OFFICE OF INSPECTOR GENERAL

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

AUDIT OF A CLINICAL RESEARCH STUDY TO TREAT TRAUMATIC BRAIN INJURY AND POST-TRAUMATIC STRESS DISORDER IN VETERANS

Brain Synergy Institute
Contractor Performance and Billing, and
HHSC Contract Procurement and Monitoring

November 22, 2016
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HHSC IG
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WHY IG DID THIS AUDIT

In December 2013, BSI was awarded a sole source, proprietary contract to treat military veterans suffering from post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI). Within 11 months of execution of the $812,500 contract, HHSC signed 2 contract amendments that increased the total value of the contract to $2.2 million. BSI was contracted to perform a clinical research study to assess treatments for PTSD and TBI including treatment with a proprietary "Off-Vertical Axis Rotation Therapy" (OVART).

This audit was performed at the request of a member of the Texas House of Representatives and at the direction of the HHSC Executive Commissioner.

The HHSC contract with BSI garnered public attention in September 2015 when a newspaper article questioned the procurement of the contract and the associated expenditures for the treatment of veterans.

The audit was designed to determine whether (a) procurement of the BSI contract was in accordance with HHSC policy, (b) BSI performed and complied with requirements of the contract, and (c) funds were expended for their intended purpose.

WHAT IG RECOMMENDS

IG recommends that HHSC follow its recently revised contracting and procurement practices, and focus on procurement practices that successfully guard against losses due to waste and abuse. IG recommends that HHSC recover $278,441 overpaid to BSI.

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WHAT IG FOUND

HHSC contracted with Brain Synergy Institute (BSI) to perform a clinical research study using proprietary treatment, and paid BSI $2.2 million in Texas state taxpayer funds for those services. This audit of the BSI contract, performed by the IG Audit Division, identified concerns with contract procurement, contractor performance and billing, and contract monitoring.

During the contract procurement process, HHSC inadequately drafted the BSI contract, which included a poorly designed research protocol, and did not include key provisions such as a participant eligibility requirement. As a result, 47 of the 134 unique participants, or 35 percent of those treated in the BSI study, were from states other than Texas. HHSC then used contract amendments to correct oversights and omissions, such as retroactively changing the cost-based payment structure to a fixed-fee structure, which allowed BSI to bill all participants at the same maximum rate, even though not all services were provided to all participants.

BSI lacked experience with clinical research studies, and did not comply with contract requirements. BSI failed to obtain an Institutional Review Board approval, which is a requirement for protecting the health and safety of human subjects involved in clinical research studies. BSI did not provide treatment in accordance with the study protocol, and treated participants who should have been excluded from the study. Thirty percent, or 40 of the 134 unique study participants, did not receive the proprietary OVART treatment because of pre-existing conditions that should have excluded them from the study. BSI was unable to meet contract requirements for final report deliverables, and because the study was not performed as valid clinical research, BSI was unable to reliably report whether and to what degree its treatments resulted in improvements to the health and quality of life of the participating veterans.

Throughout the contract, BSI billed and HHSC paid for the treatment of non-Texas veterans with state taxpayer funds. BSI billed and HHSC paid $229,217 for treatment of 14 non-Texas veterans after the contract was amended to include only Texas veterans, and $49,224 for treatment of 3 duplicate participants. While the IG Audit Division found no evidence of fraud, at least $278,441 in taxpayer funds were lost to waste and abuse under the BSI contract.

Ron Pigott, HHS Executive Commissioner for Procurement and Contracting, stated that procurement policies and procedures were improved in 2015, and under the new processes, this contract would not have been procured. Mr. Pigott will work with the Chief Counsel to issue demand letters as needed.

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INTRODUCTION

The Texas Health and Human Services Commission (HHSC) Inspector General (IG) Audit Division has completed an audit of HHSC contract procurement and monitoring, as well as contractor performance under the Brain Synergy Institute (BSI) contract. BSI was doing business as Carrick Brain Centers, and in October 2015 became Cerebrum Health Centers. The objectives of the audit were to determine whether (a) procurement of the contract was in accordance with HHSC policy, (b) BSI performed and complied with requirements of the contract, and (c) funds were expended for the intended purpose during the audit period from August 2013 through January 2016.

The audit was performed at the request of a member of the Texas House of Representatives and at the direction of the HHSC Executive Commissioner. The HHSC contract with BSI garnered public attention in September 2015 when a newspaper article[1] questioned the procurement of the contract and the associated expenditures for the treatment of veterans.

Background

Traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) occur in higher rates in war veterans than in civilian populations.[2] TBI most often occurs in active duty military when surviving a blast exposure. TBI diagnoses range from mild to severe and can cause physical, cognitive, and emotional deficits. PTSD occurs as a reaction to experiencing traumatic events such as combat, disasters, and other life-threatening events. Both TBI and PTSD are often invisible, but affect a person's mood, thoughts, and behavior. It is estimated that approximately 19 percent of United States Iraq and Afghanistan military veterans experienced a probable TBI, and 14 percent screened positive for PTSD. As discussed in a 2008 RAND report, the national need for treatment of veterans with TBI and PTSD was greater than veterans' access to evidence-based treatments.[3]

The national concern about TBI and PTSD in military veterans was heightened by a Texas tragedy. In February 2013, a former Navy Seal died in Chalk Mountain, Texas. The Navy Seal was killed while attempting to assist another veteran who was suffering from PTSD. This event brought nationwide media attention, and intensified state interest in treating Texas veterans suffering from PTSD.

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[1] Ambrose, S. and Gordon, S. "Oversight for Vet Research Project Raises Questions." Dallas Morning News, September 23, 2015. http://interactives.dallasnews.com/2015/carrick/janek.html

[2] Gradus, Jaimie. "Epidemiology of PTSD." The National Center for PTSD. U.S. Department of Veterans Affairs, February 23, 2016. http://www.ptsd.va.gov/professional/PTSD-overview/epidemiological-facts-ptsd.asp

[3] "Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery." RAND Corporation, 2008. http://www.rand.org/pubs/monographs/MG720.html

Shortly thereafter, the Texas Governor's Office expressed an interest in a veterans PTSD study to the HHSC Executive Commissioner. The HHSC Executive Commissioner reports directly to the Governor, and often works closely with the Governor's Office. The Governor's Office initiated a meeting with the HHSC Executive Commissioner and the University of Texas Southwestern Medical Center (UTSW) regarding a "line item proposal that may benefit veterans." Also in early 2013, HHSC, UTSW, and BSI discussed treating veterans with PTSD.

In the late summer and early fall of 2013, the Governor's Office and HHSC executives participated in several meetings with BSI and the University of Texas at Dallas Center for Brain Health (UTD) regarding "treatment for veterans." In August 2013, staff at UTD emailed HHSC requesting "written information from the Carrick Brain Centers as it was the emphasis when our leadership visited with [the] Governor."

In August 2013, the Governor's Office and HHSC executive management travelled to Dallas to meet with UTD and BSI. The following month BSI sent a veteran's study proposal directly to the Governor's Office, stating "Attached is our proposal letter. Please let me know if it needs any editing or change in verbiage and I will be happy to work on it." BSI was then included on an agenda item for a call between the Governor's Office and HHSC. Shortly thereafter, the HHSC Executive Commissioner made an additional trip to visit BSI, and the Governor's Office was involved in the meeting via phone.

The Governor's Office remained involved in the discussions and development of the contracts to research treatment of veterans with PTSD, and in October 2013, the Governor's Office and the HHSC Executive Commissioner met with UTD and BSI to develop an interagency contract. The Governor's Office was included in emails to BSI regarding funding determinations and number of participants. In November 2013, HHSC shared the draft BSI contract and scope of work from the "Texas Veterans Pilot Initiative" document with the Governor's Office.

An internal HHSC email in November 2013 indicated a "contact at the governor's office called on Wednesday evening saying Carrick had study participants lined up and ready to begin on December 1." The email continued, stating that the interagency contract with UTSW had not been signed and needed execution because UTSW was necessary to provide pre-assessment for the BSI study. Days after the contract was awarded, UTSW emailed HHSC to report that: the President of BSI was "very upset" and had contacted UTSW to let them know that participants were awaiting entrance into the BSI study; and the President of BSI "threatened to call the Governor's Office" because UTSW was effectively "pulling the plug" on the BSI study.

In December 2013, HHSC awarded an $812,500 sole source, proprietary contract to BSI to perform a clinical research study[4] that assessed treatments for veterans suffering from TBI and PTSD. BSI was a small business operating a single clinic in Irving, Texas to provide chiropractic and other services to treat a range of illnesses. The proprietary treatment that BSI provided was called "Off-Vertical Axis Rotation Therapy" (OVART)[5], and used a chair that spun and rocked to treat patients with TBI and PTSD. Within 11 months of contract execution, HHSC signed two contract amendments that increased the total value of the contract to $2.3 million. The final amendment also increased the scope of the contract to include efforts to improve job readiness and pre- and post-employment success by increasing veterans' ability to solve problems, work cooperatively with others, focus and accomplish assignments, manage anger and stress, and set goals.

