



Application for Research Ethics Approval

To submit a research proposal to the Ottawa Hospital Research Ethics Board (OHREB), it is mandatory to submit the actual protocol.

The application forms must be filled out completely. Please bear in mind that some members of the OHREB may not be experts in your own field so please strive, where appropriate, to make your submission understandable to those outside your area of expertise. Information Sheets and Consent Form must be included with the protocol (where appropriate).

Please submit the appropriate number of copies:

For protocols requiring **full review**:

- Application 18 copies (signed original plus 17 copies)
- Patient Information Sheet and/or Consent forms * 18 copies (original plus 17 copies)
(* English version only)
(Once the English version has been approved by the OHREB, the French version may be submitted.)
- Departmental Impact Sheet with applicable attachments 18 copies (signed original plus 17 copies)
- Detailed Budget: 18 copies
- Protocol: 8 copies
- Questionnaires, Case Report Forms, etc : 8 copies
- Investigator's Brochure: 2 copies

For protocols requiring **expedited review** :
(Survey, Chart Reviews, Non-Invasive Testing/Intervention):

- Application: 2 copies (signed original plus 1 copy)
- Patient Information Sheet and/or Consent forms * 2 copies (original plus 1 copy)
- Questionnaires, etc.
(* English version only)
(Once the English version has been approved by the OHREB, the French version may be submitted.)
- Departmental Impact Sheet with applicable attachments 2 copies (signed original plus 1 copy)
- Detailed Budget 2 copies (original plus 1 copy)
- Protocol 2 copies (original plus 1 copy)

N.B. All documentation must be typed. Incomplete protocols will be returned prior to review.

TIPS

The forms have been created in Word, using the Forms tool to allow ease of use in completing them. The following are a few tips on completing the document:

- Please use the "TAB" key to move between fields.
- The "Enter" key will create extra space in the form that is not required.
- The form fields will not accept formatting, normal type will be fine.
- It is hoped that you are able to complete the form in the space allocated, however, if you need additional space, please insert a page where appropriate.
- If you have suggestions to improve this form, please let us know.

Protocol Submission

The application form, the protocol, investigator's brochure, the consent form, patient information sheet, budget, questionnaires and any other material described above should be submitted to:

Ottawa Hospital Research Ethics Board
c/o Ms. Christine Banyard
Ottawa Hospital, Civic Campus
751 Parkdale Avenue
Suite 106
Ottawa, Ontario K1Y 1J7

or

Ottawa Hospital Research Ethics Board
Drop Box Location: Room 1812-A (in the CEP area on the main floor)
General Campus – Ottawa Hospital
501 Smyth Road, Box 201
Ottawa, Ontario
K1H 8L6

To confirm whether or not we have received your correspondence, or to request a copy of lost correspondence, please contact:

Ida Pietrantonio
Protocol Officer
613-798-5555, extension 13523

or

Jennifer Munroe
Ethics Clerk
613-798-5555, extension 17523

For information on the status of your protocol up to and including initial approval, please contact:

Christine Banyard
Secretary, Research Ethics Board
613-798-5555, extension 14902

For general inquiries about research ethics including the status of revised information sheets, amendments, renewals, terminations, etc., please call:

Patricia Sorgat
Protocol Officer, Research Ethics Board
613-798-5555, extension 14146

For information on procedural issues, problematic protocols, compensation clauses, OHREB document changes, etc. please contact:

Mary Ann Laviolette
Ethics Co-ordinator
613-798-5555, extension 15072

For information on and requests for clinical research space, please contact:

Janet Whyte
Clinical Research Manager
613-798-5555, extension 12681
jwhyte@ohri.ca

The Chair of the OHREB is:

Raphael Saginur, M.D.
613-798-5555, extension 14902

The Vice-Chair of the OHREB is:

Francine F-A. Sarazin, Ph.D., C.Psych.
613-798-5555, extension 14902

Protocols **must be signed by the Head of the Department or Division** in which the research projects are to be carried out. (**The Principal Investigator or Co-Investigator should not sign** as the Head of the Department or Division for their own research studies)

Protocols will be reviewed on a bi-monthly basis at the OHREB meeting. Please refer to the list for the exact submission deadlines listed under 'Meeting Dates'.

