

AWARD NUMBER: W81XWH-14-2-0191

TITLE: A Multicenter, Randomized, Controlled Trial of Cerebrospinal Fluid Drainage in Acute Spinal Cord Injury

PRINCIPAL INVESTIGATOR: Nicholas Theodore, MD, FACS, FAANS

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

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REPORT DOCUMENTATION PAGE

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14. ABSTRACT

This is the final report for the abovementioned study which was approved in 2014 and initiated in 2015. A total of 11 spinal cord injury patients were enrolled to the study, and four centers participated in the screening & enrollment efforts. Though the study failed to meet its target sample size, it confirmed that the investigational protocol can be successfully carried out in a multi-center setting and when managing patient care in the immediate post-injury stage. Further, the preliminary study data showed promising potential for the study intervention.

The investigators have submitted an application for a new grant that would support a follow-up study building upon the successes of this project.

15. SUBJECT TERMS

NONE LISTED

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The purpose of this project was to conduct a small randomized controlled trial (N=60) to evaluate safety and efficacy of cerebrospinal fluid drainage (CSFD) and to provide preliminary clinical efficacy evaluation of combination of CSFD and elevation of mean arterial pressure (MAP) in patients with acute spinal cord injury.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Spinal Cord Injury, Trauma, Neuroprotection, Neural impairment, Cerebrospinal, Acute, Rehabilitation, Cervical

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The **purpose** of this RCT was to evaluate the safety and efficacy of CSFD and to provide a preliminary clinical efficacy evaluation of combination of CSFD and elevation of MAP in patients with acute spinal cord injury.

Objectives of this RCT were to evaluate the (i) efficacy of reducing intrathecal pressure by CSFD in patients with acute SCI; (ii) preliminary efficacy (lack of futility) of combination of CSFD and elevation of MAP compared to elevation of MAP alone in improving neurologic motor outcomes in patients with acute spinal cord injury; (iii) safety of intensive CSFD in acute spinal cord injury patients.

Study Hypotheses was that (1) CSFD will be effective in reducing intrathecal pressure in patients with acute SCI; and that (2) CSFD in combination with elevation of MAP will not be futile when compared to elevation of MAP alone in terms of motor neurologic outcomes and that (3) Rate of complications related to combination of CSFD and elevation of MAP will not be significantly different from the rate of complications related to elevation of MAP alone.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Between Q4 2015 and Q1 2019, the trial successfully enrolled 11 SCI patients from four clinical sites. The trial proved that the project is logistically viable and, more importantly, there were no reported procedure-related Serious Adverse Events. Of the 11 enrolled patients, there were seven ASIA impairment scale conversions. The mean ASIA motor score total improved from 24.0 at screening/enrollment to 80.5 at 180 days. The Sensory Light Touch score improved from a mean score of 54.9 at screening/enrollment to 74.5 at 180 days. The Sensory Pin Prick score improved from a mean of 54.3 at screening/enrollment to 85.3 at 180 days.

Based on an exploratory evaluation of the current study data, the CSFD group had lower Intrathecal Pressure (IP) and less variability in IP compared to the control group.

Given this validation of improved perfusion leading to improved clinical outcomes, we have proposed to the DoD to continue this randomized clinical trial, with the inclusion of central cord type SCI patients and adding three additional sites. We have demonstrated feasibility of this treatment paradigm and if the trial hypothesis is confirmed, this study will pave the way for a larger Phase III RCT.

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

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

The project allowed surgeons/physicians, nurses, researchers and other hospital staff from various departments to learn about the: study intervention, participating in Department of Defense-funded grant projects, caring for subjects involved in a clinical trial, collaborating with other sites and outside vendors in a multi-center study and clinical trial execution including electronic data capture and Good Clinical Practice. This included departments such as: Trauma Centers, Orthopedic Surgery, Neurosurgery, Rehabilitation, and others.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

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

The study data remain blinded while an application for future funding is under consideration by the Department of Defense. If successful, the new trial will build upon the data from this study. If new funding is not approved, we will unblind the data and work to publish it in one or more relevant spinal cord injury journals. Nonetheless, the basic science behind the study and early clinical experience was presented at multiple meetings around the world without an unblinding of the data.

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

Will thoroughly analyze the data and prepare for a large study, hopefully with DOD funding.

- 4. IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Even the early results of this study have opened the discussion into other treatment paradigms for acute spinal cord injury given that there have been NO approved drugs or therapies in the last 20 years to help patients with this devastating injury.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Once again, this study has started discussions in the neurosurgical trauma and critical care specialties.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

The preliminary blinded results show that the study intervention may be a beneficial clinical approach to treating cervical spinal cord injury. If the results are confirmed, they may lead to the adoption of the techniques used in this study in a broader patient care setting.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

As with all spinal cord injury trials, enrollment is very challenging. This is a result of the declining incidence rate of spinal cord injury in the United States, and the concomitant injuries that often accompany SCI patients and which go against the inclusion criteria of the protocol (e.g. significant head injuries or SCI resulting from penetrating mechanism). In 2017, we set out to expand the enrollment potential of the study in order to meet this challenge. As additional funding was not available our efforts were limited to growing the study to only one additional site. Subsequently, we also obtained a one-year no cost extension which allowed us to keep the screening and enrollment efforts ongoing beyond the original study end date. This was done at no additional cost to the DoD.

