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14. ABSTRACT The overarching goal of the BADER Consortium is to advance and strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior. This will be accomplished by advancing each of the following strategic areas: 1: Strengthen and support orthopaedic rehabilitation research capabilities through infrastructures and partnerships; 2: Conduct a variety of innovative, high impact, and clinically relevant research studies; 3: Establish a self-sustaining research enterprise by broadening the scope of impact and support for the BADER Consortium. Key Accomplishments to date: Established: Administrative Core, Clinical Research Core and Scientific Technical Cores; approval and establishment of eight clinical research projects; development and implementation of an Omnibus CRADA; established a consortium-wide omnibus PDMS; partnership with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE); developed research focus (gap) areas in partnership with EACE; established and implemented a complete process for the call, submission, review and selection of Consortium funded projects; published the annual BADER call for clinical research proposals, established the BADER Consortium SOPs; completed the hiring of eight research support staff to be placed onsite at MTFs; established partnerships with the VA and NIH; obtained over \$4M of external funding					
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Introduction

The BADER Consortium

The **overarching goal** of the BADER Consortium is to Bridge Advanced Developments for Exceptional Rehabilitation. The omnibus consortium model system, as opposed to a project centric model, focuses on the rapid forming and execution of many projects within broad research initiative areas. It avails to investigators unique human resources recruitment processes, incorporates innovative strategies including an omnibus CRADA and is uniquely suited to being a vehicle for technology companies to propose clinical trials for highly advanced technologies. The BADER Consortium is a multi-institutional Consortium that works in concert and partnership with military Medical Treatment Facilities (MTFs), Veteran's Affairs Centers, Academic and Industry leaders to conduct innovative, high-impact, clinically relevant research to further strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior.

The success of the Consortium relies on strong partnerships with military Medical Treatment Facilities, the VA and non-government entities in each of the following strategic areas to:

1. Strengthen and support orthopaedic rehabilitation research capabilities:
 - infrastructures and cultures
 - partnerships
2. Conduct a variety of innovative, high impact, and clinically relevant research studies
3. Establish a self-sustaining research enterprise
 - Broaden the scope of impact and support for the BADER Consortium

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If developing research cooperation between a civilian organization and a government agency is considered by most to be a challenging endeavor, establishing an effective and dynamic research Consortium across multiple agencies, academic centers, and industrial leaders would be considered daunting. To tackle this task, the BADER Consortium has established a series of model omnibus administrative and research tools and standard operating procedures. Fundamentally, these tools and associated policies and procedures support partnership building, streamline the project initiation process, strengthens the project execution phase, enhances the scope and impact of research while ensuring protection of critical assets such as the US Governments rights to intellectual property and data, patient confidentiality, and protection of human subjects.

This report describes how the BADER Consortium has made progress based on the approved Statement of Work for the period September 29, 2011 – September 28, 2014.

Research accomplishments to date based on Statement of Work

Administrative Core:

Task 1: Financial Support and Oversight:

- 1a. Provide oversight of the overall Consortium budget including auditing for allowable expenses, managing re-budget requests and preparing all required financial reports – months 1-60
- 1b. Ensuring all Military Treatment Facilities (MTFs) receive infrastructure support as required including procurement of materials, personnel, equipment – months 1-60
- 1c. Manage costs supporting the Cores and Clinical Study Sites – months 1-60
- 1d. Perform quarterly financial audits for compliance – months 1-60
- 1e. Maintain files for internal or external audit purposes – months 1-60

- Provided financial oversight of the Consortium.
- Quarterly financial audits of the BADER Consortium have had no significant findings.
- Spending is behind due to delays in receiving administrative approvals, hiring support staff and a slower than anticipated spending rate of subcontracts. In addition, a major expense originally budgeted for the first year did not occur due to a much less expensive alternative to the originally proposed protocol and data management system.
- Complete and accurate files have been kept for internal and external auditing purposes.
- Two charges from the BADER Consortium were randomly selected for audit under the annual University of Delaware audit. Back-up for both expenses was submitted to the Research Office for audit review. This University-wide annual audit is routine for comply with federal regulations.

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Task 2: Human Resources Support and Oversight

- 2a. Manage Human Resources function including recruitment, on-boarding, facility/system access, annual performance appraisals, and handling benefits questions – months 1-60
- 2b. Provide support as needed for labor relations actions – months 1-60
- 2c. Manage payroll function for UD employees (at UD and MTF sites) – months 6-60
- 2d. Work with Steering Committee to develop appropriate job descriptions – months 1-3
- 2e. Manage recruitment activities of personnel – months 1-60

Year three saw turn over in several of the Clinical Research Core staff creating a significant uptick in recruitment activity, however, by the end of year three, all positions were filled.

Table 1: Status of BADER funded positions.

Position	Location	Current Status
Director, Administrative Core	University of Delaware	Filled, full-time
Manager, Clinical Research Core	University of Delaware	Filled, part-time
Administrative Assistant	University of Delaware	Filled, full-time
Administrative Assistant	Spaulding Rehabilitation	Filled, part-time
Research Associate	WRNMMC	Filled, full-time
Laboratory Engineer	NMCSD	Filled, full-time
Research Associate	NMCP	Filled, full-time
Physical Therapy Assistant	BAMC/CFI	Filled, full-time
Protocol and Data Coordinator	WRNMMC	Filled, full-time
Protocol and Data Coordinator	NMCSD	Filled, full-time
Protocol and Data Coordinator	NMCP	Filled, full-time
Protocol and Data Coordinator	BAMC/CFI	Filled, full-time

Notes on staffing:

- At the request of Jason Wilken, we recruited a Physical Therapy Assistant to replace the vacant Research Assistant position.
- At the request of Marilyn Wyatt, we recruited a Laboratory Engineer to replace the vacant Research Assistant position.
- Manager, Clinical Research Core: The current CRC manager is working at 25% capacity and this effort has been successful to date.
- This fiscal year has seen substantial movement towards growth and sustainment. Several proposals involving BADER staff buy-out have been recommended for funding which frees up funds to provide MTFs with additional support. Having MTFs budget for staff salary on external grants promotes sustainability and research programs.
- All BADER CRC staff are currently funded 5% on supplemental funds (F&A) to allocate time to support grant writing activities that cannot be charged directly to BADER funds.
- BADER has placed an employee at the NIH to support the CTDB implementation.
- The Administrative Core provided oversight of annual performance appraisals of CRC staff and BADER administrative staff.

- Hired Communications Specialist II. This new position is responsible for coordination and execution of a communications strategy for the BADER Consortium. This position is supported by University of Delaware F&A dollars.

Problem areas related to this task:

- The “poaching” of BADER funded positions leads to a disruption of activities and additional time commitment to recruiting. CRC staff have recently resigned due to promotions at the MTFs.

Task 3: Reporting Coordination and Management:

- 3a. Request, coordinate and submit all required technical reports – months 1-60
 - 3b. Preparation of all required financial reports – months 1-60
 - 3c. Develop templates for reports to ensure consistency – months 1-4
- Coordinated the compilation, editing and submission of annual report.
 - Oversaw timely completion of quarterly technical and financial reports.

Task 4: General Administrative Support:

- 4a. Coordinate meetings, calendars, travel, etc. – months 1-60
- 4b. Facilitate communications across Consortium
- 4c. Prepare administrative documents – months 1-60
- 4d. Coordinate all official BADER correspondence – months 1-60

4a. Coordinate Meetings:

2014 Government Steering Committee Meeting: A meeting of the BADER Consortium Government Steering Committee was held February 19, 2014 in Ft. Detrick Maryland. The agenda is attached as appendix E.

2014 State of the Science Meeting: BADER was scheduled to participate in the 2014 State of the Science meeting in January 2014, however the meeting was cancelled. BADER will discuss a path forward with planning a meeting that is specific to orthopaedic rehabilitation research at the next GSC meeting.

BADER Consortium Coordinating Center Committee (B3C) meetings: Until July 2014, these meetings were held monthly to continue the development and implementation of the BADER Consortium infrastructure. Starting in August 2014, the meetings are now combined with the BADER Consortium Committee (BCC) monthly meeting. See Appendix F for composition of B3C.

BADER Consortium Committee (BCC) meetings: Monthly BCC meetings are held via teleconference to update Consortium members on BADER activities, receive updates from MTF representatives and Core Directors, problem solve and plan activities. A topic of recent interest from the MTF

representatives the development and implementation of the human subject recruitment initiative in response to the declining number of injured soldiers returning from war. See Appendix F for composition of BCC.

MTF Representative Teleconferences: Individual monthly teleconferences with the MTF representatives and Dr. Milbourne have been initiated.

Annual Meeting: To address a gap in orthopaedic rehabilitation research specific conferences, BADER leadership (Stanhope, Kaufman) has formed a team to establish an annual state of the science conference collaborating with CDMRP (Dr. Darnell) and the American Academy of Orthotists and Prosthetists (AAOP) to be named “**WARfighters Receiving Innovative Orthopedic Rehabilitation (WARRIOR).**” It is anticipated that the conference will be held in Washington DC with dates to be determined.

The primary goal of the meeting will be to define current knowledge regarding rehabilitation of combat-related injuries for NIH, Congress, the Department of Defense, clinicians, researchers, industry, and other relevant governmental agencies.

Focus Areas:

- Improving the functional utility of assistive devices related to the human-device interface (prostheses, orthoses, and other assistive devices)
 - o Improvement in prosthetic socket comfort, residual limb health, and function
 - o Providing proprioceptive and other sensory input to the user
 - o Improving user intent control of assistive devices
- Optimizing treatment strategies and sequences of progression through the rehabilitation process following severe extremity trauma
 - o Determining the optimal combination, dose, and timing of rehabilitation techniques to minimize impairments and maximize function and performance
 - o Objective guiding prosthetic and/or orthotic prescription to minimize impairment and maximize function and performance
- Improving the ability to predict, identify and reduce secondary health effects that develop after severe neuromusculoskeletal injury
 - o Determining factors that predict development and successful treatment of osteoarthritis, osteoporosis, low back pain, or other musculoskeletal conditions
 - o Strategies to improve treatment and rehabilitation of heterotopic ossification

Meeting Format: General sessions in each topic areas to include overview presentations, followed by questions and answers, and a poster session. Small group discussion breakout sessions for each clinical area, focusing on a specific issue.

Stakeholders to be invited: O&P Alliance members, APTA, AOTA, CDMRP, Department of Veterans Affairs, Researchers, Military, Federal Government Agencies, Congressional Representatives (registration by invitation only).

Planning meetings have occurred during 2014.

BADER Principal Investigator's Meeting: Dr. Stanhope wishes to initiate a quarterly meeting of the BADER PIs to focus on project specific updates and issues. This meeting will be a forum in which the PIs can engage each other for ideas and solutions to problems.

4b: Facilitating Communications

Teleconference support: The University of Delaware has established three teleconference phone accounts that are available for use by all Consortium members. MTFs and other BADER constituents have used the teleconference lines extensively to conduct business.

Communications specialist: Using supplemental UD F&A funds, BADER hired a Communications Specialist II to oversee and manage a comprehensive communications strategy including social media, blogging and articles to support our sustainability phase. An important part of this communications strategy will be recruiting human subjects through social media. This is not a direct expense to the award, rather it is supported by UD F&A funds generated by BADER.

Website (bader-c.org): A web developer has been hired part time on supplemental funds to oversee the implementation of major enhancements to the website. This is not a direct expense to the award, rather it is supported by UD F&A funds generated by BADER.

4c: Prepare administrative documents

- Developed an operational model of the BADER Consortium.
- Provided strategic support for Defense Health Board briefing materials.
- Established partnership with team leaders at Leidos for the Homeland Defense TATs IDIQ mechanism (solicitation FA8075-12-R-0002, Leidos award: FA8075-14-D-009). The University of Delaware and BADER are exclusive team members with Leidos on this initiative. The IDIQ provides a funding mechanism to government agencies to direct dollars to entities under a limited competitive opportunity.
- Met with representatives from RESolutions, LLC and CISCRP to begin discussions on the Human Subject Recruitment Initiative.
- Coordinated travel arrangements and proffer letters for four MTF staff to attend scientific meetings per BADER travel policy.
- Provided support to John Collins, the first MTF (NMCSD) staff person matriculated into UD's PhD program in Biomechanics and Movement Science. The BADER Consortium is supporting the stipend for Mr. Collins and the University of Delaware is providing the tuition.
- Started working with David Tulskey's ROM Core team to develop a website for rehabilitation outcomes tools that have been reviewed.

- Participated in WARRIOR Conference planning meetings.
- Continued coordination of BADER Consortium Committee monthly meetings.
- Petitioned for first “third party” to the BADER CRADA.
- Supported Dr. Stanhope’s role as Chair of CDMRP 2014 Clinical and Rehabilitative Medicine Research Program Grant Review Panel
- Dr. Stanhope briefed the Health Care Delivery Subcommittee of the Defense Health Board (DHB) on May 21, 2014. The briefing focused on BADER Consortium’s work, role in traumatic amputee research and care, and partnerships with the DoD, VA and others in the landscape of amputee care. They were also interested in hearing about the research that the BADER Consortium is involved in. The briefing highlighted the number (7-9) of large scale initiatives at each MTF needed for sustainability. Following the briefing, the DHB requested a five-year projected budget. See appendix G for the proposal that was provided. Attached as Appendix H is the memorandum from the Under Secretary of Defense requesting the DHB to review the spectrum of amputee care.
- BADER leadership continues to engage the VA. A strong partnership with the VA will be essential for sustainability efforts of the Consortium. BADER looks forward to establishing a strong relationship with Dr. Brian Schulz as he replaces Dr. Jaeger on the GSC. Dr. Stanhope reviewed grant applications for the VA in the third quarter of this FY.

Task 5: Policies and Procedures:

- 5a. Develop, implement and ensure compliance of all SOPs for The BADER Consortium (months 1-60)
- 5b. Ensure compliance with all existing policies and procedures (months 1-60)
- 5c. Create a policy and procedure manual to be distributed to all BADER stakeholders (months 1-12)

Policies and Procedures:

A No Cost Extension (NCE) policy for BADER funded proposals is being developed.

Travel authorization policy:

- This fiscal year, under our travel authorization, BADER supported the travel expenses for Dr. Andrew Hansen, Director, Rehabilitation Engineering Research Program, Minneapolis VA Health Care System to present Grand Rounds at WRNMMC by invitation of Dr. Erik Wolf. This visit included a tour of the WRNMMC clinical facilities by Dr. Scoville, a grand rounds presentation to the clinical staff and a research collaboration discussion with Dr. Wolf. At the time of this report, Drs. Hansen, Linberg and Wolf have submitted three research proposals as a result of their discussions during this visit.

- Under our year three approved budget, \$25,000 was budgeted to support MTF travel under our approved travel policy. During a BCC meeting, MTF representatives agreed to split the funding equally and each MTF is able to spend \$6,250 each on research related travel per fiscal year. BAMC, WRNMMC and NMCSD have used their travel allotments to attend scientific conferences.
- WRNMMC has informally requested support of a Grand Rounds series to engage clinicians and scientists in research.
- The Administrative Core processed several proffer letters and associated travel requests to travel officials to the Government Steering Committee meeting in February 2014.
- Travel support for senior scientists to visit MTF sites resulted in several grant application submissions and awards.

Task 6: Proposal/Award Coordination and Management:

- 6a. Management of annual project solicitation process to BADER Affiliates – months 1-48
- 6b. Management of approved projects (financial, HR, administrative support) – months 13-60
- 6c. Oversight of all subawards for technical and financial compliance – months 1-60

- The second annual call for proposals was successfully executed during this quarter. The call announcement was made on August 1, 2013 and final selections made at the GSC meeting on Details about the call can be found under the Clinical Research Core activities.
- Year three subcontracts to existing contractors were released.
- We received approval on February 26, 2014 to move forward with the Pruziner (Linberg) and Grabowski projects. The subcontract with Denver Research Institute (Grabowski) has been fully executed and the project is underway with a start date of October 1, 2013. The subcontract with Henry M. Jackson Foundation (Pruziner (Linberg)) has been fully executed with a start date of March 1, 2014.
- Review and approve all invoices on subcontracts - Subcontractors are reminded to bill on a regular basis
- Provided additional materials to move PROFIT subcontract forward. The PROFIT project is the first joint project between the BADER Consortium and METRC.
- Provided support on a collaboration between UD and NMCP for a white paper submission on the most recent CDMRP call.

- Provided additional documentation to NYU for the NYU-NMCP-UD collaboration that was recommended for funding.
- Continued working with Dr. Tulsky to complete Toolbox project documentation for final review and approval.

Ongoing work related to this task:

- Establish subcontracts with three new research projects upon approval from CDMRP.
- Work with CDMRP Contract Specialist to finalize Schnall and Wilken projects.
- Continue to seek remaining documents from Dr. Tulsky on “Toolbox” project for approval by Contract Specialist.
- Work with METRC to establish subcontract for recently approved “ProFit” project.

Problem areas related to this task:

- Delays in dealing with extended response time from Contract Specialist at CDMRP.
- Delays in response time from Dr. Tulsky in establishing budgets has resulted in delays to submit information to CDMRP. Dr. Tulsky has transitioned to a full-time faculty appointment at the University of Delaware. With this transition, we anticipate significantly shorter delays in moving Dr. Tulsky’s projects forward.
- Delays in invoicing by subcontractors puts overall award spending behind resulting in excess cash on hand. Subcontractors are reminded to bill timely.
- BADER has supported the development of several successful research proposals through staff time, travel support for research collaboration meetings and proposal preparation support. Despite this effort, MTFs are still guarded on providing high-level details (title, agency, investigators) of the proposals so BADER can report the activity. Being able to report this activity will help demonstrate impact of Consortium efforts.
 - Continue to work with MTF representatives to encourage them to report the efforts and guarantee that the information is to only be shared in reports to sponsor.

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Task 7: Intellectual Property, Material Property, Inventions and Patents Management:

- 7a. Management of IP, MP, Invention and Patent agreements – months 1-60
- 7b. Consult with legal experts as necessary for compliance – months 1-60

Omnibus BADER CRADA: Current status of the CRADA is detailed in Table 2.

Table 2: List of current and pending BADER CRADA partners

Institution	Date of distribution	Date of completed agreement
University of Delaware	September 19, 2012	November 7, 2012
Brooke Army Medical Center	September 19, 2012	January 3, 2013
C-Motion, Inc	September 19, 2012	September 20, 2012
Christiana Care Health Systems	September 19, 2012	October 18, 2012
Mayo Clinic	September 19, 2012	November 1, 2012
Spaulding Rehabilitation Hospital	September 19, 2012	October 11, 2012
University of Michigan	September 19, 2012	Cancelled (Tulsky relocated)
Naval Medical Center San Diego – omnibus CRADA	September 19, 2012	Rejected
Naval Medical Center Portsmouth – omnibus CRADA	September 19, 2012	Rejected
Naval Medical Center Portsmouth – Project specific	September 19, 2013	March 2014
Naval Medical Center San Diego – umbrella Navy CRADA	November 2013	April 2014
Walter Reed National Military Medical Center	September 19, 2012	April 2013
Denver Research Institute (DRI) (Grabowski project)	September 2013	June 2014

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Navy approval status of omnibus BADER CRADA:

- Dr. Stanhope and Ms. Strickland visited with members of the Delaware Congressional delegation on November 19, 2013 to brief them on the challenges with the Office of Naval Research in approving the omnibus BADER CRADA. We have provided documents to the delegation and will continue to pursue an official inquiry. In the meantime, we are currently processing individual CRADAs on an activity-by-activity basis for both Naval sites in order to officially provide support. This activity-by-activity approach has created significant delays.

NMCP: Received fully executed project-specific CRADA on March 6, 2013.

NMCSD: Project specific CRADA has been signed. This is an umbrella CRADA, but uses the standard Navy CRADA, not the Omnibus BADER CRADA. The mechanism allows BADER and NMCSD to add projects to the CRADA without having to negotiate a new CRADA, but only if it's a single site project at NMCSD.

- We have reached out to Dr. Todd Ponzio at Office of Naval Research to arrange a meeting to discuss the BADER CRADA for use at Navy sites.
- Fully executed two CRADAs for new research projects.

- Added RESolutions, LLC as a third party to the BADER omnibus CRADA to provide access to the RETRAIN project.

Task 8: Evaluation:

- 8a. Management of internal evaluation process – months 1-60
- 8b. Primary liaison with external evaluation service (AAAS) – months 1-60

BADER Administration has presented to the MTF representatives, External Advisory Committee (EAC) and the Grants Officer Representative (GOR) a plan for having the American Association for the Advancement of Science (AAAS) perform a research evaluation for the BADER Consortium and provide consultation on a sustainment model. At this time, the AAAS evaluation has been placed on hold.

