

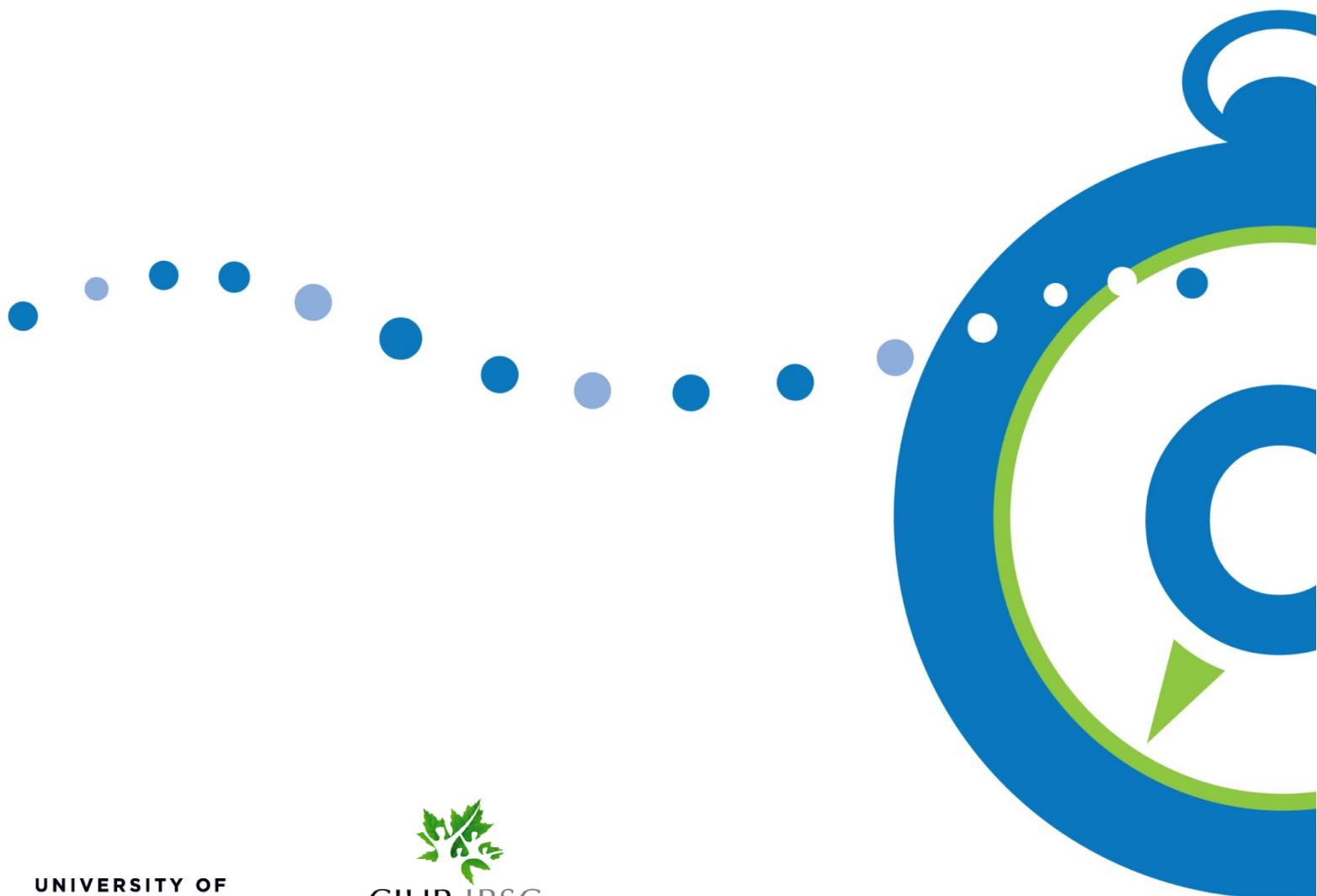


Cohort study evaluating how changes in school programs, policies, and resources impact youth health behaviours

Rationale for using an Active-Information Passive-Consent Permission Protocol in COMPASS

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Introduction

COMPASS is a longitudinal study (starting in 2012-13) designed to follow a cohort of grade 9 to 12 students attending a convenience sample of Ontario secondary schools for four years to understand how changes in school environment characteristics (policies, programs, built environment) are associated with changes in youth health behaviours. COMPASS originated to provide school stakeholders with the evidence to guide and evaluate school-based interventions related to obesity, healthy eating, tobacco use, alcohol and marijuana use, physical activity, sedentary behaviour, school connectedness, bullying, and academic achievement. COMPASS has been designed to facilitate multiple large-scale school-based data collections and uses in-class whole-school sampling data collection methods consistent with previous research [1-4]. COMPASS also facilitates knowledge transfer and exchange by annually providing each participating school with a school-specific feedback report that highlights the school-specific prevalence for each outcome, comparisons to provincial and national norms or guidelines, and provides evidence-based suggestions for school-based interventions (programs and/or policies) designed to address the outcomes covered in the feedback report (refer to: www.compass.uwaterloo.ca).

