

Long Application Submission Checklist

Please submit a single complete package for initial review by your Hospital For Sick Children (SickKids) Research Ethics Board (REB) Coordinator. Should the study require full Board review, the Coordinator will confirm how many copies will be required. The REB Coordinator will review the package to ensure that all items are included before you make copies.

(NB packages must be assembled in the order on this checklist with the application form on top)

- Completed typed application form (version date May 2007) including all necessary signatures
- A separate research proposal (NB commercial sponsors will provide you with the necessary copies confirmed by the REB Coordinator)
- Product monograph and/or investigator brochure (where applicable) (NB commercial sponsors will provide you with the required copies confirmed by the REB Coordinator)
- Questionnaire/study instrument(s)/case report forms to be used in carrying out the research (where applicable) (NB the collection of identifiable personal health information is prohibited in case report forms)
- Letter(s) of support from collaborating agencies/institutions (where applicable)
- Letter of support from academic committee/supervisor for student projects (where applicable)
- Evidence of REB approval in other jurisdictions where the research is to be conducted (where applicable)
- Itemized budget sheet
- Proof of award of funds (for grant funded research)
- Consent Form(s)/Assent Form(s) including separate forms for control subjects (conforming to the current SickKids REB consent form template)
- All other recruitment tools (e.g. information letters, advertisements, posters, notices). (If a website is being used to recruit subjects, please include the website address.)
- Completed scientific review, itemized response to recommendations by the scientific reviewers, signoff by scientific review committee Chair or reviewers on the itemized response
NB If funded by certain granting agencies (eg. CIHR, NIH) and no internal grant review occurred, a copy of the agency comments/scientific review is mandatory.

For more information, please visit our web site.

<http://www.sickkids.ca/ResearchEthicsBoard/default.asp>

Long Application for Ethical Approval of Studies Involving Humans

1. **PROJECT TITLE** The Partnered Learning Project

2. **PRINCIPAL OR QUALIFIED¹ INVESTIGATOR (MUST BE A PERMANENT SICKKIDS STAFF MEMBER)**

Name: Lorelei Lingard	Signature: _____
Department/Division: SickKids Learning Institute	Discipline (e.g., neonatology, social work): education
SickKids I.D. #:	

CO-INVESTIGATOR(S)

Name: Susan Tallett	Signature: _____
Institution: SickKids	Department/Division: SickKids Learning Institute
Position (e.g., physician, fellow): physician	Discipline (e.g., neonatology, social work): education
SickKids I.D. #:	

Name: Bonnie Fleming-Carroll	Signature: _____
Institution: SickKids	Department/Division: Nursing
Position (e.g., physician, fellow): nurse	Discipline (e.g., neonatology, social work): Nursing
SickKids I.D. #:	

Name: David Nicholas	Signature: _____
Institution: Sickkids	Department/Division: Social Work
Position (e.g., physician, fellow): Scientist	Discipline (e.g., neonatology, social work): social work
SickKids I.D. #:	

These signatures confirm that each investigator has read the proposal and agrees to conduct this study in compliance with the Tri-Council Policy Statement, the Personal Health Information Protection Act, 2004 (PHIPA), and any other applicable legislation and regulations, to adhere to the approved protocol, apply to the Hospital for Sick Children (SickKids) Research Ethics Board (REB) for approval of amendments, report adverse events to the REB, submit annual reports and cooperate with any monitoring activities determined by the REB.

3. **OTHER RESEARCH TEAM MEMBERS WHO ARE NOT CO-INVESTIGATORS** (names of individuals who will be accessing personal health information e.g. health records/Electronic Patient Charts (EPC) *Please print names (signatures not needed).*

Name(s) _____ **Position(s)** _____

¹ For clinical trials (drug, biologic, natural health product or device), must be an MD or DSS, registered in Ontario
 SickKids Research Ethics Board

4. **PRIMARY CONTACT NAME** Lorelei Lingard **Position** Scientist - SickKids Learning Institute / Research Institute

(To whom all REB correspondence will be sent. Please note that surface mail will only be sent to Hospital addresses)

EMAIL ADDRESS Lotus Notes Other lorelei.lingard@utoronto.ca

5. **ABSTRACT** (Approximately 500 words) This must be submitted in lay terms

There is growing recognition in clinical, educational, and policy domains of the need to improve the way that healthcare professionals collaborate. Effective collaboration across professional boundaries (e.g., physician and nurse) is critically necessary for effective care delivery, yet we provide little training for practicing teams toward improving their collaborative practices, and we expect pre-licensure trainees to learn how to collaborate with other professionals through a largely implicit process of trial and error. This application aims to target both levels -- practicing teams and pre-licensure trainees -- for explicit training in teamwork strategies, with the goal of improving both the collaborative delivery of care AND the way that collaboration is taught to trainees in clinical settings.

The 'Partnered Learning Project' is a multi-leveled curriculum designed to seamlessly develop interprofessional collaboration (IPC) in both pre-licensure trainees and health care providers. Two participant groups will be involved in this educational research project: practicing health professionals who work in team settings (including physicians, nurses, social workers, pharmacists and physical therapists) and pre-licensure trainees from 6 health professional faculties (medicine, nursing, social work, physical therapy, occupational therapy and pharmacy).

Healthcare professionals will participate in an 8-hour 'team training' curriculum based on existing educational tools in the team training domain. Entire teams consisting of approximately 12 individuals will be recruited for participation. The training will include case-based discussions, simulated team situations, and role play, facilitated by trained educators. The team training curriculum will be piloted in one SickKids team (neuro-oncology). Based on this pilot experience, the curriculum will be revised and implemented in two additional SickKids' teams (burns and trauma), two Toronto Rehab teams, and two teams at the Children's Hospital of Eastern Ontario. The outcome of this educational experience in all settings will be assessed using validated survey instruments (pre/post) (including staff satisfaction surveys, patient satisfaction surveys, and interprofessional attitude surveys), pre/post observations of teamwork in the clinical setting, and semi-structured interviews of patients and family members.