Clinical Research Core (CRC):

Task 1: Facilitate approvals of protocols for the use of human subjects in research through local IRBs and through HRPO

- 1a. Identify DoD requirements for the protections of Human Subjects in Research (months 1-2).
- 1b. Develop materials for and assist PIs in submitting protocols according to the United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) policies and procedures through the ORP for approval (months 2-48).
 - With regard to the conflicting Navy IRB, the CRC has connected with the Human Subjects Protection Scientist, Office of Research Protections (ORP), U.S. Army Medical Research and Materiel Command Fort Detrick. Together, they have initiated conversation about the design of a work-flow to efficiently move Navy Investigator protocols through the ORP review process. Based on those continued efforts, CRC staff have facilitated one Navy protocol through the Army HRPO approval process. Additionally, the CRC has facilitated the approval of a civilian/VA collaborative protocol through the Army HRPO.
 - The CRC has contributed significantly to the revision of the BADER Consortium SOPs specifically sections related to the conduct of human subjects research.
 - On-site Protocol and Data Management Coordinators provided by BADER funds have gained access to and utilize the military IRB electronic systems for their assigned location. They are now trained in local IRB guidelines and procedures. Each has been successful at assisting with the preparation of IRB materials and in submitting protocols through their respective IRBs.
 - Institutional Review Board (IRB) processes and expectations differ between DoD sites (MTFs) and non-DoD sites and among the DoD sites themselves. However, per the BADER Award, all

sites participating in a research project must send their IRB records and associated documentation to the Human Research Protection Office (HRPO) at the USAMRMC ORP to obtain final approval before initiating any human subjects research activities. Once HRPO approval has been obtained, BADER Administration sends a letter to the PI providing approval to begin their human subjects research activities. This process has been codified. Depending on the research project, a non-DoD participating site IRB may elect to rely on the DoD site IRB as the IRB of record. At this time, non-DoD sites cannot serve as the IRB of record.

- To help study sites navigate the multi-tiered IRB process, the CRC is developing guidelines outlining the necessary procedures and related forms. The Director of Research met with CDMRP HRPO representatives at Fort Detrick to gain a clear understanding of the IRB process at the CDMRP level.
- Clinical Research Core Protocol and Data Management Coordinators continue to fully participate in and support the approval of protocols through their respective IRBs and through HRPO when required. Specifically, they prepare protocol applications, amendments, and continuing reviews; serve on human subjects protocol administrative review committees; interface with local IRBs to coordinate audits; and maintain secure records of all human subject consent and other PII data forms.
- Interinstitutional Authorization Agreement (IAA) process: Still in progress is the design of a model process intended to facilitate a rapid process of gaining approval for human subjects research activities in a BADER supported multi-center study. The guideline allows one or more participating institutions to cede primary IRB review and regulatory oversight to another participating institution's IRB, who serves as the "central" or Reviewing IRB. The intent is to streamline the documentation work flow process necessary to secure agreements between the University and each of the participating BADER sites. The design process has involved compiling local/institutional procedures and conducting a comparison analysis to identify opportunity to share and adopt processes/procedures across sites in order to streamline and make material preparation, submission, tracking more efficient. At the time of this report, CRC staff is working with the UD IRB compliance officer to finalize the guideline so that it can be embedded into the BADER CRADA and the BADER SOPs.
- The above described guideline will enable the UD IRB to rely in whole or in part on the IRB at another BADER-affiliated institution. This will provide a mechanism for CRC staff on-site at MTFs to engage in human subjects research activities in a supportive role.
- Staff stationed at the NMCP successfully completed the background/clearance checks and now have access to various Navy information technology system including the ability to submit and monitor IRB applications, continuing reviews, etc.
- CRC staff continue to fully participate in and support the approval of human subject protocols. Per individual protocols as needed, authorization agreements are executed. The CRC Manager and Consortium Director have designed several example work flow models representing the

complex and coordinated effort necessary to fully secure approval to conduct BADER-related human subjects research. These work flow models have become a mechanism for discussion with several key individuals. For example, the CRC, along with support from the Administrative Core, is coordinating with the University IRB Compliance Officer to streamline the documentation work flow process necessary to secure agreements between the University and each of the participating BADER investigator sites. The process of enacting a standard work flow for reciprocal authorization was adopted and has been applied. A template letter was created and is now available to assist PIs and their research teams in preparing for and submitting protocols according to UD policies and procedures. Additionally, the CRC Manager has provided “view” privileges into the protocols submitted to the UD IRB and is copied on emails addressing USAMRMC ORP review of BADER-funded protocols. The CRC Manager and Consortium Director met with the UD IRB representative and identified three standard situations for which BADER investigators may submit to the UD IRB. These three situations are modeled and materials to support investigators have been distributed.

- In addition to their assignments on BADER-funded research projects, this quarter six CRC field staff additionally provided support for 24 non-BADER funded studies at MTF sites. Their contributions range including the completion of literature reviews in preparation of project presentations/ publications, conduct of volunteers for study participation, assisting with the preparation of research proposals, monitoring regulatory documents and processes, and assisting to evaluate and acquire lab equipment.
- Currently, five protocols associated with non-BADER funded projects have been submitted to the UD IRB and shared with the CRC manager.

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Ongoing work related to this task:

- Facilitate where necessary, the initial approval for human subjects research for the recently awarded BADER-funded protocols.
- Work to transfer the on-going monitoring of human subjects approval (e.g., continuing reviews) and the system for communication of these activities to the BADER administrative core.

Problem areas related to this task:

- It continues to be the case that the amount of time that passes between the initial submission of a protocol through final IRB approval is, in some cases, extensive.
- The process of approving non-Army protocols through IRB review to facilitate the approval of BADER investigator protocols in a timely manner is under discussion. Formal discussions with HRPO began in May 2014.

- The disconnect between supporting the initial IRB submission process to OHRP (responsibility of the CRC Manager) and the monitoring of study human subjects approval status across the life of the protocol (responsibility of the BADER Director of Research) continues. The CRC manager, not the Director of Research, receives copies of protocol renewal email reminders that are sent from OHRP to the BADER funded PIs.

Task 2: Assist in the development, implementation, and monitoring of standard protocol/human subject research activities that will be instituted across MTFs and Clinical Study Sites throughout the BADER Consortium:

- 2a. Compile detailed descriptions of all of the planned activities/ interventions/ testing sessions etc. in which subjects will participate in each study and identify existing research resources at MTFs and clinical study sites (months 1-3).
- 2b. Identify and hire Consortium Protocol and Data Coordinators Managers (months 1-3).
- 2c. Identify and hire On-site Protocol Managers and Technicians for MTFs and clinical study sites (months 1-6).
- 2d. Identify data storage needs and work with the Scientific Cores to set up policies and procedures relating to coding of research protocols, subjects and associated data across all MTFs and clinical study sites (months 6-12).
- 2e. Train Consortium Protocol and Data Coordinators in modeling protocols in Data Monitoring System (months 6-12).
- 2f. Implement the Protocol and Data Management System (PDMS).

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Protocol and Data Management System updates:

- Esprit Health has initiated legal action against the University of Delaware and Dr. Stanhope for not purchasing the Esphere software. Esprit alleges that since Esphere was included in the proposal, that a contract was guaranteed. As previously reported, the NIH CTDB software was chosen for implementation. Several members of the Consortium have been deposed and the final deposition is scheduled for December 18, 2014 which concludes the discovery phase of the lawsuit. The production of documents under this lawsuit has put considerable pressure on the BADER staff, however, it should be noted that no BADER funds are being used to meet this task. Under advice of counsel, it was recommended not to widely discuss the lawsuit, therefore we have limited our communications. After the discovery phase ends, we are permitted to engage in discussions.
- The BADER Consortium is in the process of renewing the UD/NIH agreement for use of the CTDB.
- CRC staff continues to collaborate with the National Institutes of Health/NICHHD. UD has embedded a BADER staff member at NIH to support CTDB implementation.

- We have successfully tested a new release of the CTDB and have developed the question bank and study forms to accommodate the first two BADER study protocols. We have also modified and made more comprehensive the currently used CTDB initial “PI Interview” intended to compile detailed descriptions of all of the planned activities/ interventions/ testing sessions etc. in which subjects will participate in each study. We officially launched the CTDB with modeling of the first two protocols and by conducting introduction training in Bethesda MD to 14 BADER investigators and research team staff.
- Work continues on the development of the user materials. A CTDB web portal has been built (<https://sites.google.com/a/udel.edu/bader-ctdb/>) and is continuously being updated with user materials.
- The new quality assurance process developed has been instituted with the first two protocols and has resulted in an efficient and effective mechanism for both CTDB administrators and the investigators. This process will be instituted with all new protocols modeled into the CTDB.
- Discussions with the BADER Outcomes Core were initiated in order to launch the design of a PDMS oversight committee. A list of potential members has been generated.
- We created an identity for the key CRC personnel who support the implementation of the CTDB, now called the CTDB Operations Core. This Core consists of the CRC Manager, the IT Consultant and the Master Protocol Administrator. Modeling a protocol starts with a meeting of the Principal Investigator and the Master Protocol Administrator to discuss the research project and how it will best use the BADER CTDB. It is the first step in an iterative process of designing and setting up the research protocol and associated data collection forms in the CTDB. The interview is an information-gathering meeting where the Master Protocol Administrator asks about specific characteristics of the protocol design. It also provides the PI the opportunity to learn more about CTDB functions and to see if particular ones will complement and benefit the protocol data management.
- We opened the CTDB user portal to the BADER community. The portal is designed to assist end-users with various related tasks including adding patients to the data base; generating a unique identifier for each patient; and entering patient data. We also launched monthly CTDB “huddles” intended to provide a short demonstration of a particular CTDB task as well as time for Q/A. BADER research teams are invited to voluntarily participate; this quarter we held one huddle with seven individuals. All huddles are audio and video recorded and will be posted as supplemental learning options on the CTDB web portal. The huddles take advantage of the Adobe Connect and conference call line capabilities that BADER has instituted.
- The CRC CTDB Operations Core has activated a total of four protocols in the CTDB system. One member of the Operations Core previously received approval to access the CTDB behind the NIH firewall and now a second member of this Core is near finished with the application

process in order to have the same access. Access behind the NIH firewall for these two individuals will maximize the Core's ability to respond to PI request for data reporting.

- The CRC Manager instituted a contract with an independent contractor that currently supports NICHD CTDB to fully establish a mirror image of the NICHD CTDB environment to ensure that BADER investigators will have access to the full capabilities of the system. These capabilities include patient self-reporting abilities and full data reporting capacity. Contract activities are currently operational.
- CTDB Operations Core continues to collaborate with the National Institutes of Health/NICHD to implement the data monitoring system (CTDB). This quarter the Core conducted an introductory training session for 14 new BADER-CTDB users. The BADER CTDB user portal was updated with two short informational videos (BADER-NICHD CTDB Partnership and CTDB Overview). Two CTDB monthly "huddle-up" sessions were conducted (July and September) and attended by an estimated 6 and 10 BADER CTDB users respectively. Instructional videos are in development; the first was posted on the portal this quarter.
- The CRC Manager is currently coordinating with NIH representatives on a renewal of the soon-to-expire Collaborative Agreement between U of Delaware and the NIH.
- A BADER-NICHD collaborative abstract was prepared and submitted to the American Medical Informatics Association – the professional home of leading informatics: clinicians, scientists, researchers, educators and students. The abstract highlights the collaborative work of the BADER-NICHD and potential to expand this model of collaborative work to other non-federal institutions. The abstract was invited for a podium presentation in April 2014.
- We have also developed work flow processes modified from current intramural processes used by the NIH/NICHD. The modified processes are intended to specifically meet the needs of extramural community of research investigators. Different from the NICHD processes, the modification includes an independent quality assurance check point for the design of new protocols.

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CRC Staff updates:

- Four BADER Dispatch articles were posted on the BADER web site: Protection of Human Subjects; Adverse Events; Essential Documents; and Continuing Review.
- One staff member was successfully relocated from BAMC-CFI to Spaulding Running Clinic. This reassignment has resulted in this individual having the opportunity to lead a study protocol and work with Dr. Davis on concept development for two additional related research initiatives.
- UD IRB and CRC Manager developed the following University policies:
 - o UD IRB to act like an agency for certain protocols
 - o Non-UD employees (e.g. MTF representatives) can be PIs on UD grants

- CRC staff continues to function as a collective as they work from each of their respective study locations. This quarter the staff gathered for a face-to-face meeting in Bethesda, MD for training on the CTDB, training at C-Motion, tour of the WRNMMC, a visit to the NIH biomechanics laboratory, and administrative meeting with the CRC manager. Ongoing: all staff actively participates in weekly phone meetings with the CRC Manager and also in a monthly “all-hands-on-deck” web-based meeting.

Problem areas related to this task:

- There appears to be differing expectations from the MTF about CRC staff roles and responsibilities. As a result, one CRC Protocol and Data Management Coordinator resigned when offered a position with an Investigator independent of the BADER Consortium. This particular Coordinator was only provided opportunity to partake in about half of the responsibilities listed in her job description.
- With the launch of a new version of the dedicated BADER instance of the CTDB (this new version was issued in parallel to the NIH/NICHHD new version); along with this launch came a few technical “bugs” and because of a delay on the part of the NICHHD in rectifying these issues BADER investigators have yet to start entering study data into the CTDB. Past inefficiencies in NICHHD response-time to rectify issues have been discussed with the NICHHD. Accordingly, a new programmer has been introduced to the NICHHD team and is currently being trained to assist in these situations. As a result, NICHHD’s response-time efficiency will improve.
- During BCC meetings MTF representatives and PIs are reporting increased challenges to recruiting human subjects. They have approved the launch and funding of a broad-based Human Subject Recruitment Initiative.
- The leader of the NIH-NICHHD CTDB team resigned from his position. Though this individual remains an NIH employee he is no longer in direct charge of NIH contractors assigned to the CTDB. To date this has not posed particular problems however, there is concern regarding the future location of the CTDB. We will soon learn if the CTDB will be moved from its current location on an NICHHD server to another server within the NIH at the Clinical Center. This potential move may bring about the need to reestablish the need for the NIH to host the BADER instance of the CTDB.

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Ongoing work related to this task:

- Initiate efforts to convene a PDMS oversight committee now that the CTDB will officially be “rolled out” to the BADER community for active use.
- Complete a working set of CTDB user materials.
- Establish a large scale Human Subject Recruitment Initiative.

- Continue planning for the launch of a CTDB (PDMS) oversight committee.
- Further build the CTDB user web-portal to include a variety of materials intended to maximize investigator/research team knowledge so they effectively and efficiently use the CTDB.
- Provide first level technical assistance to those with active protocols; activate BADER administrative protocols. Coordinate with NICHD to train and activate BADER ability to independently respond to investigator basic report requests.
- Coordinate with NICHD on the continued development of model processes for use of the CTDB in the extramural research community (for example, design of CTDB capability for investigator single-button select report production to produce basic reports).
- Continued testing of the CTDB following a July 1 new release.
- Monitor the deliverables on the current contract to establish the NICHD mirror CTDB image for BADER.
- Finalize the collaborative agreement renewal with the NICHD.
- Model remaining BADER-funded studies into the CTDB.
- Conduct three CTDB huddle sessions; edit and post video recordings on the CTDB user web portal.

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Task 3: Provide training and oversight to On-site Protocol Managers, Technicians and other relevant personnel in study procedures:

- 3a. Develop and provide training to On-site Protocol Managers and oversee the coordination and maintenance of Institutional Review Board and ORP approvals, including initial review and approval processes, continuing renewal processes, amendment, and addendum and termination approvals. (months 9-60).
- 3b. Develop and provide training to On-site Protocol Managers, and oversee procedures to recruit subjects, track accrual, track human subjects compliance, schedule tests, and report adverse events to the ORP and local IRBs. (months 9-60).
- 3c. In conjunction with the Scientific Cores, develop and coordinate training for the Consortium Data Coordinators, On-site Research Directors and Technicians and other relevant personnel in data collection and management and quality control procedures (months 12-60).
- CRC staff visited C-Motion for training/technical assistance on issues specific to current protocols. As a result, staff learned of software strategies or functions and the ability to link software data to other commonly used motion analysis software programs.

- Each CRC staff completed an individual UD performance appraisal in which they identified training goals that will enhance their professional performance and site-specific research contribution capabilities. For the first time MTF-POCs actively contributed to the UD annual performance appraisal of BADER CRC staff at their respective site.
- All CRC field staff maintain CITI certification and site-specific training requirements relevant to study procedures for conducting research with human subjects.
- CRC staffs from each assigned study site continue to participate in a weekly conference call with the Clinical Research Core Manager to discuss issues related to human subjects research generally and specific to their study site research projects. All CRC staff participate in a virtual meeting one-time per month to discuss a variety of topics related to the coordination and conduct of research.
- This quarter the first of several CRC staff facilitated “learning opportunities” was conducted. One CRC member facilitated a session on conducting highly impactful literature reviews. CRC staffs are often called upon by MTF investigators to conduct reviews for scientific posters/publications and grant proposals.
- The CRC continues to coordinate with the Outcomes Core to build into the CTDB all outcome measures identified by the Outcomes Core as commonly used and/or published measures of orthopaedic rehabilitation outcomes. Additionally, and inclusive of the Administrative Core, this group has tested the set-up of a web-based resource of a summary of these measures and has begun to secure permission from authors to post the selected measures in a new BADER on-line resource library.
- Individual CRC staff has completed as available on-site training at their research location.

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Ongoing work related to this task:

- Combine CTDB user training with data collection and management and quality control procedures.
- Build into the bi-weekly staff activity reporting system the opportunity for staff to highlight specific accomplishments – regularly share accomplishments across CRC.
- Continue the opportunity for regularly sharing resources and accomplishments across CRC.
- Facilitate the achievement of CRC staff individualized training goals as identified on their UD performance appraisals.
- Complete the set-up of select rehabilitation measures in the CTDB. Stand up and make publically available the Outcomes Core on-line library of select rehabilitation measures.

Problem areas related to this task

There is a perception among the CRC on-site staff that the more information/training/knowledge they gain through support from the BADER Consortium the more of a “threat” the staff become to the MTF setting. Select staff have expressed that they sense hesitancy on the part of the MTF to “trust” the research enterprise processes attempted to be implemented by BADER. For example, it is acceptable for a CRC staff member to design an Excel data base for tracking publications at the request of an MTF representative; however, it has been unacceptable if a CRC staff alternatively suggests the use of the CTDB publication built-in tracking function.

Task 4: Monitor protocol activities and notify Administrative Core of inadequate study procedures, training or subject recruitment that requires input from the BADER Consortium Coordinating Center

- 4a. Develop tools for reporting progress in of training activities, subject recruitment and testing, data analysis and quality control measures (months 6-24).
 - 4b. Track study progress monthly and notify Administrative Core of underperforming sites and suggest solutions to improve performance (months 12-60).
 - 4c. Provide input to Administrative Core for quarterly progress reports of clinical research studies (months 4-60).
- CRC will implement the use of “administrative protocols” which will enable progress reporting on training, subject recruitment and testing, data analysis and quality control.
 - Additionally, this is continued emphasis on tracking study subject recruitment, enrollment, and completion information. CRC will support this effort by assisting to collect this information from BADER investigators and entering all of the information into the CTDB which will allow on-going tracking of progress across all BADER studies.

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Table 3: Key dates for BADER funded research projects

	2012.1 – Step2Step	2012.2 - RETRAIN	2013.1 – ProLeg Rx	2013.2 – K2Power	2013.3 – Outcomes Toolbox	2014.1 MORE	2014.2 Backpack
Proposal submitted	Oct 2010	Oct 2010	Dec 2012	Dec 2012	Dec 2012	Nov 2013	Nov 2013
Scientific Review	May 2011	May 2011	December 2012	December 2012	December 2012	December 2013	December 2013
GSC approval	June 2012	April 2012	March 18, 2013	March 18, 2013	March 18, 2013	February 28, 2014	February 28, 2014



Contract negotiation docs sent to CDMRP	June 2012	July 2011	Aug 5, 2013	Aug 5, 2013	pending	Add'l info sent to CDMRP Dec, 2014	Add'l info sent to CDMRP Dec, 2014
CDMRP approval	August 2012	August 2012	February 2014	February 2014	pending	Pending	pending
Omnibus CRADA executed	December 2012	October 2012	March 2014	Amendment pending	Pending due to Tulskey relocation to UD	Amendment pending	Amendment pending
BADER PI agreement signed	August 2012	October 2012	April 2013	Pending	Pending	April 2014	March 2014
IRB approvals	August 2012	June 2013	October 2013	May 2014	Pending	Pending	Pending
HRPO approval	September 2012 (aim 1) April 12, 2013 (aim 2)	June/July 2013	COMIRB approval Oct 2013	June 2014	Pending	Pending	Pending
Subject pool	*	*	15	0	#	#	#
Subjects screened	23	14	3	0	#	#	#
Subjects enrolled	21 (Aim 1: 21, Aim 2:1)	2	0	0	#	#	#
Subjects Completed	21	0	0	0	#	#	#
Presentations	3	1	0	0	#	#	#
Publications	2 (under review)	0	0	0	#	#	#

* currently gathering this information # project has not started.

Task 5: Research Development

- 5a. Identify gap research areas.
- 5b. Identify and secure sources of external funding.
- 5c. Connect BCAs with potential collaborators.
- 5d. Create research pipeline of tech development to basic research to clinical trials.
- 5e. Support research development at MTFs.