Protocols submitted for '**Expedited Review**' are normally processed within two to four weeks of submission. Applications may be submitted at any time – **the submission dates do not apply** to 'expedited' studies.

Protocols submitted for '**Chart Review**' are normally processed within 24 to 48 hours of submission. Applications may be submitted at any time – **the submission dates do not apply** to 'chart review' studies.

RESEARCH ETHICS APPLICATION
NOTE: ALL DOCUMENTATION MUST BE TYPE WRITTEN.
Use the "TAB" key to move between fields.

1. PROTOCOL TITLE

Early active motion versus intermittent wrist immobilization following open carpal tunnel release surgery.

2. PRIMARY INVESTIGATOR FOR MULTICENTRE TRIALS

Last Name		First Name	
Title/Position		Department & Location	
Tel.			
Email		Fax	

3. PRINCIPAL INVESTIGATOR AT THE OTTAWA HOSPITAL

If the Principal Investigator does not hold an academic appointment, indicate who the responsible investigator will be.

Last Name	Rockwell	First Name	Gloria
Title/Position	Assistant Professor, University of Ottawa	Tel.	(613)736-6555 ext.
		Fax	(613)736-1822
Dept/Unit & Location	Department of Surgery The Ottawa Hospital – Riverside Campus Office: 1919 Riverside Drive, Suite #401	Email	info@plasticsurgerymd.ca
Division/Portfolio	Plastic and Reconstructive Surgery	Signature:	

4. CO-INVESTIGATORS AT THE OTTAWA HOSPITAL

Last Name	Benoit	First Name	Paul
Title/Position	Assistant Professor, University of Ottawa	Tel.	(613) 526-5945 ext.
		Fax	(613) 526-2391
Dept/Unit & Location	Department of Surgery The Ottawa Hospital – Riverside Campus Office: 1385 Bank St, Suite #505	Email	paulrbenoit@gmail.com
Division/Portfolio	Plastic and Reconstructive Surgery	Signature:	

Last Name	Bell	First Name	Michael
Title/Position	Assistant Professor, University of Ottawa	Tel.	(613) 739-5424 ext.
		Fax	(613) 739-7168
Dept/Unit & Location	Department of Surgery The Ottawa Hospital – Riverside Campus Office: 1919 Riverside Drive, Suite #402	Email	msgbell@cyberus.ca
Division/Portfolio	Plastic and Reconstructive Surgery	Signature:	

Last Name	Allen	First Name	Murray
Title/Position	Assistant Professor, University of Ottawa	Tel.	(613)521-6078 ext.
		Fax	(613)521-6596
Dept/Unit & Location	Department of Surgery The Ottawa Hospital – Riverside Campus Office: 1385 Bank St, Suite #415	Email	Murray.allen@rogers.com
Division/ Portfolio	Plastic and Reconstructive Surgery	Signature:	

Last Name	Jarmuske	First Name	Mario
Title/Position	Assistant Professor, University of Ottawa Chief, Plastic Surgery	Tel.	(613)737-8899 ext. 73047
		Fax	(613)737-8676
Dept/Unit & Location	Department of Surgery The Ottawa Hospital – General Campus Office: Module S, Room S6 501 Smyth Road, Ottawa, ON	Email	mjarmuske@toh.on.ca
Division/ Portfolio	Plastic and Reconstructive Surgery	Signature:	

If you need more space an additional form for co-investigators is available on the website.

APPROVAL BY INVESTIGATOR'S DEPARTMENT/DIVISION HEAD/**CLINICAL MANAGER/CHIEF** (THIS SHOULD NOT BE THE PRINCIPAL INVESTIGATOR AND/OR CO-INVESTIGATOR)

Hospital and university division and department administrators are responsible for academic activities within their unit, and may provide guidance and support to investigators. The purpose of this signature section is to ensure that administrators are aware of research activities and the impact of these activities.

