Sept. 4, 2015

Signature of Nominated Applicant | Date

1 – PROPOSAL ABSTRACT	**Maximum 250 words**
In terms that can be understood by a lay person, please describe the research project. Include the reason for the study, and the projected outcomes of the study.	

Objectives:
1. Capture metrics of spinal manipulation performance and to identify those metrics that best discriminate between levels of operator skill.
2. Translate the findings into a new instrumented 'glove' that will result in a prototype device capable of capturing and quantifying important performance metrics in real time.

Background: Methods of acquisition and evaluation of manual skills training for spinal rehabilitation professionals has been stagnant for the past 40 years. Observation and mimicry are coupled with 'expert' observer feedback to train and evaluate learners. Evaluation relies on rater experience to discriminate between appropriate or inappropriate parameters such as speed, force, and amplitude during a procedure <1 second in duration. Spinal manipulation is a controlled act under the Regulated Health Professions Act (1991) as it is not without risk. The discordance between the current methods for evaluating proficiency and the potential risks of inadequate application is a critical gap.

Methods: This study is comprised of two concurrent arms: 1. Collection of multiple performance variables in a simulated clinical environment using healthy 'patients' to explore those parameters that discriminate between novice, intermediate, and expert-level manipulators (n=10 each). 2. Parallel revision and refinement of a prototype sensorized glove with a focus on measurement accuracy and usability.

Impact: Western University graduates 75 physiotherapy students per year. There are 14 physiotherapy (PT) schools in Canada, and hundreds more throughout the world. The new intellectual property developed through this collaboration represents a dramatic shift in manual skills training, and opens exciting new opportunities for clinical trials of spinal manipulation.

2 – PROPOSAL	**Maximum 4 pages (12-point font, single spaced, with 1-inch margins)**

A) PURPOSE OF THE RESEARCH

1. To capture, quantify and compare performance metrics of novice, intermediate and expert-level spinal manipulators ('operators') when performing two standardized manipulations. Metrics include acceleration, force, amplitude, pressure, and muscle recruitment strategies.
3. To concurrently use the results from Obj. 1 to refine a prototype sensorized glove that will capture and report real-time performance metrics.

B) BACKGROUND & RATIONALE

Motion tracking and performance quantification have become ubiquitous in the form of smartphones, watches, and other consumer-oriented wearable devices. This is attributable to recent reductions in cost and size of *inertial measurement units* (IMUs) and powerful wireless computing devices that offer portable real-time capture and interpretation of many data sources simultaneously. Today's IMUs commonly include accelerometers, gyroscopes and magnetometers that accurately quantify acceleration (m/sec^2), rotation (deg/sec) and orientation (Gauss), respectively. Low cost and low power consumption coupled with high precision have allowed these microsensor units to be employed to great effect in both the consumer and academic arenas with field-changing results. (e.g. http://www.sensoriafitness.com, https://projectpole.com, www.thalmic.com).

At Western University we boast strengths in key fields such as engineering, mechatronics, and computer science in addition to our internationally recognized excellence in medical and health science disciplines. We propose to harness these resources to refine a new wearable device that will quantify key performance metrics during acquisition of manual skills training and mastery. Western is currently home to Canada's only in-person university-based residency program for advanced manual and manipulative therapy training. This accredited program results in a Master's of Clinical Science (MClSc) in manipulative therapy. Participants in this program represent all Canadian provinces. The leaders of the MClSc program are recognized amongst their peers as outstanding teachers and mentors, led by Western's 2014 Marilyn Robinson Teaching Award recipient (JS) and recipient of the Canadian Physiotherapy Association's 2014 National Mentorship Award (DW).

Manual and manipulative therapy (MMT) are cornerstones of physical therapy education and treatment. Despite a universal desire for excellence in MMT training, the field as a whole suffers from near stagnation in training and evaluation strategies since its introduction into Canada in the mid-1970s. Slight institutional differences aside, the overarching strategy has remained steadfast: learners observe an expert perform a technique and then attempt to mimic and master that technique on a colleague. Learners receive direct observation and verbal feedback from an instructor or from their (live) colleague. After some period of practice and attempted mastery, learners perform their techniques on mock patients (healthy volunteers) while being observed and rated by experts. If the rater perceives the performance to be satisfactory, then the learner is granted a credential such as that offered by our MClSc program. The 'patients' in these simulated clinical encounters being healthy volunteers, the evaluation cannot be outcomes-based (since there are in fact no symptoms to speak of), rather competence is based strictly on observed performance using indicators such as speed, amplitude, and force under the untested assumption that these parameters are important for improving clinical outcomes. This is the case in all 14 university-based entry-level physiotherapy

programs in Canada, as well as the 227 programs in the United States, 178 programs in the United Kingdom, 17 in Australia, and so on.

