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TITLE: Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel

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14. ABSTRACT This study is comprised of three trials, referred to as the Assessment of Chiropractic Treatment (or ACT). the most significant work during the last reporting period was the finalization of the protocol for ACT1 (RCT for low back pain and nested smoking cessation study) its movement into the military IRB process and the CRADA process, Further, protocols for Assessment of Chiropractic Trials study 2 (Pre/post differences in reflexes and reaction times in Special Operation Forces) and study 3 (RCT of strength, balance and likelihood of re-injury with combat ready troops, chiropractic manipulation therapy as compared to sham manipulation) have been finalized.					
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Section I –Brief Introduction, Purpose, Scope

Funded by the Office of the Congressionally Directed Medical Research Programs, under contract Number W81XWH-11-2-0107, this study is comprised of three trials, referred to as the Assessment of Chiropractic Treatment (or ACT). The study has the following specific aims:

1. To compare (a) pain and (b) functional outcomes of chiropractic manipulation therapy plus standard care to standard care alone in an RCT of active duty military personnel ages 18-50 with non-surgical acute, sub-acute or chronic low back pain. (ACT1)
2. To measure and compare changes in smoking behavior between the 2 groups. (ACT1)
3. To assess the effect of chiropractic manipulation therapy on military readiness, by comparing pre-post treatment differences in reflexes and reaction times in Special Operation Forces. (ACT2)
4. To determine differences in strength, balance and likelihood of re-injury between combat ready troops receiving either chiropractic manipulation therapy or sham manipulation. (ACT3)

ACT 1-Low back pain RCT with nested smoking cessation study will be conducted at the Walter Reed National Military Medical Center in Bethesda, MD; Naval Hospital in Pensacola, FL; Naval Medical Center in San Diego, CA; Rock Island Arsenal in Rock Island, IL.

ACT 2-Pre/post differences in reflexes and reaction times in Special Operation Forces will take place at Blanchfield Army Community Hospital, Fort Campbell, KY; and Naval Medical Center in San Diego, CA

ACT 3-RCT of strength, balance and likelihood of re-injury with combat ready troops with chiropractic manipulation therapy compared to sham manipulation will take place at Madigan Army Medical Center, Ft. Lewis McChord, WA.

Section II – Overall Progress

Advisory Board Creation and Meeting:

The Chiropractic Trials Expert Advisory Board was created and convened on May 3, 2011 through teleconference. The meeting began with introductions and the committee chairman was named (Dr. Dan Cherkin). The study protocol was disseminated, reviewed and discussed. Other topics discussed included: timelines for each trial, human subjects review board processes, site visits (conducted at Bethesda, Pensacola, San Diego, Fort Campbell, Fort Lewis-McCord, and Rock Island), suggestions for research design and possible elements to collect for the program evaluation component. The Advisory Board members noted that the implications of the results will be significant and were enthusiastic about the study, its design, and the assembled team. The Board consists of the following members: Dan Cherkin, Ph.D. (CHAIRMAN) of Group Health Research Institute; Scott Haldeman, DC, M.D., Ph.D. of the University of California, Irvine Scott Haldeman Consulting Neurology; Valerie Johnson, DC of VAGLA Healthcare System; Wayne B. Jonas, M.D. of Samueli Institute; Anthony J. Lisi, DC of Veterans Health

Administration; Dennis Marchiori, DC, Ph.D. of Palmer College of Chiropractic; Marion McGregor, DC, FCCS(C), Ph.D. of Canadian Memorial Chiropractic College; Reed Phillips, DC, Ph.D. of NCMIC Foundation, Inc.; and Thomas V. Williams, Ph.D. of TRICARE Management Activity.

