



a place of mind  
THE UNIVERSITY OF BRITISH COLUMBIA

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February 15, 2011

Dear Ms. Ward:

I am writing in response to your enquiries to the Behavioural Research Ethics Board (BREB) at UBC concerning an Human Learning Partnership (HELP) study, and in particular to address your concerns that the conduct of an HELP study violates privacy rights and informed consent requirements.

Your itemized concerns in a letter of January 21, 2011 were passed on to the HELP team and their response is summarized here,

HELP is a Research Institute at UBC which is a public university. The focus of the research is on understanding child development at the population level. In order to receive grant funding and ethical approval, HELP must demonstrate that its research has demonstrated public value, that the benefits outweigh the risks to prospective participants, and that informed consent of participants is obtained in accordance with applicable guidelines, which include the Tri-Council Policy Statement 2 (TCPS2).

The School Districts gather data in BC on an estimated 85% of children in selected years, via administration of the Early Development Instrument (EDI) which is a long questionnaire completed by kindergarten teachers. The EDI was specifically designed by child development experts for use by teachers. HELP does not collect any data other than through use of the EDI in its Early Childhood Development Program of Research, in accordance with its application for research ethics approval. EDI data is only collected for children in kindergarten, and can only be linked along their life trajectory.

HELP only links EDI data to other administrative data sets when research projects have undergone peer review, received data steward approval and an ethics certificate of approval has been issued. Those research projects must also be in compliance with applicable legislation. Access to personal income tax data has not been sought, although it has been recommended as a useful data file for linkage. Any such linkage would need to be sought in a Research Data Access Request, and would require the execution of a Research Agreement and ethical approval. If additional datasets are identified as valuable for research linkage, such linkage would require that the research project be approved by appropriate agencies, that it be designed and conducted in accordance with applicable legislation (including privacy legislation), and it would always require ethical approval. HELP's linkage function is clearly stated and explained in the parent letter, the teacher letter, the principal letter and on the EDI website. It is consistent with applicable legislation (including privacy protections).

Researchers do NOT receive identifier data from HELP. HELP stores identifier information separately from EDI content data (the de-identified responses) to remove the possibility of re-identification, and researchers only use the de-identified data. HELP has restrictions on how EDI data is disclosed, including limitations on reporting on geographic areas with small cell-size (small numbers of respondents), for the express purpose of preventing accidental or intended re-identification. All EDI responses are de-identified as the data are entered.

HELP is aware of its obligations to protect the interests of stakeholders, and specifically the privacy of the EDI participants and their families. To this end, they have a number of privacy tools and safeguards in place, including:

- On-going monitoring and annual reporting to the UBC BREB;
- Having undertaken a Privacy Impact Assessment to ensure compliance with BC Privacy legislation;
- Regular consultations with UBC's privacy and access Manager;
- Retention of a Privacy Officer specifically for the project;
- Institution of a requirement that all applications for data sharing be approved research projects, have data steward permission, ethical approval and be subject to written information sharing agreements or research agreements;
- Conducting annual privacy training sessions as well as having mandatory online privacy training with testing for access to data; and
- Creating a privacy toolkit explaining their privacy policies and procedures and having a privacy code based upon the Canadian Standards Association Model Code Protection of Privacy Principles.

In ten years of data collection, HELP has experienced no breach of privacy.

HELP's consent process has been reviewed and approved by the UBC BREB. Passive consent is used in limited circumstances where the nature of the study warrants it, as determined by the Research Ethics Board (not the HELP or other research team). Precedence exists for use of the EDI with passive consent in all other Canadian Provinces participating in the EDI, except Alberta.

HELP conveys the detail of use, access, linkage and disclosure as clearly as possible and in accordance with recommendations and requirements of the BREB. HELP translates the Parent Letter into 9 languages in addition to the English language. Letters to parents are distributed by teachers and are available online on HELP's plain language Parent Web Page. EDI teacher training sessions held regularly stress the critical importance of ensuring that parents understand the nature of the project and the fact that their participation is voluntary. When needed, the study team has worked with schools to ensure that community outreach workers assist families by translating questions and concerns and responses. Parents have 4 weeks to consider participation in the project. Parents who wish to withdraw their child from EDI research can contact their child's teacher. This can be done in many ways including a direct conversation, a written note or an email. HELP works with district training teams to provide standardized training to all teachers where they demonstrate the importance of ensuring that letters are sent home to all parents. HELP provides checklists and reminders to the school districts to support this process.

The EDI gathers information that assists researchers to understand the development of the whole child, but only for aggregates of children. HELP is interested in population level statistics, not data on individual children or their parents. HELP's objectives are to facilitate research that will benefit children and their families. Some of the ways that this has been done through this research include: revealing where there are communities or regions in the Province where there are gaps in children's development and, where improvement is needed, heightening awareness of the importance of early child development, as well as showing where programs and resources are available to assist parents, children, teachers and the community when these are needed.

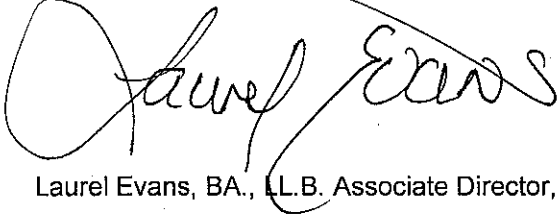
The UBC Behavioural Research Ethics Board has reviewed the Early Childhood Development Program of Research and has considered the areas of concern that you have outlined in your letter. The review was based upon University policy and TCPS2 and included the concerns expressed in relation to the protection of privacy of the participants and their data, the method currently being used for obtaining consent from the families, and the variety of data linkages that have been and are being currently proposed. The Board has, over the time that it has had oversight of the ethical conduct of this program of research, proposed changes to the recruitment process and the informed consent letters, and made

enquiries concerning implemented protections including seeking assurances that all legislated requirements have been met. The Board is required to assess the ethical acceptability of a research project through consideration of the foreseeable risks, the potential benefits and the ethical implications of the project. The criteria that must be met in order for a project to be approved are numerous, but they include the requirement that informed consent be sought and obtained in an appropriate manner, that there is adequate provision for the protection of the privacy of participants and maintaining the confidentiality of the data, and that the risks to participants are reasonable in relation to the anticipated benefits and the importance of the knowledge that may be expected to result from the research.

The Board has determined that this project has met those requirements and has, accordingly, issued a certificate of approval for the program for a one year period, at which time it will re-review the ethical acceptability of the study.

We hope that the foregoing has addressed your concerns and answered your enquiries. If, in your estimation it does not adequately provide you with the information that you are requesting, we would respectfully request that you submit your further enquires through an application under the provisions of the Freedom of Information and Protection of Privacy Act.

Yours truly,

A handwritten signature in black ink, appearing to read "Laurel Evans". The signature is written in a cursive, flowing style with a large initial "L".

Laurel Evans, BA., LL.B. Associate Director, Research Ethics

Cc: Dr. Clyde Hertzman,  
Dr. Judith Lynam (Chair BREB A Panel)  
Dr. Kenneth Craig (Chair BREB B Panel)  
Shirley Thompson, Manager, BREB