The second annual call for proposals was completed in year three. A summary of the call follows in table 4.

SECOND CALL (2013 – Year 2-3):

Timeline for 2013 Call for Proposals:

Call Announced: August 1, 2013
 LOIs due: October 1, 2013
 Proposals due: November 18, 2013
 Scientific review: December 18, 2013
 GSC selection: February 19, 2014
 Announcement: April 1, 2014

Research priorities established for the second Call for Proposals:

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1. Determine factors that predict development and successful treatment of musculoskeletal conditions following severe extremity trauma and/or deployment related musculoskeletal injuries.
2. Determine the optimal treatment strategies to minimize impairments, maximize function and performance, and/or achieve optimal quality of life.
3. Develop metrics that effectively quantify changes that result from rehabilitation or provision of novel technologies.

For this Call, we offered support to the PIs with the development of their research proposals by making available to them the services of our Administrative, Statistical, Biomechanical and Outcomes cores. BADER also offered these services to those PIs who were not funded during the last Call for Proposals in order to strengthen their proposals that may be submitted for external funding or for BADER funding in this Call.

Table 4: Summary of second call for proposals:

Letters of Intent received	4
Total number of research proposals received	4
Proposals received, administratively screened out	0
Proposals forwarded to Research Advisory Committee (RAC)	4
Total dollar amount requested	\$4,083,991
Proposed numbers of human subjects	20-1300

Number of collaborating site	3-4
VA sites identified as collaborators	1
MTFs identified as clinical sites	
WRNMMC	2
BAMC	1
NMCSD	1
NMCP	1
BADER Consortium Cores utilized in proposal preparation	
Biomechanics Core	0
Biostatistics Core	1
Outcomes Measurement Core	1

- The identification of gap research gap areas has been determined at our annual strategic planning meeting up until this year. However, this is being replaced by the Annual WARRIOR meeting. This meeting will be attended by the major stakeholders, including EACE. This will be an ideal place to identify these gap areas. Dr. Davis is serving on the organizing committee of this meeting, so will work to incorporate a discussion of research gap areas at this meeting. Additionally, Dr. Davis attended the 3rd International Soldier Performance Conference in August to be held in Boston, MA to gain some insight into gap areas at this meeting.
- Subject Recruitment Contract: In an effort to recruit subjects for the BADER Funded studies, we are looking for a contracting agency to support these activities. We were able to bring the recruitment company, RESolutions in under the BADER CRADA. After sharing the information they needed on our study, we obtained a proposal from them. Under their proposed payment schedule, BADER would pay over \$50,000 without a guarantee of any subjects. Therefore, the B2C committee decided to seek some other competing proposals. We contacted a referral by David Tulsy who did not feel she would be able to assist us. We have contacted a company in Massachusetts and are awaiting a proposal from them. Once a proposal from a recruitment company is approved, we will use the Walk-Run Retraining Study (SNRC and WR sites) as a test case to determine the cost-benefit of utilizing such services. If successful, we may move to incorporate the recruitment company as a BADER fee-for-service Core. Investigators would then be encouraged to incorporate the cost of these services into their grant applications.
- Human Subjects Recruitment Initiative: Apart from the need to recruit subjects for the current BADER studies described above, the BADER Consortium is developing a large scale Human Subject Recruitment Initiative to find solutions to the larger systemic issue of subject recruitment. We have been discussing strategies with The Center for Information & Study on Clinical Research Participation (CISCRP) a non-profit in Boston whose mission is to educate and inform the public and patients about clinical research. The B2C has been engaged in finding solutions. BADER leadership would like to engage the GSC in providing guidance moving forward with this critical initiative.

- Continue to expand the BCA information on the BADER website to assist in facilitating collaborations. We have developed a partnership with the Amputee Coalition in order to provide opportunities for individuals with limb loss to participate in BADER Consortium funded studies. We are in contact with the Wounded Warrior Program to see how we might better collaborate with them.
- Other initiatives have been put in place to support research development at MTFs including:
 - o Subject recruitment support
 - o Travel policy to promote collaborations and communications
 - o Two MTF researchers are planning to apply to the University of Delaware PhD program in Biomechanics and Movement Sciences and will utilize the free tuition support provided by UD.
- BADER Consortium Affiliates: Two new BCAs were added this year.
- Using supplemental funds, BADER funded and developed a research page on the Amputee Coalition's website that will extend our reach and provide a source of recruitment for BADER related studies across the US. We are currently working to develop a similar relationship with the Wounded Warrior Project to be able to recruit from within this group as well. Finally, we are beginning to connect with Team Red White and Blue as another source of wounded warriors who might benefit from the work of BADER.
- BADER CRC Staff have been instrumental on providing support for proposal development at the MTFs. NMCP has been notified of a funding recommendation for a proposal that includes both CRC staff members and we are currently waiting for a subcontract from NYU. This proposal, once funded, will buy-out 30% of Heibert and Faulkner salaries. This salary savings to the Consortium will be used by CAPT Ziemke to fund additional personnel at NMCP to keep the research enterprise moving forward.
- Open funding sources are listed on the BADER website. With the hiring of the Communications Specialist (using indirect funds), there will now be a coordinated effort to disseminate opportunities via electronic means.

Task 6: Development and Coordination of the Call for Proposals

- BADER has now completed our last Call for Proposals and now has two additional GSC approved projects that are recommended for funding. This brings the total to seven projects (see Table 4) and meets our original goal of funding 6-8 projects.

Scientific Technical Cores:

Biomechanics Core (BC): C-Motion, Inc.

Task 1: Assessments

1a. Assessments of all MTF equipment, facilities, motion capture technologies, clinical testing processes, and quality assurance policies and procedures (months 1-6).

- This task is completed. See previous reports for details.

1b. Assessment of MTF commonalities and collaborative standards and processes (months 1-6).

- This task is completed. See previous reports for details.

1c. Evaluation of the MTF CAREN Virtual Reality systems for Visual3D integration and data collection support (months 1-6).

- This task is completed. See previous reports for details.

1d. Evaluation of motion capture protocols, marker sets, processes, and data management (months 1-6).

- This task is completed. See previous reports for details.

1e. Dissemination of collaboratively developed protocol standards to MTFs (months 6-12).

- This task is complete.

Task 2: Standards:

2a. Develop common data management pipelines, scripts, and motion analysis techniques across all MTF and clinical research labs utilizing Visual3D (months 7-12).

2b. Support for “aggressive rehabilitation” protocol adaptations (months 7-60).

2c. Evaluate the protocols for pooling and sharing data across institutions (months 7-60).

- There is no update on this task for this reporting quarter.

Task 3: Certifications:

3a. Identify DoD processes for the implementation of initial motion analysis Certification procedures (months 7-12).

3b. Identify DoD processes for the implementation of additional Certification procedures (months 12-

18).

- 3c. Develop Certification procedures and criteria (months 12-24).
- 3d. Initiate the establishment of Certification courses (months 12-24).
- 3e. Develop Certification courses for dissemination and implementation of the criteria (months 24-30).
- On March 26, 2014 Katie Werner (C-Motion) met with BADER staff from Spaulding National Running Center (SNRC), Walter Reed National Military Medical Center, and Naval Medical Center Portsmouth at C-Motion's Germantown office to discuss options available within Visual3D and C-Motion's Real Time biofeedback projects.
- On March 4-5, 2014 Tom Kepple traveled to SNRC and conducted two days of Visual3D training the new SNRC BADER affiliated staff.
- The Biomechanics Core recommends that this task be modified to focus on customized training for the MTFs, rather than certification programs. As the number of BADER staff increases and there is movement of staff between MTFs, it is critically important to train these researchers. In the future, as the number of BADER Affiliated projects increases, we will revisit the need for certification programs.

Task 4: Support and Collaboration:

- 4a. Collaborate with the MTF sites to implement data collection protocols for proposed experiments (months 12-60).
- 4b. Collaborate with BADER projects to implement data collection protocols consistent with MTF guidelines (months 12-60).
- 4c. Implement biomechanical model templates for the MTF and BADER projects (months 12-60).
- 4d. Implement Visual3D processing pipelines for each project (months 12-60).
- 4e. Implement Visual3D reporting templates for each project (months 12-60).
- 4f. Implement process and protocol management standards across MTF sites for new data analysis routines (months 25-60).
- 4g. Implement written standards (checklists) for data collection protocols (months 25-60).

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Overall Progress on non-Protocol Specific Support and Collaboration (4a-g):

The Biomechanics Core has assisted NMCS and WRNMMC with their existing pipelines and templates on a case by case basis, but the substantive work done on Task 4 has been new software development for one of the BADER affiliated projects.

Site Visit with NMCS November 8, 2013 to discuss future projects and to identify a wish list of items for development.

Support of “Returning to High-Level Performance: Walk to Run Training with Real-time Kinetic Feedback” Protocol:

In December 2013, the Core worked with Spaulding National Running Center (SNRC) by releasing and testing an updated version of both Visual3DServer and the real-time client for the “RETRAIN” training protocol.

Also started working with getting Steve Jamison, PhD, (CRC staff assigned to Spaulding National Running Center), to get him acclimated to the C-Motion real-time software. (Steve will be operating the software upon the departure of Cindy Samaan and Evelyn Graff at the end of 2013).

The Core has made considerable progress on the ongoing development of Visual3DServer. They have implemented options to create Biofeedback clients using Matlab and Python. By creating these more accessible clients, it is straightforward for the MTF staff to prototype minor modifications to the feedback, which they can then forward to C-Motion for implementation in the actual biofeedback application.

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In January 2014, C-Motion released Visual3DServer and a re-implementation of the biofeedback client.

Over a period of January 2014 through March 2014, C-Motion worked with Steve Jamison at SNRC to examine whether the algorithm used for the Biofeedback client for detecting foot strike pattern during running was appropriate. (The current algorithm uses the foot angle to the floor at heel strike to determine the contact pattern). Through examination of some SNRC motion capture files, SNRC video files and discussion with Dr. Jamison it was determined that it was possible to have a foot in a position of dorsiflexion (relative to the lab) but still have a fore-foot strike. (This is anomaly is based on the observation the foot is much wider at the metatarsal heads than at the heel.) Tom Kepple, staff of the Biomechanics Core, and Dr. Jamison have begun looking into more robust algorithms for detecting the foot contact patterns during running.

C-Motion is continuing to explore ways to make the data from the instrumented treadmills more reliable. They have enhanced the gait detection algorithms for the biofeedback clients, and have explored more robust algorithms for filtering the force data.

At the end of this quarter C-Motion released the latest version of Visual3D server and a new biofeedback client. The communication protocols for the client have been improved dramatically and they feel that this application is ready for final testing. The latest version has been validated using data collected at both Spaulding and WRNMMC and the results were compared to values that were obtained

from Visual3D for the same measures. (There was exact agreement between the Visual3D values and both the walking and running biofeedback data when data was “streamed” from Visual3D server using .c3d files.)

In addition, improvements to the user interface allow users more options to modify the biofeedback for clients and enhanced control over the gait event detection algorithm. Modifications to the event detection during the running biofeedback were implemented to improve detection of the foot-floor angle at heel strike.

The Biofeedback client display was also enhanced giving the Spaulding and WRNMMC labs more control over what the final out display will look like including selected of display colors and the addition of grid line to the running biofeedback page.

C-Motion continues to explore ways to make the data from the instrumented treadmills more reliable. They have enhanced the gait detection algorithms for the biofeedback clients, and have explored more robust algorithms for filtering the force data.

Based on discussions with Spaulding the Core has continued to adapt the biofeedback client to satisfy requested enhancements to the protocol. At the end of this quarter C-Motion released another version of Visual3D server and biofeedback client that have been tested successfully at Spaulding. There is still exact agreement between the Visual3D values and both the walking and running biofeedback data when data was “streamed” from from Visual3D server using .c3d files. C-Motion is continuing to explore ways to make the data from the instrumented treadmills more reliable.

The gait detection algorithms for the biofeedback clients were modified and tested repeatably. The improvement in the event detection, and the increased flexibility provided to the user to allow parametric changes to the detection, have mitigated previous concerns over the calculation of the foot-floor angle at heel strike.

New Real-time biofeedback client for WRNMMC:

Erik Wolf at WRNMMC requested C-Motion to develop a new real-time bio-feedback client. While awaiting the final specs for this new client we have initiated development by creating a new GUI shell for the client as well as developing the communications protocol.

OpenSim Modeling with a prosthetic foot with some energy return

Elisa Arch (University of Delaware) has offered to provide guidance on the OpenSim development, but at a request from WRNMMC for background training and support for OpenSim modeling of a prosthetic foot, C-Motion conducted training in the Germantown office on Sept 29-30, 2014.

On Sept 3, 2014, Tom Kepple met with Dr. Steven Stanhope at the University of Delaware. During this meeting Dr. Stanhope expressed interest in the development of a new Induced Acceleration Visual3D plugin for use with prosthetic foot analysis. Following the meeting Tom Kepple started updating an older Visual3D plugin architecture to work with Visual3d version 5. This is the initial step in the development of the new plugin.

Mechanical Work calculations across the gait cycle.

No work was done on the implementation of mechanical work calculations across the gait cycle, with particular emphasis on energy loss at foot impact. C-Motion still needs to explore the requirements for this development because there are several options available based on the work of Max Donelan.

Inertial Measurement Unit (IMU) Development

At a request from NMCSD we have initiated discussions for an application to measure trunk velocity and trunk acceleration during a perturbation on the treadmill. We have conducted preliminary discussions with Delsys about their integrated EMG & IMU sensor, and we have implemented prototype software for integrating the Delsys SDK into Visual3D Server. C-Motion will receive the first batch of Delsys sensors for testing in late October, and NMCSD is expecting shipment of the Delsys sensors in January.

Ongoing work in relation to this task:

- The biofeedback applications will be refined based on further testing by the MTFs. Tom Kepple and Dr. Jamison will continue the exploration of algorithms for detecting the foot contact patterns during running.
- Test prototype IMU development on receipt of the initial batch of IMUs from Delsys. We have arranged for a meeting with Delsys in Boston for October.
- Based on the Training for WRNMMC on Sept 29-30, 2014 we will determine the requirements for ongoing support of the OpenSim project on a prosthetic foot simulation.

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Task 5: Custom Database Development:

- 5a. Custom database development for specific MTF interactions with Visual3D to facilitate concurrent protocols in use by multiple MTFs (months 13-60).
- 5b. Implement a clinical interface to the database software for clinicians within a specified clinical framework (months 13-60).
- At this time, the MTFs have not expressed interest in the implementation of a custom database.

Task 6: Visual3D Enhancements for MTFs:

- 6a. Integration of existing MTF data collection equipment into Visual3D (months 13-60).
- 6b. Perform experimental tests to estimate the effective latencies of the real-time motion capture systems, including the CAREN system (months 13-60).
- 6c. Test, or collaborate with the appropriate manufacturer, to test all force sensing equipment used in the MTFs (months 13-60).
- A formal request was received from NMCSD for the implementation of the UD segment power analysis technique in Visual3D. During this quarter C-Motion initiated this implementation. The

following steps in the process were completed:

- o The following steps in the process were completed:
 - * The existing UDPower scripts were re-written to make them more readable for the user and then made available for distribution.
 - * Since the UPPower technique does not inherently require a foot segment, a second set of scripts were developed for use when no foot segment was part of the Visual3D model. These new scripts were tested to ensure they provided the same answer as the original scripts.
 - * With the scripts in place (as a short term solution), the Core developed a new pipeline command (Compute_UD_Power) which was added to Visual3D. This new command replaces the previously developed scripts. This new command was tested against the existing scripts to make sure it returned the correct values.
 - * At the end of the quarter C-Motion released Visual3D containing the new Compute_UD_Power.
- o Modified the command Compute_UD_Power to make it easier to specify the treadmill belt velocity. The new command allows the user to enter the treadmill belt velocity in either laboratory space, the coordinate system of the treadmill force plates (which will remain constant as the treadmill locations are re-calibrated) and the coordinate systems of any Visual3d segment (which will Visual3d to handle treadmills which are moving during the trial as might occur with the CAREN system.) A new dialog was also added to the new Visual3d Compute_UD_Power command making the command easier for the user to enter the required parameters.
- o The new Compute_UD_Power command will be updated to obtain the treadmill direction directly from the c3d file rather than prompt the user. This will allow Visual3D to account for small misalignments between the different treadmill belts and also make it so the user does not have to compute and enter the treadmill direction (which can be complicated if the treadmill is not aligned with one of the principal axis of the laboratory coordinate system). C-Motion will implement the UD Power pipeline as a Visual3D model based item, which allows the calculations to be updated automatically when the workspace is recalculated, and allows the calculations to be an integral part of the report template.
- C-Motion has explored the integration of three different IMU sensors into the Visual3D server (X-IMU, APDM, and Invensense). They have made progress calibrating the X-IMU sensors, but are waiting for the next release of X-IMU sensors that will allow us to synchronize the IMU data with MoCap data.
- We have implemented prototype software that integrates with the Delsys SDK for their upcoming IMUs. NMCSD has ordered IMUs from Delsys that are expected to be shipped in January.

- We are continuing to work with data from instrumented treadmills. In response to the challenges faced with this data, we are re-implementing Visual3D's procedures for handling the data. Most of the challenges are related to partial contacts with two platforms simultaneously. This new implementation focuses on combining the force signals prior to any pre-processing of these signals.
- Since work on and testing of the new real-time biofeedback software consumed virtually all of C-Motion efforts this quarter there was a delay in turning the Compute_UD_Power command into a LinkModelBased item within Visual3D. Making this command a LinkModelBased item will allow this calculation to be updated automatically when the workspace is "Recalculated", and also allow this calculation to be an integral part of the report template. This work on Compute_UD_Power command will start up again in the next quarter.
- In addition, we also plan to finish updating the new Compute_UD_Power command so that Visual3D will obtain the treadmill direction directly from the C3D file rather than prompt the user. (Work was started on this but not completed this quarter.) This will allow Visual3D to account for small misalignments between the different treadmill belts and also make it so the user does not have to compute and enter the treadmill direction (which can be complicated if the treadmill is not aligned with one of the principal axis of the laboratory coordinate system).

Rehabilitation Outcomes Measurement (ROM) Core: University of Delaware

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Note: Dr. Tulskey relocated to the University of Delaware effective September 23, 2014 and the Core has been established at UD.

Task 1: Establish outcomes library and training libraries, develop infrastructure for working with investigators.

- 1a. Submit relevant IRB related documents as necessary.
- 1b. Conduct literature reviews to identify relevant outcomes measurement tools related to orthopedic injuries.
- 1c. Build measurement library for utilization of relevant outcomes measures for research studies.
- 1d. Provide workshops, web-ex presentations, and seminars to train BADER personnel about Patient Reported Outcome (PRO) measures.
- 1e and f. Prepare training materials for data collection of patient reported outcomes. Prepare measurement platform for BADER proposals (develop Assessment Center or alternative method for data capture).

1a. We have obtained IRB approval at NMCSD. We have transferred the grant and submitted IRB paperwork at New York University (NYU) and IRB approval is pending. We are working with Center for the Intrepid (CFI) to submit at their site.

1b. The ROM Core is updating their extensive systematic literature review to identify recently published measurement tools that have been used in orthopedic/amputation research. They are finalizing the systematic review of each identified scale, and summarizing the relevant research on the psychometric properties and construct validity. They are preparing a manuscript for publication based on these findings. Once funding is established at New York University and University of Michigan, the Core will work with BADER at University of Delaware to post the reviews on a website. Dr. Tulskey has spoken to Dr. Allen Heinemann at the Rehabilitation Institute of Chicago and informed him about the ROM reviews. Dr. Tulskey will set up further meetings with BADER leadership to discuss how to disseminate the systematic review and determine if it should be offered as part of the Rehabilitation Measures Database (www.rehabmeasures.org), a BADER dissemination output, or both.

1d. This deliverable concerned the development of training material on Patient Reported Outcomes assessment. During our site visits, we gave in-person presentations to help train BADER personnel about PRO measures. We have also provided WebEx training to the Biomechanics Core, as Dr. Scobie expressed interest in learning more about outcomes measurement tools. Finally, we have completed a draft of a “stock” patient reported outcomes assessment PowerPoint/WebEx training session to be used with any MTF personnel who will be utilizing PRO measures in upcoming studies.

1c. These literature searches and reviews have facilitated establishment of a measurement library for BADER-relevant outcomes measures. In addition to the previously described 28 measures of physical functioning, seven measures of prosthetic function and satisfaction, and eight measures of physical symptoms that have established use in orthopedic/amputation research in amputee populations have been identified. The library is presently being updated with recent 2014 publications.

1e and f. In addition to the Powerpoint/WebEx training mentioned in 1d above, we have also developed a detailed training manual for any BADER affiliated researcher who wants to utilize PROMIS measurement scales and/or the PROMIS Assessment Center platform. These training materials can be used by BADER affiliated researchers to facilitate PRO assessment in their studies, to train data collectors, and to assist researchers in developing study-specific manuals of procedures. Though training topics include the development of an Assessment Center managed study, the ROM core is available as a resource to all MTFs to prepare Assessment Center (or similar) study administration platforms.

