Take mm name—take refs to consultants obgyn—note that the care is team based already-if the patient donest want to participate this simply means that they will not fuill out a survey and the old chart forms in use currently will be used

The patient only had a copy –all original records are heldp ny clinical care givers

August 9, 2010

Ms. Jennifer Murdock, RN, RM, MHSc Manager HHR, Department of Health Project Lead for AACHHR CLE Project 1690 Hollis Street PO Box 488 Halifax, NS B3J 2R8

Dear Ms. Murdock,

Re; Skills Building for Interpersonal Collaborative practice in Community Based Health Settings

Thank you for your submission of the above noted project to the GASHA Research Ethics Review Committee. The study was reviewed at our August 9, 2010 meeting. The study was **not approved.** There were a number of concerns identified with the proposal that need to be addressed or clarified. Please respond to this letter addressing the concerns and the study will again be reviewed.

I will try to address the concerns as specifically as possible by discussing each document that was submitted.

1) The Research Ethics Review Process Application
Appendices: The revised application now includes 17 appendices all of which
are described in the application and have been numbered on the documents
themselves. Appendix 9—Service Delivery forms –is a folder which contains
the group of forms.

Appendix 1 –The interview questions in appendix 1 are intentionally open-ended. The stakeholders are being asked to indicate what they know about the project and what concerns and issues they perceive as significant to the introduction of inter-professional (IP)care.

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Appendix 9- refers to folder containing multiple service delivery forms.

Page 6, section 7: three consent forms and one patient information guide have been submitted –appendices 10-12.

Sample size: we have added the following information to application:

The number of particpiants at each site will be determined by the number of practioners in the exisiting primary care materity team or by the potential team members willing to form such a team. There are no specific sample size objectives for the CLE project as this is a project to discover and evaluate implementation processes and facilitation of interprofessional team development-objectives that can be met even with a small team of primary care providers.

At St.Martha's a primary care maternity team has already been formed by a group of primary care practioners working at the site. This group will form the CLE clinical team.

Broader participation by hospital staff in the CREW Change Management process is anticipated and a separate consent form for this component of the project will be used (appendix 12).

Page 5, section 6, second paragraph notes the researchers will be collecting observations during clinical chart review meetings where patients will not be identified. It would seem to be somewhat difficult to have chart reviews without identifying the patient.

The researchers will instruct the team to refrain from using real names and establish a pseudonym at the beginning of each meeting—a standard practice when using case reviews in IP teams.

One addition to this revised ethics submission is the decision to ask for practitioner consent to have the meetings audio-taped. The practitioner consent has been revised to reflect this change. Data confidentiality section has also been revised.

2) Patient Consent: Collaborative Learning Environment Project Site
Withdrawing from the study at St.Martha's will not in any way effect care for patients.
The low risk obstetrical care is already being delivered in a team model and should a
patient chose not to continue to participate they would simply be dropped from the list of
participants and not be asked to complete satisfaction survey. The patient consent form
has been revised accordingly.

What is the assessed literacy level of this consent form?

We had the patient consent form reviewed by a Plain Language expert. It is at a grade ** level.

3) Practitioner Cons	ent: Collaborative	Learning	Environment I	Project
site:				

ne of the forms discusses the practitioner completing one survey on 2 occasions, at the beginning and end of the project. We assumed this to be the Practitioner Satisfaction Survey which was submitted with the project. Is this correct?

The second consent form discusses completion of a short needs assessment survey. Is this the CREW Survey or another survey that was not submitted with the proposal? This second form also mentions attendance at monthly Change Management sessions. Please elaborate as to what these would involve and are these the "inter-professional learning activities" that are discussed later in the document in the paragraph entitled "Benefits to you".

Please be more specific as to what activities you are asking the practitioner to participate in for this proposal. It would appear to be the following; using new forms to document patient's medical issues, complete at least 2 and maybe 4 surveys that include 2 separate consent forms, allow facilitators to record notes at inter-disciplinary clinical team meetings regarding the functioning of the team, attend monthly Change Management meetings and participate in monthly telephone interviews. Is this the extent of participation requested? Again, please be as clear and specific as possible as to what the expectations are for the participants. It would appear team leaders have other responsibilities as well.

Again, I am not prepared to be listed as a contact person.

4) Collaborative Learning Environment Well Women and low risk obstetrical clinic information guide.

Page 2, part 1- the section states that the "roles of Doctors and Midwives "are to be found on page 3 of the document. The paragraph at the bottom of page 3 seems to be the item you are referring to but this paragraph describes the regulatory bodies for these professions, not their roles as mentioned on page 2.:

This section is unnecessary and has been removed from the guide.