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

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

- Following approval of the grant award, it took longer than anticipated to execute the funding agreement and obtain DoD HRPO approval. This resulted in an unanticipated delay in opening the sites to screening & enrollment.
- A new Level 1 trauma hospital opened in Arizona during the course of the trial. This resulted in an unexpected decrease in the spinal cord injury population presenting to the lead study site, Barrow Neurological Institute.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The grant was completed within budget.

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the

reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

In 2015, the protocol was amended as follows:

Participating sites were informed that they should increase mean arterial blood pressure to 85 mmHg as per the standard of care guidelines provided by the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. This was addressed in protocol section 5.8.3.3 as “Other treatments for both groups.” The specifics concerning the involvement of the independent research monitor were further clarified in section 11.2 “Research Monitor.” In addition, section 7.0 “Risks” was updated to provide further information concerning the study procedures. The changes were approved by each individual site IRB on the following dates. University of Arizona: June 22, 2016; University of Alabama: February 01, 2016; Barrow Neurological Institute: September 08, 2015; Chandler Regional Medical Center: September 14, 2018.

The changes to the protocol were approved by the DoD HRPO on October 02, 2015.

Significant changes in use or care of vertebrate animals

None to report.

Significant changes in use of biohazards and/or select agents

None to report.

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

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Until study completion, the results were kept blinded. We are now in the process of unblinding and will have a publication ready within the next few months.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a*

periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

None to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

None to report.

As noted above, the results from this research activity remain blinded.

• **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None to report.

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

None to report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

None to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Example:

Name: Mary Smith
Project Role: Graduate Student
Researcher Identifier (e.g. ORCID ID): 1234567
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award).

Name: Nicholas Theodore, MD
Project Role: Principal Investigator of study
Affiliation Institution: Johns Hopkins University
Contribution to Project: PI of study; responsible for oversight of project

Name: Udaya Kakarla, MD
Project Role: Principal Investigator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for oversight of project and enrollment at institution

Name: Nikolay Martirosyan, MD
Project Role: Sub-Investigator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for project oversight and data analysis at institution

Name: Jay Turner, MD
Project Role: Sub-Investigator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Contributed to enrollment at institution

Name: Laura Snyder, MD
Project Role: Sub-Investigator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Contributed to enrollment at institution

Name: Joshua Wewel, MD
Project Role: Sub-Investigator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Contributed to enrollment at institution

Name: Yashar Kalani, MD
Project Role: Sub-Investigator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Contributed to enrollment at institution

Name: Odilette Trevizio
Project Role: Coordinator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for study management at institution

Name: Jill Danielson, RN
Project Role: Coordinator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for study management at institution

Name: Norissa Honea, RN
Project Role: Coordinator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for study management at institution; Research Nurse

Name: Charlene Robinson
Project Role: Regulatory Coordinator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for regulatory affairs at institution

Name: Simon Brown
Project Role: Regulatory Coordinator
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Responsible for regulatory affairs at institution

Name: Heidi Jahnke, RN
Project Role: Other Staff
Affiliation Institution: St. Joseph's Hospital & Medical Center
Contribution to Project: Research Nurse

Name: Kaith Almefty, MD
Project Role: Principal Investigator
Affiliation Institution: Chandler Regional Medical Center
Contribution to Project: Responsible for oversight of project and enrollment at institution

Name: Annette Taylor
Project Role: Coordinator
Affiliation Institution: Chandler Regional Medical Center
Contribution to Project: Responsible for study management at institution

Name: Antonia Griego
Project Role: Coordinator
Affiliation Institution: Chandler Regional Medical Center
Contribution to Project: Responsible for study management at institution

Name: Jennine Zumbuhl
Project Role: Coordinator
Affiliation Institution: Chandler Regional Medical Center
Contribution to Project: Responsible for study management at institution

Name: Stephanie Wells
Project Role: Regulatory Coordinator
Affiliation Institution: Chandler Regional Medical Center
Contribution to Project: Responsible for regulatory affairs at institution

Name: Teresa Hills, RN
Project Role: Other Staff
Affiliation Institution: Chandler Regional Medical Center
Contribution to Project: Research Nurse

Name: Mark Hadley, MD
Project Role: Principal Investigator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for oversight of project and enrollment at institution

Name: Philip Schmalz, MD
Project Role: Sub-Investigator
Affiliation Institution: University of Alabama
Contribution to Project: Contributed to enrollment at institution