1d-f) The ROM had developed training materials so that investigators could incorporate PROMIS and other self-report scales into their research. Given the advance of the clinical trials data base, Dr. Tulskey will discuss ways to integrate self-report assessment into the clinical trials data base and determine what modifications need to be made. The ROM Core has developed training materials so that investigators could utilize PROMIS from Assessment Center. The Core is working with the CTDB team to incorporate tests into the CTDB.

Task 2: Evaluate relevant outcomes measurement instruments and ensure relevance for use in BADER studies. Ensure that floor and ceiling is appropriate for the population. Develop new item content as appropriate.

- 2a. Develop focus group guides to identify measurement issues.
 - 2b. Prepare and execute focus group meetings at collaborating DoD sites (months 2-3)
 - 2c. Transcribe focus group guides and prepare NVivo (qualitative software) coding guides (months 4-6)
 - 2d. Code and reconcile focus group data (months 7-9)
 - 2e. Develop new item content to increase measurement sensitivity/specificity of orthopedic injuries (months 10-12).
- Focus group guides have been developed and finalized and we have received IRB approval to conduct focus groups at NMCS D.
 - We have identified a Clinical Psychologist at Northwestern University who has agreed to serve as moderator for our focus groups. He has excellent clinical skills and extensive experience conducting focus groups.
 - Focus group guides have been developed and finalized. Two doctoral-level clinical psychologists with focus group experience have been identified as leaders, and this quarter a new collaborator was hired to assist with transcription and coding.
 - Dr Tulskey and the research team have IRB approvals from Naval Medical Center San Diego and Human Research Protection Office and the initial set of focus groups were conducted on May 19 – 21, 2014.

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Problem areas related to this task:

- We are through most hurdles with the initial IRB approval being granted and having identified an excellent moderator for our groups. We are close to finalizing other staffing needs to accomplish our goals as described above.
- Erin Cesario, research coordinator at NMCS D and a key staff member on this project, is transitioning out of the role and as such we will need assistance from a new coordinator at NMCS D.

Task 3: Consult and review study proposals for the BADER Consortium

- 3a: Submit relevant IRB related documents as necessary.
 - 3b: Work directly with prospective PIs of BADER projects. Provide consultation on outcomes measurement design issues and integration into proposals and research methodology.
 - 3c: Review proposal ideas and provide feedback on outcomes design.
 - 3d: Work with investigators to provide design measurement platforms and train research personnel.
 - 3e: Develop new measurement techniques tailored for specific interventions as appropriate.
- Dr. Tulsky met with BADER core personnel at University of Delaware to discuss transition of BADER Outcomes Core with Dr. Stanhope, Rachel Strickland, and Suzanne Milbourne.
 - Dr. Tulsky provided consultation to Dr. Wilken as he submitted his proposal in the new BADER consortium competition.
 - Dr. Tulsky has also consulted with Marco Campello (NYU) regarding his BADER submission. Dr. Tulsky initiated regular meetings with Dr. Campello who works actively with NMCP to develop new ideas for funding and advancing research at NMCP.
 - As soon as funding is awarded, we will meet with MTF Leaders to discuss Toolbox project.
 - 3a & b. Dr. Tulsky continues to discuss new research with other members of the BADER consortium. He will be collaborating with Jason Wilken at BAMC/CFI on the MORE project and Alison Pruziner on her proposal. They are discussing future grant opportunities with Portsmouth.
 - 3a & b. ROM Core team members continue to discuss new research with other members of the BADER Consortium. Dr. Tulsky will collaborate with Jason Wilken at BAMC/CFI on the MORE project and Alison Pruziner on her K2 Power project. Dr. Tulsky is discussing future grant opportunities with NMCP.

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Ongoing work related to this task:

- Develop IRB protocol for the new “Assessment Toolbox” BADER grant awarded to Dr. Tulsky. Coordinate submission at the MTFs and VA. Plan launch meeting at NMCSO when the project is funded.
- Provide direct support to Dr. Alison Linberg (for the “K2 Power Study”) as required.

- Continue to discuss possible collaborations with Gregg Ziemke and Marco Campello (NYU) to see if the Rehabilitation Outcomes Measurement Core can provide assistance to the Portsmouth research initiatives.

Biostatistics Core: Christiana Care Health Systems (CCHS)

Task 1: Participate in development of project specific aims and research design with investigators.

- Provided design and statistical consultation for two proposals for second cycle of BADER funding.

Task 2: Develop statistical analysis plans (SAP) for each research project.

- Statistical analysis plan and sample size calculation requested for one proposal to be submitted for second BADER funding cycle. (due November 18, 2013).
- Supported proposal development for BAMC/CFI, WRNMMC and UD.
- Statistical analysis plan and sample size calculation developed for one proposal submitted for second BADER funding cycle. This proposal was recommended for funding by the Government Steering Committee and the Grants Officer of the BADER Consortium.

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Ongoing work related to this task:

- Work in the next quarter on the Wilken MORE project will include development of data base structure, plans for data transfer, reporting cycles, and detailed statistical analysis plan.

Task 3: Assist in the design of datasets for analysis. Provide transfer capabilities and expertise.

- At this time, there have not been any requests from Consortium members for this service.

Task 4: Conduct statistical analyses.

- Statistical analysis consultation for two ongoing research projects. No data analysis requested.

Task 5: Provide assistance in developing presentations, writing reports and manuscripts.

- At this time, there have not been any requests from Consortium members for this service.

Progress Reports on Clinical Studies

**2012.1: “Improving Step-To-Step Control of Walking in
Traumatic Amputees”**
“STEP2STEP”

Abstract: Gait and balance training are essential for patients with lower limb amputation because of their high fall risk. However, little scientific evidence exists to guide efforts to develop such training programs. The purpose of this study is two-fold: to determine how step-to-step control strategies differ between patients with varying levels of amputation and to determine how these patients respond to a virtual reality based training intervention. Addressing these two issues will provide an essential foundation from which we can design more effective training protocols. Enhanced training will take place in a fully immersive virtual reality (VR) environment so we can apply well controlled and ecologically relevant motions to the walking surface. Effective VR-based gait training programs may provide significant advantages over traditional gait training, putting therapists in control of the training environment and allowing them to quantitatively monitor patient progress in real time. We expect this will yield significant generalization to real world walking. We will conduct a single-center study including 30 patients with varying degrees of lower limb amputation to determine the relative effects of VR based treatment on walking step-to-step control strategies. We will test each subject before, during, and after training as well as at an approximate 2-week follow-up while walking both in the VR environment and while walking over flat and uneven ground. Step-to-step control measures will then be compared across the group of patients using regression analyses against clinical performance measures to better understand the effects of physical ability on step-to-step control. Additional intra-subject analyses will be conducted to look at changes in walking over the course of the intervention.

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Title:	2012.1: “Improving Step-To-Step Control of Walking in Traumatic Amputees”	
Funded Amount:	\$679,300	
Principal Investigators:	Jonathan Dingwell, PhD	Department of Kinesiology & Health Education, University of Texas at Austin, Austin, TX
	Jason Wilken, PhD	Military Performance Lab, Center for the Intrepid, Department of Orthopaedics & Rehabilitation, Brooke Army Medical Center, San Antonio, TX
Collaborators:	Joseph P. Cusumano, Ph.D.	Pennsylvania State University, Department of Engineering Science & Mechanics
Accruals	Aim #1: 21 total subjects (9 patients + 13 controls) Aim #2: 1 subject	
IRB Approvals:	Our IRB application for Specific Aim #1 was determined to qualify for “ <u>exempt</u> ” status so therefore no annual renewals are required.	

	Our IRB application for Specific Aim #2 has been approved” by BAMC IRB and has received HRPO approval. Approval expires: January 2015
Amendments to IRB	
Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	None reported.
Finances:	Award amount: \$679,300 Spent to date: \$395,230 % spent to date: 58% % award period complete: 66.7%

Progress to date:

The project began in September 2012.

Personnel Changes:

- Dr. Jonathan Rylander (U. Texas Post-Doctoral Associate, hired Oct., 2012) accepted a faculty position at Baylor University in Waco, TX, starting in Aug., 2014.
- Dr. Riley Sheehan (U. Texas Post-Doctoral Associate working at CFI / BAMC) was working with Drs. Dingwell and Wilken on the separate NIH funded R01 project. Starting Sept. 1, 2014, Dr. Sheehan’s appointment was split to include 25% of his time working on this BADER project. Dr. Sheehan will continue to work in Dr. Wilken’s lab at CFI and will take over Dr. Rylander’s CFI-based responsibilities to this project.
- Dr. Nicole McLagan (U. Texas Post-Doctoral Associate working at UT Austin) recently completed her Ph.D. (May, 2014) in Dr. Dingwell’s lab at UT Austin. Starting Sept. 1, 2014, Dr. McLagan was appointed 75% time on this BADER grant to assist with data processing and analyses of existing and new data, and with preparation of new manuscripts.

Collaborative Efforts Ongoing:

- Dr. Dingwell has continued to travel to CFI / BAMC regularly for full-day meetings with Drs. Wilken, Rylander, Sheehan, and other project personnel to discuss progress.
- Dr. Wilken continues to meet regularly with Dr. Dingwell and with Drs. Rylander and Sheehan, individually and/or together, to assess progress and discuss the project.
- Dr. Rylander remains in close proximity to Austin and will continue to maintain regular contact with Drs. Dingwell and Wilken to complete on-going manuscripts.
- Dr. McLagan and Ms. Mandy Salinas (U. Texas Ph.D. Student, hired Sept., 2012) will both continue to work on BADER-related activities from Austin, TX.

Specific Aim #1:

To quantify the extent to which patients with transtibial amputation exhibit step-to-step control strategies that are different from appropriately matched non-impaired control subjects.

Specific Progress on Aim 1: To quantify the extent to which patients with transtibial amputation exhibit step-to-step control strategies that are different from appropriately matched non-impaired control subjects.

(a) This project involves secondary analyses of previously collected data. We have completed all analyses of both experimental and simulated (modeling) data. Dr. Rylander has completed the first draft of the first manuscript, in consultation with Drs. Dingwell, Cusumano, and Wilken. Two additional manuscripts are still planned. Dr. Rylander will continue to take the lead on the first of these. Dr. McLagan will assume the lead on the second one.

- Drs. Dingwell & Cusumano have submitted 2 additional related manuscripts that will help greatly strengthen the theoretical foundation of the work Dr. Rylander is doing. The first of those two papers has been reviewed and is now “In Revision”.

(b) The primary next steps are to finalize and submit Dr. Rylander’s first manuscript, and then finalize the analyses and start writing the 2nd (Dr. Rylander) and 3rd (Dr. McLagan) manuscripts.

- In addition, Dr. Rylander presented portions of his work at the World Congress of Biomechanics (WCB) meeting in Boston, MA in July 2014, and will also present at the Society for Neuroscience (SfN) meeting in Washington, DC in Nov., 2014.
- (c) (i): We have faced no “administrative” challenges as of yet.
- (ii): We currently face no “scientific” challenges at the moment. The main current focus is writing manuscripts for submission.
- (d) (i): Nothing to do as of yet.
- (ii): Dr. Cusumano is assisting Dr. Rylander and Dr. Dingwell with the mathematical interpretation and proper construction of the first manuscript. Dr. Cusumano has also worked closely with Dr. Dingwell on the theoretical aspects of this work, which have led to the 2 additional submitted manuscripts mentioned above.

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Specific Aim #2:

To determine if a VR based gait re-training intervention that explicitly exploits each patient’s own step-to-step control is more successful than VR based gait stability training and/or conventional therapy for improving walking in patients with transtibial amputation.

Specific Progress on Aim 2:

(a) Since our previous report, data from the first patient enrolled in this study have been checked and verified. Initial analyses of those data have been conducted. All the primary raw data have been checked and appear to be of high quality (we see no evidence so far of any technical issues with the data collected).

(b) We are proceeding in two next steps. First, we are working to continue to recruit new patients into the protocol. Second, in parallel to continued recruiting efforts, Dr. Sheehan is now taking over the task of finalizing and quality-checking the analyses of the data obtained from our first subject, and will then start writing up these results as a “Case Study” to be submitted for publication.

(c) (i): Our primary “administrative” challenge continues to be finding qualified and willing participants. This is a long intervention study. There are other studies going on in the MPL and there continue to be fewer new patients coming into BAMC.

(ii): There are currently no “scientific” challenges that we are working on resolving.

- (d) (i): Dr. Wilken is working with the staff in his laboratory and with the clinical staff at CFI to identify potential participants and recruit them into the study.
(ii): Nothing to do as of yet.

Preliminary Results:

For Specific Aim #1, Dr. Rylander has completed all primary data analyses. This work compared the frontal (coronal) plane stepping control strategies of patients with unilateral transtibial amputation to those of healthy controls. All subjects walked with either no perturbations or with mediolateral *visual* field or treadmill *platform* perturbations. Both subject groups most strongly corrected deviations in *step width* from stride-to-stride. These findings have been verified and validated by computational control models developed by Drs. Rylander, Dingwell, and Cusumano. Patients with amputation exhibited significantly greater variance in their stride-to-stride corrections across all conditions, but particularly during platform perturbations. Thus, although patients with amputation appeared to adopt the same overall control strategy as healthy controls, they were less successful at implementing that strategy.

Various preliminary results of this work either were or will be presented at the *Society for Neuroscience* (Nov., 2013), *Orthopedic Research Society* (March, 2014), *World Congress of Biomechanics* (July, 2014), and *Society for Neuroscience* (Nov., 2014) conferences. Dr. Rylander has completed the first complete draft of the first journal publication to be submitted from this work. Two additional subsequent publications are planned.

For Specific Aim #2, data have been collected for one patient so far. Preliminary analyses of those data have been conducted. Over the course of the intervention, this patient exhibited large decreases in mean step width and step width variability, and improvements in several other basic measures of gait performance. Moreover, these improvements were maintained at follow-up testing several weeks after the intervention ended. Dr. Dingwell presented some of these initial findings at the *World Congress of Biomechanics* meeting in July, 2014. Dr. Sheehan is now taking the lead to write up these findings to submit for publication as a case study.

In addition to the findings just described, the work we are doing on this BADER-funded project and the ideas and discussions generated as a result of this work have helped to inform the development of two new projects. In the first, we are studying the specific role that visual optic flow plays in helping to regulate sagittal plane stepping movements in healthy subjects. Ms. Salinas assisted with that study, which was conducted at UT Austin. Ms. Salinas presented her findings at the *World Congress* (July, 2014) meeting and will present again at the *Neuroscience* (Nov., 2014) meetings.

Likewise, Dr. Wilken and Dr. Dingwell have developed a new VR-based walking paradigm that directly targets lateral stepping control, as a novel extension of the work Dr. Rylander did on this BADER-funded project. The paradigm creates a “virtual obstacle course” where patients have to make various lateral shifts while walking to navigate successfully. In addition to his BADER-related duties, Dr. Sheehan is currently assisting Dr. Wilken’s research group in collecting data from both patients with lower extremity injuries (amputation and/or limb salvage) and healthy control subjects. Dr. Dingwell presented some of our initial findings at the *World Congress* (July, 2014) meeting. Additional results of this study will be presented by Dr. Sheehan at the upcoming *Neuroscience* (Nov., 2014) meeting.

Presentations (BADER-related):

Cusumano, J.P. and Dingwell, J.B. (Submitted) "On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics," ***Proceedings of the 2013 Dynamic Walking Meeting***, Pittsburgh, PA, June 10-13, 2013.

Rylander, J.H., Wilken, J.M., Cusumano, J.P. and Dingwell, J.B. (2013) "Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.

Dingwell, J.B. and Cusumano, J.P. (2013) "Using Perceptual Cues to Regulate Walking From Stride-To-Stride," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.

Rylander, J.H., Beltran, E.J., Wilken, J.M., and Dingwell, J.B. (2014) "Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking," ***Proceedings of the 60th Annual Meeting of the Orthopaedic Research Society***, New Orleans, LA, March 15-18, 2014.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (Submitted) "Able Bodied Persons and Individuals with Transtibial Amputation Employ Similar Control Strategies in the Frontal Plane during Treadmill Walking," ***Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.

Dingwell, J.B. and Wilken, J.M. (Submitted) "Integrating Virtual Reality and Motion Capture for Clinical Assessment and Rehabilitation," *Invited Symposium Presentation*, ***Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.

Salinas, M.M. and Dingwell, J.B. (2014) "How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking," ***Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2014) "Strategies for controlling lateral stepping movements in human walking," ***Proceedings of the 2014 Society for Neuroscience Annual Meeting***, Washington, DC, Nov. 15-19, 2014.

Sheehan, R.C., Rylander, J.H., Wilken, J.M., and Dingwell, J.B. (2014) "A virtual reality obstacle course to improve lateral balance control in lower limb trauma patients," ***Proceedings of the 2014 Society for Neuroscience Annual Meeting***, Washington, DC, Nov. 15-19, 2014.

2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”
“RETRAIN”

Abstract: Lower extremity amputations significantly impact a soldier’s gait function and their ability to return to active duty. Despite standard rehabilitative care that includes gait training, loading remains elevated in the intact extremity, increasing the risk for the development of degenerative joint disease. *The purpose of this study is to examine whether symmetry of loading can be improved in both walking and running using real-time feedback in individuals with unilateral, transtibial amputations.*

Title:	2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”	
Funded Amount:	\$708,524	
Principal Investigators:	Irene Davis, PhD, PT	Spaulding Rehabilitation Hospital
	Alison Linberg, DPT, ATC	Walter Reed National Military Medical Center
Collaborators:	Steve Jamison, PhD Matthew Ruder, MS Devjani Saha, PhD Elizabeth Nottingham Elizabeth Husson Amanda Wingate, BA	
Accruals:	SNRC: Potential subjects contacted: 15 Potential subjects screened: 13 Subjects enrolled: 0 WRNMMC: Potential subjects contacted: 10 Potential subjects screened: 6 Subjects enrolled: 1	
IRB Approvals/Amendments:	SNRC: IRB approval received: June 13, 2013 HRPO approval received: June 19, 2013 WRNMMC: IRB approval received: June 19, 2013 HRPO approval received: July 11, 2013 SNRC Amendment 1 (submitted 06/02/13; approved 06/13/13) a. Inclusion of subjects with non-traumatic amputation (except dysvascular amputation)	

	b. Addition of heel raise protocol to prepare subject for running portion c. Addition of Illinois agility test as a functional measure for running d. Non-identifiable data will be shared with BCTDB Amendment 2 (submitted 07/19/13; approved 08/08/13) a. Removed Nike as study sponsor b. Addition of question to telephone script (year of amputation) c. Addition of anthropometrical measurements Amendment 3 (submitted 09/03/13; approved 10/02/13) a. Separate protocols for walking and running Amendment 4 (submitted 10/25/2013; approved 11/13/2013) a. Increase age limit from 50 to 60 b. Include females c. Pregnancy added as exclusion criteria d. additional advertising text added Amendment 5 (submitted 12/16/2013; approved 12/17/2013) a. Add Steve Jamison to protocol Amendment 6 (submitted 12/19/2013; approved 01/21/2014) a. Add Steve Jamison to recruitment materials b. Modify inclusion/exclusion to not restrict all individuals with additional c. musculoskeletal injuries that might influence gait Amendment 7 (submitted 01/24/2014; approved 01/28/2014) a. Add Thaddeus Babiec, Phattarapon (Pat) Atimetin, Erin Futrell, and Zach Robbiano to protocol b. Eveline Graf and Cindy Samaan Amendment 8 (submitted 02/10/2014; approved 02/27/2014) a. Change contact information on flyers to reflect new lab gmail address Amendment 9 (submitted 02/10/2014; approved 02/18/2014) a. Add Matt Ruder to protocol Amendment 10 (submitted 03/19/2014; approved – pending) a. New flyers with more color b. Recruit via social media Continuing Review (approved 04/04/2014)
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	Amendment 11 (submitted 04/04/2014; approved 04/07/2014) a. Update colors on flyer to match those of Harvard/Spaulding Protocol Exception 1 (submitted 04/04/2014; approved 04/15/2014) a. Include one individual with a unilateral transfemoral amputation Protocol Exception 2 (submitted 06/04/2014; approved 06/13/2014) a. Include one individual with a unilateral transfemoral amputation (first individual did not qualify to continue with the study after signing consent) Protocol Exception 3 (submitted 07/31/2014; approved 08/01/2014) a. Include one individual older than our maximum age allowed of 60 years old. We used the max age of 60 years old to exclude comorbidities and inactivity that are common in older individuals. This individual is very active, even participating in several sports (i.e golf, tennis, snow skiing). Given his activity level, and desire to improve his gait, we feel that he would be able to benefit and respond from the gait retraining that this protocol is studying. WRNMMC Amendment 1 (Submitted 7/8/13. Approved 7/24/13) a. Addition of heel raise exercises during walking portion of the study (assessment and training) (Section 5.5.5). b. Delineate procedure for qualifying a training session as a full session or as a session that should be repeated (Section 5.5.5).] c. Clarification on inclusion criterion for walking portion of the study (Section 5.4). d. The CAREN system will not be used for the training, instead the treadmill in the Center for Performance and Clinical Research at WRNMMC will be used for the study. Vanessa Gatmaitan has been removed from the protocol as an Associate Investigator because she is the CAREN operator and will no longer be involved with the protocol. This change has been reflected in the protocol, consent form, and flyer. Amendment 2 (Submitted 11/15/13. Approved 1/17/14) a. Subjects can participate if they qualify for either the walking OR the running portion of the study. Prior to this amendment, subjects needed to have qualified for the running portion of the study to participate. b. The demographics form was changed to include two additional questions: a) the side of amputation and b) the cause of amputation. Amendment 3 (Submitted 2/5/14. Approved 3/10/14) a. Name change: Alison Linberg to Alison Pruziner (Linberg)
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- b. Addition of new associate investigators: Steven Jamison, PhD and Matthew Ruder.
- c. Removal of Eveline Graf and Cynthia Samaan as AI's.
- d. Update the protocol to reflect the same procedures for storing data as stated in the consent form. The master code and any will also be destroyed at the close of the study.
- e. Flyers will be distributed through Achilles Internatioanl to recruite potential participants.
- f. Subjects can participate for the running portion of the study if they use a powered ankle prosthesis. Prior to this amendment, if subjects use a powered ankle prosthesis they would be excluded from the study.

