

Institutional Review Board statement

The local Institutional Review Board approved the study as indicated below.



The University of British Columbia
 Office of Research (Services) Ethics
 Clinical Research Ethics Board – Room
 210, 828 West 10th Avenue, Vancouver,
 BC V5Z 1L8

ETHICS CERTIFICATE OF EXPEDITED APPROVAL

PRINCIPAL INVESTIGATOR: Kelly A. Lefavre	INSTITUTION / DEPARTMENT: UBC/Medicine, Faculty of/Orthopaedics	UBC CREB NUMBER: H13-00098
INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:		
Institution	Site	
Vancouver Coastal Health (VCHRI/VCHA) Other locations where the research will be conducted: N/A	Vancouver General Hospital	
CO-INVESTIGATOR(S): Gerard Slobogean Peter J. O'Brien		
SPONSORING AGENCIES: N/A		
PROJECT TITLE: Digital blinding of radiographs to mask treatment allocation of distal femur fractures		

THE CURRENT UBC CREB APPROVAL FOR THIS STUDY EXPIRES: March 1, 2014

The UBC Clinical Research Ethics Board Chair or Associate Chair, has reviewed the above described research project, including associated documentation noted below, and finds the research project acceptable on ethical grounds for research involving human subjects and hereby grants approval.

This approval applies to research ethics issues only. The approval does not obligate an institution or any of its departments to proceed with activation of the study. The Principal Investigator for the study is responsible for identifying and ensuring that resource impacts from this study on any institution are properly negotiated, and that other institutional policies are followed. The REB assumes that investigators and the coordinating office of all trials continuously review new information for findings that indicate a change should be made to the protocol, consent documents or conduct of the trial and that such changes will be brought to the attention of the REB in a timely manner.

DOCUMENTS INCLUDED IN THIS APPROVAL:	APPROVAL DATE:															
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Document Name</th> <th style="width: 15%;">Version</th> <th style="width: 25%;">Date</th> </tr> </thead> <tbody> <tr> <td colspan="3">Protocol:</td> </tr> <tr> <td>Protocol</td> <td style="text-align: center;">5</td> <td style="text-align: center;">December 3, 2012</td> </tr> <tr> <td colspan="3">Consent Forms:</td> </tr> <tr> <td>Consent</td> <td style="text-align: center;">2</td> <td style="text-align: center;">March 1, 2013</td> </tr> </tbody> </table>	Document Name	Version	Date	Protocol:			Protocol	5	December 3, 2012	Consent Forms:			Consent	2	March 1, 2013	March 1, 2013
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CERTIFICATION:

In respect of clinical trials:

- 1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.*
- 2. The Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.*
- 3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.*

The documentation included for the above-named project has been reviewed by the UBC CREB, and the research study, as presented in the documentation, was found to be acceptable on ethical grounds for research involving human subjects and was approved by the UBC CREB.

Approval of the Clinical Research Ethics Board by one of:

Dr. Peter Loewen, Chair
Dr. Stephen Hopton Cann, Associate Chair