#### IRB SYNOPSIS OF PROPOSAL # 2010W1368

**Title: Computerized Assessment of Oculomotor Function in Person with Mild Traumatic Brain Injury**

**PLEASE NOTE:**

***This proposed project is sponsored by the Research Enhancement Program at Texas State. All projects have to have IRB approval before initiation of research activities.***

1. Identify the sources of the potential subjects, derived materials or data. Describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.

* Twenty (20) healthy male and female participants will be recruited over a period of 1 year from the Texas State University campus and surrounding community using researcher word of mouth to faculty, staff, and students. In addition, participants will be referred from the Student Health Center if appropriate. The inclusion criteria will be as follows: age 18 years and older, binocular vision (can wear glasses or contacts) and recent mild head injury within past 12 months with negative imaging studies and without any skull or spine fractures. Exclusion criteria will be the inability to understand one step commands, instability or pain in the cervical spine, monocular vision and visual acuity worse than 20/100.
* This project does not require the inclusion of special populations such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.

1. Describe the procedures for recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects, and the methods of documenting consent. (Include applicable consent form(s) for review.) If written consent is not to be obtained, this should be clearly stated and justified.

* Participants will be recruited from the Texas State University campus using researcher word of mouth to faculty, staff and graduate and undergraduate students in the departments of Communications Disorders, Respiratory Care, Health, Performance Exercise and Recreation, Computer Science, Psychology, Social Work and Physical Therapy. In addition, participants will be referred by the Student Health Center. Each participant will be consented according to university policy using the attached consent form.
* The consent forms will be stored in a locked file cabinet in Dr. Gobert’s office in the Department of Physical Therapy in the Health Professions Building, Texas State University, San Marcos, Texas and then destroyed three (3) years after the conclusion of the project.
* De-identified, processed data will also be stored in a locked file cabinet or password-protected computer in Dr. Komogortsev’s office in the Department of Computer Sciences for up to 7 years after the end of the study before being destroyed.
* Information in terms of description of the study procedure will be provided to the subjects. Subjects will be invited to freely ask questions of the researchers or representatives of the Texas State Office of Research Compliance. A copy of the consent form, medical history intake form, Epworth Sleepiness Scale (ESS) and the Dizziness Handicap Index (DHI) are all attached.

1. Describe the project’s methodology in detail. If applicable, detail the data collection procedures, the testing instruments, the intervention(s), etc. If using a survey, questionnaire, or interview, please provide a copy of the items or questions.

* **Testing Procedures**:

All participants will be asked to complete a brief 20-item questionnaire asking about demographic information (i.e. age, gender) and information about head injury events and any symptoms such as vision or sleep problems. The questionnaires will include the standardized questions from the Epworth Sleepiness Scale (ESS= 8 items) and Dizziness Handicap Index (DHI= 25 items). (Please refer to attached documents) Participants will also receive a physical screen by a physical therapist to make sure that each volunteer is able to participate safely in the study. The questionnaire and physical screen during the first meeting will take approximately 30 minutes to complete.

There will be three major testing sessions (at Baseline, at 1 week and at 4 weeks). Each testing session will include: a cognitive assessment, eye movement testing lasting 30 – 40 minutes. Participants will perform the same activities all three sessions.

* **Cognitive Testing:**
  + This easy standardized computer assessment of cognition called the ImPact® is commonly used to test persons after mild head injury and will assess short term verbal and visual memory with documentation of reaction times and the number of correct responses. This self-paced test will take no more than 20 minutes.
* **Eye Movement Testing:**
  + Each participant will be asked to sit 42 cm. in front of a computer screen with the head resting comfortably on a padded chin rest while visually tracking moving targets. The Tobii® eye tracker or special camera system will be used to track smooth pursuit and saccadic eye movement in different vertical, horizontal and diagonal movement planes. Performance scores will be documented for 8 – 10 trials lasting 20 – 30 seconds each. Rest periods will be provided as needed. This portion of testing will last no longer than 10 minutes.
  + Dynamic vision using the vestibular ocular reflex will be assessed using a computerized assessment program called the InVision® (NeuroCom, Inc). Each participant will wear a headband with a lightweight sensor attached to it while sitting 10ft in front of a computer screen. Participants will be asked to move the head side to side or up/down and name the optotype “E” orientation being presented on the computer screen. Dynamic vision acuity will be compared to static visual acuity for a final score. This portion will take approximately 10 minutes to complete.
* **Computer Activity Participation:**

Participants with and without a mild head injury in the past 12 months will participate in the 3 computer activity sessions (baseline, at 1 week and at 4 weeks). All cognitive and eye assessment activities will be performed in the in the Neuromuscular Research Laboratory (Rm #331) in Department of Physical Therapy in the Health Professions Building at Texas State University-San Marcos.