Continuing Review (Submitted 5/6/2014, Approved 6/18/2014)

Amendment 4 (Submitted 5/30/2014, Approved 6/18/2014)

- a. Subjects can participate in just the walking portion of the study, but they must complete walking rehabilitation to qualify for the walking portion only. These subjects would complete 10 minutes walking on the treadmill and then complete the cognitive test. They will not be running. The 20 minute run, running biomechanics, and PEQ run will only be completed if the participant has been prescribed a running specific prosthesis and is completing the screening for potential participation in the running portion of the study.
- b. We will be recruiting non-DEERS eligible subjects through local prosthetists by distributing advertisements. If subjects are recruited for the study, we will meet them at the gates to escort them and/or add their names to the visitor log. Non-DEERS eligible subjects will also receive compensation.
- c. Between the initial screening and the baseline assessment, subjects will have a minimum of 2 weeks two to become acclimated to the study shoes and a maximum of two months. At the end of two months, we will re-assess why there was a two month delay and if the subject should be re-screened for the study.
- d. The master list will be a password-protected document stored on a secured network, only accessible to study personnel at WRNMMC. The consent forms will be secured in a locked file drawer in room B314 in the Amputee Care Center. All hard-copies of data collection forms will be secured in a locked file drawer in the Amputee Care Center (B322).
- e. Added version numbers to all data collection sheets.
- f. We will be collecting date of birth and city of birth to create a unique study code (GUID) for the Clinical Trials Database. This study ID is in addition to the one created by the study personnel. This information will be stored on the master list and will be destroyed at the close of the study. Study

	personnel will not be able to link the GUID to the name, date of birth, and city of birth after the GUID is generated. g. Removal of Devjani Saha, PhD, as AI. Addition of new investigator: Elizabeth Nottingham. h. Email address change for Alison Pruziner, DPT (PI) to alison.l.pruziner.civ@mail.mil. Amendment 5 (Submitted 9/23/2014, Approved 9/26/2014) a. Removal of Elizabeth Nottingham, as AI. Addition of new investigator: Elizabeth Husson. b. Study personnel will visit local amputee support groups to recruit non-DEERS eligible participants. c. Changed the page layout of the advertisement to landscape.
Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	While encouraged by the HRPO to pursue becoming the IRB of record for project 2012.2, the researchers met a significant roadblock with the approval of an Interagency Authorization Agreement. They were advised by HRPO for both Spaulding and WRNNMC to each submit separate IRB documentation to their respective institutions. This set the beginning of the project back as the IRB documentation needed to be revised and resubmitted the local IRB.
Finances:	Award amount: \$708,524 Spent to date: \$397,220 % spent to date 56% Project dates: 10/01/2012 – 09/30/2014 Dr. Davis has been granted a no cost extension to 09/30/2015. % complete: 67%

Research Progress Update:

Aim 1. To determine if a program of gait retraining using realtime kinetic feedback in soldiers with unilateral, transtibial amputations alters the asymmetry of gait during walking and running

Aim 2. To determine whether functional outcomes are altered with gait retraining during walking and running

Aim 3. To determine whether symmetry of loading and functional outcomes are influenced by the provision of feedback during community walking and running using a mobile monitoring device.

Following a prolonged IRB process that began in June, 2012, we received approval for aims 1 and 2 in July 2013. This delay has put us nearly 1 year behind which we expect will necessitate a 1 yr, no cost

extension to complete aims 1 and 2. We have worked to refine our feedback program as well as to develop a marker placement device needed to improve the reliability of our repeated kinematic measures.

We are now actively recruiting for the study. Recruitment has been slow.

- WRNMMC has been able to include three individuals in the running portion of the study. One has initiated running retraining and the other two are preparing to begin. They are now allowed to recruit civilians and have gained approval to recruit through local amputee support group meetings, and will begin that recruitment soon.
- SNRC has recruited and screened five people in the lab, one of which qualified for the walking portion of the study. This individual has completed the initial assessment and 9 of the 12 retraining sessions. She is on track to complete the training in early October.
- In response to a slow recruitment, we have invited local prosthetists to observe the type of feedback we provide the potential participants. We have advertised in the Spaulding Adaptive Sports Newsletter. We have also participated in the amputee running clinic held at Harvard University that was sponsored by the Challenged Athletes Foundation. We attend the weekly Spaulding amputee clinic when potential subjects are being seen. We have placed an advertisement in the online version of the Boston Globe. We have contacted the New England Amputee Association, an associate with the Amputee Coalition, a national organization. We have met with the director of the New England Chapter of the Wounded Warriors Assn and hope to place a recruitment ad in their newsletter. We are also in touch with the Spaulding Rehab Hospital Physical Therapy Department to identify potential subjects. We are placing an ad on the Amputee Coalition Website. We are attending a race with the Team Red White and Blue and we are attending the benefit dinner April 4, 2014, that precedes the race to connect with the leaders of Team Red White and Blue. We have also started an SNRC Facebook and Twitter accounts where we will soon advertise studies (IRB approval pending).

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Due to the yearlong delay in approval from Nike to utilize their instrumented insole, we have scaled back the scope of Aim 3. We will establish the validity and reliability of the instrumented insole in the lab and in the community in 5 individuals with unilateral transtibial amputations.

We have been working with Sapient, a software development company, who will develop the mobile application needed to conduct our pilot study to validate the insole with the instrumented treadmill data. Steve Jamison, will be heading this initiative. They have submitted a proposal to us to deliver a product in 5 weeks. Originally, they were asking \$80,000 to do the project. However, we only have \$20,000 in the grant for this project. Therefore, Sapient has agreed to do this project for \$20,000 with the possibility that this might become a commercial product.

We have spent the last three months working on agreements between Sapient, Nike and SNRC that satisfies each group's requirements, in particular for IP. We are currently working to bring Nike and Sapient in under the BADER CRADA as 3rd party entities. Once this is complete, Sapient has a team ready to begin work.

The new staff (Steve Jamison and Matt Ruder) travelled to Walter Reed in February, 2014 in order to assure consistency in procedures between sites.

Steve Jamison and Matt Ruder underwent 2 days of V3D training from Tom Kepple (C-Motion) at SNRC in March, 2014.

Steve Jamison, Matt Ruder and Irene Davis underwent a half day of orientation with the BADER CTDB in March, 2014.

We have worked with New Balance to donate the shoes that we will need for the retraining at both sites.

The following activities were to take place in the first year of the grant period. However, due to the delay in the approval of the project, the IRB process, which was to begin in the first year of the consortium, did not begin until 9 months into this year. The IRB process was significantly delayed and both sites were unable to begin recruitment until near the end of the second year. Therefore, we are approximately 1 year behind. The following activities of our timeline will take place in year 2 of the grant:

- Baseline gait analysis and outcome measures
- 8 Sessions of walking gait retraining
- Post-training gait analysis and outcome measures
- 1 mo. follow-up gait analysis and outcome measures
- 8 Sessions of running gait retraining
- Post-training gait analysis and outcome measures
- 1 mo. follow-up gait analysis and outcome measures
- Pilot study with instrumented shoe

The following activities of our timeline will take place in year 3 (no cost extension will be requested) of our timeline:

- Completion of Retraining
- Comparison of walking variables across time
- Comparison of running variables across time
- Data Dissemination
- Prepare RCT for submission to DoD/NIH
- Completion of pilot instrumented insole project

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Project personnel:

Eveline Graf has left in December 2013. Hannah Rice, PhD will replaced Eveline Graf and started on July 1, 2014.

Cynthia Samaan, the protocol and data manager has also left in December to accept a higher paying position in industry. Matt Ruder, MS replaced Cindy Samaan, He started Feb 1, 2014.

Abstracts:

Samaan, C, Schwartz, J, Graf, E, Davis, IS and Rainbow, MJ. A standing alignment system improves between-session repeatability in gait kinematics: a preliminary study. Presented at the American Society of Biomechanics Meeting, Omaha, Nebraska, Sept 2013.

Plans for seeking other or continued support when current funding for this research expires:

We plan on submitting a larger, multicenter clinical trial using gait retraining to improve walking and running gait patterns in unilateral transtibial amputees. We will target NIH and/or DoD. We also plan on submitting a grant on the use of mobile monitoring to reinforce proper gait mechanics in individuals with amputees. Steve Jamison is applying to the US Bone and Joint Initiative mentoring program to develop this grant.

2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma

“Trauma Outcomes”

Title:	2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma	
Funded Amount:	Funded through Research Outcomes Measurement Core budget	
Principal Investigator:	David Tulskey, PhD	New York University
Collaborators:	Erik Wolf, PhD	WRNMMC
	Marilynn Wyatt, MPT	NMCSD
	Jason Wilken, PhD	BAMC/CFI
Accruals	No patients yet enrolled	
IRB Approvals:	NMCSD IRB approval received (August 21, 2013). HRPO Approval received March 2014. HRPO Log Number A-17117.5	

Details of this project can be found under Research Outcomes Measurement Core Statement of Work, Task 2

2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?

“The ProLegRx Study”

Abstract: There are currently no science-based, objective methods for optimizing running-specific prosthesis (RSP) prescription. Existing practices can waste time, money, and resources and do not necessarily provide the best prosthetic prescription. Due to the severity of impairment caused by a leg amputation and the healthcare costs sustained over the lifetime of a person with an amputation, it is extremely important to improve RSP prescription so that Soldiers and Veterans with amputations can regain the greatest possible level of functional ability and return to active duty, if they choose. Our goal is to develop tools for clinicians to prescribe running-specific leg prostheses that facilitate optimal function for Soldiers and Veterans with transtibial amputations. We intend to systematically vary the stiffness and height of distance-running RSPs and measure the biomechanical and metabolic effects of running at the speed required for a subject’s age/sex 50th percentile Physical Fitness Test (PFT) 2 mile run and at one standardized speed, 3 m/sec. We also intend to systematically vary the stiffness and height of sprint-running RSPs and measure the biomechanical and performance effects of running across a range of speeds. Then, we will combine results from distance-running and sprint-running prostheses to develop clinically relevant, quantitative algorithms for prosthetic stiffness and height prescription based on a subject’s weight, amputation level, limb segment lengths, and desired running speed. The results of our research will be disseminated to clinicians and will improve RSP prescription for people with leg amputations. We hope to improve and expedite rehabilitation for Soldiers and Veterans with transtibial amputations and to save time, money, and resources. Optimizing RSP prescription would facilitate aerobic conditioning, reduce injury risk, improve running economy (the metabolic demand at a given running speed) and improve performance; thus improving the quality of life and reducing the healthcare needs of Soldiers and Veterans with leg amputations.

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Title:	2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?	
Funded Amount:	\$882,827	
Principal Investigator:	Alena Grabowski, PhD	Dept. of Veterans Affairs Eastern Colorado Healthcare System
Collaborators:	Rodger Kram, PhD	Dept. of Integrative Physiology, University of Colorado
	Ryan Stephenson, MD	Dept. of Veterans Affairs Eastern Colorado Healthcare System
	Michael Litavish, CP	Dept. of Veterans Affairs Eastern Colorado Healthcare System
Accruals:	Potential subjects contacted: 30 Potential subjects screened: 10 Subjects enrolled: 3	
IRB Approvals:	COMIRB: October 14, 2014	

Amendments to IRB:	None
Adverse events:	None
Serious adverse events:	None
Problems or barriers to research:	None reported
Finances:	Award amount: \$827,116 Spent to date: \$39,972 % spent to date: 4% Project dates: 10/01/2013 – 09/30/2016 % complete: 33%

Specific Aim 1: Quantify the biomechanics, metabolic demands, and socket pistoning of subjects with transtibial amputations using distance-running running-specific prostheses (RSPs) of different stiffness and height. *Number of Research Subjects:* 15 subjects will be recruited to participate in a clinical research study, 10 Service Members with unilateral and 5 Service Members with bilateral transtibial amputations that have prior experience with distance-running RSPs.

Specific Aim 2: Quantify the biomechanics, performance, and socket pistoning of subjects with transtibial amputations using sprint-running RSPs of different stiffness and height. *Number of Research Subjects:* 15 subjects will be recruited to participate in a clinical research study, 10 Service Members with unilateral and 5 Service Members with bilateral transtibial amputations that have prior experience with sprint-running RSPs.

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Specific Aim 3: Develop a clinically relevant, quantitative algorithm for RSP stiffness and height prescription based on a subject's weight, level of amputation, limb segment lengths, and desired running speed.

SA 1 and 2, Task 1:

- (a) We have obtained IRB approval from the Colorado Multiple Institutional Board Review (COMIRB) for the human experimental studies in Specific Aims 1 and 2. The University of Colorado Boulder IRB has ceded to COMIRB. We have obtained review and approval of approved IRB documents by the USAMRMC Office of Research Protections (ORP).

SA 1 and 2, Task 2:

- (a) Otto Bock, Ossur, and Freedom Innovations have provided over 60 prostheses to accommodate our subjects. We used a mechanical testing machine (MTS) within the Department of Mechanical Engineering at the University of Colorado Boulder to quantify the stiffness of each running-specific prosthesis (RSP).
- (b) We have quantified the stiffness of each prosthesis and will compile the results of the stiffness tests into a technical report that we intend to publish.
- (c) We needed to build a test jig and determine the angle to test each prosthesis.

- (d) We built a test jig, measured stiffness at different angles and have established a prosthetic testing protocol we intend to publish.

SA 1 and 2, Task 3:

- (a) We have recruited 5 participants; 2 of these participants have completed the protocol. We are continuing to recruit subjects from the Denver VA Jewell Clinic Regional Amputation Center and from an Active Duty Military population.
- (b) We will continue to network with the community to establish a subject pool. We were invited to attend the USOC Paralympic Track and Field research clinic in Chula Vista, CA, and have attended the Hanger Running Clinic in Golden, CO, and the 5480 Challenge Paralympic Track and Field meet in Cherry Creek, CO. We organized a research team meeting that included: the prosthetist that is building the sockets, the prosthetist that is fitting and aligning participants, and a prothetist from the USOC.
- (c) Because each athlete with an amputation has a different build height, we need to recruit participants in a specific order.
- (d) We have obtained measurements from about 15 athletes with leg amputations and will recruit athletes with the tallest build height first and then with shorter build heights so that we can re-use each RSP.

SA 1, Task 4:

- (a) A certified prosthetist from our research team has fit and aligned three subjects to each distance-running RSP brand during an accommodation session. Subjects then ran on a treadmill to accommodate to each of these distance-running RSPs. The height of each RSP was adjusted for each subject prior to the experiment so that they could use each RSP brand with different stiffness and height characteristics without destroying the RSP. Following the accommodation session, subjects came into the lab for three experimental data collection sessions. During these experimental sessions, we measured their biomechanics, metabolic demands, and socket pistoning while they ran with different stiffness and height distance-running RSPs on an instrumented treadmill.
- (a) We will continue to recruit subjects that can complete the protocol.
- (b) We calculated the average required speed for the Physical Fitness Test (PFT) 2 mile run for all participants and found that it is nearly the same as our standardized speed of 3.0 m/s.
- (c) We decided to reduce the number of running trials so that athletes will only run at 3 m/s with all of the different prosthetic configurations.

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The following tasks will begin shortly:

SA 1, Task 5:

- (a) Analyze the data from Task 4 to determine the optimal stiffness and height of a distance-running RSP for each individual. Prepare a manuscript and publish the results of our study in a peer-reviewed scientific journal.

SA 2, Task 6:

- (a) A certified prosthetist from our research team will fit and align each subject to each sprint-running RSP brand during an accommodation session. Subjects will then run on a treadmill at a range of speeds to accommodate to each of these sprint-running RSPs. The height of each RSP will be adjusted for each subject prior to the experiment so that they can use each RSP

brand with different stiffness and height characteristics without destroying the RSP. Following the accommodation session, subjects will come into the lab for six experimental data collection sessions. During these experimental sessions, we will measure the biomechanics, top speeds, and socket pistoning while subjects run and sprint with different stiffness and height sprint-running RSPs on an instrumented treadmill.

SA 2, Task 7:

- (a) Analyze the data from Task 6 to determine the optimal stiffness and height of a sprint-running RSP for each individual. Prepare a manuscript and publish the results of our study in a peer-reviewed scientific journal.

SA 3, Task 8:

- (a) Combine the results from Specific Aims 1 and 2 to create a comprehensive, user-friendly algorithm for prosthetists and clinicians to use so that they can make optimal RSP prescriptions. Prepare a manuscript and publish our algorithm in a free public access peer-reviewed journal. Distribute our algorithm to clinicians through VA education programs and conferences such as the American Academy of Orthotists and Prosthetists (AOPA) annual meeting and the American Orthotic and Prosthetic Association (AOPA) World Congress. Distribute our height-adjustment bracket to clinicians through VA education programs and conferences such as the American Academy of Orthotists and Prosthetists (AOPA) annual meeting and the American Orthotic and Prosthetic Association (AOPA) World Congress.

2013.2: Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3

Ambulators

“The K2POWER study”

Abstract: Advances in lower limb prostheses have allowed for improvements in function and participation in activities for individuals with transtibial limb loss. Advancements in passive ankle prostheses are still limited in their ability to assist with forward progression and push-off because of their inability to produce positive work. Recent advancements to powered prostheses have proposed the potential to provide positive work, returning these individuals to a level of function and efficiency similar to those without limb loss. The objectives of this proposal are to identify differences in gait, efficiency, function, and quality of life between using a standard passive prosthesis versus a powered ankle prosthesis, and to see if changes remain stable for up to six months after the initial fitting. We wish to address these objectives in individuals with lower limb loss that are not capable of fully interacting in their environment and community. This proposed project will assist with prosthetic prescription decisions regarding individuals with transtibial limb loss with varying levels of function, as advanced technology is often not directed at the more disabled population, despite these individuals potentially having the most to gain from this technology.

Twenty individuals with transtibial limb loss will be recruited to participate in this longitudinal study: ten who function at a Medicare Functional Classification Level (MFCL) K2-level and ten who function at a MFCL K3-level. Participants will be evaluated in their current passive ankle prosthesis, be fit with a powered ankle prosthesis, and be followed during six visits over six months. Testing during these six months will include analyzing how the participants walk, how much energy they are using to walk, their balance and endurance, and subjective reports of how they feel and what they are able to do in the prosthesis. We expect results will show differences in walking measures that indicate a change in risk of secondary injury to the intact limb, such as osteoarthritis; will identify changes in efficiency with walking and in balance and endurance; and will measure the users satisfaction with the device and how the user is able to interact with his/her home and community lives, to indicate differences in ability to re-integrate into these roles.

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Title:	2013.2: “Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators”	
Funded Amount:	\$1,529,718	
Principal Investigator:	Alison A. Linberg, DPT	Walter Reed National Military Medical Center
Collaborators:	Erik J. Wolf, PhD	Walter Reed National Military Medical Center
	Joseph B. Webster, MD	Hunter Holmes McGuire VA Medical Center
	David S. Tulsky, PhD	New York University
IRB Approvals:		

Amendments:		
Adverse events:	None reported	
Serious adverse events:	None reported	
Problems or barriers to research:	None reported	
Finances:	Award amount: \$1,529,718 Spent to date: \$406,067 % spent to date: 27% Project dates: 03/01/2014 – 09/30/2016 % complete: 19%	

Research Progress Update: The delay in funding release (5 months) greatly delayed the start of this project. Despite the funding being released in March, the subaward to hire staff and buy supplies was just recently finalized, therefore data collection has not been initiated. The protocol is approved by both WRNMMC IRB and HRPO so pre-data collection activities may begin immediately. We do not foresee any additional challenges at the moment.

2013.3: Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma

“QOL Toolbox”

This project was slated to begin October 1, 2013. At this time, we have not received funding approval from the Contract Specialist.

