

HUMAN EARLY LEARNING PARTNERSHIP

Rationale for using Passive Consent Permission Protocol in Human Early Learning Partnership (HELP) Research Studies

Early Development Instrument (EDI)
Middle Years Development Instrument (MDI)

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Human Early Learning Partnership
School of Population and Public Health
Faculty of Medicine
University of British Columbia

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Human Early Learning Partnership Implementation Team, with:

Mariana Brussoni^a

Eva Oberle^b

Maddison Spenrath^c

Michele Wiens^d

- a Professor and Director, Human Early Learning Partnership, University of British Columbia, Vancouver, BC Canada; Principal Investigator - Early Development Instrument Project.
- b Associate Professor, Human Early Learning Partnership, University of British Columbia, Vancouver, BC Canada; Principal Investigator - Middle Years Development Project.
- c Core Projects Director, Human Early Learning Partnership, University of British Columbia, Vancouver, BC Canada.
- d Privacy and Ethics Officer; Senior Manager, Human Early Learning Partnership, University of British Columbia, Vancouver, BC Canada.

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Contact:

Implementation Research Team, Human Early Learning Partnership, University of British Columbia, 440-2206 East Mall, Vancouver, BC Canada V6T 1Z3 earlylearning.ubc.ca

Table of Contents

i.	Acknowledgements.....	iii
I.	Introduction	1
II.	Background on Active and Passive Consent	2
	a. Active Consent	2
	b. Passive Consent.....	2
III.	Passive Consent Process used in the HELP EDI and MDI Research Studies	2
	a. Consent Letters	2
	b. Translation.....	3
	c. Follow-up of Consent Letter Distribution	3
IV.	Rationale for Passive Consent in the HELP EDI and MDI Research Studies	3
	a. Study Design.....	3
	b. Participation Rates and Children’s & Adolescent’s Views	4
	c. Sample Demographics.....	4
	d. Student Confidentiality.....	4
	e. Best Practices and Ownership, Control, Access, and Possession Principles.....	4
V.	Use and Benefit of Passive Consent	5
VI.	Summary.....	6
VII.	Appendix 1	7
VIII.	References.....	13

I. Introduction

As part of its research platform, the Human Early Learning Partnership has developed the Child Development Monitoring System which collects population-level data about multiple developmental stages in the early life course, from 18 months to 18 years of age. The Monitoring System gathers information on critical periods in children’s development, exploring individual, family, and community factors from a diversity of perspectives: parents, teachers and children themselves. The Monitoring System consists of five questionnaires, the [TDI](#), [CHEQ](#), [EDI](#), [MDI](#) and [YDI](#)¹, that provide connections across the early life course: from toddlerhood and into kindergarten, in Grades 4 through 8, and finally during secondary school in Grade 11. These questionnaires support the collection of population-level data about children’s outcomes, experiences and environments that are needed to address and answer the question: “What are the differences that make a difference?”

This research is longitudinal in design to allow HELP to monitor and track population-level trends including rates of childhood vulnerability and school-age well-being. Monitoring System data reflect the complexity of the contexts in which children are being raised, and over time, tell us how well our society is doing in supporting children and families.

Data from the Monitoring System support:

- Tracking changes in populations of children over time and cohorts of children through different developmental stages,
- Creating important linkages with external data sets including administrative health and education data, and national census data to understand how early vulnerability and experiences influence later health and educational outcomes,
- Identifying differences and inequities between BC jurisdictions, from neighbourhoods to government service delivery areas, and at a national level between provinces and territories, and
- Focusing on systems-change and cross-sector collaboration.

HELP engages in capacity-building and training initiatives with communities, institutions, and government to support data- and evidence-informed decision-making and planning to improve both policy and practice. For almost two decades, Monitoring System data have been routinely used in planning and decision-making processes in the health, municipal, education, social and community sectors. [Learn more about the uses and impact of Monitoring System data.](#)

The Monitoring System has been designed to facilitate multiple large-scale school-based data collections and uses in-class whole-school sampling data collection methods consistent with other research.¹⁻³

This technical report describes why HELP uses passive-consent (hereafter referred to as ‘*passive consent*’) to inform the parent(s) or guardian(s) (hereafter referred to as ‘*parent*’) of students attending schools that have agreed to participate in the EDI or MDI studies about the nature of the project and how to withdraw from participation. Specifically, this report highlights why passive consent is the most appropriate for use. Passive consent is also used in the Youth Development Instrument (YDI) survey, however the YDI is conducted by the CHART Lab and is therefore not included here. Active consent is used with the Toddler Development Instrument (TDI) and Childhood Experience Questionnaire (CHEQ), with parents completing the survey directly.