The discordance between 'simulated' evaluation and real-world application is realized when one considers that MMT is not without risk. Arguably the most recognizable risk is that of stroke or death[1] often cited by the lay press[2] most commonly associated with chiropractic 'adjustments' (manipulations) of the upper cervical spine. This has led to repeated calls to ban the practice[3,4]. Other adverse events are less serious but not completely benign and include dizziness, increased pain, headaches, or radiating numbness and tingling.[5] Adverse events are most likely to occur when these techniques are applied by novices rather than by experts,[6] yet the only way to learn the technique is to apply and practice it on colleagues or fellow students. Learners will often inadvertently harm their practice partners; every year at least 1 or 2 students in our MPT and MClSc classes must sit out a session as a result of ongoing symptoms from a prior class. We are aware of one learner in a program external to Western but of similar content that required surgical intervention for an elbow ligament tear following a manipulative technique performed by a fellow learner.

Students under the supervision of co-investigator ALT have been working on a first prototype of a sensorized glove for improving capture and feedback for MMT practitioners and students. The glove is capable of measuring hand movement and applied forces on various locations of the palm. An IMU is used to measure hand acceleration and jerk (derivative of the acceleration vector). Over 20 force sensing resistors (FSRs) are used to measure force applied on relevant positions of the user's hand. The data are sent wirelessly to a computer for real-time analysis and visualization. A graphical user interface has been developed to provide a visual display of force distribution and maximum acceleration and jerk per movement while performing a manipulation (see Fig. 1 appendix). This first iteration of the glove has served as a proof-of-concept for the feasibility of the design. Modifications are required in order to improve the overall functionality, improve fit for various hand sizes and to integrate EMG sensing capabilities. New patent-pending technology from co-applicant LF is to be integrated to allow unencumbered per-finger force quantification (Fig. 2).

Simultaneously, DW has started collecting a database of 'expert', 'intermediate' and 'novice' manipulators as they perform standardized manipulative procedures on healthy human subjects. Appended Figures provide sample surface EMG and acceleration traces of key muscles recorded from representative expert (Fig. 3a & 4a) and novice (Fig. 3b & 4b) manipulators. EMG data (Fig. 3) indicate notable differences in the motor strategies used (e.g. biceps:triceps strategy) with strong co-contraction in the novice replaced by a triphasic EMG pattern characteristic of mastery of ballistic motion[7] in the expert. The vector motion data (Fig. 4) show clear differences between the two, indicating greater peak acceleration and time-to-peak in the expert vs. the novice.

The only published attempt at quantifying and evaluating performance of people learning spinal manipulation was that of Cuesta-Vargas and Williams[7], who used a single, tri-axial accelerometer at low (100 Hz) sampling frequency to evaluate the effect of real-time acceleration feedback on learning outcomes. The only significant effect found was that of increased peak angular velocity post-training. Those authors concluded that the use of the sensors improved learning of the skill, but this is neither supported by the results nor is it clear that peak angular velocity is in fact an

important part of the performance of manipulation. We believe that the first step towards moving this field forward starts with understanding what makes a 'good' manipulation and to develop a portable method to capture those important parameters. Our pilot work has indicated that adequate description of manipulation performance will require more complex algorithms integrating multiple sensors simultaneously, a task to which our team is well suited. This will facilitate translation to the clinical arena where rigorous outcomes-based research can be conducted. For the first time it will be possible to standardize the physical performance components of spinal manipulation, and objectively explore important clinical questions that stand to have dramatic impact on the teaching, evaluation and performance of these techniques.

C) HYPOTHESES

1. Novice, intermediate and expert-level manipulators will show differences in performance metrics including peak and time-to-peak acceleration, velocity, force distribution and magnitude, amplitude of movement, and electromyographically-recorded muscle recruitment when performing two standardized spinal manipulations on healthy subjects.
2. A prototype sensorized glove will be able to accurately capture and display in real time the important performance metrics from Obj. 1 using wireless technology in a user-friendly design.

D) EXPERIMENTAL PLAN

We will follow established best practices for creating a new measurement tool, an area in which the applicants have considerable expertise.[8-15] In brief, these are: 1. define the construct to be measured, 2. identify quantifiable metrics of that construct, 3. pilot test the metrics as a prototype tool, 4. refine the prototype tool based on the pilot testing, 5. establish measurement properties (reliability, discriminative and evaluative validity) of the refined tool and revise as needed, 6. re-test the measurement properties of the revised tool, and 7. establish utility and operator satisfaction prior to wider implementation.

