

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC NICoE POC	IRBNet # Approval Date	Enroll Date	End Date				

NICoE PROTOCOLS: CURRENT PROTOCOLS AND PROJECTS - BUILDING 51

GETSmart: Guided Education and Training via Smart Phones to Promote Resilience	ROY Costanzo (USU) <i>Clayborne</i>	399461-4	May June 2014		144 30 physiological measures	93 (36 local) 0 physiological measures	CNRM \$156,227 year one. \$77,969 year two	
<p>This study seeks to assess the impact of brief, low-intensity resilience enhancement strategies, provided largely through smart phones, coupled with assessment of outcomes measurements, including in-person measurement of brain function and physiologic responses for a subset of the study population. This study is sponsored by the Center for Neuroscience and Regenerative Medicine (CNRM). Participants with subthreshold PTSD symptoms are recruited either after return from Iraq or Afghanistan, or after a domestic terrorist incident or natural disaster. Participants are then randomized into resilience enhancement or control arm and receive serial evaluations to identify how symptoms may improve as a function of smartphone app resilience enhancement strategies.</p>								
A study of bilateral prefrontal transcranial magnetic stimulation (TMS) to treat the symptoms of mild TBI (mTBI) and PTSD	PASQUINA Grammer (MM Cyborski) <i>deAlmeida Gover-Chamlou</i>	397662-4 Feb			60		CNRM \$350K	
<p>The purpose of this study is to investigate the efficacy and tolerability of TMS to enhance the rehabilitation of service members with symptoms consistent with mild traumatic brain injury (mTBI) with comorbid Post Traumatic Stress Disorder (PTSD) symptoms. Additionally, biomarkers will be collected to look at the neuronal and biological changes that may occur over the course of TMS treatment.</p>								
Dual-Task Assessment Using Computer Assisted Rehabilitation Environment: Implications for Service Members with mTBI (CAREN)	KRUGER <i>Clayborne</i>	382673-8 June 2013	Nov 2013		75 enroll <u>50 elig</u> 25 TBI 25 HV/C 25 inelig/wd	40 enroll <u>35 elig</u> 25 TBI 10 HV/C 9 inelig/wd	none	
<p>The goal of this study is to compare outcome measures obtained from a conventional dual-task assessment to a CAREN dual-task assessment to determine whether the CAREN can provide additional insight into dual-task performance.</p>								

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC <i>NICoE POC</i>	IRBNet # Approval Date	Enroll Date	End Date				
Community Balance & Mobility Scale: Assessment of SMs with mTBI & PTSD	PAPE <i>Ndiongue</i>	368749-10 May 2012	June 2013		125 enroll <u>90 elig</u> 45 TBI 45 Control 35 inelig/wd	67 45 TBI 23 Control 2 inelig/wd	none	
This study seeks to establish a collection of results for the Community Balance and Mobility scale test and compare data for the Activities-specific Confidence Scale, Functional Gait Assessment and gait speed in active duty service members with and without a history of mTBI and PTSD.								
Differential Assessment of mTBI & PTSD Using Functional Brain Imaging Techniques (MEG/EEG)	DeGRABA <i>Ndiongue</i>	365322-20 March 2012	June 2012		100 TBI+PTSD 100 TBI 100 PTSD 100 HV/C	} 77 2		
This study seeks to characterize mTBI with the utility of the MEG. Various tasks are employed to assess different areas of cognition amongst service members with a diagnosis of mTBI, PTSD and controls.								
NICoE Clinical Research Database to Study the Natural History of TBI and PH Outcomes in Military Personnel	DeGRABA <i>Neuges</i>	362504 March 2012	April 2012		N/A	Arm I (Pro): 622 Arm II (Retro): 232	Drexel UPITT (no funding)	
This study focuses on improving the understanding of TBI, PTSD and other PH conditions. Comprehensive data is collected and maintained from service members enrolled at the NICoE, to analyze injuries, symptoms and efficacy of treatment being utilized at the NICoE.								

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC <i>NICoE POC</i>	IRBNet # Approval Date	Enroll Date	End Date				
Enhancing Exposure Therapy for PTSD: VR & Imaginal Exposure with Cognitive Enhancer (<u>DCS</u>)	ROY (MM: DeGraba) <i>Clayborne</i>	361712-18 Sept 2011	October 2012		100	25	Weill Cornell Medical College \$263,662 (YR1-4), none for NICoE	
<p>This study seeks to identify the superior method for treating PTSD and determine the efficacy of D-Cycloserine (DCS) for augmenting both Virtual Reality Exposure (VRE) as well as Prolonged Exposure (PE). Service members are randomized to receive either VRE or PE, in conjunction with random selection to a cognitive enhancer called DCS or a placebo/inactive agent. The four groups will then be compared: VRE plus DCS, VRE plus placebo, PE plus DCS, and PE plus placebo.</p>								
National Capital Imaging Consortium Evaluation of <u>MRI Hardware & Software</u> in Control Subjects	RIEDY (MM: Landau) <i>Sham</i>	360721-17 June 2011			250	7	none	
<p>The study develops and evaluates software and hardware used with MRI at 3.0 Tesla to assess brain tissue structure and function in order to develop neuroimaging techniques for the MRI scanner, as opposed to examining a specific disease state. This project uses healthy control subjects for methodology development that can later be applied to TBI patients.</p>								
NICoE Traumatic Brain Injury <u>MEG Core</u>	RIEDY <i>Sham</i>	359959-15 March 2011			600 TBI 200 HV/C	102 TBI 23 HV/C	MOU with NIMH (Coppola) (Eff 10/4/11 - 10/31/15)	
<p>This study develops imaging modalities to best translate MEG findings through functional MRI.</p>								
National Capital Imaging Consortium <u>TBI NeuroImaging Core</u> Project – PT074437	RIEDY (MM: Landau)	20337-79 Dec 2008 (356785)		April 2015	1200 TBI 200 HV/C	1156 TBI 150 HV/C	Connectome	