¹ The TDI, CHEQ, EDI, and MDI are conducted through the Human Early Learning Partnership at the University of British Columbia, and the YDI is conducted through the [Capturing Health and Resiliencies Trajectories \(Chart\) Lab](#), Simon Fraser University.

II. Background on Active and Passive Consent²

Youth may consent to minimal risk studies beginning at 16 years of age, and children ages 7 and up can assent to participate in these studies. Parental consent must be sought for minimal risk studies for children and youth under age 16. There are two main methods used to obtain parental consent: active consent and passive consent.⁴⁻⁶

a. Active Consent

Active consent typically involves distributing a letter to the child's parent 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.

b. Passive Consent

Passive consent typically involves distributing a letter to the child's parent 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 parent does 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.

c. Assent

Children who receive active or passive parent consent to participate in the study still get to decide for themselves whether they choose to participate in the study. Informed assent requires that youth have a clear understanding of the purpose of the research, their role within it, and then unequivocally provide their consent to take part.⁷

III. Passive Consent Process used in HELP EDI and MDI

As part of the EDI and MDI consent process, a parent is required to be provided with consent information 2-4 weeks before the survey date to ensure that they have ample time to respond should they not want their child to participate in the study.

a. Consent Letters

Informed passive consent letters are distributed to parents in school districts and schools that are participating in the EDI or MDI project³ (following the school's method of distributing information). These informed passive consent letters are translated into languages representative of the parent population.

Parents are given a 2-4-week window of time to decline participation of their child. They can notify their child's teacher, school administrator, or HELP Implementation team through the contact information provided on the consent letter to decline participation. The Implementation team is on call to respond to parent/guardian queries during this time. There is a tear-away withdrawal slip that they can also send to

² This section is adapted from the [COMPASS Study](#).

³ The EDI and MDI processes are similar and are therefore described together.

the school. Once a child is withdrawn, their information is removed from lists of participating students by either the school administrator or the Implementation team. A parent can also withdraw their child after they have completed the survey but before the data have been exported from the database, de-identified and included in reports (typically 4 to 8 weeks after the survey is complete).

For the EDI, teachers are made aware that their participation in the study is voluntary. If a teacher decides to not complete the EDI for their students, they can inform their administration, school district, or the EDI team at HELP. There is no direct involvement of student participants in the EDI. For the MDI, students provide assent to participate in the survey. The survey administrator is instructed to read aloud an assent script which describes the purpose of the study, how student data are kept confidential, that participation is voluntary and does not count towards school grades. Students can indicate to the survey administrator that they do not want to participate, and there is a “withdrawal” button on each page of the online survey so they can withdraw at any time during the survey which automatically deletes their questionnaire responses. Students who are not participating can work quietly on another activity related to regular classroom instruction provided by the survey administrator.

The Implementation team documents every parent query and complaint received, and makes improvements to the consent process as a result.

b. Translation

Once English language consent letters have been approved by the UBC Behavioural Research Ethics Board, they are translated in French, Punjabi, Tagalog, Traditional Chinese, Simplified Chinese, Spanish, Vietnamese, Korean, Farsi, Arabic, and Japanese.

c. Follow-up of Consent Letter Distribution

To ensure consent letters have been distributed, HELP communicates with each School District to confirm the date of distribution and that sufficient time has been provided for parent review of the consent form prior to the start of the study.