The construct to be measured (manipulation) has been defined in accordance with the current operational definitions of a "high-velocity low-amplitude thrust".[16] The indicators to be captured are informed by both this operational definition and the technology currently available. These include metrics of angular and rotational movement (peak acceleration, time-to-peak, peak angular velocity), pressure metrics (peak Newtons, N/cm^2, time-to-peak pressure, pressure distribution), and muscle recruitment patterns of key muscles (EMG peak, onset, and total area). Combined metrics will also be explored, including peak EMG/unit of acceleration ($mV/m/s^2$) and the integration of EMG per unit pressure (mV/N) as metrics of movement efficiency.

The variables to be captured will be identified by their ability to discriminate between different operator skill levels. Novice operators will be drawn from the pool of 55 MPT students in their senior year of the entry-level program. Intermediate operators will be drawn from the 20 MClSc students in the second term of the program, each of whom has a minimum of 3 years of clinical experience. Expert operators will be the faculty associated with the MClSc program and other community clinicians who have earned the *FCAMPT* designation for advanced MMT. All performance indicators will be captured while the operators perform two standardized manipulation procedures, one on the lumbar spine region (L4,5) and one on the cervical spine region (C4,5). Models receiving the manipulation will be 1 of 10 healthy male volunteers (age range 18-45 years, weight 75-85kg, BMI 18-25 kg/m^2) who have been screened by an experienced physiotherapist to

ensure no contraindications to receiving spinal manipulation. For safety reasons, no model will receive a manipulation twice in a row, but to reduce bias each will receive at least 1 manipulation from operators (subjects) at each of the 3 performance levels. This will be a single session design.

Analysis will begin by comparing the groups using descriptive statistics (means, SD, or proportions as appropriate). Given the accuracy and precision of the devices and our experience with these cohorts, we anticipate that 10 subjects (operators) per group (total N = 30) will provide sufficient statistical power for key comparisons, especially of the novice vs. expert operators that are expected to yield large between-group differences. However, given the relatively early stage of this work, we cannot be certain that hypothesis testing using inferential statistics will be appropriate or meaningful, and we would rather err on the side of caution than force statistical comparisons. In the event that statistical power is insufficient for hypothesis tests to distinguish between groups, we will focus on descriptive analyses and calculate effect sizes for formal power analysis and sample size estimation that will be critical for success in external grant competitions. Those metrics with very small effect size (ES < 0.20 between any 2 groups) will be deemed 'low yield' and considered for removal from subsequent studies, thus still achieving our goal of refining the protocol. Accuracy of the metrics captured by the refined glove will be evaluated by calculating chance-corrected agreement (ICC) between data from the glove and data from a gold standard instrumented silicon 'phantom' that has been successfully implemented in previous surgery-focused research.[15]

E) TRANSDISCIPLINARITY (*briefly describe the transdisciplinary nature of the project*)

This project requires strong transdisciplinary collaboration. DMW and JS represent the clinical and measurement fields, while ALT and LF represents the engineering and mechatronics fields. Both areas of expertise are necessary for the successful completion of this project.

F) LONG-TERM GOALS & PLANS FOR LEVERAGING EXTERNAL SUPPORT

This project will position the emerging team well for ongoing external support. After 1 year we will have estimates of effect size (between group differences) that will support sample size calculations for additional large-scale projects. The refined prototype glove and identification of important/ unimportant performance parameters is of utmost value for demonstrating feasibility to external funders and refining the protocol for efficiency and relevance. The transdisciplinary nature of this project renders it potentially eligible for both CIHR and NSERC-level funding opportunities, while an eye towards industry partnership will open access to opportunities such as the Collaborative Health Research Projects (CHRP) and knowledge-to-action funding.

G) POTENTIAL SIGNIFICANCE & IMPACT

Western is the first and only University in Canada with a formal degree program for advanced MMT, but others are coming on board. The study we're proposing and the product to be developed will keep Western at the forefront of this type of training both in Canada and internationally. There is clearly new IP to be developed here with the very real potential for patentable technology and a new consumer market. Quantification of performance as described herein will revolutionize formative and summative feedback provision for mentors and students, and provide the very real possibility of developing a 'virtual mentor' platform to improve accessibility to quality Professional Development for providers in rural or underserviced areas. There are hundreds of PT programs around the world, and when Chiropractic, Osteopathic, Massage Therapy and other such manual-focused health programs are included, the numbers of programs rank well into the thousands.