- ☐ The study answers a reasonable scientific/clinical question and is consistent with hospital/faculty policies and mission.
- ☐ The study resources (budget, space, support staff) are adequate to support the study.
- ☐ The local investigators are qualified to perform the study.
- ☐ There are an adequate number of research participants suitable to be approached for enrolment for this study. This population is not already over-subscribed in clinical research.

I have reviewed this application and agree it should be submitted for ethics approval.

Name	Dr. Eric Poulin	Contact Number : 613-737-8899 ext. 71763
Title/Position	Wilbert J. Keon Chair of the Department of Surgery	Signature
Dept/Unit & Location	Department of Surgery (General Surgery) The Ottawa Hospital – General Campus 501 Smyth Ottawa, ON K1H 8L6	
Date		

6. REVIEW TYPE

Please indicate whether you are requesting full or expedited review. (Please see our website www.ohri.ca/ohreb for more information on what qualifies for expedited review.)

☐	Full Review
☒	Expedited Review

7. STUDY TYPE

Describe the Research Project by checking as many of the following as apply:	
Study Type:	
☐	Investigator driven and sponsored by OHRI
☒	Experimental Research/Clinical Trial
☐	Observational Research
☐	Pilot
☐	Sequel to previously approved project (Protocol # : ____)
☐	Genetic Research (Addendum 1 <u>must</u> be included with completed application)
☐	Program Evaluation
☐	New therapeutic method
☐	Medical Device Research Please attach a letter from sponsor indicating Health Canada application/approval.

	This is mandatory prior to final REB approval.			
	☐	Health Canada Application/Approval is attached (insert as next page)		
	☐	Health Canada Application/Approval will be forwarded.		
Location of the Study:				
☒	Single Centre Trial		☐	Multicentre Trial
Study Design:				
☒	Randomized, controlled trial			
☐	Phase I	☐	Phase II	☐
		☐	Phase III	☐
☐	Open Label	☒	Single Blinded	☐
			Double Blinded (or more)	
☐	Case-Control study			
☐	Cohort study			
☐	Interview, survey or questionnaire, observation			
☐	Chart Review			
☐	Compassionate Use			
☐	N of 1 Study			
☐	Quality Assurance			
Drug Study: ☐ Yes ☒ No				
☐	Involves unusually elevated doses of available drugs			
☐	Involves anticipated high incidence of toxicity			
☐	Drug being used for currently approved indication			
☐	Approved Drug being used for a non-approved indication Please attach a letter from sponsor indicating Health Canada application/approval. This is mandatory prior to final REB approval.			
	☐	Health Canada Application/Approval is attached (insert as next page)		
	☐	Health Canada Application/Approval will be forwarded.		
☐	Investigational non-approved drug: Please attach a letter from sponsor indicating Health Canada application/approval. This is mandatory prior to final REB approval.			
	☐	Health Canada Application/Approval is attached (insert as next page)		
	☐	Health Canada Application/Approval will be forwarded.		

8. PURPOSE AND OBJECTIVES

Please state clearly the hypothesis to be tested, in lay terms. Does two weeks of post-operative intermittent splinting (versus no splinting) improve patient satisfaction and hand function at 2, 6 and 12 weeks following open surgical carpal tunnel release in patients with clinically and/or electrophysiologically confirmed moderate to severe idiopathic carpal tunnel syndrome?

Provide the rationale for the study.

Carpal tunnel syndrome is the most common entrapment neuropathy, affecting approximately 3% of adults. Surgical decompression for advanced symptoms of carpal tunnel syndrome is performed on approximately 500,000 North Americans per year. Despite the frequency at which this procedure is performed, very little evidence exists to guide post-operative therapy.

Splinting of the wrist is performed in approximately 50% of patients following open carpal tunnel release in Canada. Immobilization of the wrist with a splint following surgery is thought to minimize or prevent bowstringing of the flexor tendons, wound dehiscence, and scar tenderness. Bowstringing refers to a rare complication (<1% in reported literature) where the nerve becomes entrapped in scar tissue superficially just beneath the skin.