Two interagency contracts provided funding for the BSI contract. A $1.85 million interagency contract between HHSC and the Department of State Health Services (DSHS) was entered into during the same month as the initial BSI contract, and provided funding from general revenue[6] to fund the initial BSI contract, as well as the UTD and UTSW contracts. This interagency contract along with additional funds from the HHSC Office of Acquired Brain Injury provided funding through the first BSI contract amendment. A $690,000 interagency contract between HHSC and the Texas Workforce Commission was executed in November 2014 and provided funding for the second BSI contract amendment. All funding was from state general revenue. Neither DSHS nor the Texas Workforce Commission provided any services or participated in the BSI contract beyond each providing funding, and the Texas Workforce Commission receiving periodic status reports as required by its interagency contract.

In December 2013, the same month as the initial BSI contract, HHSC executed two additional interagency contracts to assist veterans. HHSC awarded a $625,000 contract with UTD for a veterans' clinical research study on PTSD. The study was titled "Non-Pharmacological Treatment for Symptoms of PTSD" and utilized an emerging noninvasive neurological treatment called repetitive transcranial magnetic stimulation. HHSC awarded a $412,500 contract with UTSW to provide assistance to UTD by performing PTSD interviews to evaluate veterans for participation in the UTD clinical research study and to measure outcomes. For a BSI contract timeline, see Appendix B.

[4] A "clinical research study" is designed to determine the safety and effectiveness of medications, devices, diagnostic products, or treatment regimens to prevent, treat, diagnose, or relieve symptoms of disease.

[5] "OVART" is also sometimes referred to as OVARD, which stands for Off-Vertical Axis Rotation Device.

[6] "General Revenue" is composed of Texas state funds that may be utilized for any purpose, and are typically used for routine expenditures such as health and education. State general revenue expenditures are discretionary and have not been earmarked for a specific function.

The IG Audit Division conducted audit fieldwork to determine whether BSI had performed and complied with requirements of the contract, and whether funds were used for their intended purpose. The IG Audit Division also examined the relationships between the BSI, UTD, and UTSW contracts.

Many HHSC staff and management involved with the procurement of the BSI contract were no longer employed by HHSC at the time of the audit, and the IG Audit Division did not interview these individuals. The IG Audit Division (a) reviewed email correspondence for staff associated with the contract in order to determine how the contract was initiated and procured, (b) interviewed other key individuals associated with the contracts, and (c) reviewed participant information and files at BSI in Irving, Texas and at UTD and UTSW in Dallas, Texas. The IG Audit Division also analyzed invoices, payments, and available supporting documentation regarding contract expenditures.

The IG Audit Division conducted the audit in accordance with generally accepted government auditing standards issued by the Comptroller General of the United States. Unless otherwise described, any year that is referenced is the state fiscal year, which covers the period from September 1 through August 31.

The IG Audit Division presented audit results, issues, and recommendations to HHSC Procurement and Contracting Services and to BSI in a draft report dated September 19, 2016. Each was provided with the opportunity to study and comment on the report. HHSC Procurement and Contracting Services management responses to the recommendations contained in the report are included in the report following each recommendation. HHSC Procurement and Contracting Services concurred with the IG Audit Division recommendations.

RESULTS, ISSUES, AND RECOMMENDATIONS

Issue 1: CONTRACT PROCUREMENT

The HHSC contract procurement process is designed to ensure that contracts adhere to state requirements and agency policy, and are competitively bid and awarded to prevent fraud, waste, and abuse. HHSC awarded the BSI contract for a clinical research study of the treatment of TBI and PTSD as a sole source, proprietary contract, due to the unique OVART treatment that was available solely from BSI.

As provided in the contract procurement justification document, HHSC identified BSI because "the vendors [sic] expertise, experience, and institutional knowledge of brain injuries and the patented OVARD[7] is proprietary to Carrick and is needed to provide an assessment of how TBI and PTSD affect the brain and what therapies have a greater impact on the improvement of cognitive brain function and brain health."

Missing Procurement Document Limited External Monitoring

Most of the standard forms, documents, and signatures required by HHSC for a sole source, proprietary contract were included in the BSI contract file. The Vendor Performance Tracking Report, which was required for all purchases over $25,000 by the Texas Comptroller of Public Accounts Texas Procurement and Support Services Division, was missing.[8] This report would have required HHSC to provide an evaluation of BSI's performance for each invoice submitted. This evaluation would then have been converted into a performance score. The Vendor Performance Tracking Report is particularly important for tracking performance of sole source, proprietary contracts, and would have allowed external parties to monitor BSI's performance scores. The HHSC contract manager for the BSI contract was not aware of this requirement.

Inexperience with Clinical Research Review Created Procurement Uncertainty

Because of the nature of the contracted clinical research study, BSI was required by contract to obtain an Institutional Review Board (IRB) approval.[9] The IRB approval process is intended to protect human subjects from physical or psychological harm that might otherwise occur by participating in scientific research. HHSC knew about obstacles to BSI obtaining

[7] "OVART" is also sometimes referred to as OVARD, which stands for Off-Vertical Axis Rotation Device

[8] Texas Health and Human Services Procurement Manual, § 5.3.4: Sole Source/Proprietary Purchases (June 2010).

[9] As stated by the United States Department of Health and Human Services Office of Human Research Protections, IRB approval is required in order to ensure and protect the rights, welfare, and wellbeing of human subjects involved in research. See also, Code of Federal Regulations, Title 45, Subtitle A, Subchapter A, § 46.101 (July 14, 2009).

IRB approval prior to award and immediately following award of the contract. HHSC attempted to find alternate ways to resolve this problem, but this issue was not rectified prior to contract award, and BSI was never able to obtain IRB approval.

BSI was a new business that had a chiropractic staff, but lacked experience with clinical research studies. Interviews and emails indicated that HHSC encouraged UTD and UTSW to partner with BSI in a veterans clinical research study. However, emails in November 2013 from UTD to HHSC stated that "the folks at Carrick…have no background in performing research studies." In response to a question from HHSC about the necessity of a clinical research organization (CRO),[10] UTD stated that "the reason for the CRO was to provide oversight…so they [CRO] could be a help in organizing them [BSI] and making sure that things are done right. This is especially true from a regulatory point of view too (HIPAA training, research compliance…) as they [BSI] may not be aware of these things."

Also in November 2013, HHSC indicated that it was unable to engage a CRO for the BSI contract because the CROs were concerned about meeting HIPAA compliance, IRB approval, and other research requirements. HIPAA[11] requirements are designed to protect confidential personal health information. Because HHSC did not typically award contracts for clinical research studies, and no federal funds were involved in the contract, HHSC was unclear whether an IRB approval would be required, and if so, whether BSI could apply for IRB review through UTD or DSHS. HHSC, after discussions about how to resolve the issue of IRB approval, ultimately included the requirement for an IRB approval in the signed contract.

October 2013 contract discussions proposed that HHSC contract with UTD, and BSI partner with UTD. Emails later indicated that UTD requested a contract separate from BSI, and in early January 2014, UTSW notified HHSC and BSI that it would not provide participant assessments for BSI. UTSW emphasized that based on BSI's failure to obtain an IRB approval, and BSI's lack of adequate study protocols, informed consent, and HIPAA compliance measures, UTSW would not be able to share data with BSI or engage in a business relationship with BSI. Beyond these discussions, there were no further interactions or contractual obligations between UTD or UTSW and BSI.

Weaknesses Existed in Initial BSI Contract Provisions

The contract with BSI lacked several key components, some of which were retroactively corrected in later amendments to the contract.

[10] A "clinical research organization," also called a contract research organization, is often hired on a contract basis to perform one or more of an organization's clinical-study or clinical-trial related duties and functions.

[11] "HIPAA" refers to the Health Insurance Portability and Accountability Act of 1996. HIPAA sets national standards for protecting individually identifiable health information, protects the confidentiality, integrity, and availability of electronic protected health information, and provides standards for enforcement.

The initial contract stated that there was "no clear inclusion or exclusion criteria," omitting essential details such as eligibility requirements for participants in the BSI study.[12] The contract did not define which veterans could participate in the study, allowing veterans with pre-existing conditions, which should have excluded them from participation, as well as out-of-state veterans, to receive services. A state-specific participation requirement was added five months later in the May 2014 amendment, specifying that participants be Texas veterans.

The initial contract omitted a fee schedule. A fee schedule was referenced in the initial contract, which specified that reimbursement would be on a cost basis, but was not actually included. The lack of a fee schedule was not corrected in the first amendment of the contract, but the second amendment retroactively eliminated the fee schedule and retroactively changed the contract to a fixed fee contract.