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC <i>NICoE POC</i>	IRBNet # Approval Date	Enroll Date	End Date				

This study seeks to compile a database of over 500 neuroimaging images of eligible TBI patients. These studies are collected and analyzed in order to determine the most effective imaging methods for characterizing and tracking the TBI disease state. The highly individualized nature of TBI necessitates a large number of subjects to discover distinct sub-categories of TBI symptomatology. The study combines multiple modalities of magnetic resonance imaging (MRI) and positron emission tomography (PET) and hypothesizes that TBI diagnosis will result from careful characterization of individual modalities followed by advanced multi-modal analysis.

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC NICoE POC	IRBNet # Approval Date	Enroll Date	End Date				
NMCS D/NHCP Site (Brief only)	FRENCH Lange <i>Gartner, Smith</i>	385518-7 04NOV2013	APR 2014	MAY 2019	See CORE above	230 Brief*	DVBIC	Amendment approved by WR IRB on 25AUG2015. MRMC and USUHS are in the process of reviewing/approving.
FBCH Site (Comprehensive & Brief)	FRENCH Lange <i>Driscoll, Gartner, Smith</i>	408375-1 07AUG2015	Fall 2015	TBD	See CORE above	0 Comp* 0 Brief*	DVBIC & CNRM	WRNMMC IRB approved the protocol on 07AUG2015. MRMC and USUHS are in the process of reviewing/approving.

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC NICoE POC	IRBNet # Approval Date	Enroll Date	End Date				
Health-Related Quality of Life in Caregivers of Service Members and Veterans with Traumatic Brain Injury 15-Year Study TBI CareQOL Development CORE	FRENCH Brickell <i>Gartner, Smith</i>	367721-17 18SEP2012	JUN 2013	AUG 2027	N=600	309 Enrolled	DVBIC	
				DEC 2018	Focus Groups up to 60, Field Testing up to 200, Validation up to 600	32 in 6 Focus Groups, Field Testing and Validation not yet started	DVBIC & NIH Grant	
AIMS of 15-YEAR CAREGIVER STUDY: <ul style="list-style-type: none"> • Conduct a 15-year study of the effect of caring for a service member (SM) with a TBI on the caregiver's (CGs) overall health and well-being and identify the types of health care / social services needed to foster better CG psychological and physical health, social well-being, and resilience; • Examine the effect of the TBI on the health and behavior of the SM's children. AIMS of the TBI-CARE QoL DEVELOPMENT STUDY: <ul style="list-style-type: none"> • Address the scarcity of available caregiver health related quality of life (HRQOL) measures by developing and validating a new measure of HRQOL for use among caregivers of a service member or civilian with a TBI--the "TBI-CareQoL;" • Integrate the TBI CareQOL into the 15 year caregiver study upon completion. 								
WRNNMC Site	FRENCH Brickell <i>Gartner, Smith</i>	409648-3 08JAN2015	JAN 2015	AUG 2027	See CORE above	309	DVBIC & NIH Grant	
NMCS/D/NHCP Site	FRENCH Brickell <i>Gartner, Smith</i>	409655-3 08JAN2015	FEB 2015	TBD	See CORE above	0*	DVBIC	

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC <i>NICoE POC</i>	IRBNet # Approval Date	Enroll Date	End Date				
FBCH Site	FRENCH Brickell <i>Gartner, Smith</i>	412785-1; Not yet approved	Fall 2015	TBD	See CORE above	0*	DVBIC	

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC NICoE POC	IRBNet # Approval Date	Enroll Date	End Date				
Brain Indices Projects								
Brain Indices of Risk for PTSD after Mild Traumatic Brain Injury CORE	FRENCH Duncan <i>Auslander</i>	356540-23 (core) Jan 2010	July 2012		240	175 enrolled participants (recruitment closed)	CDMRP INTRuST Clinical Consortium and CNRM	
<p>The primary aim of this longitudinal study is to improve the ability to predict PTSD in service members who have sustained mTBI or bodily injuries with no TBI. A battery of measures of brain structure (MRI/DTI/SWI) and function (ERPs, neurocognitive, neurological) are evaluated at baseline to identify markers of risk for PTSD over a 6-month period. Secondary aims include investigating associations between brain indices and other outcome measures (post-concussion symptoms, headache, and quality of life); evaluating differences between mTBI and injured, non-TBI subjects in terms of outcome; and characterizing differences in indices of brain structure and function between blast and impact mTBI.</p>								
WRNMMC site	FRENCH/Duncan <i>Auslander</i>	366730-9				150		
FBCH site	PUROHIT/Duncan <i>Auslander</i>	373422-12 Feb 2012				25		
Brain Indices of Risk for PTSD after Mild Traumatic Brain Injury: Addition of a Healthy Comparison Group CORE	FRENCH Duncan <i>Auslander</i>	387237-9 Jul 2014	October 2014		140	78 enrolled	CDMRP INTRuST Clinical Consortium and CNRM	