* + Total time for all computer activities will take no more than 30-40 minutes for each of the three (3) sessions over a period of four (4) weeks.

1. Describe any potential risks — physical, psychological, social, legal or other — and state their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used.

* There are minimum potential risks other than slight dizziness, vertigo, and headache during head movements or eye fatigue similarly experienced during reading for 20 - 40 minutes on a computer in normal everyday activity. Rest breaks will be provided as needed if participants do experience any symptoms or fatigue during any testing or exercise activities.
* In addition, some participants may feel uncomfortable providing the information outlined in the standardized questionnaires. Participants will be advised that they may refuse to answer any questions which may make them feel uncomfortable in answering. In addition, participant students will be notified about the free services through the Student Health Center at Texas State as needed. Students will also be provided names and contact information of local services on campus and in the San Marcos areas as convenient or appropriate.

1. Describe the procedures for protecting against or minimizing any potential risks and include an assessment of the likely effectiveness of those procedures. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing mental health or medical treatment, if needed.

* Participants will receive a medical screen to ensure appropriateness for study participation. In addition, this project includes standardized eye and cognitive clinical assessment programs designed for persons with mild traumatic brain injury. Upon completion of the study, all participants will be given the opportunity to participate in the program again if study results indicate possible rehabilitation benefits.
* We will take all precautions to ensure participant safety however investigators will provide no special medical arrangements beyond calling the Emergency Services telephone number 911. Texas State University-San Marcos students may choose to be examined free of charge at the Texas State Student Health Center on campus. The investigators will report an adverse event per institutional policy.

1. Describe and assess the potential benefits to be gained by the subjects, as well as the benefits that may accrue to society in general as a result of the proposed study.

* Participation in this study will help participants learn more about personal thinking abilities, quality of sleep and ability to track targets with the eyes while assisting researchers to better understand how persons with a mild head injury respond to a customized rehabilitation program. Some participants may also experience a decrease in symptoms with improved function in response to some of the special exercises. As a student possibly suffering from symptoms common to mild head injury, this program will further reinforce a supportive relationship between the student and the university. In addition, results will help develop better rehabilitation techniques for persons recovering from traumatic head injury.

1. Clearly describe any compensation to be offered/ provided to the participants. If extra credit is provided as an incentive, include the percentage of extra credit in relation to the total points offered in the class. Also, if extra credit is provided, describe alternatives to participation in your research for earning extra credit.

* Participants will receive $30.00 at the end of participation in this study which will be provided at the third and last testing session for 4-weeks of participation ($10/session). This compensation will be provided in the form of a check drawn up under the guidance of the Office of Sponsored Programs. Checks will be given to all participants as an incentive to return for final testing.

1. Discuss the risks in relation to the anticipated benefits to the subjects and society.

* There are only minimal discomforts and risks associated with this study and can be classified as 2/10. The benefits out-weigh these known risks at a level of 8/10 because participants will be performing traditional eye movements common to rehabilitation strategies used for persons with mild traumatic brain injury. Participants will learn more about common symptoms experienced by persons with mild head injury and may experience improvements in functional areas such as cognition, sleep, and eye/head coordination and the education program will provide helpful strategies for campus and community reintegration during activities of daily living.

1. Identify the specific sites/agencies to be used as well as approval status. Include copies of approval letters from agencies to be used (note: these are required for final approval). If they are not available at the time of IRB review, approval of the proposal will be contingent upon their receipt.

* All research activity will be conducted at Texas State University-San Marcos.

1. If you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member.

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1. In the case of student projects, pilot studies, theses, or dissertations, evidence of approval of Supervising Professor or Faculty Sponsor should be included. Thesis and dissertation proposals must be approved by the student’s committee before proceeding to the IRB for review.

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1. If the proposed study has been approved by another IRB, attach a copy of the letter verifying approval/disapproval and any related correspondence. If the proposed study has not been reviewed/approved by another IRB, please state this explicitly.

-NA-

1. Identify all individuals who will have access, during or after completion, to the results of this study, whether they be published or unpublished.

* Dr. Denise Gobert, Department of Physical Therapy
* Dr. Oleg Komogortsev, Department of Computer Sciences
* Graduate student assistants trained specifically for this project (all will have a completed Citi Training certificate on file)

**In addition to this synopsis, you are required to submit all relevant documentation for review. This may include, but is not necessarily limited to: 1) recruiting documents (e.g., flyers, letter, e-mails, brochures, etc.), 2) a consent form, 3) an assent form, 4) letters of approval from relevant organization(s), 5) surveys/instruments/questionnaires, esp. those created by the researcher, 6) a list of questions that the researcher may ask (e.g., focus groups questions, questions for qualitative studies, etc.), and 7) all documents in translated versions.**