Abstract: As a result of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND), an unprecedented number of wounded warriors have had combat-related major traumatic limb injuries that include amputation of one or more limbs. These wounded warriors are typically treated for long periods of time at Military Treatment Facilities (MTF) within the Department of Defense (DoD) and later, upon discharge from active duty, at Department of Veterans Affairs Medical Centers (VA) or civilian hospitals. Unfortunately, the health care that is provided across the DoD MTF sites and the VAs is not well coordinated. Individual clinicians and researchers use a wide variety of measurement tools to assess their patients and the lack of standardization across sites makes it difficult to track progress or compare functioning and outcomes across the major treatment facilities. This often results in a lack of coordination of medical care. From a research perspective, the lack of uniformity in measurement tools makes it difficult to compare patients across studies or follow individuals over time as they are transferred to and receive care from different medical facilities. This hinders our ability to study these injured service persons over time to better understand their course of recovery and identify the most effective types of treatments. Because upper limb injury was a rare occurrence prior to OEF/OIF/OND there have been few studies on this patient group and little evidence to inform the design of optimal clinical care guidelines.

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People who have had upper extremity amputation of one or both hands and/or arms, major traumatic damage to their limbs without amputation, or who have had multi-limb amputations are understudied groups. When research is performed, the medical community has focused on assessment of patient physical functioning (e.g., limitations in an individual's strength and their ability to walk and stand) and placed less emphasis on measuring the injured individual's ability to return back to a healthy and productive life by participating in society, and resuming work and social relationships (known as community reintegration). Entire areas of functioning revolving around social participation have been largely ignored in clinical practice. Moreover, without coordination between the MTFs, the VAs, and civilian hospitals, researchers and clinicians at the different sites will use different measures, making it very difficult to accumulate data across sites. A coordinated approach to assessment for this population would help improve clinical care and allow research at different sites to be aggregated. This grant hopes to improve all of these things.

A central aim of this grant is to develop a “toolbox” of outcome assessments that is comprehensive and includes measures of community integration and quality of life, as well as assessments of physical activity and limitations in body functions. The proposed study is unique because it brings together a large group of clinicians and researchers from the major military treatment facilities that treat individuals with traumatic amputation (i.e., the Center for the Intrepid/San Antonio Military Medical Center, Naval

Medical Center in San Diego, Walter Reed National Military Medical Center) and one of the largest VA hospitals and amputation centers (Tampa VA) and one of the oldest and largest civilian hospitals (Rusk Rehabilitation at New York University) along with leaders in measurement from the University of Michigan and Providence VA. This grant will bring together a diverse team of stakeholders (individuals who have had catastrophic limb trauma, clinicians, policy makers, and research investigators) with many representatives from our participating sites to discuss and agree on a series of common measures and scales that can help bring standards and uniformity to the field.

Given the dearth of research on individuals with upper extremity amputation, we plan to validate the toolbox by administering the upper extremity toolbox measures to individuals who have had upper limb amputation at 3 MTFs, a VA, and a civilian hospital. The instrument will be reassessed to help us ascertain reliability and other psychometric properties. Through this collective work we will introduce a new level of cooperation and uniformity to the field. We will study individuals with upper extremity amputations, a subgroup of injured service people who have been underrepresented in research in the past. We will also emphasize the vital areas of community reintegration and quality of life assessment with MTF and VA clinical practice to improve the lives of individuals who have had these traumatic limb injuries. These efforts will ultimately result in improvements to clinical practice which will directly benefit persons with both combat and non-combat related limb trauma and amputation.

Title:	2013.3: "Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma"	
Funded Amount:	\$1,999,969	
Principal Investigator:	David Tulskey, PhD	New York University
Collaborators:	Erik Wolf, PhD	WRNMMC
	Jason Wilken, PhD	BAMC/CFI
	Marilynn Wyatt, MPT	NMCSD
	Tamara Bushnik, PhD	NYU Langone Medical Center
	Linda Resnik, PT, PhD	Providence VA Medical Center
	Gayle Latlief, DO	James A. Haley Veteran's Hospital, Tampa FL
	Claire Kalpakjian, PhD	University of Michigan
	Pamela Kisala, MA	New York University

2014.1 Maximizing Outpatient Rehabilitation Effectiveness (MORE)

Abstract: In 2012, 31.7% of 20,452,769 outpatient visits recorded across the Department of Defense were for rehabilitation services associated with musculoskeletal disorders, the number one cause of disability among active duty service members. Data across all branches of the military indicate that the largest burden of injury from the Global War on Terror is extremity trauma, representing 64% of a projected \$1.9 billion in disability benefit costs, and causing the largest percentage of days on limited duty. Nearly 50% of all extremities injuries involve the lower limb and fewer than 25% of service members with extremities injuries returning to their previous occupation. Service members with lower extremity injuries commonly undergo several months of outpatient rehabilitation in an effort to improve motion, strength and function, and reduce pain and disability. The rehabilitation process for injured service members includes personnel from many different healthcare specialties. Physical Therapists play a major role in the recovery process typically spending more time with the patient than individuals from any other specialty. While treatments interventions are commonly focused on physical deficits, clinicians have long recognized that a multitude of additional factors can affect rehabilitation outcomes. Over the past decade, there has been an increased emphasis on determining which factors affect how well an individual recovers from their injury, how they improve or change during the course of rehabilitation, and whether or not they are likely to fully recover to pre-injury function. Given the current climate of high patient volumes and limited clinical resources, it is increasingly important to characterize persistent deficits and identify predictors of positive and negative rehabilitation outcomes.

In this study, we seek to “(d)etermine factors that predict ... successful treatment of musculoskeletal conditions following severe extremity trauma and/or deployment related musculoskeletal injuries.” This study will provide valuable information that can be used to “(d)etermine the optimal treatment strategies to minimize impairments, maximize function and performance, and/or optimize quality of life.” Findings from this study will also help lessen the overwhelming negative impact these injuries have on service members, their families, and our military healthcare system. The proposed study will be conducted with a large group of service members with lower extremity injuries receiving care at three physical therapy clinics at Fort Hood, TX and Joint Base San Antonio, TX. This patient subject group is the exact patient population this study is intended to positively affect, and will result in actionable information to improve current and future clinical care within the military. A range of measures that characterize physical deficits, functional limitations, activity restrictions, and health related quality of life will be collected by clinical research staff fully imbedded within the physical therapy clinics of Fort Hood, TX and Joint Base San Antonio, TX. This approach not only ensures that a large percentage of service members with extremity injuries at these clinics will be enrolled, but that also enhances the ecologic validity of this study. Physical, cognitive, and psychosocial measures will be administered in parallel with rehabilitative care. There are three primary sources of data in this proposed study: 1) self-report surveys, 2) participant medical records, and 3) physical assessments. Imbedded clinical research staff will directly observe, measure, record, and report functional changes that occur throughout the rehabilitation processes at each of these sites. Assessments metrics contained in the National Institutes of Health’s (NIH) Patient Reported Outcomes Measurement Information System (PROMIS) will be leveraged for this study and electronically collected with additional outcome metrics using computer tablets (i.e. Apple iPads). De-identified data will be entered into the BADER Clinical Trials Database system for analysis. An improved understanding of the types and magnitudes of deficits present, and their relative contributions to treatment success, goal attainment, and health related quality of life in a military setting is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness. As final study results become available, information will be

directly shared with treating therapists through incorporation into educational programs to promote evidence based practice and accelerate patient recoveries.

Title:	2014.1: Maximizing Outpatient Rehabilitation Effectiveness (MORE)	
Funded Amount:	\$1,487,036	
Principal Investigator:	Jason Wilken, PhD	Brooke Army Medical Center, Center for the Intrepid
Collaborators:	David Tulsy, PhD	University of Delaware
	COL Scott Shaffer, PhD	US Army Baylor University
	LTC Kevin Houck, PT, DPT	Darnall Army Medical Center, Ft. Hood
	MAJ Owen T. Hill, PhD	Center for the Intrepid, Joint Base San Antonio

We are currently completing contract negotiations to begin this project.

2014.2 Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation

ABSTRACT: Our work is motivated by the lack of objective criteria for evaluating and prescribing prosthetic ankle-foot components for Service Members with transtibial amputations wishing to perform load carriage and other physically demanding tasks. Healthy intact ankle-foot systems adapt to added load by maintaining similar ankle motion and effective rocker shapes during walking. In contrast, most prosthetic feet are spring-like and continue to bend with added load, suggesting they may not mimic the physiologic system they are trying to replace during weighted walking. Additionally, there are currently no data to suggest which types of prosthetic feet will be most resistant to breakage during impact loading (e.g. loads that would be experienced when jumping off of a Humvee). We expect that mechanical testing will show a large diversity of mechanical properties of prosthetic feet based on marketing materials (some companies market extreme flexibility while others market limited flexibility). For the testing in Aim 2, we expect that the more flexible prosthetic foot (one that deforms considerably with added weight) will lead to increased loading on the intact limb during walking compared with the less flexible prosthetic foot. The planned testing will provide quantitative data to support the selection of prosthetic feet for highly active Service Members with lower-limb amputations, including data on impact durability and response to added loads above body weight. Prosthetic feet that can reduce loading to the intact limb may be prescribed to reduce the chances for long-term secondary complications of the intact limb (e.g. knee osteoarthritis). Although studies have been conducted on weighted walking in able-bodied persons and persons with lower-limb amputations, none have examined the effects of different prosthetic foot properties on gait. This study is innovative in that it combines the use of mechanical testing, functional testing, and clinical testing of prosthetic feet for persons in the highest functional levels. This comprehensive investigation should greatly improve our knowledge of these types of prosthetic feet and have direct implications for their prescription.

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Title:	2014.2: Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation	
Funded Amount:	\$398,735	
Principal Investigator:	Barri Schnall, MPT	Walter Reed National Military Medical Center
Collaborators:	Andrew Hansen, PhD	Minneapolis VA, University of Minnesota
	Bradford Hendershot, PhD	Walter Reed National Military Medical Center
	Joan Bechtold, PhD	University of Minnesota

We are currently completing contract negotiations to begin this project.

KEY RESEARCH ACCOMPLISHMENTS
FOR THE PERIOD
SEPTEMBER 30, 2011 – SEPTEMBER 29, 2014

BADER Consortium

W81-XWH-11-2-0222

Annual Report – Year 3

Key Research Accomplishments

Key Accomplishments in the third year of performance (September 30 2013 – September 29 2014):

- Approval of two additional BADER funded research projects bringing the total to 8
 - o Project 2014.1 – Maximizing Outpatient Rehabilitation Effectiveness (MORE)
 - o Project 2014.2 – Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower Limb Amputation
- Successfully filled all vacant BADER funded staff positions at the MTFs
- Provided research support to over 24 non-BADER funded on-site protocols at the MTFs
- Began exclusive partnership with Leidos on Homeland Defense TATs IDIQ mechanism
- Established a collaborative agreement with NIH for the use of the CTDB and modeled two protocols in the system.
- Presented the BADER Consortium to the Defense Health Board, Health Care Delivery Subcommittee on May 21, 2014
- Enrolled first MTF staff member into Biomechanics and Movement Science PhD program at the University of Delaware.
- Established a policy at the University of Delaware for external PIs
- Developed a process for receiving donations for research support
- Multiple (n=6) BADER-supported proposals recommended for funding
- First BADER-METRC Collaboration proposal recommended for funding
- Omnibus CRADA dramatically streamlining project initiation
- IRB – HRPO process is improved
- CTDB being implemented on a large scale across Consortium
- WRNMMC received approval to recruit non-military, civilian human subjects
- Initiating nationwide Human Subjects Recruitment Initiative
- Realized an uptick in additional grant submissions and funded projects across the Consortium
- Planning underway for Orthopaedic Rehabilitation Research Annual Meeting
- BADER Operations model finalized

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Key Accomplishments in the second year of performance (September 30 2012 – September 29 2013):

- Approval of three additional BADER funded research projects bringing the total to 5:
 - Project 2012.2 – Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback.
 - Project 2012.1 – Improving Step-To-Step Control of Walking in Traumatic Amputees.
 - Project 2013.1 – Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?
 - Project 2013.2 - Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.
 - Project 2013.3 - Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.
- Recruited all eight BADER funded positions at the MTFs
- Provided research support to nine on-site MTF research projects.
- IT and videoconference infrastructures
- Continue to increase the ranks of BADER Consortium Affiliates (n=96)
- Support NMCS D with use of UD Power Segment technique
- Streamlined the IRB approval process by establishing blanket Institutional Award Agreement (IAA).
- In concert with the MTFs, began development of a central research subject repository.
- Held the first BADER Consortium annual meeting.
- Providing valuable research support through Consortium funded on-site employees.
- On-boarded multiple agencies to the omnibus CRADA to reduce administrative hurdles and allow rapid execution of research studies.
- Established a research related travel support policy and supported travel expenses for collaborators to visit MTF sites and two MTF personnel to present at the American Society of Biomechanics (ASB) scientific meeting.
- Supporting multiple proposals for external funding.
- Strengthen research collaborations and partnerships between MTFs, VA and research focused institutions.
- The live instance of the NIH supplied Protocol and Data Management System (PDMS) is up and running on BADER servers.
- Development of table and announcement for alternative project funding models.
- Strategizing with NIH officials.
- Outreach and meetings with VA.
- BADER Consortium Web-site development continues:
 - o Secure log-in to the website completed
 - o Core services request form completed
 - o Additional enhancements being explored

Key Accomplishments in the first year of performance (September 30 2011 – September 29 2012):

- Approval and establishment of two clinical research projects
- HRPO clearance and start of first project (Dingwell)
- Initiated the development of first IRB of record outside the MTFs (Davis)
- Initiated the development of partnership with Nike, USA (Davis)
- Development and implementation of an Omnibus Cooperative Research and Development Agreement (CRADA)
- Established a consortium-wide protocol and data management system
- Partnered with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE)
- Worked with the EACE to develop research focus (gap) areas for the BADER Consortium call for proposals
- Established a complete process for the call, submission, review and selection of Consortium funded projects
- Published the BADER Consortium call for clinical research proposals
- Established the BADER Consortium web site and standard operating procedures (SOPs)
- Initiated the hiring of eight research support staff to be placed onsite at MTFs.
- Open communication with all MTFs and partners through bi-weekly teleconferences
- Established partnerships with the VA and NIH

REPORTABLE OUTCOMES
for the period
September 30, 2011 – September 29, 2014:

Research Projects:

BADER Funded Projects:

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** \$679,300. Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid. Start date: September 2012.

Davis, I., and Pruziner, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** \$708,524. Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center. Start date: October 2012.

Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”** \$882,827. Sites: Eastern Colorado Healthcare System – Department of Veterans Affairs, Jewell Regional Amputation Clinic. Start date: October 2013.

Pruziner, A., Wolf, E., Webster, J., Tulskey, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”** \$1,529,718. Sites: Walter Reed National Military Medical Center, Hunter Holmes McGuire VA Medical Center. Start date: March 2014.

Tulskey, D., Wolf, E., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”** \$1,999,969. Sites: New York University, University of Michigan, Walter Reed National Military Medical Center, Brooke Army Medical Center/Center for the Intrepid, Naval Medical Center San Diego, NYU Langone Medical Center, Providence VA Medical Center, James A. Haley Veterans Hospital, Tampa FL. Start date: Pending.

Wilken, J., Tulskey, D., Shaffer, S., Houck, K., Hill, O. **“Maximizing Outpatient Rehabilitation Effectiveness (MORE)”**. \$1,487,036. Sites: Joint Base San Antonio, TX; Ft. Hood, Killeen TX; University of Delaware. Start date: Pending.

Schnall, B., Hansen, A., Hendershot, B., Bechtold, J. **“Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation.”** \$398,735. Sites: Walter Reed National Military Medical Center; University of Minnesota; Minneapolis VA. Start date: Pending.

BADER Scientific Technical Core Supported projects:

Tulskey, D., Wyatt, M., **“A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma.”** Sites: University of Michigan, Naval Medical Center San Diego, Brooke Army Medical Center/Center for the Intrepid.

Externally Funded Projects Supporting BADER Activities or Supported by BADER:

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013. Recommended for funding, awaiting subcontract. This is a METRC/BADER Collaboration.

Ziemke, G., Campello, M. **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.”** Proposal to CDMRP/PRORP, July 2013. Recommended for funding, awaiting subcontract. Sites: NMCP, NYU.

Gillespie, J., et al. **“Rapid Prototyping of Advanced Passive Dynamic Ankle-Foot Orthoses Designs for Wounded Warriors.”** \$3,000,000. Sites: University of Delaware. Funded by: DARPA

Whittelsey, S., Selbie, W.S. **“Development of a Low Cost, Real-time Biofeedback Gait Retraining System”** \$149,995. Funded by: NIH, Phase I – SBIR. Sites: C-Motion, LLC

Kaufman, K. **“Comparison of 3-D Gait Analysis Data Across Department of Defense Sites.”** Funded by: Center Rehabilitation Sciences Research (CRSR). Support by Biomechanics Scientific Technical Core. Sites: Mayo Clinic, MTFs

Deluzio, K. J., Selbie, W.S., **“Statistical Models for Establishing a Control Data Set for Biomechanical Gait Analysis”** \$25,000. Natural Sciences and Engineering Research Council of Canada.

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Pending Proposals for External Funding Supported by BADER:

None at this time.

Research Proposals - BADER Supported

Ziemke, G. **“Rate of Surgical Revision in Active Duty Service Members After Anterior Cervical Disc Arthroplasty or Fusion for Spinal Post-Traumatic Osteoarthritis”**. CDMRP/PRORP pre-application, not invited for full submission.

Ziemke, G. **“Identifying Obstacles and Facilitators of Work Re-Integration in Active Duty Sailors and Marines with Deployment and/or Combat-Related Musculoskeletal Injuries.”** CDMRP/PRORP pre-application, not invited for full submission.

Stanhope, S. **“BADER Consortium – A Five Year Budget Projection”** proposal for sustaining Consortium Operations. Submitted July 16, 2014 to the Health Care Delivery Subcommittee of the Defense Health Board.

Buchanan, T. “**OA study.**” CDMRP/PRORP pre-application, not invited for full submission.

The BADER Consortium Administrative Core supported, at their request, the VA with planning the upcoming, DEKA arm multi-center clinical trial.

The MTF/BADER Consortium limb salvage team submitted an unfunded pre-proposal to the PRORP TRPA program.

Dr. Tim Judkins with Intelligent Automation, Inc. has completed a DoD funded Phase I SBIR, Virtual Therapist PTSD, project and wishes to develop and execute the Phase II, clinical trial effort, through the BADER Consortium.

MTF Research Projects Supported by CRC Staff:

Adaptation Study	WRNMMC	CRC Staff (Saha)
OA Project	WRNMMC	CRC Staff (Saha)
Trunk	WRNMMC	CRC Staff (Saha)
BL (case report)	BAMC/CFI	CRC Staff (Jamison)
RE	BAMC/CFI	CRC Staff (Jamison)
AFOR	BAMC/CFI	CRC Staff (Jamison)
RG	BAMC/CFI	CRC Staff (Jamison)
AF	BAMC/CFI	CRC Staff (Jamison)
Level Belt Validation	OSU/(Boston)	CRC Staff (Jamison)
EACE P2M	BAMC/CFI	CRC Staff (Metzger-Abamukong)
MPL	BAMC/CFI	CRC Staff (Metzger-Abamukong)
Rehab Effectiveness	BAMC-CFI/WRNMMC	CRC Staff (Metzger-Abamukong and Amanda Wingate)
Visual Feedback	WRNMMC	CRC Staff (Amanda Wingate)
Weight Shifting	WRNMMC	CRC Staff (Amanda Wingate and Devjani Saha)
CHAMP	WRNMMC	CRC Staff (Amanda Wingate)

Manuscripts, abstracts, presentations

BADER Funded Projects

Publications:

None at this time.

Abstracts:

- Cusumano, J.P. and Dingwell, J.B. (2013) "On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics," ***Proceedings of the 2013 Dynamic Walking Meeting***, Pittsburgh, PA, June 10-13, 2013.
- Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2013) "Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.
- Dingwell, J.B., and Cusumano, J.P. (2013) "Using Perceptual Cues to Regulate Walking From Stride-to-Stride," ***Proceedings of the 43rd Annual Meeting of the Society for Neuroscience***, San Diego, CA, November 9-13, 2013.
- Samaan, C., Schwartz, J., Graf, E., Davis, I., and Rainbow, M.J. (2013) "A Standing Alignment System Improves Between-Session Repeatability in gait Kinematics: A Preliminary Study," ***Proceedings of the Annual Meeting of the American Society of Biomechanics***, Omaha, NE, September 4-7, 2013
- Rylander, J.H., Beltran, E.J., Wilken, J.M., and Dingwell, J.B. (2014) "Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking," ***Proceedings of the 60th Annual Meeting of the Orthopaedic Research Society***, New Orleans, LA, March 15-18, 2014.
- Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (Submitted) "Able Bodied Persons and Individuals with Transtibial Amputation Employ Similar Control Strategies in the Frontal Plane during Treadmill Walking," ***Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.
- Dingwell, J.B. and Wilken, J.M. (Submitted) "Integrating Virtual Reality and Motion Capture for Clinical Assessment and Rehabilitation," ***Invited Symposium Presentation, Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.

