 | 66 | 66 | 56 | 49 (88%) | 39 | 31 (79%) | 0 | 0 | 0 | 0 |
| **Total** | **678** | **645** | **644** | **582** | **572** | **471 82%)** | **482** | **363 (75%)** | **282** | **190 (69%)** | **28** | **16 (59%)** |

| | | |
|---|---|---|
| *Milestone Achieved: Report initial, per site FAI-2 Enrollment* | 18 | In process: As stated earlier in this report, prospective ANCHOR FAI-2 enrollment successfully initiated at all performance sites except BocaCare Orthopedics and Beaumont.<br><br>Ongoing Enrollment and Impact of COVID-19: (1) The world-wide emergence of this novel coronavirus, and its infection resurgence through all variants, has significantly impacted orthopedic surgery practice and in-person clinic visits at each performance site. 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 continues to respond more effectively to resurgent infection rates, elective surgeries are still being postponed when scheduled patients test COVID-19 positive because of highly infectious sub-variants.<br><br>In order to better elucidate COVID-19's most recent impact on performance sites, please review **Table 5** also included in our YR3 Q2 PR. |

| Performance Site | **Table 5. COVID-19 Problems/Delays Experienced at Several Performance Sites (Reporting Period covered by and reported in our YR3 Q2 Progress Report)** |
|---|---|
| **WUSTL** | All elective surgeries were cancelled for a period lasting 6 weeks from January – February. |
| **BCH** | While most COVID restrictions lifted, a mandatory 21-day surgery delay was imposed when a patient tested COVID-19 positive. This happened with some regularity causing a number of surgical cases to be postponed. |
| **CHEO \| TOH** | Starting in late December 2021, the Omicron wave led to a provincial hospital mandate to decrease and/or cease non-urgent surgeries. Consequently, these sites were severely limited (essentially entirely limited) from any hip arthroscopies from late December 2021 - late March 2022 after which recruitment/surgeries re-started but were relatively limited through until June/July. Sites continue to try to catch up with all types of non-urgent surgeries. |
| **CHU de Quebec** | From Jan. 1 – Feb. 14, 2022, the fifth wave of COVID-19 halted most elective surgeries. Clinic visits were slowed to 80%. New patients were held back for one month. Thus, the site lost 7-8 weeks of recruitment. Since Feb. 18, site was back to 60% surgical volume & by March 14, scheduling was at 120% normal surgical volume as their administration worked to recover missed OR time within the next 3 months. |
| **SAMMC** | Three (3) patients cancelled during that timeframe due to positive COVID-19 test results. Site also experienced decreased OR capabilities leading to less OR time than usual. |

| Performance Site | Table 5. COVID-19 Problems/Delays Experienced at Several Performance Sites (Reporting Period covered by and reported in our YR3 Q2 Progress Report) |
|---|---|
| **Twin Cities** | Because of COVID/space constraints, Site Coordinator still restricted from attending in-person clinic. This continued restriction directly led to slower than normal enrollment as Coordinator was only able to email or call patient *following* clinic; Patients had to be vaccinated or test COVID-19 negative within 96 hours of surgery. |
| **U of Colorado** | Prior to surgery, all patients required to be COVID-19 tested. This caused an approximate 10-15% cancellation rate due to last minute positive tests. As of 3.9.22, the requirement for surgical patients to be pre-tested for COVID-19, was lifted except for patients who'd recently been exposed or exhibiting symptoms. |
| **U of Iowa** | During the month of January, 30% of Dr. Westermann's scheduled surgeries were cancelled due to positive COVID-19 results in the surgical patients. |