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC <i>NICoE POC</i>	IRBNet # Approval Date	Enroll Date	End Date				

The purpose of this study is to establish a normative database of measures of brain structure and function and overall health and well-being in healthy Service Members (healthy SMs) with no history of TBI or blast exposure. This data repository will be important in increasing the availability of normative data in this population, which can ultimately be used as a comparison group in various research protocols concerning a wide variety of behavioral and neurological outcomes in military Service Members.

WRNMMC Site	FRENCH/Duncan <i>Auslander</i>	392178-5				44		
FBCH Site	PUROHIT/Duncan <i>Auslander</i>	392179-7 Sept 2014				34		

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC NICoE POC	IRBNet # Approval Date	Enroll Date	End Date				
Brain Fitness Center Projects								
Expanding Our Understanding of Computer Based Cognitive Rehabilitation in the Military Population—a Longitudinal Brain Fitness Center Database (Retrospective/Prospective)	FRENCH Sullivan <i>Perta</i>	375962-6 March 2013	March 2013		N/A	779		
<p>The purpose of this study is to improve our understanding of computer-based cognitive rehabilitation tools in the military population by developing a database that contains demographic information, clinical data, self-report questionnaires and objective cognitive assessments collected from the Walter Reed National Military Medical Center (WRNMMC) and Fort Belvoir Community Hospital (FBCH) Brain Fitness Centers (BFC). Data from Walter Reed Army Medical Center (WRAMC) collected prior to August 2011 (official integration date for BRAC) will also be included. The data collected for the study will provide the foundation for the development of hypothesis-driven protocols, and will ultimately advance our understanding of characteristics of treatment responders and non-responders, aspects of cognitive change, and self-perceived symptom change following Brain Fitness Center participation.</p>								
WRNMMC Site	FRENCH Sullivan <i>Perta</i>	389348-1				658		
FBCH Site	FRENCH Sullivan <i>Green-Oakes</i>	389243-2				121		
Biofeedback Treatment of mTBI Pathology Utilizing an Optimized Training Environment	FRENCH Sullivan <i>Perta</i>	384227 Oct 2013	Sept 2014	Apr 6 2015	90	mTBI/PTSD	HAPI and Evoke Neuroscience	

NICoE PROTOCOLS

PROTOCOL	PI	TIMELINE			ACCRUAL CEILING	ENROLLED	AFFILIATES & FUNDING	COLOR DESIGNATION
	SC NICoE POC	IRBNet # Approval Date	Enroll Date	End Date				
<p>A prospective randomized controlled study design will be used to evaluate the benefits of performing brain computer interface (BCI) and heart rate variability (HRV) biofeedback treatment within an optimized environment, called the Orrb. The purpose of this project is to (1) research mechanisms and interventions that promote recovery of function after brain injury, and (2) demonstrate the efficacy of innovative rehabilitation strategies.</p>								
<p>BRAVE Trial: Broad-spectrum Cognitive Remediation Available to Veterans--Effects of a Brain Plasticity-based Program in Mild Traumatic Brain Injury CORE</p>	<p>FRENCH Sullivan <i>Marble</i></p>	<p>386521-11 11 April 2013</p>	<p>March 2014</p>		<p>60</p>	<p>8 enrolled, 38 consented</p>	<p>Posit Science Corporation</p>	
<p>A standard parallel arm, prospective, randomized, controlled, double-blind trial design will employ a treatment group using CRBI vs. an active control group using computer games in 36 participants with persistent post-concussive symptoms (PPCS) following mild traumatic brain injury (mTBI), with an intervention period and a follow-up period. Participants will perform a pre-assessment to establish their baseline cognitive function, then work with either computerized cognitive remediation treatment CRBI or the active control program for three months, then perform a post-assessment to evaluate changes in cognitive function. Participants will then stop using their assigned program for three months, and return for a follow-up assessment to evaluate the endurance of changes in cognitive function in the absence of further program use.</p>								
<p>WRNMMC Site</p>	<p>FRENCH Sullivan <i>Marble</i></p>	<p>405572-3 10 Oct 2014</p>	<p>March 2014</p>		<p>36</p>	<p>3 enrolled, 24 consented, 1 withdrawn</p>		
<p>Tripler Site</p>	<p>FRENCH Sullivan <i>Marble</i></p>	<p>404126-4 10 Oct 2014</p>	<p>Oct 2014</p>		<p>24</p>	<p>5 enrolled, 15 consented</p>		