- Salinas, M.M. and Dingwell, J.B. (2014) "How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking," **Proceedings of the 7th World Congress of Biomechanics**, Boston, MA, July 6-11, 2014.
- Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2014) "Strategies for controlling lateral stepping movements in human walking," **Proceedings of the 2014 Society for Neuroscience Annual Meeting**, Washington, DC, Nov. 15-19, 2014.
- Sheehan, R.C., Rylander, J.H., Wilken, J.M., and Dingwell, J.B. (2014) "A virtual reality obstacle course to improve lateral balance control in lower limb trauma patients," **Proceedings of the 2014 Society for Neuroscience Annual Meeting**, Washington, DC, Nov. 15-19, 2014.

Patents:

None at this time

BADER Supported Projects

Publications: None at this time.

Abstracts: None at this time.

Patents: None at this time.

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BADER Related Projects

Publications:

Takahashi KZ, Kepple TM, Stanhope SJ. A unified deformable (UD) segment model for quantifying total power of anatomical and prosthetic below-knee structures during stance in gait. *Journal of Biomechanics* 2012;45:2662-2667. PMID:22939292

Schrank E and Stanhope SJ. Dimensional accuracy of ankle-foot orthoses constructed by an automated fit customization and rapid manufacturing framework. *Journal of Rehabilitation Research & Development* 2011;48(1):31-42. PMID:21328161

Schrank ES, Stanhope SJ. Orthotic Device Research. In *Full Stride: The Past, Present, and Future of Lower Extremity Gait Systems*. Springer Publishing. in preparation.

Abstracts and Presentations:

- Schrank ES, Higginson JS, Stanhope SJ. A Repeatable and Predictable method to Rapidly Manufacture Function-Customized Passive-Dynamic Ankle Foot Orthoses. **Proceedings of the ASME**, 2012
- Razzook A, Gleason C, Willy R, Fellin R, Davis I, Stanhope S. Average Ankle Dynamic Joint Stiffness During Heel Strike Running. (**Proceedings**) **American Society of Biomechanics**, 2012

- Takahashi KZ, Stanhope SJ. Net Efficiency of the Combined Ankle-Foot System in Normal Gait: Insights for passive and Active Prosthetics. **(Proceedings) American Society of Biomechanics**, 2012
- Schrank ES, Higginson JS, Stanhope SJ. Compensatory Muscle Control Strategies when Walking with a Customized PD-AFO. **(Proceedings) American Society of Biomechanics**, 2011
- Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Kepple TM, Stanhope SJ. Unified Deformable Segment Model of the Combined Ankle-Foot System that Does Work. **(Proceedings) American Society of Biomechanics**, 2011
- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. A proposed method for PD-AFO stiffness prescription procedure. **(Proceedings) Center for Biomedical Engineering Research Symposium**, University of Delaware, 2011.
- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. Ankle Pseudo-Stiffness is Greatest During Gait Initiation. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
- Razzook AR, Takahashi KZ, Guinn LD, Schrank ES, Stanhope SJ. Predictive Model for Natural Ankle Stiffness During Walking: Implications for Ankle Foot Orthosis Prescription. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
- Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Stanhope SJ. A Model of Normal Gait Roll-Over Dynamics One Step Closer to Customizing Prosthetic Ankle-Foot Components. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
- Khattra NS, Tierney JJ, Yarlagadda S, Shevchenko N, Gillespie JW, Schrank ES, Stanhope SJ. Carbon fiber based custom orthoses for augmenting net ankle moment in gait. **(Proceedings) Society for the Advancement of Material and Process Engineering**, 2013.

Patents:

None at this time.

Informatics such as databases and animal models:

The Consortium, through the Clinical Research Core, has executed a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This unique partnership is supported by leadership at both NIH and UD and brings substantial

opportunities to both parties for future development and now offers the Consortium a secure and dedicated instance of the NIH Clinical Trials Database.

Funding applied for based on work supported by this award:

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013.

Judkins, T. **“Development of a Mobile Advanced Real-Time Kinetic System (MARKS) for Balance Rehabilitation.”** Proposal to Department of Defense SBIR, June 2013.

Ziemke, G., Campello, M. **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.”** Proposal to CDMRP/PRORP, July 2013.

Van Citters, D. **“Active Implant”** Proposal to CDMRP/PRORP, July 2013.

Employment or research opportunities applied for and/or received based on experience/training supported by this award:

John David Collins, a biomechanist in the gait analysis laboratory at NMCS D has been accepted in to the University of Delaware Biomechanics and Movement Sciences PhD program under the BADER Consortium waived tuition program.

CONCLUSION

As we complete year 3, efforts continue to be focused on the “Engagement” phase of the Consortium and working toward successful accomplishment of tasks as outlined in the proposed statement of work.

The Consortium has experienced a number of successes over the first three years. The partnerships with the MTFs are strengthening, the relationship with EACE is strong and the VA is actively engaged with the Consortium. The first six research projects are underway and have started recruitment of human subjects. In addition, plans for establishing administrative, personnel, IT and support infrastructures are on schedule or have been fully realized.

Over the first three years of performance, we have run into a few rate limiting factors which may impact the success of the Consortium.

- o The IRB approval process is lengthy and follows a “learn as you go” model. The Clinical Research Core is working diligently to thoroughly model and streamline the IRB/HRPO approval process. The Consortium has implemented the IAA process model for IRB approval.
- o Administrative approvals from CDMRP continue to be lengthy which delays the start of the most recent approved research projects.
- o Human Subject Recruitment. Our MTF partners have informed us that as the current conflicts come to a close, the number of wounded service members is declining drastically. While this is a very good thing, it has a significant impact on the existing MTF subject recruitment scenes. To address the issues, we have launched a subject recruitment initiative. Our goal is to work in concert with MTFs to establish a broader, far more robust and active recruitment system.
- o Navy’s Office of Naval Research refusal to consider omnibus BADER CRADA. The current Navy practice of single CRADAs based on a specific project has put our partners at NMCP and NMCS D at a severe disadvantage in limiting their participation in BADER activities.
- o Potential shifts in MTF research priority areas. Our MTF representative partners have indicated they may be experiencing shifts in MTF research priority areas. We plan on further exploring this topic with EACE leadership.
- o Delays in EACE hiring of Senior Scientist positions has negatively impacted the sustainability model.

As we begin to focus on sustainability efforts, BADER will effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of the Consortium.

Regular monthly meeting of MTF and BADER personnel will continue and focus on engagement and sustainability efforts of the Consortium. Through these meetings and continued support of the MTF needs, initiative focused teams are forming and evidence of impact and sustainability is mounting.

At the request of a MTF representative, BADER leadership is actively working to implement a policy allowing non-University personnel to be Principal Investigators on research projects submitted through UD. As part of this policy, the University would return a portion of the F&A recovered back to the program. This contribution of F&A back into the research would make the UD F&A profile similar to that of Henry Jackson and Geneva Foundations.

At the request of a Consortium member, the University of Delaware has established an account to receive charitable donations directed to support and conduct specific research projects. This fund will not carry indirect costs, making it highly attractive to individual donors wishing to fund research.

Having obtained nearly \$4 million in additional external funding and initiated four BADER related, but not BADER funded projects, our omnibus Consortium model is rapidly gaining evidence of success.

Continuing to strengthen ties with EACE is critical. BADER and EACE bring unique resources to amputee rehabilitation care across the Department of Defense and working in partnership toward well-established goals will achieve great success.

BADER is currently exploring numerous proposal opportunities including the Medical Technology Enterprise Consortium (MTEC), the NIH Medical Rehabilitation Research Resource R24, and the BAA for additional funding opportunities. We also look to fully leverage our IDIQ relationship with Leidos.

We look forward to continuing our work in strengthening orthopaedic rehabilitation research to bring all Wounded Warriors back to optimal function.

APPENDICES

APPENDIX A:

Affiliations:

Government partners:

- CDMRP
- Brooke Army Medical Center
- Naval Medical Center Portsmouth
- Naval Medical Center San Diego
- Walter Reed National Military Medical Center
- National Institutes of Health
- Department of Veterans Affairs
- Denver Rehabilitation Institute
- ECBC/ADM

Academic partners:

- University of Delaware
- Spaulding Rehabilitation Hospital
- Mayo Clinic
- University of Texas Austin
- University of Colorado
- University of Michigan
- New York University
- Christiana Care Health System
- Simbex, LLC

Industry partners:

- C-Motion, Inc
- Independence Prosthetics and Orthotics
- BiOM
- Ossur
- Otto-Bock
- Hanger Orthopedics

Non-Profit partners:

- Amputee Coalition
- Agrability

APPENDIX B:

BADER Consortium Affiliates

Total as of September 30, 2014: 98

Aldridge, Jennifer	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Anne Andrews, LTC, PhD, RD, CSSD, CSCS	BADER Consortium Affiliate, Director of Othopaedic Rehabilitation Research	Walter Reed National Military Medical Center (WRNMMC)
Archer, Kristin R., PhD, PT, DPT	BADER Consortium Affiliate, Research Advisory Committee Member	Vanderbilt
Bonato, Paolo, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	Spaulding Rehabilitation Hospital
Brown, Douglas	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Buchanan, Thomas S., PhD	BADER Consortium Affiliate	University of Delaware
Campello, Marco, PhD	BADER Consortium Affiliate	New York University
Carney, Joseph	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Casler, Rick	BADER Consortium Affiliate	BiOM
Cella, David, PhD	BADER Consortium Affiliate	Northwestern University
Cesario, Erin	CRC Staff BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Childs, John D., PT, PhD, MBA	BADER Consortium Affiliate, Research Advisory Committee Member	Dept. of the Army
Collins, John-David	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Crandell, David, MD	BADER Consortium Affiliate	Spaulding Rehabilitation Hospital
Dankmeyer, Charles H., CPO	BADER Consortium Affiliate	Dankmeyer, Inc.
Davis, Irene Sprague, PhD, PT	Director, Clinical Research - BADER Consortium	Spaulding Rehabilitation Hospital
Davis, Samuel, PhD	BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)

de Lateur, Barbara J., MD, MS	BADER Consortium Affiliate, Research Advisory Committee Member	Johns Hopkins Medicine
DeMaio, Marlene, CAPT	BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
Dingwell, Jonathan B., PhD	BADER Consortium Affiliate	University of Texas at Austin
Dromsky, David	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Evans, Boyd	BADER Consortium Affiliate	Oak Ridge National Labs
Farrell, Todd R., PhD	BADER Consortium Affiliate	Liberating Technologies, Inc.
Fatone, Stefania	BADER Consortium Affiliate	Northwestern University
Faulkner, Danielle	CRC Staff BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
Ferguson, John	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Ficke, James R., PhD	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Fitzgerald, G. Kelley, PhD	BADER Consortium Affiliate	University of Pittsburgh
Friedman, Matthew J., MD, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	Dartmouth
Gard, Steven A., PhD	BADER Consortium Affiliate	Northwestern University
Gill, Norman "Skip" LTC	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Gillespie, John W., PhD	BADER Consortium Affiliate	University of Delaware
Grabowski, Alena, PhD	BADER Consortium Affiliate	Massachusetts Institute of Technology
Greenwald, Rick, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	Simbex
Groer, Shirley, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	Department of Veterans Affairs

Hansen, Andrew, PhD	BADER Consortium Affiliate	Department of Veterans Affairs
Hendershot, Brad	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Hicks, Gregory E., PhD, PT	BADER Consortium Affiliate, Research Advisory Committee Member	University of Delaware
Hiebert, Rudi	BADER Consortium Affiliate	New York University
Hopkins, Mark S., PT, CPO, MBA	BADER Consortium Affiliate	Dankmeyer, Inc.
Hsu, Joseph, PhD, LTC	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Jamison, Steve, PhD	CRC Staff BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Jarzombek, Sandi	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Kaufman, Kenton R., PhD, PE	Director, Scientific Cores	Mayo Clinic
Kelley, Kevin	BADER Consortium Affiliate	Ottobock
Kingsbury, Trevor	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Klute, Glenn K., PhD	BADER Consortium Affiliate	University of Washington
Kolm, Paul, PhD	BADER Consortium Affiliate, Director, Biostatistics Core	Christiana Care Health Services, Inc.
Kram, Rodger, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	University of Colorado
Kuiken, Todd, MD, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	Rehabilitation Institute of Chicago
Linberg, Alison	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Logerstedt, David, PT, PhD, MPT, SCS	BADER Consortium Affiliate	University of Delaware
Ludewig, Paula M.	BADER Consortium Affiliate	University of Minnesota

Metzger-Abamukong, Melinda	CRC Staff BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Milbourne, Suzanne A., PhD	BADER Consortium Affiliate	University of Delaware
Miller, Ross H., PhD	BADER Consortium Affiliate	University of Maryland
Mulroy, Sara, PhD, PT	BADER Consortium Affiliate	Rancho Los Amigos National Rehabilitation Center
Myers, Grant	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Neptune, Rick	BADER Consortium Affiliate	University of Texas at Austin
Nordin, Margareta	BADER Consortium Affiliate	New York University
Nowinski, Cindy, MD, PhD	BADER Consortium Affiliate	Northwestern University
Owens, Johnny, PT	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Pasquina, Paul, COL	BADER Consortium Affiliate	Uniformed Services University of the Health Sciences
Powers, Christopher M., PhD, PT	BADER Consortium Affiliate	University of Southern California
Rabago, Chris	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Resnick, Linda, PhD	BADER Consortium Affiliate	Brown University
Richards, James G., PhD	BADER Consortium Affiliate	University of Delaware
Ritland, Bradley, CAPT	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Rodriguez, Kelly	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Rosenthal, Michael D., CAPT	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Royer, Todd, PhD	BADER Consortium Affiliate	University of Delaware

Sacher, Richard S	BADER Consortium Affiliate	University of Delaware
Saha, Devjani, PhD	CRC Staff BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Schaffer, Scott, LTC	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Schnall, Barri	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Scoville, Charles	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Selbie, William Scott, PhD	BADER Consortium Affiliate, Director, Biomechanics Core	C-Motion, Inc.
Sessoms, Pinata	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Shim, Jae Kun, PhD	BADER Consortium Affiliate	University of Maryland
Silverman, Anne	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Sluka, Kathleen A., PT, PhD	BADER Consortium Affiliate, Research Advisory Committee Member	University of Iowa Health Care
Snyder-Mackler, Lynn, PT, PhD, FAPTA	BADER Consortium Affiliate	University of Delaware
Stanhope, Steven J., PhD	Director, BADER Consortium	University of Delaware
Swiontkowski, Marc F., MD	BADER Consortium Affiliate, Research Advisory Committee Member	University of Minnesota
Takahashi, Kota, PhD	BADER Consortium Affiliate	North Carolina State University
Thesing, Nancy	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
Tulsky, David, PhD	BADER Consortium Affiliate, Director, Outcome Measures Core	University of Michigan Medical School
Vernon, Michael	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Ward, Samuel R., PT, PhD	BADER Consortium Affiliate	University of California, San Diego

Weir, Richard, PhD	BADER Consortium Affiliate	University of Colorado
Wilken, Jason, PhD, MPT	MTF Representative	San Antonio Military Medical Center (SAMMC)
Wingate, Amanda	CRC Staff BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Wolf, Erik, PhD	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
Wyatt, Marilyn	MTF Representative	Naval Medical Center San Diego (NMCSD)
Yack, John	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
Ziemke, Gregg, CAPT	MTF Representative	Naval Medical Center Portsmouth (NMCP)

APPENDIX C

Omnibus BADER CRADA partners:

Institution	Date of distribution	Date of completed agreement
University of Delaware	September 19, 2012	November 7, 2012
Brooke Army Medical Center	September 19, 2012	January 3, 2013
C-Motion, Inc	September 19, 2012	September 20, 2012
Christiana Care Health Systems	September 19, 2012	October 18, 2012
Mayo Clinic	September 19, 2012	November 1, 2012
Spaulding Rehabilitation Hospital	September 19, 2012	October 11, 2012
Walter Reed National Military Medical Center	September 19, 2012	April 15, 2013

Projects on-boarded to Omnibus BADER CRADA:

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** \$679,300. Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid.

Davis, I., and Linberg, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** \$708,524. Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center.

Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”**

Linberg, A., Wolf, E., Webster, J., Tulsy, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”**

Tulsy, D., Wolf, E., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”**

APPENDIX D

Meetings

Attended

- Amputee Coalition National Conference. Orlando, FL. June 27-29, 2013.
- 2013 AAOS/OTA/SOMOS/ORS Extremity War Injuries VIII: Sequelae of Combat Injuries. February 11-13, 2013 at the Mandarin Oriental Hotel in Washington, DC
- American Society of Biomechanics, Omaha NE, September 4-7, 2013.
 - o BADER Consortium funds supported travel for Stanhope, Wilken, Wolf
- 2013 Military Health System Research Symposium, Ft Lauderdale, FL, August 12-15, 2013.
- American Orthotic & Prosthetic Association, O&P World Congress 2013. Orlando, FL, September 18 – 21, 2013.
- Government Steering Committee meeting to discuss proposals. February 2014 at Ft. Detrick MD.

APPENDIX E

Government Steering Committee Meeting – February 19, 2014

Agenda:

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)

PEER REVIEWED ORTHOPAEDIC RESEARCH PROGRAM (PRORP) FISCAL YEAR 2010 (FY10)

THE BADER CONSORTIUM

GOVERNMENT STEERING COMMITTEE (GSC) MEETING

19 February 2014

AGENDA

Teleconference numbers: DCO Connect: <https://connectcol.dco.dod.mil/r8p08nf6s79/>
Inside the U.S.: 1-855-462-5367

Conference code: 9321352

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8:00 a.m. – 8:05 a.m.	Welcome	CDMRP Leadership
8:05 a.m. – 8:10 a.m.	Moment of silence	CAPT Boswell
8:10 a.m. – 8:20 a.m.	Introductions Purpose of GSC meeting	Dr. Darnell
8:20a.m. – 9:20a.m.	<u>Progress Report</u> • Brief background • Operational Model • Consortium Cores • Partnerships • Infrastructures • Integration with DoD: MTFs and VA	Dr. Stanhope
9:20 a.m. – 10:00 a.m.	MTF Updates	MTF Representatives
10:00 a.m. – 10:15 a.m.	Break	All Participants

10:15a.m. – 11:15 a.m.	<u>Current Studies</u> • STEP2STEP clinical trial update • RETRAIN clinical trial update • ProLegRX clinical trial update • K2Power clinical trial update • QOL Toolbox clinical trial update • ROM Focus Group Study	Principal Investigators
11:15a.m. – 11:45 a.m.	<u>Study selection process</u> • Call for Proposals • Submissions • Peer review and summary statements	Dr. Davis
11:45 a.m. – 12:30 p.m.	Lunch (on your own) NCl cafeteria is available for your use.	All participants
12:30 p.m.	<i>BADER staff and MTF representatives depart</i>	
12:30p.m. – 1:00p.m.	Opportunity for Clarification	Dr. Stanhope
1:00 p.m. – 2:45 p.m.	GSC review of proposed research projects (closed GSC session)	GSC Members
2:45 p.m. – 3:00 p.m.	Break	GSC Members
3:00 p.m. – 4:00 p.m.	GSC review of proposed research projects (closed GSC session)	GSC Members

APPENDIX F

BADER Consortium Committee Memberships

BADER Consortium Coordinating Center (B3C) Committee

Steven J. Stanhope, PhD - University of Delaware
Irene Davis, PhD - Spaulding Rehabilitation Hospital
Kenton Kaufman, PhD – Mayo Clinic
Suzanne Milbourne, PhD – University of Delaware
Rachel Strickland – University of Delaware

BADER Consortium Committee (BCC)

Steven J. Stanhope, PhD – University of Delaware
Irene Davis, PhD – Spaulding Rehabilitation Hospital
Kenton Kaufman, PhD – Mayo Clinic
Suzanne Milbourne, PhD – University of Delaware
Rachel Strickland – University of Delaware
Jason Wilken, PhD – BAMC/CFI
Marilynn Wyatt - NMCS
CAPT Greg Ziemke - NMCP
Alison Pruziner, DPT - WRNMMC
Scott Selbie, PhD – C-Motion
David Tulsy, PhD – University of Delaware
Paul Kolm, PhD – Christiana Care Health System
Chris Dearth, PhD - WRNMMC

Appendix G

BADER Consortium: A five-year budget projection



July 16, 2014
Submitted by Steven J. Stanhope, PhD
Director, BADER Consortium
Associate Vice Provost for Research, University of Delaware

Prepared for Katrina Badger, Task Lead,
Defense Health Board

BADER Consortium is funded by the
Congressionally Directed Medical
Research Program



Mrs. Dana Herndon
Grants Officer
Miriam Darnell, PhD
Scientific Officer

Award number: W81XWH-11-2-0222
Cycle: Oct. 1, 2011 - Sept. 30, 2016



THE BADER CONSORTIUM

BADER Consortium Vision Statement: Wounded Warriors and civilians with limb loss and limb difference will routinely benefit from significant advancements to obtain optimal functional clinical outcomes and fully re-engage life and work activities.