IV. Rationale for Passive Consent in HELP EDI and MDI

The use of parent informed passive consent with the EDI and MDI is supported by peer-reviewed research on children’s health and well-being that indicates that active consent procedures result in lower response rates and under-representation of subpopulations of children.⁸⁻¹¹ For low risk research, such as the case with the EDI and MDI projects, the informed passive consent approach is well supported in the literature within population-based research.¹²⁻¹⁵ In recent, unique research, van Woudenberg et al. (2023) investigated parents’ perceptions of parental consent procedures for social science research in the school context.¹⁶ They concluded that how appropriate parents perceive passive consent procedures depends strongly on the type of research. Passive consent was reasonably as appropriate as active consent in types of research such as surveys, longitudinal, observation and co-creation studies. In addition, in the sample of parents with a child in secondary school, the appropriateness of passive consent was equivalent to active consent in focus groups and longitudinal survey studies,^{16, 17} such as the design of the EDI and MDI studies. Moreover, the results of the exploratory analyses suggest that the appropriateness of passive consent coincide not only with the type of research, but also with the type of questions that are being asked within the study. As long as the questions do not ask about identifiable information, parents are open to passive consent. Irrespective of the consent procedure, parents indicated a strong liking for digital communication (i.e., email or website), preferably via the existing communication channel of the school.

a. Study Design

Passive consent makes the large-scale population-based EDI and MDI studies feasible compared with using an active consent model. The purpose of HELP Monitoring System research is to understand where systematic differences in the prospects for healthy child development are emerging among clearly defined populations of children in British Columbia. This requires looking at the whole population involved and complete subsets of marginalized and/or “underrepresented” groups. Past studies have found that active consent procedures underrepresent boys, ethnic minorities, and students with lower academic achievement.^{4, 8, 11, 12, 18} In large population samples, representativeness is challenged with active consent and it is not possible to evaluate systematic differences and change by relying on active recruitment.

b. Participation Rates and Children’s & Adolescent’s Views

Passive consent is reported to lead to higher participation rates and more representative samples without compromising data quality.^{8, 11, 19-22} Passive consent can also enable greater access to children’s views,²³ and gain direct access to children’s perceptions of issues such as violence which can be extremely important.²³ Guided by Article 12 of the United Nations Convention on the Rights of the Child, the findings support the ethical decision to adopt a passive consent procedure and demonstrated children’s competence to express the ways in which violence has affected them.²⁴ Heath et al. (2007) state that in respect of the rights of children and young people,²⁵ they should be able to opt in and out of research on their own behalf.²⁶ Coyne (2010) notes that there may be instances where it is not necessary or appropriate for parents to give consent, for example, in the case of minimal risk research.²⁷ Dockett et al. (2013) report an approach to engaging with children in research, emphasizing strategies to facilitate their informed, and ongoing, consent.²⁸ In investigating whether active parental consent, compared with passive parental consent, creates a bias in response rate, demographic makeup, and adverse outcomes in adolescent samples, Liu et al. (2017) concluded that active consent can lead to a systematic bias in the sample where the population under study is misrepresented and may limit the voice of high-risk adolescents.⁸

c. 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.^{4, 6, 29, 30} Given that the EDI and MDI studies gather information related to various domains such as physical activity, nutrition, sleep, behaviour, school connectedness, bullying, and academic achievement, and these outcomes have been shown to vary by age and gender, it is important to have data that are not biased on these important demographic characteristics 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 HELP research.

d. Student Confidentiality

There is minimal risk of individual identification because student’s identifiable data (e.g. PEN, postal code) are stored separately from the student’s responses to the survey. Additionally, data are analyzed on an aggregate (group) level, and never on the individual level. That is, individual data will never be used when reporting results. As such, this project contributes positively to public health and policy development. The Principal Investigators of HELP’s studies and researchers, highly sensitive to group privacy concerns, also ensure data do not implicate any group negatively. This is done through meetings with groups using the data to create awareness around appropriate ways to articulate findings in non-discriminatory ways, and

by holding workshops to create awareness of data sensitivity and ways to disseminate results in an appropriate way.

e. Best Practices and Ownership, Control, Access, and Possession Principles

We learned from a previous literature review (Appendix 1), discussions with the BC Teachers' Federation and the UBC Office of Research Ethics about best practices and processes for consent procedure, ensuring that a) all parents are informed of the study, b) parent withdrawals are reliably tracked at the school and c) children can comfortably opt out without feeling social pressure from peers or the survey administrator.