Site visits:

The following site visits were conducted over the past year:

- *Rock Island Arsenal- Rock Island, IL- Jan. 11, 2011/Jan. 31, 2011*
- *Naval Medical Center- San Diego, CA- Jan. 18, 2011*
- *National Navy Medical Center- Bethesda, MD- Feb. 2, 2011*
- *Naval Air Station- Pensacola, FL- Feb. 7, 2011*
- *Blanchfield Army Community Hospital, Fort Campbell, KY- May 2, 2011*
- *Madigan Army Medical Center, Ft. Lewis McChord, WA- May 2-3, 2011*
- *Naval Medical Center, San Diego, CA- June 21-22, 2011*
- *Ft. Campbell, KY- October 3, 2011*
- *Naval Hospital, Pensacola, FL- October 4, 2011*

The following site visits occurred this quarter. Summaries are provided below:

Ft. Campbell, KY- December 5, 2011

Drs. Christine Goertz, James DeVocht, and Katie Pohlman from Palmer College and Dr. Dean Smith (ACT 2 Consultant) met with the following Ft. Campbell personnel: Drs. Thomas Jones, Tamari Moreland. We were provided with another tour of the Traumatic Brain Injury Department and an opportunity to use the equipment. Dr. Moreland demonstrated the highly sophisticated reaction time equipment. Brief discussions with MAJ David Twillie (director of the Traumatic Brain Injury Department) followed the demonstration regarding how the use of this equipment has been added to the ACT 2 protocol. We also discussed logistical issues. Everyone was optimistic that the equipment could be utilized without interrupting everyday operations.

Drs. Jones, Goertz, DeVocht, Smith, Pohlman then met with COL Helwig to discuss the study in depth. COL Helwig was supportive of the study. He believes the recruitment goal is realistic and logistical concerns are minimal. After the first of the year, COL Helwig and Dr. Mona Bingham (Samueli Institute) will begin working on the necessary documentation to gain permission to work the 5th group at Ft. Campbell.

Naval Hospital, Pensacola, FL- Feb 29, 2012

Dr. Katie Pohlman and newly hired Pensacola Site Project Manager Sharon Phillips from Palmer College of Chiropractic visited the Naval Air Technical Training Center. This visit included LT Payne, LT Hayes, CDR Penta, and Dr. Greg Lillie. Initial conversations included logistical concerns, which were minimal. LT Hayes gave Ms. Phillips a tour of the facility and showed her the office they have set aside for her. The

office is equipped with a desk and filing cabinets. Additionally, Ms. Phillips and Dr. Pohlman met with Shirley Callan who has been working on the CRADA for the Pensacola site.

Personnel Hire:

The Pensacola Project Manager position was posted on November 23, 2011 on the Palmer College of Chiropractic website and SoCRA website. Phone interviews occurred between December 7-9, 2011. On December 19, 2011, two candidates were interviewed by Dr. Greg Lillie and CDR Penta at the Naval Air Technical Training Center in Pensacola, FL. Following the interview, both candidates were then flown to Palmer College of Chiropractic in Davenport, IA for day-long interviews on January 5-6, 2012. The top candidate, Sharon Phillips, was hired on February 20, 2012 and was trained at Palmer from February 20-24, 2012.

The San Diego Project Manager position was posted on February 29, 2012.

Development of Protocols:

Protocols for Assessment of Chiropractic Trials study 2 (Pre/post differences in reflexes and reaction times in Special Operation Forces) and study 3 (RCT of strength, balance and likelihood of re-injury with combat ready troops, chiropractic manipulation therapy as compared to sham manipulation) have been finalized.

IT/Operational Updates:

All web modules are complete.

ACT full team meeting:

This meeting is planned for March 15, 2012 in Las Vegas, Nevada. All site principle investigators, site chiropractors, site project managers, site medical monitors and investigators have been invited to attend this meeting. The first half of the day will consist of mandatory tobacco cessation training for the ACT 1 clinicians. The afternoon will include an introduction of team members, an overview of all studies, followed by an open discussion about site-specific and project-wide facilitators and barriers to study implementation.

IRB Updates:

In December, RAND Corporation and Palmer submitted IRB amendments for ACT 1, "The Study of Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness, and Smoking Cessation in Military Active Duty Personnel", which were both approved along with their respective annual continuing reviews.

The Naval Medical Center Portsmouth IRB for the study site at Naval Hospital Pensacola is pending. It is our understanding that this approval is pending finalization of the CRADA.

The National Medical Center-San Diego has reviewed the IRB protocol twice and is pending final approval of a medical monitor. We have subsequently found an on-site medical monitor and are working to complete the final documentation on this issue.

Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD protocol was submitted on Oct. 3, 2011; administratively reviewed and revisions completed Oct 31, 2011. Since then the facility has moved which required further document updating of the protocol and informed consent document templates displaying the new Bethesda site and name.

The fourth site for ACT 1 is the US Army Health Clinic at Rock Island Arsenal. This site will be added to the WRNMMC IRB, since they are the IRB on record for Rock Island Arsenal.

Please see more descriptions of IRB and CRADA activities in Section III Problem Areas.

ACT Newsletter

The ACT newsletter entitled “Back to ACTION” was initiated in October 2011. Initially the newsletter was sent to the internal and external steering committees and to all personnel involved with the study at the Military Treatment Facilities. The newsletter was very well received and so it was decided to forward to RAND’s marketing department, Samueli Institute’s marketing department, Palmer Center for Chiropractic Research employees and chiropractors working in the VA and military sites. Each newsletter has a message from one of the Co-Principal Investigators, highlights from recent events, spotlight on a team member and information on upcoming events.

In the last quarter, the project staff continued to produce and email to constituents the newsletter with summary of newsletter activities as follows:

- November: Message from Principle Investigator Joan Walter; Spotlight on Joan Walter; Highlights on the Samueli Institute.
- January: Message from Principle Investigator Christine Goertz; Spotlight on Christine Goertz; Highlights on the Palmer College of Chiropractic.
- February: Message from Principle Investigator Joan Walter; Spotlight on Kimberly McConnell; Highlights on IRB approval process

Section III – Problem Areas

IRB Status for Initial Approval for the Protocol, “Assessment of Chiropractic Treatment for Low Back Pain and Smoking Cessation in Military Active Duty Personnel” (ACT 1):

IRB applications have been submitted for the ACT 1 study protocol, “The Study of Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness, and Smoking Cessation in Military Active Duty Personnel” to three of the four sites within the last quarter of this annual report and all have had some IRB review activity. Unfortunately final approval letters have not been received from any of the

sites primarily due to two overall issues: (1) Inability to complete this IRB application as a multi-site IRB research project, and (2) Difficulty moving the CRADA forward for military signatures.

During this annual year, the ACT 1 study was approved in January 2011 by Palmer Chiropractic Research Institutional Review Board and the RAND Corporation Human Subjects Protection Committee. The Continuing Review documents for Palmer Chiropractic Research Institutional Review Board have already been submitted.

In accordance with the funding award process, this protocol was also reviewed by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, U.S. Army and USAMRMC human subjects protection requirements. (Email approval received Feb 9, 2012). Submitted by Ian D. Coulter, PhD, RAND Corporation, Santa Monica, California, Proposal Log Number CR100015, Award Number W81XWH-11-2-0107, HRPO Log Numbers A-16734.1a (Palmer College of Chiropractic Site) and A-16734.1b (RAND Corporation Site).

Military IRB updates by each site are listed below, followed by information on the issues with the military CRADA document.

- Walter Reed National Military Medical Center, Bethesda, MD

IRB protocol was submitted on Oct. 3, 2011; administratively reviewed and revisions completed Oct 31, 2011. Since then more updates have been completed for the protocol due to change in template since the permanent move to Bethesda of the IRB.

The research team has had lengthy conversations with individuals at all sites to discuss the possibility of a multi-site IRB protocol and approval to reduce the workload and hours of energy spent doing separate protocols for each site. WRNMMC was in support of this but the final decision to reject this route was primarily due to differences and hesitation in the Navy locations. The team is in discussion with WRNMMC to defer to RAND IRB as the Primary IRB of the study. Currently an IAIR is in progress to complete the requirements for RAND's primary role with WRNMMC serving in a consultant role for DoD. A POC in the WRNMMC IRB will continue to assist with the development of site specific documents required for local review here in Bethesda to ensure that institutional policies and DoD regulations are being followed before endorsing the protocol to RAND for IRB review. Once the endorsement is complete, the fourth site for ACT 1, the US Army Health Clinic at Rock Island Arsenal which will be added to the WRNMMC IRB package as an amendment, since WRNMMC is the IRB on record.