Pre-licensure trainees who volunteer for an elective "Interprofessional Education" placement in pediatrics will be assigned to learner groups for a 4-week placement. The placement will follow an established curriculum and evaluation procedure supported by the University of Toronto. Trainees will spend time shadowing members of a healthcare team that has received team training instruction, and an interprofessional Preceptor will meet with trainees weekly for structured discussion of their interprofessional placement experience. The outcome of the educational experience will be assessed using validated survey instruments (interprofessional attitude survey), semi-structured interviews with Preceptors, and an analysis of trainees' end-of-placement assignments.

6. **FUNDING & BUDGET**

Division/Department/ PI Committed funding Amount \$ _____
(includes discretionary funds, start up funds etc)

External funding – Non – industry: Amount \$413,000.00
(eg. Grants/donations/graduate student personal funds)

Funding source Health Force Ontario (Ministry of

Health)

(please include proof of award)

External funding - Industry: Amount \$ _____
(includes industry granting foundations)

The REB must be informed if funding for this study changes (e.g., a study sponsor is found).

Is industry involved in this study?

No (Please go to question #7)

Yes (Contact Corporate Ventures at ext. 7739 to determine if a contract/agreement is required)

What is the company's involvement?

Funding

Other (e.g., provision of drugs, devices or equipment)

Please describe _____

Is the study being initiated by the company?

No (A REB review fee line must be included in the final budget negotiated with the company for investigator-initiated studies)

Yes (The company will be invoiced for a REB review fee. Please provide the following company information)

Company Name: _____
Contact Person: _____
Mailing Address: _____
Email Address: _____
Phone #: _____ **Fax #:** _____

7. IS THIS A MULTICENTRE STUDY?

- No
 Yes (Please contact Corporate Ventures at ext.7739 to determine if a contract/agreement is required)

8. CONFLICT OF INTEREST DECLARATION BY PRINCIPAL INVESTIGATOR

EXPLANATION

Researchers hold trust relationships with research subjects, research sponsors, SickKids, their professional bodies, and society. Researchers, SickKids, and the REB are required to identify and address actual, potential, and perceived conflicts of interest (“Conflicts of Interest”) to maintain public confidence and trust, ensure the integrity of research, discharge professional obligations, and ensure accountability.

A Conflict of Interest does not necessarily imply wrongdoing, as a Conflict of Interest depends upon the circumstances, not on the character of the staff member.

A Conflict of Interest does not mean that the research cannot proceed. Many, but not all, Conflicts of Interest can be managed, but always require identification of the Conflict of Interest, disclosure to research subjects, and if required, other steps to manage the Conflict of Interest. It will be up to the REB to determine if the Conflict of Interest can be managed and if the proposed mitigation measures are adequate.

All Conflicts of Interest must be clearly identified by the Principal Investigator. The Principal Investigator is making this Declaration on behalf of himself/herself and the members of the research team (collectively referred to in the Declaration as “Researcher”)

Categories of Conflict or Potential Conflict of Interest:

There are many types of Conflict of Interest which may affect the research. The Conflict of Interest may arise in relation to the Researcher or a “Related Person” to the Researcher (e.g., spouse, domestic partner, immediate family member or close acquaintance). The categories of Conflicts of Interest include the following:

(i) Financial

The Researcher or Related Person stands to gain financially in the undertaking or outcome of research (e.g., share ownership in study sponsor, bonus for positive test results) outside the normal compensation of the Researcher.

(ii) Direct Status Benefit

The Researcher or Related Person stands to gain through direct rewards in respect of his or her status (e.g. career status) in the undertaking or outcome of research (e.g. promise of promotion for successful research). It is recognized that undertaking research will usually be viewed positively in terms of enhancing career advancement. The question is whether the link between the career enhancement and the outcome of the research is so strong as to bring into question the objectivity of the Researcher or the process and outcome of the research.

(iii) Undue Influence

The position of the Researcher or Related Person is such that the Researcher or Related Person may exert an undue influence over the research or influence or coerce research subjects, because of his or her position or the vulnerability of the research subjects. This

influence may be due to a personal or professional relationship between the affected individuals (e.g. a physician recruiting his/her own patients or the subjects are to be recruited from Researcher's students or employees).

(iv) Competing Interest

The Researcher may be influenced to draw conclusions against the interest of the sponsor or another interested party to the study because the Researcher or a Related Person has an adversity in interest related to the research (e.g. the Researcher has an interest in a competitor drug or product or the Researcher involved in litigation against sponsor).

DECLARATION - CONFLICT OF INTEREST

A. I have spoken with members of my research team and hereby declare that neither I nor (to the best of my knowledge) any members of my research team have an actual, potential or perceived Conflict of Interest with respect to the attached Application for Research.

(check this box if applicable)

OR

I have spoken with members of my research team and have identified a Conflict(s) of Interest with respect to this application for research in the following categories and as specified below. *(Please check all appropriate boxes and attach a separate sheet describing the conflict of interest in full detail).*

(i) Financial: Yes No Member with Conflict of Interest _____

(ii) Status: Yes No Member with Conflict of Interest _____

(iii) Undue Influence: Yes No Member with Conflict of Interest _____

(iv) Competing Interest: Yes No Member with Conflict of Interest _____

Details of Conflict of Interest: _____

B. *(If you have checked yes to any of the items in section A above, please complete sections B and C)* I intend to manage the Conflict(s) of Interest as set out below (e.g. disclosure in consent form, declining role/position with sponsor or additional monitoring strategies such as monitoring consent). **Please note Conflicts of Interest must be disclosed on the consent form.**

C. I have declared all Conflicts of Interest to the Research Institute. *(If you have not disclosed the Conflicts of Interest to the Research Institute or are not obliged to declare, please explain why.)* Please attach a copy of the Research Institute approval of the Conflict(s) of Interest.

Yes No N/A

D. Should a Conflict of Interest arise for me or any member of my research team during the course of the research, I shall declare this in writing to the Research Ethics Board.