Name: Christopher Shank, MD
Project Role: Sub-Investigator
Affiliation Institution: University of Alabama
Contribution to Project: Contributed to enrollment at institution

Name: Esther Dupepe, MD
Project Role: Sub-Investigator
Affiliation Institution: University of Alabama
Contribution to Project: Contributed to enrollment at institution

Name: Mary Jane Avant
Project Role: Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for study management at institution

Name: Rachel Becker
Project Role: Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for study management at institution

Name: Rhonda Whidden
Project Role: Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for study management at institution

Name: Austin Kadiri
Project Role: Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for study management at institution

Name: Christine Orrison
Project Role: Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for study management at institution

Name: Cindy Atkins
Project Role: Regulatory Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for regulatory affairs at institution

Name: Lisa Nelson
Project Role: Regulatory Coordinator
Affiliation Institution: University of Alabama
Contribution to Project: Responsible for regulatory affairs at institution

Name: Vicky Conner-Hearn
Project Role: Other Staff
Affiliation Institution: University of Alabama
Contribution to Project: Financial Officer

Name: Michael Lemole, MD
Project Role: Principal Investigator
Affiliation Institution: University of Arizona
Contribution to Project: Responsible for oversight of project and enrollment at institution

Name: Nikolay Martirosyan, MD
Project Role: Sub-Investigator
Affiliation Institution: University of Arizona
Contribution to Project: Contributed to enrollment at institution

Name: Christina Walter
Project Role: Coordinator
Affiliation Institution: University of Arizona
Contribution to Project: Responsible for study management at institution

Name: Laurel Rokowski
Project Role: Coordinator
Affiliation Institution: University of Arizona
Contribution to Project: Responsible for study management at institution

Name: Hannah Curtis
Project Role: Coordinator
Affiliation Institution: University of Arizona
Contribution to Project: Responsible for study management at institution

Name: John Santoro
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Andrea Seach
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Jean Chang
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: David Bradford
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Michelle Naour
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Joshua Black
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Tyler Martino
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Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

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Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Nirushan Narendran
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Research Assistant

Name: Sara Perotti
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Nurse Practitioner

Name: Willard Kasof
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Neurosurgery Resident

Name: Leonardo Brasiliense
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Neurosurgery Resident

Name: Robert Bina
Project Role: Other Staff
Affiliation Institution: University of Arizona
Contribution to Project: Neurosurgery Resident

Name: Allan Levi, MD
Project Role: Independent Safety Monitor
Affiliation Institution: University of Florida
Contribution to Project: Responsible for providing independent assessments of Serious Adverse Events for project

Name: Branko Kopjar, MD
Project Role: Lead Biostatistician
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for data analysis at institution

Name: Veljko Kopjar
Project Role: Clinical Project Director
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for oversight of project at institution

Name: Bridget Dancs
Project Role: Project Manager/ Lead Monitor
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for oversight of project and data monitoring at institution

Name: Wynne Xie
Project Role: Monitor
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for data monitoring at institution

Name: Tolu Aladejana
Project Role: Monitor
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for data monitoring at institution

Name: Samyukta Erabati
Project Role: Project Manager
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for project oversight at institution

Name: Stan Abramov
Project Role: Database Manager
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for data management at institution

Name: Kevin Beverly
Project Role: Clinical Data Programmer
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for data management at institution

Name: Marketa Hnilova
Project Role: Clinical Data Coordinator
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for data management at institution

Name: Tassia Hollemon
Project Role: Clinical Research Assistant
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for study-site management at institution

Name: John Willey
Project Role: Clinical Research Assistant
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for study-site management at institution

Name: Dominique McDaniel
Project Role: Clinical Research Assistant
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for study-site management at institution

Name: Christina Lo
Project Role: Clinical Research Assistant
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for study-site management at institution

Name: Wasinee Opal Sriapha
Project Role: Clinical Research Assistant
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for study-site management at institution

Name: Anna McCann
Project Role: Clinical Research Assistant
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for study-site management at institution

Name: Jay Dobson
Project Role: Regulatory Specialist
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for regulatory affairs at institution

Name: Jenny Grice
Project Role: Regulatory Specialist
Affiliation Institution: Nor Consult, LLC
Contribution to Project: Responsible for regulatory affairs at institution

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial

or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Barrow Neurological Institute
Phoenix, Arizona
Enrollment Center

University of Arizona, Department of Surgery, Division of Neurosurgery
Tucson, Arizona
Enrollment Center

University of Miami Health System, Department of Neurosurgery
Research Monitor

University of Alabama School of Medicine, Department of Neurosurgery
Birmingham, Alabama
Enrollment Center

Chandler Regional Medical Center
Chandler, Arizona
Enrollment Center

University of Washington School of Public Health
Seattle, Washington
Study Design & Biostatistical Support

Nor Consult, LLC
Seattle, Washington
Contract Research Organization

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

none