Some of the fundamental weaknesses of the BSI contract may have stemmed from the lack of Texas Health and Human Services (HHS) program staff assigned to initiate, draft, award, monitor, and manage the contract. Executive management does not generally solicit or award a clinical research study. However, executive management directly drafted, awarded, and managed the BSI contract. Typically a program area would initiate and award a contract for research. Then the program area associated with the expenditure would manage and monitor the contract. This lack of program staff expertise may account for some of the contract's missing components.

Procurement Risks

The BSI procurement process was poorly controlled and created risks that materialized as significant issues, including the risk of:

- Drafting a contract with critical elements missing.
- Awarding the contract to a contractor who is unable to demonstrate the experience, knowledge, and abilities to provide the required services and deliverables.

Subsequent to the BSI contract being awarded, HHSC made significant contracting reforms that address these and other risks. If subsequent contracts are procured in accordance with the revised HHS Procurement Manual[13] (Procurement Manual) and the revised HHS System Contract Management Handbook[14] (Contract Handbook), similar risks should be mitigated.

[12] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Exhibit D: Research Protocol (December 27, 2013).

[13] Texas HHS Procurement Manual (April 2015).

[14] Texas HHS System Contract Management Handbook (April 27, 2016).

In particular, improvements to the contract planning and drafting processes should mitigate poorly written contracts. Contracts must include all necessary detail to be effective. The revised Contract Handbook now requires all contracts (including sole source and proprietary contracts) to complete the "Procurement & Contracting Planning Questionnaire" as part of the planning and drafting process to clearly define needs and contract outcomes.

The revised Procurement Manual requires that the HHS program area take steps to enhance mutual understanding of the contract terms by parties to the contract by ensuring that all agreements between contractual parties are in writing and in the contract or contract files as appropriate; developing and including in contracts clearly defined sanctions, penalties, or administrative damages for noncompliance; and specifying in contracts the required deliverables, accounting, and reporting.

Recommendations 1.1 – 1.3

HHSC should:

1.1 Follow procurement statutes and rules, and HHSC policy, and fairly select the most qualified contractors.

1.2 Ensure that contractors are adequately vetted to have the skills and ability to perform the services required.

1.3 Solicit and engage only qualified providers and facilities to perform human subjects research and treatment.

HHSC Management Response

HHSC updated its procurement manual in April 2015 and updated its contracting procedures. The BSI contract would not be procured as a sole source under the updated policies and procedures.

Responsible Manager

Deputy Executive Commissioner for Procurement and Contracting Services

Target Implementation Date

Complete.

Issue 2: CONTRACTOR PERFORMANCE AND BILLING

The BSI contract was executed to study resources, treatments, and services that may assist veterans and their families in coping with the effects of two combat-related injuries: TBI and PTSD. BSI agreed to maintain the capacity to perform in accordance with the terms and conditions of the contract. The contract scope of work[15] required that BSI:

- Develop and submit a research protocol to HHSC for the treatment of TBI and PTSD in compliance with the "Research Protocol Guidance" in Exhibit D of the contract.
- Obtain the written approval of HHSC to conduct treatments described in the protocol.
- Ensure that services are reviewed and approved by an IRB that currently has a relationship with Carrick Brain Centers or an affiliate of Carrick Brain Centers.
- Obtain informed consent from all participants.
- Conduct or assist in conducting medical evaluations prior to treatment to avoid physical risk to participants.
- Provide applicable services to veterans seeking assistance in accordance with the protocol.
- Protect the integrity and confidentiality of protected health information and maintain veterans' privacy.
- Reasonably cooperate with a third party engaged by HHSC to conduct pre- and post-assessment of services using the Clinician-Administered PTSD Scale (CAPS).
- Design the data analysis process to ensure the integrity and reliability of pre-assessment, treatment, and post-assessment statistics and findings.
- Analyze outcomes and report findings to HHSC for potential dissemination and legislative reporting.
- Submit recommendations or information regarding potential policies that may impact or be affected by the services.

[15] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Article 4: Scope of Work, § 4.01 (December 27, 2013).

The final amendment to the contract added to the scope of work with the requirement that BSI provide services that would increase participants' job readiness and pre- and post-employment success.[16]

The recognized standard for diagnosing PTSD is a structured interview conducted by a skilled clinician using the CAPS assessment. CAPS was specified in the contract for participant assessment, and determined a categorical diagnosis as well as measured the severity of PTSD symptoms as defined by the DSM-IV.[17]

The research protocol listed in Exhibit D of the contract was titled, A First Pass Study on the Impact and Effectiveness of Dynamic Functional Neurological Therapy (DFNT) on Post-Traumatic Stress Disorder in Military Veterans who have Suffered Traumatic Brain Injuries.[18] This protocol defined the treatments and services that BSI was to perform. An individual who was certified as a Nurse Practitioner, a Doctor of Chiropractic, and a Fellow of the American College of Functional Neurology, was cited as the principal investigator[19] for the study. The protocol described the expected outcomes. Treatment was expected to:

- Improve CAPS scores
- Reduce symptoms associated with TBI and PTSD
- Improve ocular function
- Improve gait function
- Reduce vestibular and cognitive complaints

The IG Audit Division considered Exhibit D to be the HHSC approved treatment protocol based on its inclusion in the signed contact. Exhibit D specified that sixteen assessments and treatments would be provided to study participants, and that treatment outcomes would be measured by changes to CAPS scores.

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[16] HHSC Contract 529-14-0086-00001-B, Amendment Two to the Services Agreement between the Health and Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Article 2: Amendments to Scope of Work, § 2.01 (November 6, 2014).

[17] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (1994).

[18] Functional neurology is the rebranding of chiropractic neurology, a field pioneered by Canadian chiropractor Fred Carrick. Practitioners treat a multitude of conditions by using electroencephalography (EEG) to diagnose "weak" areas of the brain, and then treating these weak areas through a combination of diet, massage, and brain training.

[19] The "principal investigator" is generally the lead researcher for a grant project such as a laboratory study or a clinical trial. The title is also often used to refer to the research group leader. While the title is common in the sciences, it is also used broadly to refer to the person who makes final decisions and supervises funding and expenditures on a given research project.

Research Study Was Conducted Without Institutional Review Board Approval

The BSI clinical research study involved human participants and therefore required written approval and monitoring by an IRB. IRB approval was required by the BSI contract, is an international[20] and a federal requirement for human subjects research,[21] and was also required by DSHS,[22] which provided funding for the BSI contract. The goal of the IRB is to protect human subjects from physical or psychological harm by reviewing and approving research protocols and related materials. This is a fundamental ethical requirement for biomedical research involving human subjects, and must be in place prior to the initiation of a clinical research study.[23] The contract reinforced this requirement, stating that BSI and HHSC must "ensure that the services are reviewed and approved by an institutional review board that currently has a relationship with Carrick or an affiliate of Carrick."[24]

There is no evidence of IRB approval for the BSI study. Four separate IRB letters were contained in multiple summary reports of the work BSI performed; however, all four letters were non-compliant with the contract requirement, as described below.

One of the non-compliant IRB letters was dated December 31, 2013. This letter was from The National Institute for Brain and Rehabilitation Sciences-Israel located in Karmiel, Israel, and was addressed to the individual listed as the principal investigator in the BSI contract, but at the address of a pediatric group, not BSI. It could not be verified that the Israeli entity adheres to the United States Department of Health and Human Services Office of Human Research Protections[25] requirements. This IRB letter was clearly not considered adequate for the BSI clinical research study based on numerous emails during the contract that indicated that BSI still needed to obtain IRB approval.

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[20] "For studies in humans…the protocol must be approved by the local, institutional or equivalent ethics committee and/or national ethics committee." World Health Organization, A Practical Guide for Health Researchers, Section 5.2: Format for the protocol (2004).

[21] Code of Federal Regulations, Title 45, Subtitle A, Subchapter A, § 46.101 (July 14, 2009).

[22] DSHS, "Institutional Review Boards," Policy Number PA-4002. (July 21, 2011).

[23] "Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB." Code of Federal Regulations, Title 45, Part 46, Subpart A: Basic HHS Policy for Protection of Human Research Subjects, § 46.103(f).

[24] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Article 4: Scope of Work, § 4.01.9 (December 27, 2013).

[25] The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the United States Department of Health and Human Services (HHS). An institution must have a Federal wide Assurance (FWA) in order to receive HHS support for research involving human subjects. Each FWA must designate at least one IRB registered with OHRP. The FWA is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR Part 46, Subpart E. IRBs must be registered with OHRP before the IRB may be designated on an FWA as reviewing proposed research for the FWA-holding institution.