Patients that are not splinted following surgery are encouraged to begin exercise as early as possible. Early mobilization of the hand and wrist is thought to minimize the very common complaints of stiffness and swelling in the hand. It is thought that if swelling and stiffness can be minimized in these patients, an improved outcome may result.

Previous studies investigating the utility of splinting after open carpal tunnel release have shown mixed results. Some studies suggest it to be beneficial, while others conclude that it has no effect on outcome over early motion (no splinting). Previous studies comparing post-operative management of patients have suffered from a number of methodological errors including poor study design and small sample size. Due to the conflicting evidence that exists, approximately 50% of hand surgeons in Canada splint post-operatively, while the remaining surgeons do not use splinting after surgical decompression.

In this study, we will acquire sufficient data using a well designed randomized clinical trial to provide adequate evidence to answer this important clinical question.

STUDY DURATION	Start Date : 01/01/2009 DD/MM/YYYY	End Date : 01/01/2010 DD/MM/YYYY
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9. RECRUITMENT

Describe how these research participants will be identified and recruited. **(Only members of the participant's health care team should contact patients at the Ottawa Hospital.)**

In addition, please ensure you address the following:

- If initial contact is by letter or if an **advertisement** is to be used, attach a copy.
- How will the researcher ensure that there are no breaches of patient **privacy**?
- How will the possibility of **coercion**, duress or undue incentive be avoided or minimized?

Eligible patients will be recruited from the current waiting lists of all involved investigators. Currently there is a waiting list of patients available for each of the investigators that will allow us to reach the calculated sample sizes. Patients will not be recruited by a letter or advertisement but will be notified either at the time of their consultation prior to surgery or by a telephone call prior to surgery. All patients will have the opportunity to ask questions regarding the study at the time of their consultation prior to surgery. Patients will be able to accept or decline the offer to enroll at any point.

Patient privacy will be maintained throughout the study. In addition to following standard hospital privacy policies, we will ensure that all identifying information is removed from patient data from treatment through to analysis and publication. This will be an important aspect of our study both for patient privacy as well as to maintain blinding throughout the study.

All patients enrolled in this study will be provided with information with the consent package that clearly describes the fact that they will be randomly placed in either the treatment or control group while also stressing that there is currently no evidence in the literature to suggest an improved outcome in either group. It will also be made clear to the patient that enrollment or refusal to enter the study will have no impact on their medical treatment and will not affect when they receive their treatment (patients will not be offered an earlier time for surgical decompression by entering the study). Monetary incentives will not be provided to the patients and therefore enrollment will be a personal decision with no undue incentive to enroll in the study.

Are recruitment incentives provided? ☐ Yes ☒ No
If yes, please describe.

Are controls involved? ☒ Yes ☐ No

Does the study include subjects in a control group? ☒ Yes ☐ No

If controls are involved, if their selection and/or recruitment differs from the above, provide details.

Patients in the control group (no splinting post-operatively) will be recruited in the same way as other patients and will be randomized after they have agreed to participate in the study and immediately following surgical decompression.

Does the research include research participants who may not be competent to give informed consent? ☐ Yes ☒ No If yes, justify and explain how consent will be obtained and from whom.

- Number of Centres recruiting globally: **1**

☒ National Study – Country **Canada Only**

☐ International Study – Country

- Total number of research participants being recruited at all centres globally: **370**

- Number of research participants to be recruited at each Ottawa Hospital campus:

☐ Civic

☒ General
60

☒ Riverside
310

☐ Other

Provide the rationale for the selected sample size and the methodology used to calculate the sample size:

Sample Size Calculation

We used the following equation to determine group size: $N_{\text{per group}} = 2(Z_{\alpha/2} + Z_{\beta})^2 (\sigma/\delta)^2$

- Estimated variability in the control (σ): 15%
- Estimated minimally clinically important difference (δ): 5%
- Type I error α 2 sided : 5%
- Power $1 - \beta$: 80%
- Estimated percentage lost to loss to follow-up ($\emptyset$): 15%
- $N_{\text{adjusted}} = n / (1 - \emptyset)$

Using the above calculation, with the estimated effect size and variability in results, we calculated that we would require 185 participants in each of the 2 groups once a dropout rate of 15% was incorporated. Therefore, we suggest that each group has 185 participants, resulting in a total of 370 patients in this study.