| **Major Task 5: FAI-2 cohort baseline & follow-up data** | **Timeline (in Months)** | **Year 3 Completion Status** |
|---|---|---|
| ***Subtask 1: ANCHOR site clinical Follow Up*** | | |
| Phone contact | 4-42 | <u>REDCap Automated Survey Invitation Function – 3M, 6M, 1YR, 2YR PRO collection</u>): When a specific study window opens, REDCap delivers an automated *survey invitation* to each participant's master email address. A follow-up *survey reminder* is sent to the participant every 5 days/up to 5 times if s/he does not complete their PROs before the close of the study time point window. This automated *survey invitation* process continues throughout the entire course of each subject's longitudinal participation.<br>**Enrollment and Data Progress Collection Report:** As stated earlier, this report is generated every Monday morning and immediately emailed to all Site Coordinators/PIs to focus their FU efforts in contacting participants who are about to "exit" each study window. After the full report is emailed, WUSTL staff sends a separate email alerting the Site PI/Coordinator of all participants who will "exit" a window within the next 7 days. This added attention is meant to increase study time point FU rates to 80% or higher, at each performance site.<br>The process has increased follow-up rates on the project. |
| Mail and email contact | 4-42 | |
| ***Subtask 2: Central site Follow Up*** | | |
| Phone contact | 4-42 | To date, no performance site has activated WUSTL to assist with centralized FU/advance search strategies (to re-locate their participants). WUSTL remains ready to assist each performance site, 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 performance site has activated WUSTL to assist with centralized FU/advance search strategies (to re-locate their participants). WUSTL remains ready to assist each performance site, if activated. |
| Radiographic & CT transfer to central site (WUSTL) | 4-42 | <u>Per Participant, Per Site</u>: In accordance with transfer guidelines and timeframes elucidated within the study's protocol, all required pre-op/post-op radiographic, CT, and intraoperative fluoroscopy imaging data continues to be transferred to WUSTL BOX (a cloud-based file storage & collaborative tool system providing automatic backup & encryption of data in transit/at rest. Provides both FERPA and HIPPA compliance). |
| Radiographic and CT analysis for all site data | 4-42 | <u>Ongoing Process of Analysis</u>: In accordance with study deliverables, all newly transferred preoperative low-dose CTs are WUSTL-reviewed to ensure timely and accurate FAI hip impingement evaluation. Dyonics, a software application developed specifically for CT orthopaedic analysis of the Hip and Pelvis, is being employed for this evaluation.<br>At the end of each month, WUSTL provides each Site PI/Coordinator their monthly *Imaging Report* defining all transferred/missing images per enrolled subject, per pre- op/post-op time point. |

| | | |
|---|---|---|
| *Milestone Achieved: Report Results of CT transfer and analysis (by sites)* | 20 | Ongoing: This milestone represents continuous and time-sensitive study procedures related to image transfers and QC analysis. Ongoing work efforts continue in accordance with site deliverables elucidated within each site's SOW. For current image transfer progress, please refer to **Tables 6, 7 and 8** below. |

**Table 6. Preoperative/Intraoperative Imaging Report Through September 30, 2022**

| Site Name | Cases Enrolled | Surgery Completed (SC) | N = % of *Surgery Complete* Images Received at WUSTL | | | |
|---|---|---|---|---|---|---|
| | | | X-Rays Rec'd | Low Dose CT | Hip Scope | Fluoroscopy |
| **Colorado** | 30 | 30 | 27 | 27 | 25 | 26 |
| **Boston** | 66 | 66 | 66 | 64 | 61 | 66 |
| **Mayo Clinic** | 110 | 110 | 109 | 108 | 109 | 108 |
| **Iowa** | 122 | 120 | 102 | 101 | 102 | 102 |
| **SAMMC** | 25 | 25 | 19 | 18 | 18 | 19 |
| **TSRH** | 12 | 12 | 12 | 12 | 11 | 11 |
| **TWO** | 66 | 64 | 63 | 62 | 63 | 63 |
| **WUSTL** | 116 | 116 | 114 | 108 | 96 | 105 |
| **Quebec** | 21 | 21 | 19 | 19 | 19 | 19 |
| **CHEO** | 18 | 18 | 18 | 18 | 17 | 18 |
| **TOH** | 15 | 15 | 15 | 15 | 13 | 15 |
| **Wisconsin** | 76 | 76 | 65 | 65 | 65 | 64 |
| **Michigan** | 1 | 1 | 1 | 1 | 0 | 0 |
| **Total** | **678** | **674** | **630 (93%)** | **618 (92%)** | **599 (89%)** | **616 (91%)** |