Emails indicated that UTSW refused to provide CAPS assessments in January 2014 in part because of BSI's failure to obtain an IRB approval. An email from the HHSC contract manager to the HHSC Executive Commissioner and the Governor's Office in March 2014 indicated that the Meadows Mental Health Policy Institute and BSI would "need to contract with a private IRB," and also asked for "additional thoughts how Meadows can best position Carrick [BSI] before the funding announcement is published." A BSI email dated June 6, 2014, references this Israeli IRB letter stating that this "goes back to the…IRB issue…but I have no earthly idea at this moment on how to handle that without someone getting thrown under the bus, or at least making someone look like an idiot in front of HHSC."

Another non-compliant IRB letter was written by the Carrick Institute for Graduate Studies, in Cape Canaveral, Florida. This letter did not contain any dates to identify when it was written or intended to be effective. This letter did contain an Office for Human Research Protections Federal-wide Assurance number and an IRB number registered to Carrick Brain Centers; however, it referred to a study titled, "Effectiveness of Carrick Brain Centers Strategies, Vestibular Rehabilitation Treatment in PTSD Patients who have suffered Combat Related Brain Injuries." The title did not correspond to the BSI clinical research study, which was titled "A First Pass Study on the Impact and Effectiveness of Dynamic Functional Neurological Therapy (DFNT) on Post-Traumatic Stress Disorder in Military Veterans who have Suffered Traumatic Brain Injuries."

The two other letters were from a company called Ethical and Independent Review Services.[26] These letters suggested that BSI would be exempt from the need for IRB approval based on the study title: "Retrospective Chart Review Study of Patients who Have Completed Treatment for PTSD Symptoms." A chart review is not considered a human study and therefore would be exempt from IRB review. The Ethical and Independent Review Services letters clearly stated that this was not approval of a clinical research study. The letters were dated April 22, 2014 and May 22, 2014, four and five months after the study began. These two letters were not related to the contracted research protocol approved by HHSC, and there were no contract amendments changing the clinical research study to a chart review.

Veterans Who Should Have Been Excluded from Participation Were Treated and Services Were Not Provided in Accordance with Protocol

BSI failed to provide sufficient evidence that the established clinical research study protocol was administered as required by the contract. The IG Audit Division examined 134 unique participant medical files. The participant medical files did not include documentation indicating methodical and consistent BSI treatment administration. Table 2.1 shows the number of participants with evidence of receiving protocol-specific assessments and treatments. The data shows high percentages of initial assessment, but low percentages of

[26] Ethical and Independent Review Services is a midsize company providing independent institutional review board services.

treatment and follow-up assessment. The OVART therapy, which was the primary rationale for a sole source, proprietary contract, was provided to 70 percent of the participants.

Table 2.1: Summary of BSI Study Protocol Services Provided to Participants

	Clinical Research Study Protocol	# of Unique Participants with Evidence of Completion (out of 134 total)	% of Completion
	Pre-Treatment Assessment		
1	Intake Summary and Physical Exam	129	96%
2	CAPS Pre-Test	131	98%
3	Laboratory Assessment	124	93%
4	Ocular Evaluation and VNG	130	97%
5	Postural Studies (D2 and Gait)	126	94%
6	Dietary and Metabolic Evaluation	89	66%
	Treatment		
7	OVART	94	70%
8	Ocular Exercises	115	86%
9	Repetitive Peripheral Somatosensory Stimulation	88	66%
10	Dynavision Therapy	62	46%
11	Vestibular Rehabilitation	87	65%
12	Dietary and Metabolic Management	76	57%
	Post-Treatment Assessment		
13	CAPS Post-Test	129	96%
14	3 Month Follow-Up	47	35%
15	6 Month Follow-Up	36	27%
16	1 year Follow-Up	5	4%

Source: IG Audit Division Review of Participant Medical Files

BSI explained that OVART could not be utilized on individuals with certain health conditions such as hypertension or stroke. These veterans should not have become participants in the study. Only veterans that meet specific inclusion and exclusion criteria should be permitted to participate in a clinical research study in order to apply a standardized protocol to all participants and ensure reliability and validity.[27]

[27] "Reliability" indicates that a specific treatment or protocol will provide the same or similar results consistently across multiple clinical research studies. "Validity" indicates that the clinical research study contains adequate controls and measures what it was designed to evaluate.

The contract stated that there was "no clear inclusion or exclusion criteria."[28] Valid clinical research studies clearly define which populations can be included in a study, and which medical conditions, previous treatments, and other factors will exclude them from a study.[29] In addition, the research protocol guidance included in the contract stated that "the scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology…[and] should include information on…who can take part (e.g., inclusion and exclusion criteria…)."[30]

In the May 2014 final comprehensive report,[31] BSI excluded the data of 14 of 50 participants in its analysis. Twelve of the 14 were excluded because the participants did not have a PTSD diagnosis at the start of the study based on the CAPS assessment. Data from another two participants was excluded from the report analysis because the participants failed to meet other CAPS criteria. Inclusion and exclusion criteria are intended to define those who can and cannot participate in a study, not which data can be analyzed. These 14 participants should not have been treated as they should have been excluded from participating in the study. The research protocol stated that a change to the CAPS scores was to be the primary outcome measure of the study, but this change could not be assessed for any participant without a CAPS score that indicated a PTSD diagnosis prior to treatment, or who failed other CAPS criteria.

In the subsequent June and July versions of the final comprehensive report, BSI reported that it treated "all patients with a history of combat military service," but did not specify that participants have a TBI or PTSD diagnosis, and only excluded the outcome data of those who were "currently abusing alcohol or illicit drugs during the clinical treatment period." The September 2014 and January 2015 final comprehensive reports were the only reports to include some appropriate clinical research study inclusion and exclusion criteria. However, though the exclusion criteria was more robust, these reports did not exclude participants who

[28] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Exhibit D: Research Protocol (December 27, 2013).

[29] "All clinical trials have guidelines, called eligibility criteria, about who can participate. The criteria are based on such factors as age, sex, type and stage of disease, previous treatment history, and other medical conditions. This helps to reduce the variation within the study and to ensure that the researchers will be able to answer the questions they plan to study. Therefore, not everyone who applies for a clinical trial will be accepted." United States Food and Drug Administration, "Clinical Research Versus Medical Treatment" (February, 24, 2016). http://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/ucm20041761.htm

[30] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Exhibit D: Research Protocol Guidance (December 27, 2013).

[31] Final Report for Phase 1 of Service Contract 529-14-0086-00001 between the Health and Human Services Commission and Carrick Brain Centers (May 30, 2014).

had pre-existing conditions that would prevent them from safely being treated with the proprietary OVART and the full BSI research protocol.

The principal investigator explained that he employed his preferred standard treatment protocol rather than the one specified in the contract. As a result, each participant received individualized treatment without sufficient documentation to explain the variation. Providing individualized treatments is not consistent with the scientific rigor required in clinical research. Adherence to the study protocol[32] and a consistent application of assessments and treatments is crucial to producing valid research results.

The principal investigator also indicated, during interviews with the IG Audit Division, that he never read the contract, was not the principal investigator for the study, and was not accountable to the protocol. The IG Audit Division noted that this individual was specifically identified by the contract, and listed as the principal investigator in multiple other BSI documents including the "Consent for Treatment" forms.

BSI Did Not Provide Proprietary Services as Contracted

BSI did not provide all services to all participants in the clinical research study. For example, the OVART treatment, the primary rationale for the issuance of a sole source, proprietary contract, was only provided to 70 percent of participants. BSI explained that the 40 veterans who did not receive OVART were unable to complete the treatment because of pre-existing conditions.

BSI failed to appropriately screen out participants from the study who would not be able to receive the proprietary OVART treatment. BSI was paid $651,744.88 for these 40 participants who should have been excluded from the research study as they could not receive the complete treatment protocol as defined by this contract.

Additional Services Were Not Provided in Accordance with the Second Contract Amendment

In addition to the services required by the initial contract, HHSC added services to the contract in the final amendment. BSI was expected to improve "job readiness and pre- and post-employment success by increasing veterans' ability to solve problems, work cooperatively with others, focus and accomplish assignments, manage anger and stress, and set goals (the 'Desired Results')." The contract gave BSI the option to consult with the Texas Workforce Commission, collaborate with Workforce Solutions Dallas, and use the resources of the Texas Veterans Leadership Program at BSI's discretion in order to obtain the Desired Results outlined in the contract amendment. In addition, BSI was expected to "provide reasonable

[32] World Health Organization, A Practical Guide for Health Researchers, Section 7.2: Scientific Rigor (2004).

opportunity for veterans participating in the program to access additional resources and referral services available through the Texas Veterans Leadership Program and local workforce development boards."[33]

Funding for this final amendment was drawn from an interagency contract with the Texas Workforce Commission. The IG Audit Division interviews with Texas Workforce Commission staff indicated that the contract provided funding for the BSI study. BSI provided a list of individuals who had completed the study as of October and November 2014 to the Texas Workforce Commission's Veterans Leadership Program in Dallas. There was no evidence that job readiness and employment success services were provided to participants by BSI or the Veterans Leadership Program. As stipulated in the contract, BSI provided periodic status reports to HHSC which were forwarded to the Texas Workforce Commission and contained the number of individuals treated in the study and basic demographic information.