Yes No

E. I hereby declare that I have read this Declaration, have discussed this Declaration with the members of my research team, and that to the best of my knowledge and belief, my responses are true and complete.

Name of Principal Investigator

Signature of Principal Investigator

Date

9. HEALTH CANADA APPROVAL

Does this study involve the use of an investigational new drug, biologic, natural health product or device, or the use of an approved drug, biologic, natural health product or device for a new indication (eg. new age group or disease entity) or in a new way (eg. new route or different dosage)?

No

Yes *Health Canada approval may be required. Please submit a copy of the Health Canada approval (or No Objection Letter) when available or contact the Clinical Research Office ext. 8481 for assistance in preparing an application or to obtain an email confirmation that this study is exempt*

10. SICKKIDS SCIENTIFIC PEER REVIEW

Documentation of all 3 items below must be enclosed prior to submission to Division or Department Head for signature.

Granting agency scientific review

(e.g. CIHR, NIH, NSERC, SSHRC, CCFF, MS & MD Societies, JDF, American Epilepsy Society)

(please note: nursing studies are not exempt from internal nursing scientific peer review)

OR

Internal peer review

Itemized response

Final reviewer(s) sign-off

disciplines involved in research	disciplines of investigators	disciplines of scientific reviewers
medical education	medical education	nursing
nursing	nursing	child health evaluative sciences
social work	social work	

11. SIGNATURES OF APPROVAL

I have reviewed and accept this proposal:

Division OR Department Head²: Name: _____ Signature: _____

Director Unit/Clinic (including CHS)³: Name: _____ Signature: _____

Division/Department Head⁴: Name: _____ Signature: _____

12. OBJECTIVES OF STUDY INCLUDING IMMEDIATE AND LONG TERM OBJECTIVE

(Must be written in lay language in this space; do not refer to appendix, grant or other material)

The study has several layers of objectives & potential outcomes and will be divided into domains.

² The signatures of Division or Department Heads, and of Clinic Heads who are named as investigators in this application are not accepted here; sign-off in such cases is done by an existing (e.g., not created specifically for this research project) deputy, or by the person to whom the Head reports for patient care matters

³ If you plan to use Child Health Services.

⁴ If different from investigators' departments.

Overall objectives & outcomes related to the overall Partnered Learning Project are to:

1. Integrate IPE/IPC across the education & professional spheres, yielding a model for simultaneous improvements
2. Develop & test a Partnered Learning Project module, yielding a toolkit & guidelines for adaptation to other settings
3. Create an outcomes database, to facilitate longitudinal assessment of impact over repeated implementations.

Objectives & outcomes related to the practice-based team training component are to:

1. Develop a team-training curriculum, yielding a toolkit for supporting IPC team training
2. Train 2 SickKids, 2 Rehab, and 2 CHEO teams in IPC roles & responsibilities related to transitions in complex care, promoting improved collaboration around "transition" points (where patient care is transferred between teams, division, or institutions)
3. Evaluate the impact of team training on learner, process & patient outcomes, producing evidence of effectiveness
4. Build capacity for pre-licensure IPE placements, producing a cadre of 6 trained teams for use in future placements

Objectives & outcomes related to the pre-licensure IPE placement component are to:

1. Adapt an existing MOH-funded IPE placement toolkit for pediatrics, yielding a UofT pediatric IPE placement & a provincial model for such placements tested at CHEO
2. Offer 6 IPE placements (Yr 2=2 SickKids, 2 Rehab, 2 CHEO), producing a cadre of ~36 students (6/placement) trained in IPE/IPC
3. Evaluate the placements' impact on student attitudes & knowledge, towards evidence of effectiveness
4. Train selected SickKids & CHEO faculty as IPE preceptors, creating a cadre to support ongoing IPE placements.

Long-term objectives are to:

1. Contribute to evidence-based models that link IPC and IPE
2. Foster a culture of sustainable IPC through effective IPE
3. Encourage a more effective, integrated healthcare system.

13. BACKGROUND, RATIONALE, SIGNIFICANCE

(Please limit to a few sentences)

The Romanow Report (2002) identified that more effective collaboration would be necessary to ensure the long-term sustainability of healthcare delivery in Canada. Internationally, the UK and the US have been leaders in developing models of how interprofessional collaboration should work. Few situated models of how IPC works in practice are available, and fewer models situate the link between IPC and IPE in the context of multisite, multicontext investigations across the care continuum. This project seeks to address the need for collaboration identified in the Romanow Report by developing situated, cross sectional research across the care trajectory at both the level of education and practice in order to address this need.

14. FOR CLINICAL TRIALS OF DRUGS, BIOLOGICS, NATURAL HEALTH PRODUCTS OR DEVICES, OR FOR RESEARCH INTO MECHANISMS OF DISEASE INVOLVING INVASIVE PROCEDURES:

Have the methods been used in the following subjects, and if not, is it feasible to do so?

	<u>It has been studied</u>	<u>It is feasible</u>	<u>No/ Not Applicable</u>
Adult experimental animals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Experimental animals at analogous stage of development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Adult humans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Older children where relevant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Healthy children	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. WHAT METHODS WERE USED TO CALCULATE SAMPLE SIZE?

The purpose of this study is both capacity building and descriptive. Thus, the sample size is based on the desire to train two teams per institution and provide two pre-licensure placements per institution, as well as to produce sufficient descriptive data to provide insight into the process and some early outcomes of these educational experiences. This is a mixed methods study, combining qualitative and quantitative methods. Qualitative samples (e.g., observations of teams; interviews with patients and families) will be determined using theoretical sampling, to explore emergent themes to saturation. Quantitative samples will be small, but will provide the basis for an ongoing database of satisfaction and attitudes data, for longterm evaluation of the impact of the educational program.