**Table 7. Follow-Up Imaging Report Through September 30, 2022**

| Site | Cases Enrolled | Eligible for 3M | 3M Archived | 3M Protocol Compliant | Eligible for 1YR | 1 YR Archived | 1 YR Protocol Compliant |
|---|---|---|---|---|---|---|---|
| **Colorado** | 30 | 29 | 6 | 2 | 10 | -- | -- |
| **Boston** | 66 | 62 | 21 | 1 | 40 | 11 | 11 |
| **Mayo Clinic** | 110 | 106 | 61 | 47 | 69 | 0 | -- |
| **Iowa** | 122 | 113 | 84 | 83 | 79 | 28 | 28 |
| **SAMMC** | 25 | 24 | 5 | 3 | 10 | 0 | -- |
| **TSRH** | 12 | 12 | 10 | 2 | 9 | 7 | 6 |
| **TWO** | 66 | 63 | 53 | 49 | 20 | 3 | 3 |
| **WUSTL** | 116 | 115 | 102 | 70 | 73 | 15 | 12 |
| **Quebec** | 21 | 19 | 19 | 19 | 3 | -- | -- |
| **CHEO** | 18 | 18 | 12 | 9 | 7 | -- | -- |
| **TOH** | 15 | 15 | 7 | 6 | 4 | -- | -- |
| **Wisconsin** | 76 | 70 | 40 | 12 | 9 | -- | -- |
| **Michigan** | 1 | 1 | 0 | 0 | 0 | -- | -- |
| **Totals** | **678** | **647** | **420** | **303** | **333** | **64** | **60** |

| Table 8. Overall Preoperative CT Protocol Compliance Report Through September 30, 2022 | | | | | | |
|---|---|---|---|---|---|---|
| **Site Name** | **Cases Enrolled** | **Surgery Completed** | **CT Complete (CC)** | **Protocol Complaint n (% of CC)** | **Protocol Non-Compliant (PNC) or CT Not Done (ND) Prior to Surgery - n (% of CC)** | **CT Not Centralized, QI/QC Checked, or Not Yet Ordered (n)** |
| **Colorado** | 30 | 30 | 27 | 23 (85) | 4 (15) - PNC | 3 |
| **Boston** | 66 | 66 | 64 | 62 (97) | 2 (3) – PNC \| 2 - ND | 0 |
| **Mayo Clinic** | 110 | 110 | 108 | 102 (94) | 6 (6) - PNC | 2 |
| **Iowa** | 122 | 120 | 101 | 99 (98) | 2 (2) – PNC \| 1 - ND | 18 |
| **SAMMC** | 25 | 25 | 18 | 18 (100) | 0 | 7 |
| **TSRH** | 12 | 12 | 12 | 12 (100) | 0 | 0 |
| **TWO** | 66 | 64 | 62 | 57 (92) | 5 (8) - PNC | 4 |
| **WUSTL** | 116 | 116 | 108 | 106 (98) | 2 (2) - PNC | 8 |
| **Quebec** | 21 | 21 | 19 | 18 (94) | 1 (6) – PNC | 2 |
| **CHEO** | 18 | 18 | 18 | 18 (100) | 0 | 0 |
| **TOH** | 15 | 15 | 15 | 14 (93) | 1 (7) - PNC | 0 |
| **Wisconsin** | 76 | 76 | 65 | 56 (86) | 9 (14) – PNC | 11 |
| **Michigan** | 1 | 1 | 1 | 1 (100) | 0 | 0 |
| **Total** | **678** | **674** | **618** | **586 (95)** | **32 PNC (5) \| 3 ND** | **55** |