The Study Was Not Valid and Did Not Produce Valid Outcome Data

The work performed by BSI did not reflect a valid clinical research study. BSI's research protocol was missing many critical elements, and the assessments and treatments administered and the reports and supporting documentation delivered throughout the contract did not add up to a reliable and valid clinical research study.

The BSI research protocol included in the contract stated that the study design was "to be determined based upon all the conclusions of the investigators." A clinical research study must have a valid study design as part of the methodology in order to be approved by an IRB and produce valid research results.[34] BSI's study design lacked a control group to compare and evaluate treated and non-treated participants in order to determine efficacy. A research study that is designed with only a pre- and post-test design, and without a control group, must still have sufficient controls in place to obtain valid results.

The research protocol stated that "we will stratify subjects and then within groups we will randomize" and that "stratified randomization will prevent confounding and is important in a small group such as represented by our sample." There was no evidence of randomization and no discussion of randomization in the final comprehensive report. BSI failed to meet the contractual requirement for data analysis that would ensure the integrity and reliability of treatment statistics and findings.

[33] HHSC Contract 529-14-0086-00001-B, Amendment Two to the Services Agreement between the Health and Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Article 2: Amendments to Scope of Work, § 2.01 (November 6, 2014).

[34] "The methodology section has to be thought out carefully and written in full detail. It is the most important part of the protocol." World Health Organization, A Practical Guide for Health Researchers, Section 5.2: Format for the protocol (2004).

Many individuals in the later cohorts also received treatments that were not listed as part of the research protocol including testosterone, human growth hormone, and specially blended BSI intravenous supplements. Providing treatments not specifically identified in the study design is not consistent with a clinical research study that requires consistent application of assessments and treatments in order to produce valid research results.

In addition to a lack of a valid study design and inconsistent application of the study protocol, other variables were not controlled. For example, the study was conducted in groups of eight to ten individuals. The participants received approximately twelve days of hotel lodging, [35] meals, and group exercise activities with local sports celebrities. The provision of meals, accommodations, group treatment, and camaraderie with other veterans could contribute to a generalized sense of improved well-being and affect study results. Group treatments are expected to provide benefits like social connection and a safe environment for participants to build trust that go beyond individual treatment. Participants tend to positively influence one another, which can lead to a correlation of outcomes and cause results of treatment to be overstated.[36] In designing and analyzing a clinical research study, factors like group accommodations and group treatment must be controlled or adjusted through statistical analysis to avoid overstatement of treatment results. In an analysis of 33 treatments provided in groups, less than half of the studies had statistically significant results after adjusting for group effects.[37] The IG Audit Division could find no evidence that group effects were anticipated or controlled in the BSI study, nor that the data was statistically adjusted to account for group effects. Without proper controls and statistical analysis, it is unclear what combination of treatments or other factors were driving any improvements to TBI or PTSD symptoms in participants in the BSI study.

In September 2014, the Dallas-based Meadows Mental Health Policy Institute[38] issued a report evaluating BSI's July 2014 final comprehensive report. The Meadows Mental Health Policy Institute oversaw the participant assessments under BSI's initial contract, and was listed as a sponsor of the BSI study for all final comprehensive reports issued after the May 2014 report. Their analysis concluded that although the results of the BSI treatments were promising for those resistant to more established approaches like cognitive processing therapy or prolonged exposure therapy, the results could not be established without further evaluation. The report

[35] The treatment was administered from Monday through Friday. Veterans stayed in the hotel for twelve days with a weekend between the two weeks of treatment.

[36] Sloan, D. M., Bovin, M. J., & Schnurr, P. P. (2012). "Review of group treatment for PTSD." Journal of Rehabilitation Research and Development, 49(5), 689-701.

[37] Baldwin, Scott A.; Murray, David M.; Shadish, William R. (Oct 2005). "Empirically supported treatments or type I errors? Problems with the analysis of data from group-administered treatments." Journal of Consulting and Clinical Psychology, Vol 73(5), 924-935.

[38] "Analysis of Summary Report by Carrick Brain Centers of an Intensive Treatment Program for Military Veterans with Post-Traumatic Stress Disorder."

recommended modifications to the study design and analysis such as controlling for TBI, identifying previous PTSD treatment, and adjusting the timing of the post-assessments. In addition the report stated that efficacy of BSI treatment could not be determined without implementation of a control group. The report concluded that the outcomes were "only one half to one third the magnitude of established treatment and the costs were many times higher." The BSI study costs were 15 times higher than established evidence-based treatment approaches.

BSI failed to provide the most fundamental requirement of its contract with HHSC, a valid clinical research study. Failure to provide consistent services in accordance with clinical study protocol, and failure to provide sufficient controls, led to a study that did not produce valid results. Consequently, the efficacy of BSI treatments in reducing symptoms of PTSD and TBI could not be established.

Final Report Deliverables Did Not Meet Contract Requirements

The BSI contract required that BSI submit periodic status reports to HHSC on the demographics and number of participants.[39] Emails indicated that the HHSC contract manager requested and received the biweekly reports on a timely basis.

The initial contract also necessitated a final comprehensive report on May 30, 2014 in a mutually agreed upon format. The HHSC contract manager provided a report template to BSI on March 24, 2014. BSI provided a final report on May 30, 2014 titled "Final Report for Phase 1 of Service Contract 529-14-0086-00001 between the Health and Human Services Commission and Carrick Brain Centers."

The HHSC contract manager wrote in an email to BSI on June 5, 2014, "upon review of the 'Final Report,' submitted on 5.30.2014, the study is described as a 'medical record review' and that an exception to IRB approval was obtained. The scope of work described in the contract includes among other items, to perform the treatments, therapies, and activities, relating to the protocol titled 'A First Pass Study on the Impact and Effectiveness of Dynamic Functional Neurological Therapy (DFNT) On Post-Traumatic Stress Disorder in Military Veterans who have Suffered Traumatic Brain Injuries.' I am troubled that the final report changes the protocol to a 'retrospective chart review' and the study design is '50 medical charts.' This is not the protocol nor the agreement." As stated by the HHSC contract manager, this final BSI clinical report was not in agreement with the contracted protocol or the contractual reporting requirements.

[39] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Article 4: Scope of Work, § 4.01 (December 27, 2013).

On June 6, 2014, an internal BSI email was included in an email thread to HHSC and stated that as for the HHSC contract manager's "concerns about the study protocol being changed to a retrospective design, that's going to have to be addressed in some way. This goes back to the…IRB issue…but I have no earthly idea at this moment on how to handle that." BSI sent a revised report dated June 11, 2014, and titled "A Case Series of The Treatment of PTSD Using Vestibular and Functional Neurologic Therapies." The updated report utilized different parameters for the data analysis and organized the information in a different format than the May report. It also included the May 2014 IRB letter from Ethical and Independent Review Services that suggested that BSI was exempt from IRB approval requirements. The IRB letter explained that the exemption was being provided based on the BSI research study being limited to a chart review.[40]

Another report was uploaded into the HHSC contract management system dated July 25, 2014. It was titled "A Summary Report of an Intensive Treatment Program for 50 Military Veterans with PTSD Using Vestibular Rehabilitation and Functional Neurology Therapies." The report addressed the same time period and research participants as the June report, but added substantially more information to the introduction, more graphics, and more comprehensive statistical analysis and reporting. The July report omitted the methodology information from the synopsis. In the June report, this section had stated that a "retrospective chart review" was utilized. However, the same conclusion about the change to CAPS scores was used as in the previous report. A December 2013 IRB approval letter from Israel was provided, along with the same May 2014 letter that was included in the June report.

The HHSC contract manager expressed valid concerns in the June 5, 2014, email to BSI. BSI had not conducted the work to support the completion of the report template. However, the contract continued, and payments for two additional cohorts of participants were made through two contract amendments.

The two amendments also required periodic status reports and a final comprehensive report for each new group of veterans. All reports were submitted by BSI on a timely basis and the final comprehensive reports used the same format as the July 25, 2014, report. The reports were titled "A Summary Report of an Intensive Treatment Program for 50 Military Veterans with PTSD Using Vestibular Rehabilitation and Functional Neurology Therapies: Second Patient Cohort" dated September 15, 2014, and "A Summary Report of an Intensive Treatment Program for 40 Military Veterans with PTSD Using Vestibular Rehabilitation and Functional Neurology Therapies: Third Patient Cohort" dated January 6, 2015.

