DGIM Project Summary

**Name of Project:** Advanced Magnetic Resonance Imaging for Mild Traumatic Brain Injury

**Investigator(s):**
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**Research question(s):**
In the sub-acute period of mild traumatic brain injury (mTBI), do correlations exist between neurological assessments and MR image data characteristics which may indicate temporal evolution patterns? The intent of this study is to broadly generate potential biomarkers of temporal evolution of mTBI, as detected in MR images and data.

**Brief Background/Significance:**
Over 1.1 million people each year are treated for traumatic brain injury (TBI) in emergency departments in the United States alone, with 50,000 of these injuries resulting in fatalities and approximately 43.4% resulting in chronic disability. mTBI is a special type of TBI that often goes untreated. Notably, military- and sports-related injuries are among the leading cause of mTBI, and these subjects are at highest risk of long-term adverse effects because they may be injured repeatedly and often do not receive prompt diagnosis or treatment. While the biomarkers of more severe forms of TBI are often readily apparent, the biomarkers of mTBI remain extremely heterogeneous and complex and are often difficult to detect. Many clinicians and researchers now recognize that minute abnormalities following mTBI can result in potentially serious and adverse chronic conditions, including sleeping abnormalities, cognitive impairments, post-traumatic stress syndrome, increased suicide risk, depression, and anxiety. Comprehensive characterization of mTBI pathophysiology using modern technologies, such as contemporary Magnetic Resonance Imaging (MRI) systems, is required to attain objective and precise information on brain injury magnitude and location. Unlike computed tomography (CT) systems, which have limited usefulness in mTBI due to relatively low sensitivity to diffuse brain damage, MRI has greater utility for reliably and safely detecting regional brain abnormalities. Currently, the advantages of cost and convenience for CT have limited the wide use of MRI for acute management of mTBI in the vast majority of clinical settings; however, and there is a growing interest in MRI assessment of TBI, particularly of mTBI.

**Inclusion Criteria:**
1. Be aged ≥15 and ≤50 years old at the time of enrollment;
2. Be diagnosed with mTBI according to the standard diagnostic procedures within 10 days of injury.

**Exclusion Criteria:**
1. Loss of consciousness (LOC) ≥15 minutes
2. Posttraumatic amnesia lasting ≥24 hr following a recent TBI event
3. Diagnosis of moderate to severe TBI or GCS <13
4. Structural brain injury indicated by previous neuroimaging findings
5. Previous history of moderate to severe TBI
6. Any previous history of mild TBI within the past 12 months
7. Previously diagnosed brain white matter disease
8. History of seizures within the past 10 years
9. History of self-reported recreational drug usage in past 10 years
10. History of alcohol abuse or dependence (per DSM-IV-TR Diagnostic Criteria)
11. Current primary Axis I or II psychiatric disorder
12. History of brain mass
13. History of neurosurgery
14. History of stroke
15. History of dementia
16. Known cognitive dysfunction
17. Known structural brain disease or malformation
18. Current anti-psychotic, psychotropic, or antiepileptic medication usage
19. Unable or unwilling to complete study procedures accurately or have any conflict of interest that could affect study results, in the opinion of the investigator;
20. Contraindications to MRI scanning
21. Current or suspected pregnancy

**Method of contact/recruitment (be specific)**
Clinical Research Coordinators will monitor daily SACC appointments to screen for patients who potentially have experienced mTBI within the past 10 days. CRCs will make contact with the patient either in the waiting rooms or exam rooms at SACC, dependent on the clinic schedule and what appears the best opportunity to speak with the patient without interfering with clinic operations. If permitted by DGIM, CRCs may also contact patients following their visit via phone to notify patients of the project.

**Benefits/burden for participants (clearly identify potential for harm)**
Participants will receive a copy of their study MRI and will be notified of any incidental findings within their scans, which may have clinical significance. This project has been classified by CHR has having no greater than minimal risk for participants. Loss of privacy is a risk, however multiple steps are taken to minimize this. MRI is a non-invasive imaging technology and is considered a minimal risk clinical procedure.

**Any benefits or burden to DGIM practitioners?**
We do not anticipate their being any burden to DGIM practitioners. There is no direct benefit for DGIM practitioners, however they may be able to recommend patients enroll in this project to receive MRI imaging at no cost. There may be incidental findings within the MRI images collected as part of this project that could benefit the patient’s clinical care and treatment.

**Timeline:**
- **Start date:** September 1, 2014
- **End Date:** September 1, 2016

**Funding Source:**
This project is funded by General Electric HealthCare

**Potential for DGIM collaborators?**
While we do not see an immediate potential for DGIM collaborators, we would be open to discussing collaboration with any interested parties.

**Do you agree to notify us when recruitment is completed?**
Yes, we will notify DGIM when recruitment is completed.

**Date form completed:**
10.16.14 by Nicholas Pojman (CRC)