| **Major Task 6: FAI-2 Data Analysis** | **Timeline (in Months)** | **Year 3 Completion Status** |
|---|---|---|
| Data cleaning and quality checks | 42-48 | Ongoing: Data cleaning continues as WUSTL DCC refines QC/QA measures. Monthly *Data Auditing Query Reports,* that identify missing data forms and/or missing key item-level data points, are produced monthly and provided directly to each performance site. These DCC reports are securely housed on WUSTL BOX for ease of accessibility by all Site Coordinators. These baseline and follow-up data reports include, but are not limited to: Missing baseline PROMs *completion dates*; Missing *Surgeon intraoperative* form; Missing *Dates for surgery* and *Day of Birth*; Missing *Surgeon Follow-up Form*; Missing *Complications Form.*<br>Other QC measures that continue to clean study data include: Range checks that flag values outside a pre-defined acceptable range; Accepting 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. |
| Univariate data analysis | 42-48 | Executive and Data Coordinating/Management Committees are discussing plans for **FAI-2** statistical data analysis once data collection is complete. |
| Multivariate data analysis | 42-48 | |
| *Milestone Achieved: Report Results of Data Analysis* | 42-48 | Executive and Data Coordinating/Management Committees are discussing plans for **FAI-2** statistical data analysis once data collection is complete. |

| **Major Task 7: Data Analysis of PROMIS vs. Legacy PROs** | **Timeline (in Months)** | **Year 3 Completion Status** |
|---|---|---|
| Data cleaning and quality checks | 7-42 | As stated earlier in this report COVID-19, and all sub-variants, 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 **FAI-2** enrollment and data collection are complete, this new cohort will be the partial source for Specific Aim 3 investigations focused on determining if PROMIS measures correlate with legacy PROs in patients undergoing FAI surgery. |

| | | |
|---|---|---|
| | | Data cleaning and quality checks are ongoing within WUSTL DCC. As PROMIS data is collected from participants and REDCap entered, QC data check reports, generated and provided by DCC at WUSTL BOX, will continue to assist performance sites with their data cleaning procedures. |
| Correlation analysis for PROMIS subdomains vs legacy PROs | 30-48 | These major tasks/milestones have been delayed due to COVID-19s negative impact on our enrollment of a new cohort of **FAI-2** participants**.**<br><br>The Executive and Data Coordinating/Management Committees are discussing their plans for **FAI-2** statistical data analysis once data collection is complete. |
| Subgroup stratification analysis | 30-48 | |
| *Milestone Achieved: Report Results of Correlation & Subgroup Stratification Analysis* | 30-48 | |
| Data reporting; Manuscript preparation | 30-48 | |
| *Milestone Achieved: Report Manuscript Preparation Results* | 24-48 | |

## Other, Ongoing Achievements since our last quarterly progress report:

- Continued enrollment of our new FAI-2 cohort; Continued FU of these participants at each study time point
- Continue archiving of images pre-and-post surgery
- **Ongoing IRB Continuing Reviews:** On behalf of each performance site, WUSTL coordinates all USAMRD HRPO ORP CR submissions.

A. Since our last PR, the following performance sites have had their yearly CR's submitted and approved by USAMRD HRPO ORP:

- CHEO/OH: Submitted to USAMRD HRPO ORP on 7/27/2022 and approved on 8/16/2022
- CHU de Quebec: Submitted to USAMRD HRPO ORP on 8/5/2022 and approved on 9/9/2022

B. Since our last quarterly PR, the following performance sites - determined to be no greater than minimal risk and no longer requiring review for continuation - have confirmed that no post-approval events (requiring prompt reporting to USAMRD HRPO ORP) have occurred:

- Mayo Clinic
- San Antonio Military Medical Center
- Boston Children's Hospital

- **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.

