Date: July 3, 2014 at 1:54:11 PM PDT	Print	Close

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

H09-02860-A007 **TAMER: study team member additions (Version 0.1)**

Principal Investigator: Karon E. MacLean

Post Approval Activity Options [View Form]

Select one of the following options to submit to the Research Ethics Board based on the guidelines listed on the right:	Amendments to Study
Nickname Enter a nickname for this PAA. What would you like this PAA to be known as to the Principal Investigator and study team? (If you are notifying the REB of a protocol deviation or an unanticipated event or local serious adverse event please include the words protocol deviation or unanticipated event or local SAE as applicable in the nickname)	TAMER: study team member additions

Amendment to the Study - Clinical NEW [View Form]

1.1 Proposed changes to study 1.1. Briefly describe the nature of the proposed change(s).	Added three new student members to study team: - Michael Phan-Ba (Master's student) - Laura Cang (Undergrad USRA; MSc in September 2014) - Jeff Allen (PhD student, beginning in September 2014). Removed members no longer connected with project or program: Pan, Van der Loos, Nejat, O'Brien 2014.07.02: Also removed Croft, Sefidgar. They have been on study in past, but are not involved moving forward. Since it is not appropriate that they appear on new consent forms, I have removed them from the approval as well. Consent Form and Study Invitation Letter have been updated to reflect the above changes.
1.2. Please explain the reason for the proposed change(s).	Incoming students have or will shortly join the research team.
2. Changes in Principal Investigator Will the Principal Investigator (PI) be changed on the study?	no
If Yes, you must select here and complete the form with signatures then add the form below by clicking Add. Select Add to attach the signed letter for changing the Principal Investigator.	
Select the new PI for the study. Once you hit Select, you can enter the PI's name, or enter the first few letters of his or her name and hit Go. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading. New PI for this study:	
3. Study Progress Describe the study progress, e.g. are	The study is ending its 'dormant' period (as described in last renewal) as we take possession of new apparatus and new student researchers have joined the team. We

there participants on treatment or follow-up only etc.	anticipate data collection to recommence in the next month or two.
4. Risks to Participants Indicate whether or not this amendment will result in any increase in risk or discomfort for the study participant. If so, please explain what these are and why they are required.	No change in risk.
5. Level of Review 5.1. Please review the guidance notes on the right and indicate whether this amendment qualifies for Minimal Risk/Delegated Review. Note that if this amendment requires Health Canada approval it does not qualify for delegated review.	yes
5.2. Is Health Canada Approval required for this amendment? (Please review the guidance notes to the right for further information.)	no
Additional Comments:	
6. Changes to the Consent Form/Process 6.1. Does this study involve the recruitment of human participants? If yes, answer 6.2. and 6.3. below.	yes
6.2. Are the amendments such that participants still to be recruited to the study will receive an amended consent form?	no
6.3. Will already enrolled participants be updated with any new information included in this amendment? Please provide your rationale below, including details of how and when participants will be re-consented, if applicable.	no
Details:	New student investigators have been added to the consent and invitation forms. Both version and dates have been updated. 2014.07.02: Consent and invitation forms now include ALL co-investigators, not just those directly involved in data collection and analysis at present stage of research.
Revised Proposal:	no
Revised consent and/or assent forms:	yes
Other revised or new document(s):	yes
If Yes, list each document(s) name and provide a brief summary describing the changes being made to that document. These changes must be highlighted /track changed in the revised document and uploaded into the appropriate sections of the application form after completing this coversheet.	New student investigators have been added to the consent forms. Both version and dates have been updated. (Study Participation Consent Form v1.6 - July 2, 2014.) We have also updated student investigator contact information in the study invitation letter. Version and dates have been updated. (Study Recruitment Letter v1.6 - July 2,2014.)
7.2. Are you adding any documents that have already been approved by the REB in order to bring your application up to date? If yes, list these documents below, clearly indicating the document name, version, and the PAA number during which it was approved.	No
End of PAA Coversheet [View Form]	
View Differences Click to view changes made in the body of the application	
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