

Amendment Request Form

- 1- REB File Number: _____
- 2- Study Title: _____ The Partnered Learning Project _____
- 3- Describe the proposed study amendment or modification with rationale. For each item, please specify whether it is **Minor** eg, administrative changes such as deleting the name of a co-investigator, or **Major** eg, change in sponsorship that causes the investigator to have a conflict of interest, adding an intervention such as additional blood tests, or any substantive change that will be made to the consent form.

Please note; commercial sponsors will be charged a \$500 REB review fee for amendments that require full Board review.

We would like to propose an additional consent form for students who participate in our first IPE placement, which will take place in the Burns Unit at the Hospital for Sick Children. This would be a minor amendment. This consent form will be used in place of Consent form #2 for Students, version date 2008-01-31. The new consent form will be used for the Burns Unit student placement only. Consent form #2 will still be used for all other student placements. This amendment would create a new Consent form #7, version date 2008-05-02 for Students (attached). Consent form #7 is identical to Consent form #2, except for changes to the section entitled "Observations" on page 2.

As outlined in our Research Ethics Application, IPE placement students will participate in the research in 3 ways: completion of a survey, allowing a researcher to observe their interactions with a clinical team member, and analysis of their anonymized final project. Because the Burns unit participated in the pilot team training workshop, we are not conducting observations on the unit as we will for other teams that participate in the study. However, a medical student who is participating in the student placement will do an auto-ethnography of her experience participating in the placement. She will not evaluate the placement, but rather she will record reflective observations of her own experience as a placement student and write a report based on these. There is no structured data collection form for the auto-ethnography. Standard ethnographic techniques for writing field notes will be used (Martyn Hammersley and Paul Atkinson, *Ethnography: Principles in Practice*, London: Tavistock, 1983). The student's research will be supervised by the Principal Investigator for the study, Lorelei Lingard. The student will record abbreviated field notes while participating in placement activities and afterwards she will produce a reflective auto-ethnography of her experience as a placement student.

The "Observations" section on page 2 of Student Consent form #2 currently reads:

We are also asking you to take part in this study by allowing a researcher to observe your interactions with your assigned clinical team member, should you be present during scheduled observations of that clinical team's regular work. A trained observer will record observational data regarding the team's collaborative practices. He or she may also, at convenient moments, ask for explanations of these practices. No names will be recorded in these observation notes; you will be identified by your role on the team only (e.g., "IPE student"). The observations will last for 2–3 hours and will take place 2–3 times per week. Observers will not interrupt the team's work and will not observe in individual patients' rooms.

We propose the creation of a new Student Consent form #7, which is identical to Student Consent form #2, except that the "Observations" section will read:

A medical student participating in the placement will take reflective notes on her own experience as a placement student. She will keep a reflective journal regarding her experience and perceptions of the team's collaborative practices. She may also, at convenient moments, ask about your

reflections on your experience as a placement student. No names will be recorded in these observation notes; you will be identified by your role on the team only (e.g., "IPE student").

4- Science Review: Science review may be needed for **major** amendments. If in doubt, please take advice with the REB Office. Please attach a copy of the completed science review form.

5- Will this amendment alter the study monitoring requirements?

No

Yes (please describe) _____

6- What follow up action do you recommend for HSC study subjects who are already enrolled in the study?

Inform study subjects ASAP

Revise the consent/assent forms (Please attach a copy with the changes highlighted)

Other (please describe)

No action Required

7- Does this amendment alter the level of monitoring required for this study? If uncertain, please discuss with the Clinical Research Office staff; xxxxx or xxxxxxxxxx.

Yes No Perhaps

8- If Health Canada approved the original protocol (effective September 2001), their approval may also be required for this proposed amendment.

9- If the study sponsor requires a formal letter of approval, please attach a draft letter and forward an electronic copy as well.

10- Signature of Primary Investigator _____ Date _____

11- Signature(s) of Co-Investigator(s)* _____ Date _____

*for Major amendments only

12- Signature of Clinical Chief
or Supervisor _____ Date _____

13- Approved & Signature of REB Chair _____ Date _____