BADER Consortium Mission Statement: The mission of the BADER Consortium is to help establish sustainable world-class programs in orthopaedic rehabilitation research at the Department of Defense Medical Treatment Facilities and US Department of Veteran's Affairs sites that results in evidence-based orthopaedic rehabilitation care.

BADER Consortium Objectives:

1. Support the advancement of orthopaedic rehabilitation research capabilities at Medical Treatment Facilities (MTFs) and Department of Veterans Affairs (VA) sites that promote optimal functional patient care outcomes.
2. Conduct a variety of innovative, high impact and clinically relevant BADER funded research studies that lead to sustainable externally funded research programs.
3. Preserve advancements in orthopaedic rehabilitation research by establishing a self-sustaining clinical research enterprise.

To accomplish our mission and objectives, the BADER Consortium has developed and successfully executed a clinical research development program based on the National Institutes of Health (NIH) IDeA Networks of Biomedical Research Excellence (INBRE) program (<http://www.nigms.nih.gov/Training/IDeA/Pages/default.aspx>).

Key components of this highly effective model for developing self-sustaining biomedical research capabilities include: a competitively awarded developmental research project program (clinical studies), support for critical centralized scientific and technical cores, essential administrative infrastructures and education/training activities.

The Department of Defense has developed exceptional technology development programs and uniquely gifted patient care services. The BADER Consortium is designed to bridge the gap between technology development and patient care (Figure 1) by explicitly establishing translational and clinical research infrastructures and promoting biomedical research capabilities. The BADER Consortium is ideally positioned to coordinate a technology translation pipeline that links technology development efforts (e.g. TATRC, DARPA) to clinical research programs/initiatives at MTF and VA sites. Rapid translation of these technologies into clinical care will continue to advance the research and care of America's Wounded Warriors.

Since its inception on September 30, 2011, the BADER Consortium has partnered with MTF and VA sites to fully established eight (8) clinical studies at MTF and VA sites, bolstered MTF clinical research capabilities by hiring eight (8) on-site research support staff, fully established four scientific and

technical cores (e.g., clinical research core, biomechanics core, outcomes core, and biostatistics core) , and developed a collection of essential administrative infrastructures (e.g., Omnibus Cooperative Research and Development Agreement [BADER CRADA], Government Official Travel Authorization (BADER GOTA), NIH Clinical Trials DataBase [CTDB] agreement, and the establishment of an annual orthopaedic rehabilitation conference.)

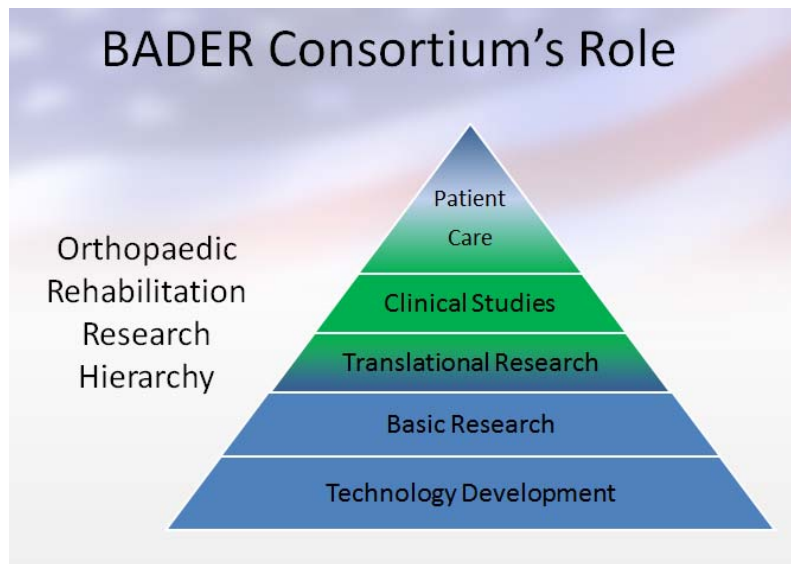


Figure 1: Image indicating the BADER Consortium role in promoting translational and clinical research capabilities among the five levels of orthopaedic rehabilitation research.

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MTF and VA sites are actively engaged in all aspects of the BADER Consortium Research Initiative Cycle. This includes the development of new research teams, the execution of BADER funded projects, the submission of competitive grant applications to federal agencies and the awarding of external grants and execution of externally funded clinical projects. Simply stated, MTF and VA clinical research capabilities have been significantly enhanced but have yet to reach a level of optimal impact and self-sustainment.

In addition to the foundational components of the BADER Consortium, this response to the request for a BADER Consortium five-year budget projection includes but is not limited to the following:

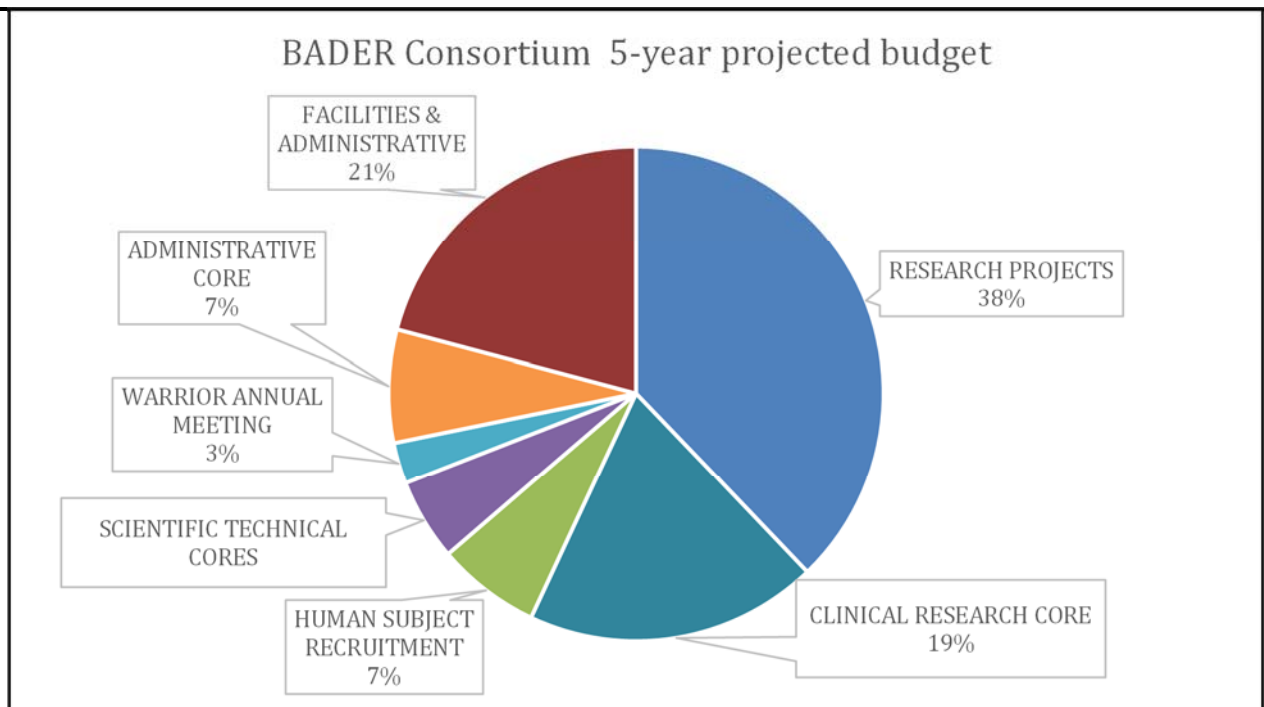
- Expansion (n=14) of the consortium research initiative cycle to align with pending Extremity Amputee Center of Excellence (EACE) hires and to reach desired MTF and VA levels of clinical research sustainment (<http://www.health.mil/About-MHS/Organizational-Overview/Extremity-Trauma-and-Amputation-Center-of-Excellence>)
- Establishing a model system for the translation of advanced technologies into clinical research studies and patient care
- Coordinated national effort in human subject education and recruitment
- Fully realize the capabilities and impact of the NIH CTDB
- Institutionalize omnibus CRADA mechanism for rapid start-up of large scale and highly collaborative clinical research projects

- Grow key consortium scientific support cores – primarily the Clinical Research Core
- Expand key administrative clinical research support structures

A forward funding modular budget is provided in this projection. This format supports the rapid alignment of priorities across foundational components and activities. In addition, the modular format is useful for indicating a unique and impactful attribute of the BADER Consortium model – the remarkable level of support and high degree of focus on the identification and execution of impactful clinical studies. Immediately following the budget projection, a brief justification section provides useful insights on each item.

BADER Consortium Modular Budget Projection for the period 10/01/2016-09/30/2021

	Year 1	Year 2	Year 3	Year 4	Year 5	TOTALS
Research Projects	3,500,000	3,500,000	3,500,000	3,500,000	0	14,000,000
Clinical Research Core	1,363,547	1,389,318	1,415,604	1,442,416	1,469,750	7,080,636
Human Subject Recruitment	500,000	500,000	500,000	500,000	500,000	2,500,000
Scientific Technical Cores	395,000	395,000	395,000	395,000	395,000	1,975,000
WARRIOR Annual Meeting	200,000	200,000	200,000	200,000	200,000	1,000,000
Administrative Core	526,844	535,881	545,099	554,501	564,091	2,726,415
TOTAL Direct Costs	6,485,391	6,520,199	6,555,703	6,591,917	3,128,841	29,282,051
F&A (56%)	1,576,619	1,512,111	1,545,994	1,552,274	1,530,951	7,717,949
TOTAL	8,062,010	8,032,311	8,101,697	8,144,191	4,659,792	37,000,000*



*To facilitate execution of future funding of the BADER Consortium, the University of Delaware (BADER Consortium) has executed a teaming agreement with Leidos, Inc (formerly SAIC) to be exclusive partners on the recently awarded Homeland Defense TATs IDIQ Mechanism (solicitation: FA8075-12-R-0002, Leidos award: FA8075-14-D-000). Working in partnership with Leidos, BADER services and activities can now be funded directly by federal and state agencies using this IDIQ mechanism effective immediately. For additional information about this mechanism, contact Rachel Strickland, Director, Administrative Core, rs@udel.edu.

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THE BADER CONSORTIUM

Five Year Projected Budget for the period

October 1, 2016 – September 30, 2021:

Research Projects: Establish a total of 12-14 (3-4 per year) highly impactful clinical trials averaging \$1M – \$1.5M each. These research projects are awarded based on an annual competitive call for proposals process open to the BADER Consortium Affiliates. The proposals are scientifically reviewed by the BADER Research Advisory Committee and selected by the Government Steering Committee. Large multi-center clinical trials spanning MTF and VA sites are highly encouraged. These pilot projects generate the data needed for research teams to submit for external funding and generate the 8-10 NIH R01-type research initiatives at each site. Furthermore, these pilot projects provide necessary funding to propel junior scientists into independent researchers leading sustainable research programs at

each MTF and VA sites. This funding mechanism is ideally suited for establishing a technology translation pipeline by taking emerging technologies from TATRC and DARPA programs and rapidly moving the technology into clinical trials.

Clinical Research Core: The Clinical Research Core (CRC) is the arm of the BADER Consortium that is the central body of study execution and for providing on-site research teams with day-to-day support, education and training. We have organized the CRC research support infrastructures to further develop and support a research-intensive culture by assisting MTF and VA investigators with establishing a uniform and sustainable research capability that will facilitate ongoing and new clinical research protocols across all participating study sites.

Suzanne Milbourne, PhD. Manager, Clinical Research Core. 25% effort. Dr. Milbourne oversees the Clinical Research Core staff and implementation of the BADER Clinical Trials Database (CTDB).

Michelle Mattera. 85% effort. Consortium Protocol Manager. Ms. Mattera oversees the protocols in the BADER CTDB.

Clinical Research Core Staff. BADER currently provides two full-time on-site staff members to each of the MTF sites, however, those sites have indicated a need for additional support personnel. The proposed budget includes three BADER funded personnel for each MTF. The direct incremental cost (while it varies based on location and position classification) of adding research support staff to a site is approximately \$88,000 (salary and benefits) per person. BADER has been successful in placing staff in both Army and Navy sites and is prepared to work with VA sites in providing the same levels of support.

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CRC Staff Travel: Travel funds are allocated to each CRC staff member to attend conferences and other training opportunities.

Clinical Trials Data Base (CTDB): The University of Delaware has partnered with the National Institutes of Health to create the first extramural instance of the NIH Clinical Trials Database (CTDB). This unique partnership allows for the BADER Consortium to have a central repository for clinical trials that is web based for easy access and FISMA compliant for data safety. Hiring a dedicated programmer will allow BADER to further expand the capabilities of the CTDB and add enhancements to support the MTFs.

Human Subject Recruitment Core: As the conflicts continue to wind down, human subject recruitment has become difficult across MTF sites. The BADER Consortium proposes a new centralized effort to educate and actively recruit human subjects (military and civilians) to into clinical and translational studies. This will be a nation-wide coordinated effort across the Department of Defense and the Department of Veteran's Affairs supporting research efforts by actively engaging active duty, veterans and civilians in clinical research studies.

The two main components of this initiative will be to recruit subjects for existing studies and human subject education. Partnering with RESolutions, LLC for the subject recruitment component, this California based company specializes in assisting clinical studies that are falling behind in subject recruitment efforts. Funds are budgeted to support clinical trials funded by BADER by getting ‘boots on the ground’ to specifically support subject recruitment efforts. A second component is human subject education. BADER has started discussions with The Center for Information and Study of Clinical Research Participation (CISCRP), a non-profit company located in Boston, that specializes in education efforts to inform the public on the importance of participating in clinical research, to collaborate on a nationwide effort to inform and educate the limb loss and limb difference population of the importance of clinical research and how participating in clinical studies advances technology and rehabilitation for both military and civilian populations. Funds are budgeted to collaborate with CISCRP to provide a nation-wide education effort on the importance of participating in research.

Walter Reed National Military Medical Center (WRNMMC) has been given authority to enroll civilians into studies deemed minimal risk and Brooke Army Medical Center (BAMC) is exploring the possibility of doing the same. While there is no official policy published, this recent authorization should be formalized across the DoD and VA and will dramatically strengthen clinical research capabilities.

Knowing that some subjects will need to travel to clinical study sites, funds are budgeted to provide travel assistance.

Scientific Technical Cores: The BADER Consortium has established three Scientific Technical Cores to support BADER funded researchers and the MTFs. Each Core has demonstrated the capacity to provide world-class support for orthopaedic rehabilitation research. The Cores support current research projects, but also provide support and expertise for research ideas that become new research proposals. Maintenance and expansion of the Scientific Technical Cores is essential to the Institutional Development Award concept that the BADER Consortium is modeled after.

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Biomechanics Core: C-Motion, under the direction of Scott Selbie, PhD provides biomechanics expertise to the BADER Consortium. The services of the Core have been widely used by the MTFs to solve on-site problems with hardware and software, provide expert advice for research proposals and develop new strategies to address clinical research problems.

Biostatistics Core: Christiana Care Health Systems, under the direction of Paul Kolm, provides biostatistics support under a fee-for-service mechanism. The Core provides pre- and post-award support to BADER funded investigators including power analysis, statistical modeling, and data analysis.

Rehabilitation Outcomes Measurement (ROM) Core: The ROM Core is under the direction of David Tulskey, PhD. The ROM Core provides pre- and post-award support to BADER funded investigators. Dr. Tulskey also serves as key personnel on several BADER funded studies.

Mobile Monitoring Core: There have been discussion of implementing a Mobile Monitoring Core. The approximate additional cost for this core would be \$150,000/year plus F&A. The site location for this

core is to be determined. The total cost over 5 years would be approximately \$1.17million. This cost is not included in the above budget.

Director of Research: Irene Davis, PhD, Spaulding Rehabilitation Hospital. The Director of Research oversees the annual call for proposals and works to bring teams of researchers together to conduct large scale clinical trials. The Director of Research is responsible identifying and facilitating future clinical studies, and the expansion of the Consortium's clinical research site portfolio to large-scale clinical trials.

Director of the Scientific Technical Cores: Kenton R. Kaufman, PhD, Mayo Clinic. The Director oversees all of the Scientific Cores, including Biomechanics, Rehabilitation Outcome Measures and Biostatistics. The Director works to assure that these Cores provide the needed service to the investigators. In addition, the Director works with the Director of Research to facilitate partnerships between clinical investigators, scientific cores, and Consortium partners (both industry and government). The Director also facilitates technology transfer activities and expansion of the partnership pool.

WARRIOR Annual Meeting: **The need for a national effort to coordinate the array of orthopaedic rehabilitation activities occurring nationwide has been identified. To address this need** in orthopaedic rehabilitation research the BADER Consortium, partnering with others, is leading efforts to establish an annual orthopaedic rehabilitation research coordinating conference to be named **“WARfighters Receiving Innovative Orthopedic Rehabilitation (WARRIOR).”**

The primary goal of this annual meeting will be to define current knowledge regarding rehabilitation of combat-related injuries for NIH, Congress, the Department of Defense, clinicians, researchers, industry, and other relevant governmental agencies.

The **Goals** of the conference are:

1. Define current and emerging knowledge regarding non-operative, neuromusculoskeletal rehabilitation of combat-related injuries for the Department of Defense, NIH, Congress, clinicians, researchers, industry, governmental agencies, and consumer organizations
2. Bring professional, political and consumer stakeholders together, for the first time, around the unified theme of injured warfighter rehabilitation to raise awareness of the current state of the art and future needs
3. Enhance coordination and partnerships between programs, agencies, organizations, researchers, and clinicians associated with orthopedic rehabilitation in order to work together even more effectively to reach specified goals of improved patient care
4. Identify research opportunities and gap areas

Administrative Core: Housed at the University of Delaware, the Administrative Core is responsible for the overall management of the Consortium.

Steven J. Stanhope, PhD. PI and Consortium Director. 50% effort (30% direct, 20% cost share). Dr. Stanhope provides overall direction of the BADER Consortium.

Rachel Strickland, MBA. Director, Administrative Core. 100% effort. Ms. Strickland oversees and manages the daily operations of the Consortium. Her primary duties include budget, human resources, legal matters, the omnibus CRADA, subcontracts, reporting and policies and procedures.

Dawn Montgomery. Administrative Assistant IV. 100% effort. Ms. Montgomery provides support services to the Administrative Core and the Clinical Research Core. Ms. Montgomery provides travel support to MTF representatives under the approved BADER travel policy.

Grants Specialist, to be named. 100% effort. Expansion of the Administrative Core with the addition of a grants specialist will provide additional proposal support services to BADER Affiliates including grant writing, a peer review process prior to submission, budget expertise and other support in proposal submission. Providing these services to the researchers allows them to focus on the science and allows BADER to support the administrative aspects of proposal submission providing a method for efficient and effective research support.

Scientific Research Training Program: Per request of our MTF partners, we look to expand the Scientific Research Training Program. Under an agreement with the College of Health Sciences at the University of Delaware, the BADER Consortium now provides graduate stipends for MTF staff that want to pursue higher education degrees in Biomechanics and Movement Sciences (BIOMS) at the University of Delaware. These staff are identified by the MTF sites. The UD BIOMS program is ranked in the top ten programs in the country. By adding additional research PhD scientists to the staff, MTFs are better positioned to seek external funding and grow their research programs.

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We propose to provide training for two additional students. Two twelve-month stipends at \$36,000/year + benefits for the duration of studies. Funds are requested to provide stipends to MTF employees who successfully matriculate in the UD BIOMS program. The University pays the tuition for these students. The first student under this program will begin his PhD studies in the Fall of 2014 and we have received interest from other MTFs to have staff members participate in this program.

Travel: BADER has received authorization to travel government personnel for research related purposes. These funds have supported research collaborations, travel to scientific meetings and Grand Rounds presentations to clinical staff. Travel is also budgeted to allow administrative travel to required meetings.

Supplies: Funds are budgeted to support Consortium efforts including: recruitment of staff, miscellaneous supplies for MTF on-site staff, computers, printers, teleconference support, publications, advertising, etc.

APPENDIX H



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

JUN 20 2013

MEMORANDUM FOR PRESIDENT, DEFENSE HEALTH BOARD

SUBJECT: Request to the Defense Health Board Pertaining to Sustaining and Advancing
Amputee Care

In a memorandum dated June 5, 2013 (attached), the Chairman of the Joint Chiefs of Staff indicated the sustainment of current practices and the continuing advancements in treatment and rehabilitation of amputees should be a high priority for the Defense Health Board (DHB). He recognizes the need to ensure there is no loss of knowledge and skills due to the drawdown of the Afghanistan conflict with the welcomed reduction of war-related amputations.

I request DHB review the full spectrum of amputee care, and define a strategy for preserving and continuing these advancements, identifying the best possible care to our beneficiaries. Your thoughtful advice and guidance would greatly assist us in this matter. Please provide a response on these items to the Assistant Secretary of Defense for Health Affairs. Thank you for the highly professional and considered work of the Board and for your efforts on this new initiative.



Jessica L. Wright
Acting

Attachment:
As stated

cc:
Assistant Secretary of Defense
for Health Affairs

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END OF REPORT