This technical report describes why COMPASS uses active-information passive-consent permission protocol (hence referred to as '*passive consent*') to obtain permission from the parent(s) or guardian(s) (hence referred to as '*parent*') of students attending schools that have agreed to participate in the COMPASS study [5]. Specifically, this report highlights why passive consent is the most appropriate for use in COMPASS as it pertains to: (a) the research design of the COMPASS study; (b) ensuring there is appropriate sample to answer the research questions in COMPASS; and most importantly, (c) in order to best protect the confidentiality of students participating in COMPASS.

Background on Active and Passive Consent

In general, any research involving youth under 18 years of age requires the parent to provide the researchers with consent for their child to participate. There are two main methods used to obtain parental consent: active consent and passive consent [6-9].

Active Consent

Active consent typically involves distributing a letter to the child's parent(s) that describes the nature of the study and provides a method to document permission. The parent must then sign and return the consent form indicating whether or not they want their child to be able to participate in the research. Only children who return a signed consent form that indicates that they have parental permission are included in the survey. Those who do not return a form, or who return a form indicating that permission is not granted, are excluded from the survey. At any time during the consent process or during the data collection, an eligible student is allowed to decline to participate or withdraw from the study.

Passive Consent

Passive consent typically involves distributing a letter to the child's parent(s) that describes the nature of the study and then the parent is asked to contact the research team should they not want their child to participate. All eligible students whose parents do not contact the research team to withdraw their child are deemed eligible to participate. At any time during the consent process or during the data collection, an eligible student is allowed to decline to participate or withdraw from the study.

Passive Consent Process used in COMPASS

As part of the COMPASS protocol, parents were required to be provided with consent information at least 2 weeks before the survey date to ensure that they had ample time to respond should they not want their child to participate in COMPASS. As described previously [10], there were two methods used for the passive consent protocol among eligible students under 18 years of age in the baseline sample of the COMPASS study: consent letters and consent via voice-relay.

Consent Letters

Thirty five of the participating schools in the COMPASS baseline sample (2012-13 school year) used information letters for obtaining passive parental consent. This involved distributing a letter to the child's parent that describes the nature of the COMPASS study and then the parent was asked to either (a) call the COMPASS recruitment coordinator using the free 1-800 phone number provided in the information letter, or (b) email the COMPASS recruitment coordinator using the COMPASS email address provided in the information letter if they did not want their child to participate. The COMPASS parent information and consent letters were reviewed through an English Plain Language Assessment to help ensure parents understand the information in the letter when making the decision to allow their child to participate in the survey. As a result of the assessment, the parent information letters are at a grade 5 reading level. All eligible students whose parents do not contact the COMPASS team to withdraw their child after receiving the letter and prior to the start of the survey were deemed eligible to participate. At any time during the consent process or during the data collection for COMPASS, an eligible student is allowed to decline to participate or withdraw from the study.

Voice-Relay

Eight of the participating schools in the COMPASS baseline sample (2012-13 school year) used voice-relay (or *syner-voice*) technology for obtaining passive parental consent since this was the schools' preferred method for sharing information with parents (i.e., voice-relay was already an established communication protocol at these schools). In this method of contacting parents, the voice-relay system at a school telephoned all student households with an automated message from the school administration. For COMPASS, this message was a script of the COMPASS information letter (identical to the mailed consent letter). All eligible students whose parents did not contact the COMPASS team to withdraw their child after receiving the automated telephone message and prior to the start of the survey were deemed eligible to participate. At any time during the consent process or during the data collection for COMPASS, an eligible student is allowed to decline to participate or withdraw from the study.

Ensuring ineligible students did not participate in COMPASS

The COMPASS recruitment coordinator fielded all phone calls and emails from parents pertaining to having their child excluded from participating in COMPASS. Upon receiving communication from a parent that they did not want their child to participate in the baseline sample of the study, the COMPASS recruitment coordinator asked for the student's name, grade and school they attend and recorded the information in the Online Survey Implementation System (OSIS); the purpose of OSIS has been described previously [10]. As a precaution, the recruitment coordinator's voicemail was set with a specific recording to parents who wish to have their child withdrawn from the study, if a call was made before or after working hours. These messages were checked daily and recorded in OSIS immediately. Any parent information letters that were returned to the recruitment coordinator (due to a wrong address, "no longer at this address", etc.) were also recorded in OSIS under refusal calls since it was inferred that the parents did not receive or read the letter and hence did not have the opportunity to provide consent. All

student names for returned letters were automatically uploaded onto the 'no permission' list for their particular school.