16. WHAT CONSIDERATIONS LED TO YOUR PROPOSED CONTROL GROUP (OR LACK OF ONE)? FOR TRIALS INVOLVING THE USE OF PLACEBOS, PLEASE EXPLAIN WHAT CONSIDERATIONS LED TO YOUR PROPOSED USE? (Please refer to the Tri-Council Policy Statement Part 7.4 for acceptable criteria)

N/A

17. HOW WILL THE DATA BE ANALYZED STATISTICALLY?

Evaluation of the educational program will employ both validated quantitative scales and rigorous qualitative methods. Analysis of covariance will assess change on continuous outcomes from validated surveys. As data accrue over repeated implementations in future, a team/time interaction effect will be able to be explored. Observational and interview data will be analyzed for emergent themes in a constant comparative manner, using analytical principles from grounded theory (Corbin and Strauss). Analytical rigor will be ensured through the use of an audit trail, member-checking, and analytical memo-ing.

18. IDENTIFICATION OF POTENTIAL RESEARCH SUBJECTS

Through one or more of the following (please specify):

- Physician/other care-giver of patient
- Health Record
- Existing database
- Other (specify) Students in various health disciplines

19. ACCESS TO POTENTIAL RESEARCH SUBJECTS

A) Describe in detail how initial contact will be made with prospective subjects/parents; e.g., in person, by phone, by letter.

Healthcare professionals

Potential teams will be contacted by an appropriate co-investigator member of the Partnered Learning Project (PLP) team by email or by telephone to secure permission to approach the full team for an information session. An in person information session will be conducted by members of the Partnered Learning Project team, outlining the details of involvement in the team training curriculum and answering any questions or concerns. Information and consent forms will be distributed at the meeting, with instructions to deposit completed forms (for participants AND nonparticipants) in a location to be determined in discussion with the team leaders (e.g., envelope at nursing station).

Pre-licensure trainees

Lynne, how does this work??

Patients/families

A physician member of the healthcare team caring for the patient will approach selected patients and families in person to determine their interest in participating in a semi-structured interview with a co-investigator or research associate from the PLP team. If the patients and families are interested, a PLP team member will approach in person with information and consent forms, which they will return to pick up 1-3 days later.

B) Who will make initial contact (must be known to the potential subject)?

See above explanations.

20. SITE OF RESEARCH AND ELIGIBILITY/EXCLUSION CRITERIA

CASES

Total Number at SickKids: 36 team members; 18 pre-licensure trainees Age Range: 25-60

Location: (e.g., CIU, Inpatient, Ambulatory Clinic, etc.) Please specify Neuro-oncology, burns, and trauma teams

Total Number at other location: Toronto Rehab: 24 team members, 12 pre-licensure trainees

CHEO: 24 team members, 12 pre-licensure trainees Age Range: 25-60

Home School Community Other _____

EXCLUSION CRITERIA

Health professionals must be members of clinical teams.

CONTROLS

Total Number at SickKids: N/A Age Range: _____

Location: e.g., CIU, Inpatient, Ambulatory Clinic, etc. Please specify _____

Total Number at other location: _____ Age Range: _____

Home School Community Other _____

EXCLUSION CRITERIA

21. INTERVENTIONS

Include only those interventions which are **NOT** considered part of the diagnostic/therapeutic (e.g., "routine") care of subjects including all subject contact (e.g., telephone surveys, number of additional blood samplings, volumes of additional blood, etc.).

<u>INTERVENTION</u>	<u>HOW & BY WHOM</u>	<u>REFERENCE TO PROTOCOL</u> (page number, paragraph)
Obtaining consent ⁵	See above.	
Special clinic visit (number & timing)		
Diagnostic imaging (type, number & timing)		
Blood tests (taken with routine blood work or by separate blood work)		
Questionnaires (number & timing)	<p>Attitude surveys will be distributed to staff in person and/or by email. 12 staff on 2 teams per institution (24 SickKids, 24 Toronto Rehab, 24 CHEO) will complete 2 surveys each (1 pre, 1 post). The SickKids pilot site will NOT include survey data collection.</p> <p>Preceptors will distribute attitude surveys to pre-licensure trainees during the placement. 6 trainees on 2 placements per institution (12 SickKids, 12 Toronto Rehab, 12 CHEO) will complete 2 surveys each (1 pre, 1 post).</p> <p>Staff satisfaction and patient satisfaction survey results for study units will be accessed through the hospital administration. Analysis will occur at the unit level only.</p>	
Interviews (number & timing)	Approximately 6 patients and/or families will be interviewed per team setting (not including SickKids pilot site). Interviews will last approximately 1 hour, and will be held at a time and location of the participants' choosing.	

⁵ Refer to "Free and Informed Consent in Research" Policy to confirm that the person assessing capacity to consent is qualified according to law

Other (specify)		
How long will each subject be studied	<p>Health professional staff will be studied before they undergo team training (2 weeks) during their team training curriculum (8 hours spread over 4 weeks) and during their interaction with pre-licensure trainees in the interprofessional placement (4 weeks after team training is completed). Pre-licensure trainees will be studied for the duration of their 4 week placement. Patients and families will be the focus of study only during their semi-structured interviews; during observations of team work, they will be part of the study context but will not be the focus of the observations themselves. Following our past experience with team observations, our intent is to post information sheets in the clinical settings to inform patients and families that observations of teamwork are occurring, but not to consent patients and families for these observations since they are not the focus of the study.</p>	

22. POTENTIAL HARMS, DISCOMFORTS AND INCONVENIENCES TO SUBJECTS

For each study intervention, describe probability and magnitude (whether greater than “minimal risk”). *Minimal risk is defined as the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research. The term "that relate to the research" refers to the risks that are inherent in the treatment that the patient will be undergoing as a part of his or her current everyday life.*

Among potential harms, is enrollment to multiple studies likely to be an issue with this patient population? Yes No

23. POTENTIAL BENEFITS TO SUBJECTS

For each study intervention, describe probability and magnitude of potential benefits to subjects. The subjects in this study include both the individuals participating in the study and the institutions involved. On the institutional level, The Partnered Learning Project promises 2 significant impacts on the involved institutions. The first is an established institutional relationship for developing shared curriculum. This relationship will serve as a model for inter-institutional collaboration and resource-sharing, and will create the framework for ongoing educational and research initiatives by this project team. Second, each institution benefits from having multiple units participate in team training, which will produce a cadre of IPC care champions and partners for pre-licensure placement students. Additionally, SickKids and CHEO will benefit from the implementation of a pre-licensure IPE placement in pediatrics, which will serve as a provincial model for operationalizing IPE placements.