Page 2, part 111. About St. Martha's. The second item is "Tours" which is to be found on page 5. There is no mention of any tours of St. Martha's anywhere in the document. The tours are a regular part of the existing teams activity and not an expectation or newly introduced project activity. The Patient Information Guide was reviewed with two members of the existing clinical team for accuracy of its representation of care. As the tours are not something the CLE Project is introducing they are not included in the consent form.

At times, it is unclear if obstetricians are included as primary practitioners in the project. At times the documents indicate that they are part of the project (or you hope that they would be successfully recruited) and at other times they are listed as a consultant. Please clarify.

There is one obstetrician who is a member of the existing team. The Information guide simply explains to patients that they may under some circumstances be referred during the course of their care. The latter is again not an innovation of the CLE project but rather a standard practice of the care given by the existing clinical team.

5) **Practitioner Satisfaction Survey** – no concerns with this document.

6) Patient Satisfaction Survey

Prenatal care section, second question, perhaps you may want to reword this question in order to make it grammatically correct.

Hospital Postpartum section, first 2 questions. It there a reason that the questions were asked in this way, as they seem somewhat redundant?

Patient Record Binder section - It would appear that at some point in the project patients are responsible for some of their own medical records. Is this the usual practice for St. Martha's patients when receiving care on this unit or is this specifically for the project? If it is an expectation for the project it is not mentioned in either the Consent Form or the Information guide as an expectation for participants.

It is not a requirement or expectation and so was not included. Clinical Team members may chose to provide <u>copies</u> of records to their patients and ask them to bring them to each appointment with team members. We have revised the information guide to include this possible occurrence.

Website section:

This was an error casued by information left in the form from an earlier project. Reference to a website has been removed.

7) Partner for Inter-professional Cancer Education, Inter-professional Facilitator Competencies. This document was created as part of a Cancer Care program. How will this be used as part of or adapted for your project? The tool was published as a generic framework for use by others to assess IP Facilitation competencies. Are the facilitators staff that have special training and are considered competent in these areas? Are the facilitators staff that are hired specifically for this project with these competencies? Our IP facilitators have experience with IP education and were hired for that expertise. While they have not worked with this specific framework we have adapted it to the CLE IP tools we are using and our researchers have access to the authors of the IP Facilitator Competencies framework and will consult with them if they require assistance.

8) Consent form for CREW

Second last page, fifth line from the bottom, refers to the IWK, not St. Martha's. Last page, first paragraph. This timeframe has already passed. Third paragraph – who is Dr. Leiter? Again, omit my name.-

This is another consent form that outlines different expectations than the expectations that were outlined in the other Practitioner Consent form. The application form submitted to the committee does not clarify if you are selecting different groups of practitioners for the

different consent forms that detail different processes, or if you are expecting all of the practitioners participating in the project to meet the expectations of both consent forms. Are the Change Management sessions mentioned in the Practitioner Consent Form the same as the CREW meetings mentioned in the CREW Consent Form? This is all quite confusing.

9) CREW Canada Workplace Survey

Second page (first page of survey). What is meant by Therapeutics? Is this social work, occupational therapy, physiotherapy, psychology or other disciplines?

Third question- what does this mean?

10) Inter-professional Education protocol which mentions Appendix 1, a Readiness for Inter-professional Learning Survey which is not included with the submission and does not appear to describe the Appendix 1 that was described earlier which was described as Stakeholder Survey.

The other forms submitted for the project appeared to be fine. These included the following

- a) A letter entitled "To whom it may concern"
- b) An invitation letter to Community Practitioners
- c) The project agreement between Price- Macdonald and Associates consulting INC and GASHA
- d) CLE Process evaluation
- e) Observational IP Tool
- f) CREW Facilitator Report
- g) A series of forms that relate to patient care including
 - 1) Flow of work in an episode of care
 - 2) Community based practitioner chart discharge summary
 - 3) Patient appointment schedule and notes
 - 4) Baby's first days
 - 5) Case log
 - 6) Case Review Details
 - 7) Client intake

All of these forms appear to be the forms to be used as part of the documentation for the project (except for the Baby's first days form) and appear to be fine. However, it would have been helpful to link them explicitly to the application ie; the forms to be used for documentation are Appendix

This is a worthwhile project. However the proposal that was submitted was very poorly organized and inconsistent. This made it difficult to evaluate and raised many questions for the reviewers. Please respond to this letter and we will review the submission. In some ways it may be better to submit a whole new package as there as so many issues to be addressed however we will review your response.

Yours truly,

Mary Mac Farlane, MSW, RSW Chair, GASHA Research Ethics Review Committee 902-625-7200