[40] BSI report: "A Case Series of The Treatment of PTSD Using Vestibular and Functional Neurologic Therapies." Protocol Amendments, § 8.8.1 (June 11, 2014).

BSI Failed to Bill for Services Based on an Established Fee Schedule

The initial December 2013 contract specified that BSI would bill for services based on the cost for each evaluation, procedure, service, report, or other item as described and set forth on the standard fee schedule. The charges were to be based on cost, and were not-to-exceed $16,250 per veteran participant. The contract also specified that BSI would bill based on an established fee schedule. However, there was no approved fee schedule included in the contract documentation. An HHSC email dated December 20, 2013, included a fee schedule with a breakdown of costs, as shown in Table 2.2. These costs totaled $15,750 for all costs associated with a single participant.

Table 2.2: Fee Schedule for BSI Contract

Treatment	Cost	Multiplied by # of Days (as appropriate)	Total Cost
Initial evaluation	$ 750.00		$ 750.00
Each day of care	$ 1,000.00	10	$ 10,000.00
CAPS	$ 500.00		$ 500.00
Labs	$ 2,000.00		$ 2,000.00
Travel and Lodging	$ 2,000.00		$ 2,000.00
Miscellaneous	$ 500.00		$ 500.00
Total			$ 15,750.00

Source: Fee Schedule from HHSC Email Correspondence

The first contract amendment in May 2014 also stated that the charges were to be billed on a cost basis, but reduced the not-to-exceed amount from $16,250 to $16,000. The final November 2014 amendment to the BSI contract expressly eliminated the fee schedule as a basis for allocating cost. Instead the amendment retroactively established a fixed fee of $16,250 per participant for the first 50 individuals treated, and $16,000 per participant after the first 50 participants.

The final amendment also added an additional fee for the performance of the CAPS assessments. In the initial contract, CAPS charges were listed as part of the fee schedule. Lifeworks Counseling Center performed the CAPS assessments for BSI throughout the contract. Per interviews with BSI, the Meadows Mental Health Policy Institute paid for CAPS assessments under the initial contract. HHSC was not invoiced for CAPS until after the May 2014 amendment. After the May amendment, BSI invoiced HHSC an additional CAPS fee for each participant based on the amount of time that each CAPS interview required. Table

2.3 shows a breakdown of amounts paid by HHSC for the BSI contract. In total, BSI treated 137 veterans[41] under this contract, and HHSC paid BSI $2,232,311.47 for these services.

Table 2.3: Total Payments to BSI and Number of Participants by Contract and Amendment

BSI Contract	HHSC Paid to BSI	# of Participants	Contract Billing Terms per Participant
Initial Contract	$ 812,500.00	50	At Cost Not-to-Exceed $16,250
Amendment 1	$ 795,366.97	49	At Cost Not-to-Exceed $16,000
Amendment 2	$ 624,444.50	38	Fixed Fee: $16,250 for 1st 50 Fixed Fee: $16,000 after 1st 50 Plus CAPS fees at cost
Total	$ 2,232,311.47	137	

Source: IG Audit Division Analysis of BSI Invoices

The billing of services provided by BSI did not adhere to an established fee schedule and introduced the risks of overpayments and misappropriation of funds to the BSI contract.

BSI Billed for Services Not Provided

One issue was that BSI did not provide all services to all participants but billed for the full not-to-exceed amounts for all. Some participants traveled to receive treatment, and some did not have to travel. Regardless of each individual's travel distance to BSI, all participants resided at a nearby hotel during the treatment. Each participant received different services, and no participants received 100 percent of the assessments and treatments. The contract stated that "the price of treatment will vary slightly for each individual."[42] However BSI billed and was paid the maximum amount for every single study participant.

Non-Texas Veterans Were Treated by BSI and Billed to HHSC

Of the first 50 veterans who participated in the study, 33 were from states outside of Texas. The initial contract failed to specify that the participants be Texas residents, and this initial group of out-of-state participants cost Texas taxpayers $533,931.99 from state general revenue funds.

[41] Includes three duplicate participants.

[42] HHSC Contract 529-14-0086-00001, Services Agreement between the Health And Human Services Commission and Brain Synergy Institute, LLC, doing business as Carrick Brain Centers, Exhibit D: Research Protocol (December 27, 2013).

The May 2014 amendment to the contract clarified that the participants in the BSI study were to be Texas veterans. Even after the contract amendment, BSI treated another 14 veterans[43] from outside of Texas. These additional charges to treat out-of-state veterans are shown in Table 2.4, and include the additional charges for CAPS assessment that were added with the final contract amendment. These additional costs to the state for treating non-Texas veterans totaled $229,217 and were inappropriately billed by BSI and paid by HHSC.

Table 2.4: Charges for 14 Non-Texas Veterans Treated After the May 2014 Contract Amendment which Limited Participation to Texas Veterans

Participant ID	Date of Participation	Participant Home State	Amount HHSC Paid for Non-Texas Participants
1263	8/11/2014	LA	$ 16,412.50
1720	7/18/2014	MI	$ 16,388.50
1724	7/14/2014	NC	$ 16,399.00
1825	8/27/2014	AZ	$ 16,387.00
1957	9/22/2014	WA	$ 16,450.00
1986	11/3/2014	IL	$ 16,363.00
1987	11/8/2014	MD	$ 16,388.50
1989	6/15/2014	FL	$ 16,400.50
1991	11/3/2014	OH	$ 16,388.50
1992	11/3/2014	VA	$ 16,388.50
2037	11/10/2014	NC	$ 16,000.00
2055	12/12/2014	VA	$ 16,501.00
2058	11/9/2014	VA	$ 16,262.50
2187	12/19/2014	MO	$ 16,487.50
Total			$ 229,217.00

Source: IG Audit Division Analysis of BSI Invoices

In total, $763,148.99 of the $2.23 million of Texas taxpayer funds that HHSC paid to BSI under this contract was for treatment of non-Texas veterans.

BSI failed to limit study participation to Texas veterans. During IG Audit Division interviews with BSI staff, none of the staff claimed accountability for administering the contract or for recruiting participants for the study. The BSI staff also could not identify the individual responsible for ensuring that the veterans allowed into the study were from Texas. In

[43] Participant number 1439 was also a non-Texas veteran, however, the costs for this participant's treatment were not included in Table 2.4, but are addressed in the section of this report titled: "Three Participants Were Treated Multiple Times and Duplicate Billed to HHSC" in Table 2.5.

contrast, based on a March 2014 UTD status report, all participants in the UTD study were residing in Texas.

As a result BSI was overpaid $229,217 by HHSC for 14 non-Texas veterans who participated in the study after the May 24 contract amendment clarified that only Texas veterans should be participants. HHSC should recover $229,217 from BSI.

Three Participants Were Treated Multiple Times and Billed to HHSC

Three participants completed the BSI study during two separate cohorts several months apart. Table 2.5 shows the participant billing detail for these duplicate participants. A valid clinical research study would exclude any individual from participating in the study more than once, because an individual receiving treatment multiple times would skew the outcome data and invalidate the study results. As a result, BSI was overpaid $49,224.

Table 2.5: Study Participants Treated Multiple Times and Billed to HHSC

Participant ID	BSI Billed for Cohort 1	BSI Billed for Cohort 2	BSI Billed for CAPS	BSI Billed to HHSC	Amount Paid for Duplicates
1400	$15,815.04	$16,000.00	$525.00	$32,340.04	$16,525.00
1439	$16,084.54	$16,000.00	$436.50	$32,521.04	$16,436.50
1452	$16,125.04	$16,000.00	$262.50	$32,387.54	$16,262.50
Total					$49,224.00

Source: IG Audit Division Analysis of BSI Invoices

The IG Audit Division also examined study participant information to determine whether there was funding and treatment duplication between the BSI and UTD studies. Two individuals participated in both studies out of 134 BSI and 56 UTD participants. One of these individuals started but did not complete the UTD study, and approximately five months later began the BSI study. The other completed both studies roughly a year apart. The duplication between the BSI and UTD studies was minimal, but the duplication of participants within the BSI study was a problem that further undermined the BSI data and wasted taxpayer funds.

BSI failed to limit participants to a single round of treatment in the study.

Contractor Performance and Billing Risks

Contractor performance under the BSI contract was inadequate and created risks that materialized as significant issues, including the risk of a contractor:

- Not providing contracted services
- Not complying with contracted requirements
- Not providing contracted deliverables

Additional risks that materialized as issues were the risk of paying a contractor for:

- Research that was not conducted according to the contract
- Services that were not performed
- Treating participants that should be excluded from participation
- Treating the same participants more than once

Subsequent to the BSI contract being awarded, HHSC made significant contracting reforms that address these and other risks. If contracts are monitored in accordance with the revised Contract Handbook, similar risks should be mitigated.