- **FAI-1 Data Analysis:** The Executive and Data Management Committees are developing their statistical plan to analyze the mid-term follow-up (T8 FU) of the ANCHOR FAI-1 cohort identify important predictors of treatment outcomes and failures in FAI surgery in order to improve clinical care and treatment decision-making by establishing refined patient selection criteria for surgery and by correlating disease and patient characteristics with clinical outcomes.
- **FAI-2 Data Analysis:** Executive and Data Coordinating/Management Committees are discussing plans for FAI-2 statistical data analysis once data collection is complete.

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

**Answer for YR 3 Annual PR:** Nothing to Report at this time

**How were the results disseminated to communities of interest?**

**Answer for YR 3 Annual PR:** Nothing to Report at this time

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

**Answer for YR 3 Annual PR:** By the end of YR4 Q1 (our next reporting period), we plan to:

- Fully complete ANCHOR FAI-2 participant enrollment
- Initiate ANCHOR FAI-1 data analysis and develop a preliminary report
- Continue post-op, participant data collection (PRO and imaging) at each FU study time point.
- Continue to expand QC procedures (data cleaning and quality checks) to include additional data checks of item-level data points
- Launch the data analysis of the **ANCHOR FAI-1** cohort
- 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 for YR 3 Annual PR:** Nothing to Report at this time

**What was the impact on other disciplines?**

**Answer for YR 3 Annual PR:** Nothing to Report at this time

**What was the impact on technology transfer?**

**Answer for YR 3 Annual PR:** Nothing to Report at this time

**What was the impact on society beyond science and technology?**

**Answer for YR3 Annual PR:** Nothing to Report at this time

5. **CHANGES/PROBLEMS:**

**Answer for YR3 Annual PR:** **(1)** In March 2022, William Beaumont completed their DoD "data sharing" enrollment and collection of T8 FU PRO data from eligible ANCHOR FAI-1 participants. As a result, their local IRB application was closed and all documentation was submitted to USAMRDC HRPO ORP on 9/6/2022. Closure documentation, of their subaward contract, was submitted to WUSTL *Office of Sponsored Research Services* on 9/19/2022. Once completed, WUSTL will forward all documentation to William Beaumont and Jennifer Shackle (DoD Grants Specialist); **(2)** With the September completion of data cleaning at the *University of Michigan,* we've begun the same site closure process now that Site PI, Asheesh Bedi MD, has left their institution.

**Changes in approach and reasons for change**

**Answer for YR3 Annual PR:** No changes in objectives or scope have occurred.

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

**Answer for YR 3 Annual PR:** Please see **Table 5** *COVID-19 Problems/Delays Experienced at Several Performance Sites* for more specifics regarding the most recent delays in enrollment caused by the COVID-19 pandemic.

## Actions | Plans to Resolve the delays in recruitment/enrollment

**Answer for YR 3 Annual PR:**

- Continued use of technology to drive efficiency, transparency and maintain remote, intra-and-inter site communication (WUSTL BOX, ZOOM; REDCap)
    - Continued leveraging of efficient, technology-based communication systems used to stay connected with all Site PIs/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).
- Ongoing surgeon use of post-op telemedicine visits when participants cannot attend in-person FU visit.
- Continued use of expanded procedures that allow consenting through multiple methods not reliant on traditional, in-person/in-clinic/face-to-face interactions with patients (e.g. REDCap, using IRB-approved *waivers of documentation of written consent* for verbal consenting).
- Continued agile navigation of COVID-19's impact on enrollment by realigning block enrollment to reinforce performance sites whose surgical FAI volumes support expansion of initially proposed targets
- 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.
- Ongoing continuation of our monthly study-wide Coordinator ZOOM conference calls
    - 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.
- Continued use of 100% virtual data collection for the ANCHOR FAI-2 cohort.
    - A separate REDCap subject payment database continues to be utilized for the per-site per-participant collection of PII (including SSN) needed by WUSTL to reimburse 1-yr and 2-yr subject participation ($25 for PRO completion and an additional $25 for in-clinic/telemedicine visit completion)
- As needed, modification of specific REDCap data entry points to accommodate telemedicine collection and surgical data collection at follow-up study time point/clinic visits.