10. DESCRIPTION OF POPULATION

Inclusion Criteria - Who is being recruited and what are the criteria for their selection?

In this study, we will recruit patients with clinically and/or electrophysiologically confirmed diagnosis of carpal tunnel syndrome using criteria that have been widely used in the past and are well accepted. Only those patients that fulfill the following criteria will be included in this study:

- Clinically confirmed diagnosis of moderate to severe carpal tunnel syndrome
 - symptoms of numbness and tingling nocturnally or with use in the distribution of the median nerve
 - Positive Tinel's sign, Phalen's sign, Durkan's sign, moving two point discrimination, or decreased thenar muscle strength
- Electrophysiologically confirmed diagnosis of carpal tunnel syndrome will be used if available to confirm the clinical diagnosis. If the patient does not have a completed nerve conduction study, treatment will not be delayed if a clear clinical diagnosis exists based on the surgeon's examination. If nerve conduction velocity is available, moderate/severe carpal tunnel will be defined using the following parameters:
 - Median nerve sensory nerve conduction velocity <41.9 m/s in patients less than 55 years old or median nerve sensory conduction velocity <37.3 m/s in patient greater than or equal to 55 years old
 - Distal Sensory Latency of the index finger >3.5 ms
 - median nerve distal motor latency >4.34 ms
- Patients over 18 years of age
- Able to communicate verbally and comprehend and complete written questionnaires in English

Exclusion Criteria - What research participants are excluded from participation?

In this study, we will exclude patients with specific criteria that could confound the results of the study. Patients will be excluded from the study if they possess any of the following criteria:

- Workers compensation board patients
- History of:
 - Recent wrist trauma (<3 months)
 - Previous carpal tunnel release on the same hand

11. DESCRIPTION OF METHODS AND PROCEDURES

If additional space is required, insert one additional page)

Summary of Methods and Procedures. Please include a summary of the following:

- any specific manipulations;
- type, quantity, and route of administration of drugs and radiation; operations; tests; use of medical devices that are prototype or altered from those in clinical use;
- type, and number of interviews or questionnaires; are the questionnaires validated, reliable and have they been pilot tested?
- Are procedures/treatments standard practice or new, what is the risk level?

(Flow diagrams and point form discussion are encouraged and should be appended separately.)

Procedure/Treatments

All procedures performed in this study will be standard practice with no variation from the currently accepted standard of care. Carpal tunnel release will be performed under local anesthesia in an outpatient setting according to currently accepted guidelines. All patients enrolled in this study will undergo identical procedures to those already used at The Ottawa Hospital for surgical carpal tunnel release. Differences between the treatment and control arms in this study will be limited to the presence or absence of intermittent splinting in the two weeks following surgery. Patients will be assigned to each group randomly.

Additional requirements of patients in this study will be to fill out the questionnaires prior to surgery and during each follow-up visit and to perform some basic hand strength tests during consultation and post-operative visits. The questionnaires are described below and require less than ten minutes of the patient's time to complete. The strength tests to be used in this study are very simple and require less than two minutes on each visit. The test that will be performed is abductor pollicis brevis strength using a handheld measuring device in both hands of the patient.

Medications

Medications used in this study will not differ from those currently used for carpal tunnel release and will include:

- Local anesthesia and median nerve block – This varies slightly by surgeon preference but typically would include approximately 10ml of a mixture of Lidocaine with epinephrine (50%) and Bupivacaine (50%)
- Pain control post-operatively – Patients will be provided a prescription for pain medication as per surgeon's standard routine. One common prescription provided, if needed, is for Tylenol #3 although pain medication will not be limited to only this. Pain medication use will be recorded in this study to ensure it is not a confounding factor.