- Naval Medical Center Portsmouth (NMCP) IRB for the study site at Naval Hospital Pensacola, FL
The IRB protocol was submitted Oct 20, 2011; administratively reviewed Nov 9, 2011 with questions and updates requested. Changes were completed Nov 25, 2011 and the Human Subjects IRB review was completed and approved on Dec 14, 2011. The research study team has received verbal approval of the

IRB proposal following this meeting but a formal approval letter is pending, awaiting the final approved CRADA.

- National Medical Center-San Diego

The IRB protocol was submitted Nov 16, 2011. Administrative review was conducted and revisions submitted Nov 18, 2011. After further administrative review, additional documents and revisions were completed Dec 7, 2011 and the IRB human subjects review was completed Jan 11, 2012.

Written documentation that the protocol was approved pending revision of an on-site Medical Monitor was received Feb 23, 2012. Final documents needed for this individual are in progress, but have not been submitted by the end of this reporting period.

CRADA Update:

The multi-party NAVY CLINICAL TRIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT, known as the CRADA is still not approved with final military signatures. First contact was made with Shirley Callan in April 5, 2011 to obtain the correct information and contacts. The request and CRADA question was forwarded to Cecil DelRosario, the representative POC at Naval Medical Center Portsmouth IRB, who responded that a multi-party CRADA could be written and referred us to Elaine Cleveland. The first draft of CRADA was initiated by Ms. Elaine Cleveland, Management Specialist, Responsible Conduct of Research, National Naval Medical Center, and forwarded to Pls (RAND, Palmer, Samueli Institute) on June 7, 2011 for review. The CRADA was returned to WRNMMC 9/30/2011 (Version dated 18 Aug 2011) and the initiation of name change for WRNMMC was completed Oct 12, 2011 and the JAG representative reviewed wording of the document. This revised CRADA was reviewed and approved. Shirley Hall forwarded CRADA back to Elaine Cleveland (WRNMMC) with Legal Representative Signatures from Samueli Institute (11/8/2011), Palmer (11/9/2011) and RAND (11/09/2011).

Despite multiple attempts to follow-up with Elaine Cleveland from numerous representatives of SI, RAND, Palmer, WRNMMC IRB, and HRPO at USAMRMC there has been no response or communication with Ms Cleveland since the packet was submitted Nov. 2011. The IRB and CRADA approval seems to be a confusing circular ineffective systematic process. IRB offices do not want to release approval documents without an approved CRADA, although all levels of authority have stated the two documents are completely independent. After the multi-site IRB protocol was rejected by Navy IRB sites, the dilemma with a CRADA POC was noticed by members of the WRNMMC and thanks to Ms Mary Kelleher, contact was made with Alan Cash (WRNMMC ORTA) who has been able to update the document and contact POCs for NMCP, Naval Hospital at Pensacola, and NMCSD to review the updated CRADA as well. In an email dated Feb 29, 2012, Mr. Cash verified that he had sent the CRADA for signatures. Per his information via email, we believe that the CRADA is in process for signatures at this time.

Section IV – Work for Next Reporting Period

Work for the next reporting period will include the following tasks:

- Hire site Project Manager for San Diego and Bethesda.
- Obtain IRB approvals for ACT2 and ACT3 protocols.
- Begin recruitment at Pensacola and San Diego.
- In January, Palmer's IRB approved the protocol for ACT 2, "The assessment of military readiness by evaluating pre-post differences in reflexes and reaction times following chiropractic treatment using a pre-post interventional cohort trial in members of SOF." This will be submitted to the RAND IRB in March, 2012.
- ACT 3 protocol will be submitted to Palmer's IRB in April, 2012 and following approval from Palmer it will be submitted to RAND IRB.
- The ACT newsletter will continue to be produced and disseminated. The March newsletter will have an address from Principle Investigator Christine Goertz with a spotlight on the newly hired project manager for Pensacola Sharon Phillips and highlights from the ACT meeting taking place March 15, 2012.
- A site visit is scheduled for May 14 to Ft. Lewis, WA.

The work is collaboration between RAND Corporation, Palmer College of Chiropractic, and Samueli Institute.

Section V – Administrative Comments (optional)

Not Applicable