**Changes that had a significant impact on expenditures**

**Answer for YR 3 Annual PR:** 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 for YR 3 Annual PR:** Nothing to Report at this time

**Significant changes in use or care of vertebrate animals**

**Answer for YR 3 Annual PR:** Not Applicable

**Significant changes in use of biohazards and/or select agents**

**Answer for YR 3 Annual PR:** Not Applicable

6. **PRODUCTS:**

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

**Answer for YR 3 Annual PR:**

  - Dr. Clohisy presented at the January 2022 *Extremity War injuries XVI Conference* in Washington D.C. His talk occurred during Session IV: Readiness Research from the 30,000 Foot Perspective and was titled: **Building a Multicenter Network: How to Do It and Lessons Learned**

**Journal publications.**

**Answer for YR 3 Annual PR:** Nothing to Report at this time

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

**Answer for YR 3 Annual PR:** Nothing to Report at this time

**Other publications, conference papers and presentations**.

**Answer for YR 3 Annual PR:** Nothing to Report at this time

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

**Answer for YR 3 Annual PR:** Nothing to Report at this time

- **Technologies or techniques**

**Answer for YR 3 Annual PR:** Nothing to Report at this time

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

  **Answer for YR 3 Annual PR:** Nothing to Report at this time

- **Other Products**

  **Answer for YR 3 Annual PR:** Nothing to Report at this time

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

**What individuals have worked on the project?**

**Answer for YR 3 Annual:** Please refer to **Table 9** that starts on next page.

| Table 9. DoD Quarterly Technical Progress Report for Period Covering:<br>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 | 1.2PM | Dr. Clohisy directs the Clinical Coordinating Center, the Executive and Data Management 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 | 0.6PM | Dr. Nepple serves on the Executive and Data Management Committees 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 | 0.36PM | 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 | 0.36PM | Dr. Yanik serves on the Executive and Data Management Committees and participates in all activities of the executive and steering committees. She is involved in the project's statistical activities, data analysis and data reporting activities. |
| | Susan Thapa | Research team Member | 0000-0002-4795-1116 | 0.12PM | Dr. Thapa serves on the Executive and Data Management Committees and participates in all activities of the executive and steering committees. She is involved in the project's statistical activities, data analysis and data reporting activities. |
| | Tanner Thornton | Research Team Member | 0000-0001-9041-0203 | 6.00PM | Mr. Thornton serves as both a Data Analyst and REDCap Data Manager for the project. In this role, he closely works with Drs. Salter, Thapa, Nepple and Clohisy in the development of the data management plan (REDCap) and analysis of data. |
| | Caroline E. Drain | Research Team Member | NA | 6.00PM | Ms. Drain serves on both the Executive and Data Management Committees. 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 | 6.00PM | Mr. Robben serves on both the Executive and Data Management Committees 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 | 6.00PM | Mr. Akers serves on both the Executive and Data Management Committees 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. |

| Table 9. DoD Quarterly Technical Progress Report for Period Covering:<br>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** |
| **UTSW** | Amber Salter | Associate Professor Section Head, Statistical Planning and Analysis | 0000-0002-1088-110X | 3.00PM | Dr. Salter serves on the Executive and Data Management Committees 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. |
| | | | | | |
| **Beaumont Hospital** | Ira Zaltz | Site PI/Collaborator | 0000-0003-4036-6149 | .12 PM | In March 2022, Beaumont completed their final ANCHOR FAI-1 DoD data "sharing" enrollment of participant's T8 FU PRO data. Local IRB application has been closed and paperwork was submitted to DoD HRPO on 9/6/2022. On 9/19/2022 the subaward closure documentation submitted to WUSTL's *Office of Sponsored Research Services.* |
| | Shalinee Mylvaganam | Research Team Member | NA | 1.20PM | In March 2022, Beaumont completed their final ANCHOR FAI-1 DoD data "sharing" enrollment of participant's T8 FU PRO data. Local IRB application has been closed and paperwork was submitted to DoD HRPO on 9/6/2022. On 9/19/2022 the subaward closure documentation submitted to WUSTL's *Office of Sponsored Research Services.* |
| | | | | | |
| **Boca Raton Regional Hospital** | James Ross | Site PI/Collaborator | 0000-0002-8465-8250 | 0.12PM | 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 | 0.06PM | 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 CR. |
| | Amy Abreu | Research Nurse | NA | 0.06PM | Ms. Abreu would have been involved with patient enrollment, data collection, data entry and imaging uploads, data cleaning. Ms. Abreu has left the project. |
| | | | | | |
| **Boston Children's Hospital** | Eduardo Novais | Collaborator | 0000-0002-9187-3100 | 0.12PM | 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 | 0.12PM | 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 | 0.24PM | 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 | 0.12PM | 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. |