Questionnaires/Rating Scales

In this study, we will use two questionnaires to assess hand function pre- and post-operatively. Validity and reliability of these questionnaires has been demonstrated in previous studies and the investigators in this study have experience using these questionnaires in the past.

1. Boston Carpal Tunnel Questionnaire - A disease specific questionnaire that is the most commonly used outcome measure in carpal tunnel syndrome studies. This questionnaire includes two main components; a symptom severity score and a functional status score. The validity of this questionnaire has been well documented, with scores on the questionnaire being highly correlated to objective measures of outcome. Additionally, the reliability of this questionnaire has been proven with excellent test-retest correlation in patients with carpal tunnel syndrome.
2. DASH (Disabilities of the Arm, Shoulder, and Hand) - This questionnaire provides simple questions with responses scored on a number scale and has been used widely in the past for assessing carpal tunnel patients. This test is heavily weighted on daily activities and can be used to assess the return of hand function following surgical decompression.

12. RISKS

Describe the discomfort or risks that participants may incur as a result of their participation in this research. Also note the following:

- particular risks associated with each procedure, drug, test or other aspect of the protocol.
- delineate, when appropriate, what risks relate to standard care,
- what risks relate to participation in the study.
- quantify risks where possible by providing percentages, or by describing as rare, common, etc.

There will be no additional known risk introduced to patients who are enrolled in this study.

Currently accepted risk and complications from carpal tunnel release are rare (<5% of all patients) and well documented. The most significant risks include damage to the median nerve, ulnar nerve, or recurrent branch of the median nerve during surgery. Other possible complications resulting from open carpal tunnel release are infection of the surgical site, significant scarring, lack of improvement in symptoms, pillar pain, hypersensitive scars, wound dehiscence, pain, swelling, stiffness and bowstringing. There is no reason to expect any increase in the incidence of these risks and complications for patients enrolled in this study.

Will the management of the participant's condition be prolonged or delayed as a result of the research? ☐ Yes ☒ No

If yes, explain, specifying any risks associated with prolongation or delay.

Are there any standard therapies, diagnostic procedures or information to be withheld from participants for the purpose of the study? ☐ Yes ☒ No

If yes, explain, specifying the risks and benefits to the participants and justify.

Are there stopping rules for the study? **(This does not apply to individual patient withdrawal, but to the study as a whole)** ☐ Yes ☒ No

If yes, please describe.

An interim analysis will be performed after collecting data from approximately 185 patients. Data will be assessed to determine if a significant difference exists between the treatment and control group. If evidence exists that shows one group with a significantly better outcome, this information will be provided to all patients enrolling in the study.

Is there a data safety monitoring board in place? ☐ Yes ☒ No

If yes, describe the composition of the board.

What procedures in this protocol are additional to those required for **routine** patient care? **(Include the Impact Sheet with applicable attachments for all procedures which are attributable to this study)**

Since both arms of this study are currently accepted standard of care for patients following surgical carpal tunnel decompression, there will be very minimal additional resources required for this study.

The only additional procedures required in this study will be the measurement of abductor pollicis brevis strength and questionnaire completion at each of the follow-up visits. Assessments will be performed during regularly scheduled follow-up visits and will not require any additional appointments or resources. One additional set of questionnaires will be completed by patients at home and returned by mail to the principal investigator's office at approximately three months after surgery. Additional costs required for this study will include the cost of the splint for patients in the treatment arm that do not have an appropriate splint pre-operatively.

Is a placebo used? ☐ Yes ☒ No

If yes, please justify:

13. POSSIBLE BENEFITS

Describe any possible benefits to the participant as a result of their participation in this research.

Individually, there are no direct benefits to the patients enrolled in this study. Due to the conflicting evidence in the literature, there is no distinct benefit known for patients enrolled in either the treatment or control arm of this study. Splinting is thought by some to minimize or prevent a number of complications that include bowstringing of the flexor tendons (a rare but serious complication in <1% of patients where the nerve becomes entrapped in scar tissue) whereas early mobilization after surgery is thought to minimize the much more commonly observed complications of stiffness and swelling in the hand. Upon completion of the study, we will have a conclusive answer to determine whether there is any benefit to splinting versus early motion following carpal tunnel release surgery. Completion of this study will have a significant impact on the post-operative management of carpal tunnel syndrome patients in the future.