Recommendations 2.1 – 2.2

HHSC should seek recovery of overpayments to BSI, consisting of:

2.1 $229,217.00 for 14 non-Texas veterans participating in the study after the contract amendment that excluded non-Texas veteran participation was executed.

2.2 $49,224.00 for three participants who received treatment more than once.

HHSC Management Response

Procurement and Contracting Services will coordinate with the Chief Counsel's Office to send any appropriate demand letters to BSI and involve the Attorney General's Office, as needed.

Responsible Manager

Deputy Executive Commissioner for Procurement and Contracting Services

Target Implementation Date

June 2017

Issue 3: CONTRACT MONITORING

Contract monitoring is the systematic review of a contractor's records, business processes, deliverables, and activities, performed to ensure compliance with the terms and conditions of the contract. Monitoring should include planned, ongoing, periodic, or unscheduled activities to protect the health and safety of clients that receive services, to ensure delivery of quality services, and to protect the financial interest of the State.

Contract monitoring responsibilities include:

- Developing a contract monitoring plan.
- Examining the quality of required tasks and deliverables.
- Tracking the timeliness of contract deliverables and other contract requirements.
- Identifying, requiring corrective action, and tracking the resolution of contractor performance issues that may hinder the timely completion of contract requirements at the expected level of quality.
- Reviewing invoices for accuracy and validating that billed services have been provided before approving invoices for payment.
- Reporting on the progress of contractor performance to the appropriate levels of management.
- Escalating critical issues to the appropriate levels of management when timeliness and quality expectations are not met.

HHSC did not effectively monitor BSI performance. HHSC did not effectively review BSI invoices, validate that performance related to the invoices had been adequately performed, or verify that adequate deliverables had been timely submitted, before approving invoices for payment. In addition, HHSC did not prepare a contract monitoring plan as required by HHS contracting policy. Effective contract monitoring by HHSC would have identified and addressed many of the performance issues detailed in Section 2 of this report, and effective financial monitoring of BSI invoices would have addressed the billing issues also detailed in Section 2.

Contract Monitoring Risks

Monitoring of the BSI contract was inadequate and allowed inherent contracting risks to materialize as significant issues, including the risk of failure to:

- Ensure delivery of quality services
- Protect the financial interest of the agencies funding the project
- Document, report, and escalate issues to the appropriate levels of management

Subsequent to the BSI contract being awarded, HHSC made significant contracting reforms that address these and other risks. If subsequent contracts are monitored in accordance with the revised Contract Handbook, similar risks should be mitigated.

Recommendation 3

HHSC should follow the Contract Handbook and identify and track risks related to contract delivery by establishing a monitoring plan to verify and document contractor compliance with contract terms and conditions.

HHSC Management Response

HHSC updated its contract handbook in April 2016. The handbook addresses these issues.

Responsible Manager
Deputy Executive Commissioner for Procurement and Contracting Services

Target Implementation Date
Complete.

CONCLUSION

The IG Audit Division completed an audit of HHSC service procurement through the BSI contract. The audit included an evaluation of contract procurement practices, service delivery, and utilization of taxpayer funds. The IG Audit Division conducted site visits in February 2016.

HHSC and BSI shared accountability for ensuring that state dollars were used effectively to research and deliver cost-effective treatments to eligible Texas veterans. Ethical and standardized contract and service procurement processes are essential to ensure that:

- Qualified contractors are selected to provide services.
- State funds spent on programs are used appropriately.
- State funds are protected from fraud, waste, and abuse.
- Funds lost to fraud, waste, and abuse are recovered and reported to HHSC.

Based on the results of its audit, the IG Audit Division determined that (a) contract procurement led to a contract that was missing critical elements, (b) BSI was not properly vetted and monitored to ensure that it complied with the contract, and (c) funds were not expended for their intended purpose. While there was no evidence of fraud related to the BSI contract, the IG Audit Division concluded that:

- The BSI contract for a clinical research study was inadequately drafted and included a poorly designed research protocol.
- HHSC used contract amendments to correct contractual oversights and omissions.
- HHSC used contract amendments to retroactively change the cost-based payment structure to a fixed-fee structure, allowing BSI to bill all participants at the same maximum rate, even though not all services were provided to all participants.
- BSI did not provide all participants with the proprietary services that were the basis for the sole source procurement.
- The services that BSI provided did not constitute a clinical research study as required by the contract.
- The study was not valid, and therefore it is unknown whether and to what degree the BSI services resulted in improvements to the health and quality of life of the veterans who participated.
- BSI put the health and safety of participants at risk by performing a clinical research study on human subjects without IRB approval.
- BSI provided final completion reports to HHSC that did not meet the requirements of the contract.

- BSI billed for treatment of veterans who should have been excluded based on pre-existing conditions.
- BSI billed for treatment of non-Texas veterans and duplicate participants.
- Taxpayer funds were lost to waste and abuse under the BSI contract.

The IG Audit Division offered recommendations to HHSC which, if implemented, will:

- Ensure contract procurement practices are followed.
- Ensure that contracts are only awarded, monitored, and managed by program areas with applicable knowledge of federal and state rules and requirements.
- Identify sensitive contracts that would contain research or clinical studies and ensure a program area is prepared to understand and enforce the rules and requirements for the study type and monitor the treatment of participants.
- Award contracts to qualified providers that have been adequately vetted to perform the services required.
- Protect the health and safety of individuals who participate in scientific studies that involve research on human subjects.
- Provide contract managers with training for monitoring and managing contracts.
- Strengthen controls over the review and approval of invoices for payment.
- Ensure contract monitoring practices are (a) adequate, (b) risk-based to ensure that services are provided as intended, and (c) contain processes that allow for immediate escalation of issues that are considered abuse of the contract terms.

HHSC should solicit recovery of the $278,441 paid to BSI for failing to follow the requirements of the contract as amended and for treating the same participants multiple times.

HHSC has implemented changes to contracting and procurement practices in the Procurement Manual dated April 2015, and in the Contract Handbook dated April 2016. The new manual and handbook include control procedures to address the contract drafting, procurement, and monitoring weaknesses identified in this report. HHSC should also focus on procurement practices that successfully guard against losses due to fraud, waste, and abuse.

The IG Audit Division thanks management and staff at BSI, UTD, UTSW, DSHS, the Texas Workforce Commission, and HHSC Procurement and Contracting Services, as well as the Deputy Executive Commissioner of Health Policy and Clinical Services for their cooperation and assistance during this audit.

Appendix A: OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objectives of the audit were to determine whether:

- Procurement of services through the contract with BSI adhered to state law and agency policies, rules, and regulations.
- BSI performed and complied with requirements of the contract.
- Funds were used for their intended purpose.

Scope

The scope of the contracting and procurement audit of BSI included the period from August 2013 through January 2016, as well as review of relevant activities through the end of fieldwork in March 2016. The IG Audit Division focused on procurement, performance, and the contracting lifecycle for the $2.3 million contract between HHSC and BSI, which included two contract amendments.

During audit planning, the IG Audit Division became aware of several contracts in addition to the BSI contract that related to veterans health studies of TBI and PTSD. These additional contracts were included in the audit scope to determine any interactions with BSI. The Meadows Mental Health Policy Institute oversaw CAPS assessments for the first cohort of the BSI study and was listed as a sponsor of the BSI study for all final comprehensive reports after the May 2014 report, and Lifeworks Counseling Center conducted the CAPS assessments throughout the entire BSI study, but there were no contracts for either entity for IG Audit Division review. Audit fieldwork was limited to expenditures, contracting activities, and interactions with BSI for these additional contracts:

- The interagency cooperative contract between HHSC and DSHS ($1.85 million).
- The interagency cooperative contract between HHSC and UTD ($625,000).
- The interagency cooperative contract between HHSC and UTSW ($412,500).
- The interagency cooperative contract between HHSC and the Texas Workforce Commission ($690,000).

Methodology

To accomplish its objectives, the IG Audit Division collected information for this audit through discussions and interviews with responsible staff at BSI, HHSC, UTD, UTSW, and the Texas Workforce Commission, and by:

- Reviewing policies and contracting practices in effect during the procurement of the BSI contract.

- Examining existing documentation and deliverables contained in the HHS Contract Administration and Tracking System for each contract.
- Interviewing key staff at BSI, HHSC, UTD, UTSW, and the Texas Workforce Commission.
- Reviewing emails obtained from HHSC from August 2013 through January 2016.
- Evaluating documentation contained in participant files to verify that services provided met contractual requirements and associated deliverables.
- Reviewing contract deliverables and reporting of outcomes.
- Reviewing contractor invoices, supporting documentation, and participant records.
- Analyzing contract costs, invoices, and payments.

The IG Audit Division issued an engagement letter on February 4, 2016, to BSI providing information about the upcoming audit, and conducted fieldwork at BSI's facility in Irving, Texas from February 10, 2016, through February 12, 2016. While on-site, the IG Audit Division interviewed responsible personnel, evaluated policies and practices relevant to the BSI contract, and reviewed relevant documents related to billing and contract requirements.