| Table 9. DoD Quarterly Technical Progress Report for Period Covering:<br>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** |
| | Lauren Hutchinson | Research Team Member | NA | 0.6PM | 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 | 4.5PM | Ms. Ferraro was involved with patient enrollment, data collection, data entry and imaging uploads, data cleaning. Ms. Ferraro has left the project. |
| | Nancy Wan | Research Team Member | NA | 1.5PM | Ms. Wan is involved with patient enrollment, data collection, data entry, imaging uploads to WUSTL, and data cleaning. |
| | Madison Earle | Research Team Member | NA | 4.5PM | Ms. Earle was involved with patient enrollment, data collection, data entry and imaging uploads, data cleaning. Ms. Earle has left the project. |
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| **The Ottawa Hospital Research Institute**<br><br>**Children's Hospital of Eastern Ontario (CHEO)** | Paul Beaule | Site PI/Collaborator | 0000-0001-7667-9994 | 0.24PM | 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 | 0.24PM | Dr. Carsen is the key enrolling surgeon at The Ottawa Hospital/CHEO involved in all aspects of the project including patient enrollment, surgical treatment, study implementation, and study oversight. |
| | Stephanie Karch | Research Team Member | 0000-0002-0928-333X | 1.8PM | Ms. Karch is Clinical Research Coordinator assisted with enrollment, data collection/entry and all ethics submissions at The Ottawa Hospital Research Institute. She is no longer working on the project. |
| | Holly Livock | Research Team Member | 0000-0003-3171-4447 | 0.12PM | Ms. Livock is a Clinical Research Coordinator assisting with the ethics submission and study-start up locally at The Ottawa Hospital Research Institute/CHEO. Once enrollment starts, she will support local enrollment and data collection for participants. |
| | Patrick Sachsalber | Clinical Research Assistant | 0000-0001-6674-8909 | 2.4PM | Mr. Sachsalber is a Clinical Research Assistant assisting with enrollment, data collection, imaging transfer to WUSTL, and data entry /cleaning. |
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| **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 | 3.6PM | Ms. Turmel is a Clinical Research Specialist assisting with the IRB ethics approval and project preparation. She supports the enrollment of patients, data reporting, entry, collection and imaging transfers to WUSTL. |
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| **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 | 0.12PM | 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. |

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| | Bruce Levy | Collaborator | 0000-0002-7694-1814 | 0.12PM | 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 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. |
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| **SAMMC** | Matthew Schmitz | Site PI/Collaborator | 0000-0002-4156-5177 | 1.20PM | 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. |
| | Roseann Eberhardt | Research Team Member | NA | 1.2PM | Ms. Eberhardt is assisting Dr. Schmitz with enrollment of patients, follow-up and REDCAp data entry. She took over Mr. Richardson's role on the project. |
| | Cornell Richardson | Research Team Member | NA | .12PM | Mr. Richardson assisted Dr. Schmitz with enrollment of patients, follow-up and REDCAp data entry. He has left the project. |
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| **Twin Cities Orthopedics** | Christopher Larson | Site PI/Collaborator | 0000-0002-9910-0145 | 0.6 PM | Dr. Larson is the Site PI 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. She assisting with enrollment, data collection, and data imaging transfer to WUSTL, and data entry /cleaning. |
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| **SCH (formally TSRH)** | Henry Ellis | Site PI/Collaborator | 0000-0001-5444-094X | .12PM | Dr. Ellis is the Site PI involved in all aspects of the project including patient enrollment, surgical treatment, study implementation, and study oversight. |
| | Daniel Sucato | Collaborator | 0000-0003-3352-5551 | .06PM | Dr. Sucato is involved in study implementation while assisting with efforts on the retrospective arm of the study. |
| | David Podeszwa | Collaborator | 0000-0002-2367-2657 | .06 PM | Dr. Podeszwa is involved in study implementation while assisting with efforts on the retrospective arm of the study. |