Rationale for Passive Consent in COMPASS

There are five primary reasons why passive consent was more appropriate than active consent for the COMPASS study.

COMPASS Study Design

Active consent procedures have been found to falsely increase the homogeneity of students within a school, thus artificially inflating the school-level variance values in school-based studies [7,9]. Since COMPASS is designed to understand how changes in school environment characteristics (policies, programs, built environment) are associated with changes in youth health behaviours (i.e., models where school-level variance is rather important), any inflation of the school-level variance via active consent would have an important impact on biasing the results of the analyses examining how changes in school characteristics impact youth behaviour. To correct for this bias in an active consent study, more schools would need to be recruited and more students per school would need to be recruited [7], which would have severe implications for the study budget as increasing response rates in active consent studies is very expensive [8]. As such, passive consent helps to ensure that we have robust data which does not artificially inflate our school-level variance estimates, thereby improving the ability of COMPASS to accurately examine and evaluate how changes in school environment characteristics (policies, programs, built environment) are associated with changes in youth health behaviours.

Participation Rates

Active consent procedures have been found to result in substantially lower student participation rates in school-based research. For instance, research examining the impact of active vs. passive consent procedures on student participation rates in research has found that active consent resulted in lower participation rates (55% to 60%) compared to passive consent (80% to 98%) [6-9,12]. Since COMPASS is purposefully designed to provide each participating school with a school-specific COMPASS feedback report (known as the *School Health Profile*) that provides school-specific data and evidence-based suggestions for interventions, programs, or policies aimed at improving the health of the student population at their school [13], we require robust data from 'whole' student populations at each participating school. Low student-level participation rates from active consent would result in COMPASS School Health Profiles that are not representative of the 'whole' student body at the school, reducing their ability to accurately inform and guide prevention programming initiatives within each participating school. As such, passive consent helps to ensure that we have robust 'whole' school student-level data to use in the development of the School Health Profiles for each participating COMPASS school.

Biased Sample Demographics

Active consent has been found to have an impact on the types of students who participate in school-based research. For instance, research has shown that active consent studies result in student samples that are largely biased in relation to age (older students are less likely to participate), and gender (male students are less likely to participate) compared to passive consent studies [7-9,11]. Given that COMPASS is designed to address obesity, healthy eating, tobacco use, alcohol and marijuana use, physical activity, sedentary behaviour, school connectedness, bullying, and academic achievement, and these outcomes have been shown to vary by age and gender [1,14], it is important to have data that are not biased on these important demographic characteristics if we want to best understand how to target interventions so that they have optimal impact. As such, passive consent helps to reduce the potential

bias associated with the student-level sample pertaining to demographic characteristics in COMPASS (i.e., males and older students are more apt to participate).

Different Estimates of Substance Use

It has been suggested that studies examining youth substance use (e.g., tobacco, alcohol, and marijuana), should not use active consent procedures [7-9]. Evidence clearly indicates that the procedure of active consent produces substance use prevalence estimates that are largely underestimated and non-generalizable since youth substance users are substantially less likely to participate in active consent studies [8-9]. Not only does this bias reduce the robustness of the conclusions resulting from active consent studies of substance use, but this also creates a problem whereby the procedure of active consent directly results in the researchers not having access to the very students (i.e., substance users) they are trying to help with prevention programming [9]. Given that COMPASS is designed to understand and prevent substance use behaviour, it is critical to use passive consent to ensure that we have accurate measures of substance use within COMPASS schools and to ensure that we are not excluding the very students to whom we are trying to provide prevention programming.

Student Confidentiality

Utilizing active consent procedures would require the student name, grade level and classroom teacher name to be collected and tracked by the COMPASS team for each eligible student within a school (i.e., the COMPASS team would know the name of each individual student within a participating school). By contrast, using passive consent protocols, the consent information letters for parents are prepared based on total enrolment numbers and are addressed to parents and mailed out by the school; the COMPASS team only collects information pertaining to students where his/her parent has withdrawn them from the study (i.e., the COMPASS team would know the name of each individual student deemed ineligible within a participating school). This process helps to ensure that there is an additional layer of confidentiality for participating students within the passive consent protocol because the COMPASS team does not need to record any personal information pertaining to the eligible participating students within each school.

Summary

The passive consent approach used for COMPASS has received ethics clearance from the University of Waterloo and University of Alberta Offices of Research Ethics. Passive consent is robust and ethical for use in COMPASS since it provides the option for a parent to withdraw their child, provides the option for the student to participate or opt out on their own, it is appropriate for the COMPASS study design, it results in robust participation rates and whole school data, produces data that are less prone to different types of bias, and it helps to maintain student confidentiality.

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