The IG Audit Division also conducted fieldwork at UTD and UTSW in Dallas, Texas from February 8, 2016, through February 9, 2016. The IG Audit Division performed limited audit work for the UTD and UTSW contracts to determine their relationships to BSI, and to verify veteran participation, treatment protocols, invoices, and payments.

The IG Audit Division tested 134 unique participant medical records, and reviewed all invoices and supporting documentation submitted by BSI to HHSC to develop a complete representation of expenditures and services provided for veterans under the BSI contract.

The IG Audit Division analyzed information and documentation it collected to determine whether (a) BSI performed and complied with requirements of the contract, (b) interactions with other related contracts were appropriate, and (c) funds were expended for the intended purpose. Professional judgment was exercised in planning, executing, and reporting the results of this audit.

The IG Audit Division conducted the audit in accordance with generally accepted government auditing standards issued by the Comptroller General of the United States. Those standards require that auditors plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the issues and conclusions based on audit objectives. The IG Audit Division believes that the evidence obtained provides a reasonable basis for the issues and conclusions based on audit objectives.

The IG Audit Division used the following criteria to evaluate the information provided:

- HHSC Contract 529-14-0086-00001, including Amendments One and Two to the Services Agreement between HHSC and BSI.
- HHSC Contract 529-14-0083-00001, Interagency Cooperation Agreement between HHSC and UTSW.
- HHSC Contract 529-14-0084-00001, Interagency Cooperation Agreement between HHSC and UTD.
- HHSC Contract 529-14-0146-00001, Interagency Cooperation Agreement between HHSC and DSHS.
- HHSC Contract 529-14-0148-00001, including Amendment One to the Interagency Cooperation Contract between the HHSC Texas Veterans Treatment and Workforce Connection Project and the Texas Workforce Commission.
- Texas HHSC Uniform Terms and Conditions.
- Texas HHS Contract Procurement Manual.
- Texas HHS System Contract Management Handbook.
- State of Texas Contract Management Guide.
- Texas Administrative Code.
- Texas Occupations Code.
- Code of Federal Regulations.

Appendix B: BSI CONTRACT TIMELINE

Early 2013

A former Navy Seal dies in Chalk Mountain, Texas. The Navy Seal was killed while attempting to assist another veteran who was suffering from PTSD. This event brought nationwide media attention, and heightened interest in treating Texas veterans suffering from PTSD.

The Governor's Office initiates a meeting with HHSC and UTSW regarding a line item proposal for veterans.

Discussions occur between HHSC, UTSW, and BSI about treating Texas veterans with PTSD.

July 2013

The Governor's Office meets with UTD and discusses BSI.

August 2013

The Governor's Office and HHSC executives visit UTD and BSI in Dallas.

BSI sends a proposal letter to the Governor's Office.

September 2013

The HHSC Executive Commissioner visits BSI in Dallas and Governor's Office staff participates via conference call.

October 2013

The Governor's Office and HHSC Executive Commissioner and staff meet with UTD and BSI to develop an interagency contract. It is proposed that BSI will be a subcontractor to UTD.

November 2013

UTD requests a contract with HHSC separate from BSI so that BSI is not included as a subcontract under the UTD contract.

HHSC prepares a draft BSI contract to send to Governor's Office.

HHSC emails indicate that it does not expect that BSI will be able to obtain an IRB approval.

HHSC drafts UTSW contract to conduct pre- and post-assessments for BSI.

December 2013

HHSC emails indicate an increasing sense of urgency to finalize the BSI, UTD, UTSW, and DSHS contracts.

HHSC Executive Commissioner signs a $1.85 million interagency contract with DSHS which funds the initial BSI contract and the first amendment.

HHSC awards a $625,000 interagency contract with UTD for a veterans' clinical research study on PTSD.

HHSC awards a $412,500 contract with the UTSW to provide assistance to UTD by performing PTSD interviews to evaluate veterans for participation in the UTD clinical research study and to measure outcomes.

HHSC awards an $812,500 initial contract to BSI, which is to be paid on a cost basis not-to-exceed $16,250 per participant.

Emails from UTSW to HHSC express concern about information to be provided by BSI to UTSW relating to research authorizations, HIPAA language, research compliance language, and sharing of protected health information.

January 2014

The President of BSI indicates in emails that participants are awaiting entrance into the study, and he threatens to call the Governor's Office to report that UTSW is causing HHSC to delay the start of the research study.

UTSW states to HHSC that it will neither be able to share data with BSI nor provide CAPS assessments for veterans in the BSI study.

BSI begins treating veterans under its HHSC contract for a clinical health study.

February 2014

The HHSC Executive Commissioner states that the Governor's Office urged HHSC to award the BSI and UTD contracts, and that the Meadows Mental Health Policy Institute will oversee the pre- and post-assessments.[44]

March 2014

HHSC makes the first payment to BSI.

[44] HHSC Council meeting minutes (February 28, 2014).

HHSC provides the final report template to BSI so that BSI can meet the scheduled May 2014 deadline for a final comprehensive report.

April 2014

Non-compliant IRB letter is issued to BSI by Ethical and Independent Review Services.

May 2014

HHSC signs the $799,500 first amendment to the BSI contract, which is to be paid on a cost basis not-to-exceed $16,000 per participant. The amendment adds the requirement that participants be Texas veterans.

A second non-compliant IRB letter is issued to BSI by Ethical and Independent Review Services.

BSI provides a final report to HHSC.

June 2014

HHSC informs BSI that the final report does not comply with the contract, and that no approval has been given to change the contract from a clinical research study to a retrospective chart review.

BSI provides a revised final report to HHSC.

July 2014

BSI submits another revised final report to HHSC.

August 2014

HHSC informs BSI that the Governor's Office will contact BSI to discuss payment for CAPS pre- and post-assessment testing.

September 2014

The Meadows Mental Health Policy Institute issues a report evaluating the BSI study.

BSI submits a status report to HHSC related to treatment of the participant cohort included under the first amendment.

October 2014

DSHS Commissioner signs the December 2013 interagency agreement with HHSC.

November 2014

HHSC enters into a $690,000 interagency contract with the Texas Workforce Commission which funds the second amendment to the BSI contract.

HHSC signs a $640,000 second amendment to the BSI contract, which eliminates the cost basis for payment, and retroactively establishes a fixed fee of $16,250 per participant for the first 50 individuals treated, and $16,000 per participant after the first 50 participants. This final amendment also adds an additional $25,000 fee for performance of the CAPS assessments.

December 2014

Non-compliant IRB letter is issued to BSI by The National Institute for Brain and Rehabilitation Sciences-Israel located in Karmiel, Israel.

January 2015

BSI submits a status report to HHSC related to treatment of the participant cohort included under the first amendment.

February 2015

HHSC makes the final payment to BSI.

Appendix C: REPORT TEAM AND REPORT DISTRIBUTION

Report Team

The IG staff members who contributed to this audit report include:

- Kacy J. VerColen, CPA, Audit Director
- Melissa Larson, CIA, CISA, CFE, HCISPP, Audit Manager
- Dace Ward, CPA, Audit Project Manager
- Carolyn Cadena, CRMA, Auditor
- Telvina Cole, MSFS, CFE, Auditor
- Karla Lief, RN, Medical Auditor
- Lorraine Wayland, CFE, Auditor
- Lawrence Gambone, CPA, Quality Assurance Reviewer
- Collette Antoine, MBA, MPH, Senior Audit Operations Analyst

Report Distribution

Health and Human Services Commission

- Charles Smith, Executive Commissioner
- Cecile Erwin Young, Chief Deputy Executive Commissioner
- Kara Crawford, Chief of Staff
- Karin Hill, Director of Internal Audit
- Karen Ray, Chief Counsel
- Ron Pigott, Deputy Executive Commissioner, Procurement and Contracting Services

Appendix D: IG MISSION AND CONTACT INFORMATION

Inspector General Mission

The mission of the IG is to prevent, detect, and deter fraud, waste, and abuse through the audit, investigation, and inspection of federal and state taxpayer dollars used in the provision and delivery of health and human services in Texas. The senior leadership guiding the fulfillment of IG's mission and statutory responsibility includes:

- Stuart W. Bowen, Jr. — Inspector General
- Sylvia Hernandez Kauffman — Principal Deputy IG
- Christine Maldonado — Chief of Staff and Deputy IG for Operations
- Olga Rodriguez — Senior Advisor and Director of Policy and Publications
- James Crowley — Deputy IG for Investigations
- David Griffith — Deputy IG for Audit
- Quinton Arnold — Deputy IG for Inspections
- Anita D'Souza — Chief Counsel

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To Contact the Inspector General

- Email: OIGCommunications@hhsc.state.tx.us
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