Within the partner organizations, our study results will advance momentum around achieving culture change through innovative interprofessional education. By drawing together SickKids, Toronto Rehab & CHEO leaders, building capacity through preceptor training and 'train the trainer' programs, and attracting graduate students and enthusiastic staff to participate in the initiative, the proposed project will catalyze our IPC care communities. Further, we will have produced a cadre of IPE-trained pre-licensure students who are well-versed in collaborative philosophies, knowledgeable about health professional roles, and prepared for advanced IPC electives. Similarly, the cadre of trained teams will serve as IPC care champions which can be featured and drawn on to trigger a ripple-effect of enthusiasm and participation across the three institutions.

The individual people involved as subjects in this study stand to personally benefit from increased experience in how to facilitate collaboration on their present and future healthcare teams. The overall impact of this benefit will allow these subjects to develop 'in-demand' skills on how to foster collaboration within the healthcare context. This may lead to further training opportunities and/or to leadership opportunities within and outside of their existing employment and/or educational settings.

POTENTIAL BENEFITS TO SOCIETY

For each study intervention, describe probability and magnitude of potential benefits to society.

By developing an evidence base that links IPC and IPC, this study has the potential to increase efficiency across the healthcare sector. If our objectives are met, the long-term potential benefits to society are increases in the efficiency of healthcare teams and ultimately healthcare delivery in this province. Building a model that addresses multiple points in the care continuum also has the potential, through the dissemination of findings, to encourage more effective IPC through IPE beyond this province as well.

Further, impact on the broader health education system is anticipated, through our extension of the pre-licensure IPE placement program. At the University of Toronto, this project will have produced a new IPE placement in pediatrics for UofT's 2009 IPE curriculum. Our testing of a clinical focus for the placement curriculum -- transitions in complex care -- will serve as a model for other university-affiliated organizations who wish to tailor the placement experience to topical problems of relevance to collaborative care delivery. Finally, the pediatric IPE placement may serve as a model for implementing IPE in pediatric training provincially and nationally, particularly given the web-based accessibility of our curriculum tools and processes.

Impact on local health care delivery systems is also expected, given the powerful track record of team training initiatives for improving collaboration in industries such as aviation. By drawing on sound approaches and tools from these domains, we anticipate that collaboration around transitions will be improved, that team member satisfaction with their work environment will increase, and that staff recruitment and retention will benefit in the long term.

24. PAYMENTS/RECOGNITION TO SUBJECTS

Reimbursement for out of pocket expenses incurred as a result of research Yes

Thank you letter or certificate of participation Yes

Compensation for participation No Yes Description _____ Value \$ Our
budget includes 'staff replacement' funds to enable health professionals to participate in the 8 hr team training curriculum. An average of \$50/hr will be available to buy-out team members' time for this activity.

25. PLAN FOR DISSEMINATION OF RESULTS TO SUBJECTS AND WHO WILL DISSEMINATE.

Presentations and plain language reports will be developed to disseminate results to subjects. Where feasible, collaborative creation of materials involving study participants will be employed, including involving participants in presentations to their own and other clinical groups. Members of the PLP investigator team will participate in all dissemination activities.

26. PLAN FOR DISSEMINATION OF RESULTS TO COMMUNITIES (SCIENTIFIC, ADVOCACY GROUPS) AND WHO WILL DISSEMINATE.

We envision 3 audiences for our results. Educators will be targeted for sharing information about our innovative Partnered Learning curriculum. By creating web-based curriculum materials, we anticipate broad knowledge transfer. Second, hospital leaders and administrators will be targeted for sharing information about how a partnered IPE initiative across the learning spectrum can influence collaborative attitudes and practices. We will present findings at board and executive meetings and in plain language reports, towards influencing hospital policy regarding IPC expectations and infrastructure. Third, education scientists will be interested in our elaboration of current models of interprofessional collaboration and education, as well as our results from observational study of team collaboration following this strategic IPE intervention. We will produce peer-reviewed publications and presentations, as well as sharing our results on the CIHC website for uptake and further exploration by other education research groups.

27. SECURITY AND CONFIDENTIALITY OF PERSONAL HEALTH INFORMATION AND RESEARCH DATA

(Please check all steps which will be taken)

Are any sensitive issues raised in this study or its publication (e.g. HIV status, mental health status), which could result in harm (e.g. cause embarrassment, refusal of employment or insurance coverage, stigmatization) and therefore require subject consent?

No

Yes

If “yes”, please specify how such consequences would be addressed:

Identifying information de-linked

Use of study subject names, initials, SickKids patient numbers, and other identifying information is strictly prohibited on data collection forms, adverse event reports, and other research subject-specific documents. Subjects must be assigned a unique identification code. The code-breaking information must be kept separate from the data extraction files. It is the responsibility of the Principal Investigator to ensure that the code-breaking information is totally inaccessible to individuals who are not on the research team.

Data collection sheet for any data not collected as part of study instruments is attached

Records / computers secured

Method: Patients coded Files/Folders passworded Computer passworded

Computer in locked office only

Other (specify): _____

Chart/Computer Access limited to research team

Method: Cabinet/Office keys ONLY with research personnel

Computer passwords ONLY with research team

Other (specify): _____

28. DATA SOURCES & STORAGE

- a) Identify all sources of data (e.g. database, registry, health record, clinic files, physician office files etc.) Data sources include: observational fieldnotes, interview transcripts, completed attitudinal surveys, staff and patient satisfaction data from hospital survey (collected at the unit level only).

