Nova Scotia Health Authority Research Ethics Board
Centre for Clinical Research, Room 118
5790 University Avenue
Halifax, Nova Scotia, Canada B3H 1V7
pamela.trenholm@nshealth.ca

August 08, 2016

Dr. Duncan Smith
Division of Orthopaedic Surgery
4554-1796 Summer Street
Halifax, Nova Scotia B3H 3A7

Delegated Review
Full Approval Letter
(August 08, 2016 to August 08, 2017)

Dear Dr. Smith:

RE: The incidence of heterotopic ossification following hip arthroscopy

NSHA REB ROMEO File #: 1021503

Thank you for your response regarding your proposed study.

Document Name	Comments	Version Date
Investigator Response/Revisions	Cover Letter for Addressing Clarifications Requested	2016/07/21
Researcher's Checklist for Submission	HO Study (checklist submitted 2016/08/04)	2016/07/21
Researcher's Commitment Form	Researchers Committments (SI) - Dr. Ivan Wong	2016/08/08
Research Protocol	v5	2016/07/21
Waiver of Consent Addendum	Updated Addendum with BMI and AGE added to OTHER (submitted 2016/08/04)	
Curriculum Vitae (CV)	Signed CV - Dr. Ivan Wong	2016/07/19
Certificate of Completion TCPS 2: CORE	Dr. Ivan Wong	2013/06/01

I have reviewed these documents on behalf of the Research Ethics Board (REB) and note that all requested changes have been incorporated.

I am now pleased to confirm the Board's full approval for this research study, effective today. This includes approval / favorable opinion for the following study documents:

Document Name	Comments	Version Date
Certificate of Completion TCPS 2: CORE	Duncan Smith TCPS-2: Core certificate of completion.	2016/05/27
Letter of Support	PI Letter of Support - Signed and Dated by Dr. William Oxner	2016/05/10
Letter of Support	SI Letter of Support - Signed and Dated by Dr. William Oxner	2016/05/10

Investigator Response/Revisions	**Cover Letter for Addressing Clarifications Requested**	**2016/07/21**
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Researcher's Commitment Form	**SI - Dr. Ivan Wong**	**2016/08/08**
Research Protocol	**v5**	**2016/07/21**
Waiver of Consent Addendum	**Updated Addendum with BMI and AGE added to OTHER (submitted 2016/08/04)**	
Curriculum Vitae (CV)	**Signed CV - Dr. Ivan Wong**	**2016/07/19**
Certificate of Completion TCPS 2: CORE	**Dr. Ivan Wong**	**2013/06/01**

Continuing Review

1. The Board's approval for this study will expire one year from the date of this letter **August 08, 2017.** To ensure continuing approval, submit a Request for Annual Approval to the Board 2-4 weeks prior to this date. If approval is not renewed prior to the anniversary date, the Board will close your file and you must cease all study activities immediately. To reactivate a study, you must submit a new Initial Submission (together with the usual fee) to the REB and await notice of re-approval.
2. Please be sure to notify the Board of any:
* Proposed changes to the initial submission (i.e., new or amended study documents or supporting materials),
* Additional information to be provided to study participants,
* Material designed for advertisement or publication with a view to attracting participants,
* Serious unexpected adverse reactions experienced by local participants,
* Unanticipated problems involving risks to participants or others,
* Sponsor-provided safety information,
* Additional compensation available to participants,
* Upcoming audits /inspections by a sponsor or regulatory authority,
* Premature termination / closure of the study (within 90 days of the event).
3. Approved studies may be subject to internal audit. Should your research be selected for audit, the Board will advise you and indicate any other requests at that time.

Important Instructions and Reminders

1. Submit all correspondence to Ethics Coordinator, Pamela Trenholm at the address listed at the top of this letter (do not send your response to the REB Chair or Co-Chair).
2. Login to the Research Portal; click Applications (Submitted - Post Review), browse through files to locate the study in which you wish to make revisions to; click the Events Button and choose the type of revision you wish to make from the table provided; complete the electronic form and attach document under the attachments tab if required and Click on the Submit button.
3. Be sure to reference the Board's assigned file number, Romeo No. 1021503, on all communications.
4. Highlight all changes on revised documents, and remember to update version numbers and/or dates.

Best wishes for a successful study.

Yours very truly,

David Macdonald, MD FRCPC
Co-Chair, NSHA Research Ethics Board

This statement is in lieu of Health Canada's Research Ethics Board Attestation:
The Research Ethics Board for the Nova Scotia Health Authority operates in accordance with:

- Food and Drug Regulations, Division 5 "Drugs for Clinical Trials Involving Human Subjects"
- Natural Health Products Regulations, Part 4 "Clinical Trials Involving Human Subjects"
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)
- ICH Good Clinical Practice: Consolidated Guideline (ICH-E6)

cc: Lisa Underwood, Director, Research Services

/pt