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| | Lauren Osborne | Clinical 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). |
| | Baylee Selee | Clinical Research Coordinator | NA | 1.2PM | Ms. Selee assists in management and oversight of the day-to-day operations of the project (e.g. patient enrollment, study implementation, consenting). |
| | Laura Mayfield | Clinical Research Coordinator | NA | 1.2 PM | Ms. Mayfield assists in management and oversight of the day-to-day operations of this project (e.g. patient enrollment, study implementation, consenting, and study administration). |
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| **Univ of Iowa** | Robert Westermann | Site PI/Collaborator | 0000-0002-5289-4689 | 0.6 PM | Dr Westermann is the Site PI and enrolling surgeon involved in all aspects of the studies including patient enrollment, data analysis and data reporting. |
| | John Gentile | Research Team Member | NA | 1.8 PM | Mr. Gentile is involved in all aspects of the study including patient enrollment, data collection, and data imaging transfer to WUSTL, and data entry /cleaning. |
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| **University of Michigan** | Asheesh Bedi | Site PI/Collaborator | 0000-0001-8926-7139 | 0.12PM | Dr. Bedi was the Site PI and key enrolling surgeon at University of Michigan. As noted in our Year 3 Quarter 3 progress report, Dr. Bedi left the University of Michigan and is no longer the Site PI (as of 4/1/2022). We are in the process of closing their subcontract and IRB application. |
| | Jaimee Gauthier | Research Team Member | NA | 0.12PM | Mrs. Gauthier was the project manager for University of Michigan Orthopaedics. She helped ensure that the MedSport program had the resources, personnel and support needed to effectively execute this protocol. Ms. Gauthier has left the project. |
| | Melissa Li, PhD | Research Manager | NA | 0.60PM | Ms. Li is the new Research Manager handling 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. |
| | Ryan Mills | Clinical Research Coordinator | NA | 0.12 | Mr. Mill's assists with patient screening, consenting, follow-up and data collection for all enrollees. He also submits all open projects to their IRB for CR review and approval. |
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| **Univ of Colorado / Children's Hospital of Colorado** | Stephanie Mayer | Site PI/Collaborator | 0000-0002-9432-8191 | .40PM | 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 | 1.20PM | Ms. Imoe assists in management and oversight of day-to-day operations of the project. She supported patient enrollment. Ms. Imoe has left the project. |
| | Alexandra Orahovats | Research Project Manager | 0000-0002-9433-5420 | 0.6PM | Ms. Orahovats has taken over for Ms. Imoe and assists in management and oversight of day-to-day operations of the project including: Screening, consenting, enrollment, data collection, and patient follow up. |
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| **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. |
| | Amie Armstrong | Regulatory Manager | NA | 0.60PM | Ms. Armstrong has taken over for Ms. Schjei and assists in management and oversight of day-to-day operations of the project including: Screening, consenting, enrollment, data collection, and patient follow up. |
| | Katie Schjei | Clinical Research Manager | NA | 0.60PM | Ms. Schjei assisted in management and oversight of day-to-day operations of the project including: Screening, consenting, enrollment, data collection, and patient follow up. She has left the project |

**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?**

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**