- b) Where will the data be stored? Hard copy data will be stored in Principal investigator's locked office (Lingard). Electronic data will be stored in computer files accessible only to PLP team members. These data will be anonymized (e.g., Team 2, physician 6). Code-breaking information will be kept separately as required.
- c) How will the data be stored and protected while in storage? Locked office door, locked filing cabinet, password protected computers.
- d) For how long will the data be stored? 5 years
- e) Who will have access to these data in the future? Only PLP research team members.
- f) How will the data be returned and/or destroyed? Hard copy data will be shredded; electronic files will be erased; audio and video tapes will be destroyed.
- g) Will data be sent outside of the institution?
- No
- Yes Please specify where and how the data will be sent, noting any security measures and strategies for protecting study subject privacy:

In order to facilitate comparison of the educational program across the three study institutions, data will be shared once it has been anonymized. For instance, anonymized transcripts that have been stripped of identifying features will be emailed to PLP team members for group analysis.

29. DO YOU PLAN ON LINKING LOCALLY COLLECTED DATA WITH ANY OTHER DATA SET (e.g. OHIP DATA)?

If so, identify the data set, why these linkages are required, identify how the linkage will occur, and provide a list of data items contained in it

No

30. INDICATE WHETHER THERE IS A CONTRACT/RESEARCH AGREEMENT OR DATA SHARING AGREEMENT INVOLVED:

Yes If "yes", please submit to the REB office a copy of the signature page for the contract or data sharing agreement when available

No

PRIVACY AND SECURITY ACKNOWLEDGEMENT:

On behalf of all members of my research team, I recognize the importance of maintaining the confidentiality of personal health information and the privacy of individuals with respect to that information. I will ensure that the personal health information is used, only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB. This includes all conditions and restrictions imposed by the REB governing the use, security, disclosure, return or disposal of the research subjects' personal health information. I agree to take any further steps required by the REB or SickKids to ensure that the confidentiality and security of the personal health information is maintained in accordance with the *Personal Health Information Protection Act* (PHIPA), its accompanying regulation and the Tri-Council Policy Statement.

Principal Investigator Signature

Date

31. PROPOSED MONITORING OF RESEARCH

In addition to the reporting of Adverse Events, what other monitoring activities do you propose?

For Clinical Trials only:

DSMB or Efficacy and Safety Committee⁶

Consulted with the Clinical Research Office for advice

Yes No

Yes No

Interim Analysis performed by independent committee

Yes No

CONTINUING REVIEW MATRIX

Indicate the Level of Continuing Review with an X in only ONE of the boxes in the matrix below.

1. RESEARCH CATEGORY	2. LEVEL OF CONTINUING REVIEW			
	LEVEL I Adverse Events & Annual REB reports	LEVEL II Level I & Audit 10% of subjects	LEVEL III Levels I, II & Audit >10% of subjects; + -DSMC	LEVEL IV Level I to III & observe consent
A. Retrospective observational	<input type="checkbox"/>			

⁶ Also known as Data Safety Monitoring Board (DSMB) Please refer to the REB website for guidelines.

Studies involving personal health information NO patient contact			
B. Prospective observational studies: NO physical exams	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
C. Prospective observational studies: Physical exams and physiological assessments without biological specimens		<input type="checkbox"/>	<input type="checkbox"/>
D. Prospective observational studies: with biological specimens (blood, urine, tissue) *		<input type="checkbox"/>	<input type="checkbox"/>
E. Clinical intervention trials (×) <input type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Surgical <input type="checkbox"/> Behavioural <input type="checkbox"/> Biologic <input type="checkbox"/> Natural Health Product		<input type="checkbox"/>	<input type="checkbox"/>

* If study includes administering a drug, biologic, natural health product or device, then study must be a Category E

3. FOR CLINICAL INTERVENTION TRIALS ONLY: For drug, biologic, natural health product or device trials, indicate the **phase** of the trial (×).

Phase I <input type="checkbox"/> (initial use in humans; to determine the safest dose, route and schedule for a new drug; to identify toxic side effects)
Phase II <input type="checkbox"/> (to provide preliminary information about how well the drug works; to generate more information about safety and benefit of the drug)
Phase III <input type="checkbox"/> (to compare a new drug or combination of drugs or a procedure with the current standard therapy; to obtain additional safety and efficacy data)
Phase IV <input type="checkbox"/> (following regulatory approval of the drug; study drug is used for the approved indication; to determine if efficacy can be improved)

UTILIZATION OF HOSPITAL SERVICES

Study Title: The Partnered Learning Project

Date:

Indicate service(s) to be used together with the signed agreement of Department Head concerned.

SERVICE(S)	AGREEMENT OF DEPARTMENT HEAD (Signature)	Check if applicable
Anaesthesia	_____	<input type="checkbox"/>
Diagnostic Imaging	_____	<input type="checkbox"/>
Dietetics	_____	<input type="checkbox"/>
Emergency Medicine	_____	<input type="checkbox"/>
Genetic Counseling	_____	<input type="checkbox"/>
Immunology	_____	<input type="checkbox"/>
Health Records (a fee may be charged)	_____	<input type="checkbox"/>
Child Health Services	_____	<input type="checkbox"/>
Paediatric Laboratory Medicine	_____	<input type="checkbox"/>
Pharmacology	_____	<input type="checkbox"/>
Pharmacy ⁷	_____	<input type="checkbox"/>
Psychology	_____	<input type="checkbox"/>
Rehabilitation Services	_____	<input type="checkbox"/>
Social Work	_____	<input type="checkbox"/>
Other Clinical Services (non-research)	_____	<input type="checkbox"/>

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⁷ Contingent on the availability of resources at the time the study is to start and funding from investigator. All Protocols involving pharmaceutical agents/biologics or Natural Health Products MUST be submitted to the Research Support Pharmacist (RSP) (Room 3717) for a mandatory review. A minimum of 2 weeks is required.

CHECK IF APPLICABLE

*All Protocols using a pharmaceutical agent/biologic or Natural Health Product MUST be submitted to the Research Support Pharmacist (RSP) (Room 3717) for a mandatory review. The RSP, in consultation with the Principal Investigator or delegate, will determine the level of review and ongoing support required by Pharmacy (see www.sickkids.ca/ResearchEthicsBoard/documents/Pharmacyguidelines). A minimum of 2 weeks is required for RSP to complete this review.