14. CONFIDENTIALITY

How will data be protected against breaches in security/privacy? If the information will be housed in a database, will it be password protected? There should not be any patient identifiers such as hospital unique number, OHIP #, etc. (An independent study number should be assigned to each patient, and the link between the patient and the study number housed separately and securely) Will there be written documentation kept? If so, how long will the information be kept? Where? Who will have access? **It is the policy of the OHREB that no records with the patient's name leave the Ottawa Hospital. For all drug studies, records must be kept by the investigator for a period of 25 years as outlined in Health Canada's Food and Drug Regulations, Division 5 – Drugs for Clinical Trials Involving Human Subjects, Section C.05.012. For all other studies, records must be kept by the investigator for a period of 15 years.**

All patient files will remain at The Ottawa Hospital and the investigator's office throughout the study and will not leave the property. Files will be accessible only to those individuals involved in the study (research coordinator, medical student, principal investigator). Following completion of the study, all files will be retained by the principal investigator for a period of 15 years at which point they will be destroyed and removed by a document shredding company. Research documents will be available for auditing by members of the OHREB and OHRI at all times. Prior to any data analysis, all identifying information will be removed from the study data with only a unique study number used to identify each patient. All electronic records with identifying information, including the link between each patient's study number and their identity will be password protected, encrypted, and maintained on a computer at the principal investigator's office. By following these procedures, patient privacy and blinding of the analysis will be maintained throughout the study.

15. BUDGET

Has this research been funded? ☐ YES ☒ NO	
☐ If <u>YES</u> provide the: Name of the Agency/Sponsor: Amount of funding received: \$	☒ If <u>NO</u> complete the following: Has funding been applied for: ☐ YES ☒ NO Name of the Agency/Sponsor: The Ottawa Hospital – Department of Surgery (<i>An application has been submitted – deadline was November 1, 2008</i>) Amount of funding applied for: \$ <u>25,000</u> Date submitted: <u>31/10/2008</u> DD/MM/YYYY
If no funding has been applied for, how will the research be supported? A \$5,000 scholarship has been awarded to Blake Murphy (medical student) through the University of Ottawa, department of medicine. This covered three month's salary to help with the organization and study design. The student will assist with the follow-up assessments of patients in this study. Additionally, the principal investigator (Dr. Gloria Rockwell) currently employs a research assistant that will be involved in the study.	
If the study was peer-reviewed, please provide the name of the individual or agency that completed the review.	
Does the industry-sponsored budget contain appropriate overhead?	☐ YES ☐ NO ☒ N/A
☐ A Clinical Trial Agreement has been forwarded to the Contracts Officer	
☐ A Clinical Trial Agreement is attached to the OHREB application	
Have you included a budget summary for the protocol?	☒ YES ☐ NO ☐ N/A
(If this is not included, approval of protocol will be delayed. Details on the disbursement of any excess funds received for this study should also be provided.)	
Does the REB review fee apply to this study?	☐ YES ☒ NO ☐ N/A
☐ A cheque is enclosed	
☐ An invoice request is enclosed	
☐ A transfer request is enclosed	
(All industry sponsored research projects are subject to a \$2,000.00 administration fee, and any cooperative group studies that are funded in excess of \$3000 per patient.)	

POTENTIAL CONFLICTS OF INTEREST

Please indicate if you have a conflict of interest or separate financial agreements with the sponsor of this study.
If yes, please explain.

☐ YES ☒ NO ☐ N/A

16. STAFFING

What staffing will be required? All staff should be listed and this list maintained during the course of the study.

This includes research nurses, research coordinators, etc. Research nurses should provide a copy of their Nursing Certificate for the current year, to the Research Services Office if this has not already been done for another study.