**THE HOSPITAL FOR SICK CHILDREN
DEPARTMENT OF PHARMACY**

CLINICAL INVESTIGATIONAL DRUG INFORMATION FORM

GENERIC NAME (and placebo if applicable):

TRADE NAME/MANUFACTURER (source of drug supply):

If the product requires compounding by Pharmacy, submit information to the Pharmacy Department on stability, storage, dosage form and strength desired, solubility, and literature references.

REGULATORY STATUS IN CANADA:

THERAPEUTIC CATEGORY:

DOSAGE FORM AND STRENGTH:

ROUTE OF ADMINISTRATION:

INDICATION FOR USE:

DOSAGE REGIMEN:

KNOWN OR SUSPECTED ADVERSE REACTIONS:

KNOWN OR SUSPECTED DRUG INTERACTIONS:

HAS THIS DRUG BEEN USED (If yes give reference):

In Adults -

In Children /Adolescents -

In Neonates –

COMMENTS:

PRINCIPAL INVESTIGATOR(S):

AUTHORIZED DELEGATE(S):

This form is to be completed for each clinical investigational drug. The entire stock of the drug will be maintained in the Pharmacy and dispensed only upon receipt of a prescription signed by an authorized physician.

DATE _____

Principal Investigator(s)' signature

DATE _____

Research Pharmacist- Mark Bedford/Darcy Nicksy

*All Protocols using a pharmaceutical agent/biologic or Natural Health Product MUST be submitted to the Research Support Pharmacist (RSP) (Rm 3717) for a mandatory review. The RSP, in consultation with the Principal Investigator or delegate, will determine the level of review and ongoing support required by Pharmacy (see www.sickkids.ca/ResearchEthicsBoard/documents/Pharmacyguidelines). Allow a minimum of 2 weeks to complete the review. If it is determined that a pharmacy review is not required, the RSP will sign this Cost Finder as “not applicable”.

DEPARTMENT OF PHARMACY
INVESTIGATIONAL DRUG STUDY COST FINDER

PROTOCOL TITLE:

SPONSORSHIP/FUNDING:

PRINCIPAL INVESTIGATOR(S):

PRE REB PROTOCOL REVIEW: (Usual range \$100 to \$850 depending on complexity)

- Review of protocol/meetings with investigator(s)
- Completion of REB forms: Pharmacy Cost Finder, Investigational Drug Info form, Utilization of Diagnostic Services Signature Page
- Review Feasibility of Formulating Product/Placebo (blinding, placebo, physical stability studies)
- ad-hoc meetings and pre-initiation site visit

PHARMACY DISPENSING PROCEDURES AND SET UP: (Usual range \$300-\$2000)

- Write Dispensing Procedures
- Preparation of randomization / enrollment table / worksheets
- Finalization of Manufacturing Pharmacy formulation / production set up
- Staff education i.e. study design/written pharmacy procedure
- Procurement/storage of drug supplies
- Set-up of billing account for monthly charges
- Set-up of Rx3000 and/or Kidcom databases
- Initiation meeting, ongoing education

MONTHLY FEE includes: (\$20 - \$100 month)

- Storage of inventory. Maintenance of drug inventory, accountability & records
- Billing administration
- Ad hoc meetings with investigator(s), sponsors and suppliers

DRUG ACQUISITION COSTS (who is supplying & paying for study drug, control arm drug &/or placebo)

MANUFACTURING COSTS

- Manufacture of product/placebo including supplies/labour (+/-drug cost)
- NP oral Unit dose (\$1-\$5/dose) / NP IV Intravenous dose preparation (\$10 - \$50/dose)

DISPENSING FEES

- Inpatient(\$10 – 20 / Rx); Outpatient (\$15 - \$40/Rx)
- Return drug tablet/liquid counts for patient compliance (\$5 - \$20/Rx)

MISCELLANEOUS CHARGES

- Return or destruction of any study medications or supplies (sponsor/PI will provide courier)
- Pharmacy involved Interactive Voice Randomization Systems (IVRS) \$10 to \$20 per patient.
- Shipping of medications to patient (\$25 handling fee + cost of courier)

STUDY CLOSURE FEES: (Usual range \$50-\$150)

- Return/Destruction of drug supplies to sponsor at conclusion of study
- Preparation for storage of Pharmacy study documents for 25 years

TOTAL

Comments:

DATE _____

DATE _____

Principal Investigator(s)' signature

Research Pharmacist- Mark Bedford/Darcy Nicksy

*This is only an estimate valid for 6 months. Prices are subject to change depending on the final study procedures, design and pharmacy staffing availability. Research Support Pharmacy services are provided on a cost recovery basis. PI is responsible for ensuring assumptions used here are valid.

DIAGNOSTIC IMAGING STUDIES REQUEST FORM

FOR RESEARCH PURPOSES

Section A **This section to be completed and signed by the primary investigator(s).**
Please submit completed form to Wendy Doda, Senior Project Manager, Research Room 2239.

Research Project Title:

Principal Investigator(s) (PI):

Radiologist Involved:
(If not already the PI)

Modality:

Type of Study Requested:
(Please attach PROTOCOL)

Patient Safety Issues:
 (It is the responsibility of the PI to ensure that patients arrive safely. If medical supervision is required, it is his/her responsibility to make the necessary arrangements prior to study date).

Estimated Number of Patients:

Storage of Research Images: Digital only Hard copy

*Expected Start Date:

Expected Completion Date:

Signature – Principal Investigator_____
Contact Person_____
Date of Request_____
Phone #_____
Pager #

It is the Principal Investigator's responsibility to notify Wendy Doda (x1922) of approval by the Hospital Committee. Upon notification, Research Consultation Request Forms (pink form) will be provided. DI will not accept any research patient without this pink form.

Project No.