Name & Role in Study	Already Employed?	Full-time vs. Part-time	Office/Laboratory Location and Telephone Number If <u>new office or laboratory space</u> is required, the Space Planning & Management section of the Departmental Impact form must be signed and submitted Campus:
1. Blake Murphy, (Medical Student)	☐ YES ☐ NO	☐ FT ☒ PT	Office/Lab # 1919 Riverside, Suite 401 (613) 736-6555 x.
2. Jenny Grabowski (Research Assistant)	☐ YES ☐ NO	☐ FT ☒ PT	Campus: Office/Lab # 1919 Riverside, Suite #401 (613) 736-6555 x.
3.	☐ YES ☐ NO	☐ FT ☐ PT	Campus: Office/Lab # () - x.
4.	☐ YES ☐ NO	☐ FT ☐ PT	Campus: Office/Lab # () - x.
5.	☐ YES ☐ NO	☐ FT ☐ PT	Campus: Office/Lab # () - x.

In the space below please provide:

a) a list of their qualifications:

Blake Murphy

- BSc (hons) Kinesiology – Simon Fraser University (2002)
- PhD Medical Biophysics – University of Western Ontario (2006)
- M.D. program – University of Ottawa (Third year medical student)
- Various Research Assistant and Consultant positions - Neurostream Technologies (2002), Robarts Research Institute (2002 & 2007)

Jenny Grabowski

- Bachelor of Science
- Masters of Science
- currently employed by Dr. Rockwell as a research assistant and has considerable research experience with other investigators as well

b) a list of the duties to be performed, including delegated/sanctioned medical acts and acts performed under the Regulated Health Professions Act if this has not already been done for another study:

Blake Murphy will be partially responsible for the following:

- contacting patients by phone, email, or in the clinic to explain the research project and distribute questionnaires
- answering patient questions regarding the study or requirements of the study (e.g. questionnaires)
- collecting and analyzing data

Jenny Grabowski will be partially responsible for the following:

- contacting patients by phone, email, or in the clinic to explain the research project and distribute questionnaires
- answering patient questions regarding the study or requirements of the study (e.g. questionnaires)
- collecting and analyzing data



DEPARTMENTAL IMPACT

Protocol Title:

Early active motion versus intermittent wrist immobilization following open carpal tunnel release surgery.

Does the protocol require use Hospital and/or OHRI resources (equipment, staff, space) over and above those normally required in the standard care of a patient?

Equipment	☐ YES	☒ NO
Staff	☐ YES	☒ NO
Space	☐ YES	☒ NO

Will hospitalization or outpatient visits be required beyond what is required for standard care?

Outpatient Visits	☐ YES	☒ NO
Hospitalization	☐ YES	☒ NO

Indicate impacts associated with this Protocol, by Department:

IF YES is indicated, a signature of an individual authorized to sign for the department must be obtained. (Please see our website for a list of contact names <http://www.ohri.ca/ohreb/>)

Signature:

Nursing	☐ YES	☒ NO
Emergency Department	☐ YES	☒ NO
Health Records (See Appendix A)	☐ YES	☒ NO
Laboratory Services	☐ YES	☒ NO
Radioisotopes (See Appendix B)	☐ YES	☒ NO
Diagnostic Imaging (See Appendix B and C)	☐ YES	☒ NO
Pharmacy	☐ YES	☒ NO
Nutrition And Food Services	☐ YES	☒ NO
Space Planning & Management	☐ YES	☒ NO
Clinical Investigation Unit	☐ YES	☒ NO
Cardiopulmonary Services	☐ YES	☒ NO
Others:	☐ YES	☒ NO

Please submit signed Health Records form. www.ohri.ca/ohreb/forms.htm

Please submit signed Lab Impact form. www.ohri.ca/ohreb/forms.htm

Please submit Radiation Safety form. www.ohri.ca/ohreb/forms.htm

Please submit signed Diagnostic Imaging form. www.ohri.ca/ohreb/forms.htm

Please submit signed Pharmacy form www.ohri.ca/ohreb/forms.htm