DIAGNOSTIC IMAGING STUDIES REQUEST FORM

FOR RESEARCH PURPOSES

Section B This section to be completed by Radiologist/Modality Team Leader.

Research Project Title:

Protocol (As approved by Radiologist):

Who is to report studies?

Estimated time per study:

Number of Technologists/RNs involved:

Booking arrangements: a) during regular hours _____

b) after regular hours _____

Cost Estimate:

(To include tech/RN time, film cost, supplies, use of equipment, contrast, sedation, etc.)

Method of Billing:

() By cheque. Please make cheque payable to Diagnostic Imaging.

() By internal transfer of funds. Please provide Fund # _____

Approval: _____ **Date:** _____
Signature - Radiologist-in-Chief**Acceptance:** _____ **Date:** _____
Signature - Principal Investigator**DI Contact List**

Dr. Paul Babyn	Radiologist-in-Chief	Rm 2107	x6026	Dr. Martin Charron	NucMed	Rm. 2234C	X2006
Dr. Bairbre Connolly	Interventional	Rm2173A	x6034	Dr. Charles Raybaud	CT/MRI/MEG	Rm.2135	X5171
Dr. K. Oudjhane	GI/GU	Rm 2132	x8457	Dr. David Manson	Gen X-ray	Rm.M642	X6031
Dr. Alan Daneman	Ultrasound	Rm M465	x6922	Ms. Wendy Doda	Research Project Manager	Rm.2239	X1922

DEPARTMENT OF DIAGNOSTIC IMAGING

RADIATION EXPOSURE

RADIATION USED (Isotope, X-Ray)

DOSE ADMINISTERED (Bq) PER SUBJECT/STUDY (1Bq 2.7×10^{-10} Ci)

IS RADIATION FROM ESTABLISHED PROCEDURE?

ABSORBED DOSE IN GRAYS (Gy) FROM EACH PROCEDURE? (1Gy=100 Rads)

GONAD (cite reference if available)

OTHER ORGANS RECEIVING HIGH DOSE (i.e.: Target Organs)

WHAT OTHER RADIATION EXPOSURE (not trial)?

SPECIAL PRECAUTIONS (e.g., Shielding, Blocking Agents, etc.)

Hazards Committee Chairperson
Dr. Sylvester Chuang

Date

RESEARCH STUDY APPLICATION FORM**PLEASE NOTE:**

1. Requests for costing of studies will require a minimum of 7 days advance notice, total time dependent on the complexity of the study.
2. Four weeks will be required from the time of notification to the lab of study/grant approval to study onset.

Protocol Title:**Principal Investigator(s):****Research Fellow:****Brief Summary of Proposal:**

(or copy of REB application form)

Laboratory Component:*ie. purpose and methods proposed***Proposed Number of Patients (and samples):***eg. Gram stain and culture at time 0, 1 week, 4 weeks, 8 weeks per patient
eg2. CBC, glucose and TSH at time 0 weeks, with 10 subsequent weekly repeats***Expected Start Date:****Expected Duration of Study or Finish Date:**_____
Principal Investigator's Signature(s)_____
Contact Name_____
Telephone #._____
Pager #.

For Laboratory contacts, please see the
"Research Study Costing" form attached.

Lab use Only:
Study I.D. #:

RESEARCH STUDY COSTING

This form to be completed after contact and discussion by investigator(s) with appropriate Laboratory Division Head(s) and DPLM Operations Manager.

DPLM – Contact List August 2004	
Bacteriology	Dr. Susan Richardson x5992
Biochemistry	Dr. Khosrow Adeli x8682
Haematology	Dr. Mohammed Abdelhaleem x6434
Molecular Diagnostics	Dr. Peter Ray x6590
Pathology	Dr. Glenn Taylor x7747
Virology	Dr. Susan Richardson x5992
Transfusion Medicine	Dr. Wendy Lau x5440
Research Coordinator	Suzan Hanna X8382

Protocol Title:

Study Specimens Will Be Labeled as:

Principal Investigator(s):

Costing Analysis:

(eg. For costs of supplies, labour, preparation time, data collection, referral out of specimens, etc.)

Request for Costing Submitted:

Date: _____

Costing Reviewed by Team Leader:

Date: _____

Billing and Work Performance Agreement:

Signature Lab Division Head: _____

Date: _____

Signature Lab Division Head: _____

Date: _____

Signature Principal Investigator: _____

Date: _____

Signature Financial Operations Director: _____

Date: _____

Method of Billing:

Study Approval Notification by: _____

Name: _____

Date: _____

Fund #: _____

Contact Telephone #: _____

Name: _____

Pager # / E-mail: _____

CRSU Cost Structure for Statistical Analysis

CHECK IF APPLICABLE

(Please note that Database Design and Data Entry are not included).

The Research Institute set the cost at \$75/hour. Ball park estimates of costs per study are listed below. Any specific study may fall between the levels and cost will be adjusted accordingly.

1. Basic I

- t-tests
- Chisq-tests
- Descriptive stats
- Less than 5 variables to test against 2 groups
- Clean data by our standards

Estimated time: 5hrs

2. Basic II

- Includes Basic I
- Up to 20 variables
- ANOVA
- Some categorical data
- Classical designs
- Regressions -- model building with variables given by investigator
- Data modification

Estimated time: 20 hours

3. Intermediate I

- Includes Basic II
- Plus up to 30 variables
- Complicated repeated measures ANOVA
- Standard complex designs for categorical data
- Extensive modeling - variables to be defined by statistical methods
- A few multivariate techniques maybe necessary
- Some data modification

Estimated time: 45 hours

4. Advanced

- Includes Intermediate I
- Plus up to 50 variables
- Complicated repeated measures ANOVA
- Nonstandard designs
- Nonstandard complex designs for categorical data - **research required**
- Extensive modeling - variables to be defined by statistical methods
- Multivariate techniques should be performed
- Data modification
- Write stats section - **research required**

Estimated time: 70-100 hours

5. Extensive Involvement

- Involvement in the study over several years
- Time and cost will be worked out with investigator