Clear procedures are in place to ensure parents are aware of the study and how to opt out. Parents can find information on the HELP website for either the EDI (<https://earlylearning.ubc.ca/monitoring-system/edi/edi-overview/>) or the MDI, (<https://earlylearning.ubc.ca/monitoring-system/mdi/mdi-overview/>).

In 2017-18, in response to the recommendation of HELP's Aboriginal Steering Committee, the Implementation Team added a description to the parent letter about how HELP respects Indigenous data sovereignty and community-based ethics codes and the process of sharing Indigenous data.

V. Use and Benefits of Passive Consent

Informed passive consent is a way to inform parents of the nature of a project and the use of the data. For assurance of HELP's care and attention in the use of informed passive consent, it is important to share that...

- All parents are provided notice of a research project that would involve their child and there is a wide window – two to four weeks -- to review the project and decline participation, if they wish. Reminders in school newsletters and communications are also part of the notification for parents so the information goes out and there is time for questions to be answered at any point. Participation is always completely voluntary.
- HELP translates consent letters into the most commonly spoken home languages representative of the parent population.
- Data collected about children are confidential and are reported only in a grouped way -- there is no individual level public reporting and results are not used for individual assessment of children.
- Participation in our projects is of minimal risk for students. All data are confidential and stored securely.
- In our projects where students complete surveys, HELP makes sure they know that their participation is voluntary, that their grade at school will not be affected by whether or not they complete the survey and that they can withdraw at any time.

High ethical standards are integral to HELP research. Good data begins with good ethics. HELP depends on population-level data and is able to collect these data using sound, strong, ethical research methodology for which HELP is well-known and respected.

What the EDI and MDI research studies provide, as validated, internationally-used tools, are comprehensive, population-level data – AND there are many benefits of population-level data:

- These data accurately reflect the state of well-being AND level of vulnerability which WE NEED TO KNOW for the WHOLE population of children in our communities.

- These data can help us answer complex questions and better understand how various factors can influence children’s development, well-being, and health. Findings generated by research questions can benefit policy makers, researchers, educators, and community stakeholders.
- These data provide reliable evidence for developing policies and programs to support healthy development across the life course.
- These data are available to schools and communities for planning.
- These data are inclusive and representative and, as well, these data can be used to examine distinct populations, such as rural and indigenous.
- These data can help identify patterns of development and “differences that make a difference” for children and families.
- These data lead to sound investments for children and families in British Columbia.

VI. Summary

In summary, the EDI and MDI research studies use informed passive consent to collect population-level data representative of the whole student population — data which are used to improve the lives of children and families and with that, contributes to immeasurable public good.

The passive consent approach used for the EDI and MDI in the Monitoring System has received ethics clearance from the University of British Columbia Behavioural Research Ethics Board. Passive consent is robust and ethical for use in the Monitoring System 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 Monitoring System study design, it results in robust participation rates and whole school data, produces data that are less prone to different types of bias, and the study involves minimal risk.

Please contact HELP if you have any questions about the EDI or MDI research programs and informed passive consent.

VII. Appendix 1: Literature Review

Objectives

The primary objectives of the literature review were to:

- Gather key, relevant papers pertaining to active and passive consent in social science or non-therapeutic research involving young and middle years children (5 to 13 years of age)⁴, and;
- Outline issues and summarize the literature regarding the use of passive consent in studies involving children.

Methodology

Publications in peer-reviewed journals were accessed to identify studies involving consent issues in research in children and adolescents. Search terms were selected to allow for the identification of studies examining a variety of consent and a range of outcomes for comparative purposes. A literature review was first completed in 2018 and no limits were applied with respect to the date of publication. An update to the first review was completed in April 2023 and the date restriction “2018 to 2023” was added to capture more recent, relevant publications on passive consent. Clinical, therapeutic, and health services studies were excluded as were studies of adolescents/youth in the first literature review, however adolescents were included in the update. Although the focus of this review is published, peer-reviewed journal articles, consideration is also given to Canadian health and behaviour surveys of children and adolescents.

Through initial scoping using EBSCOhost (to access MEDLINE, CINAHL, PsycINFO, Biomedical Reference Collection, and Academic Search Complete), Ovid (to access Elsevier Science Direct, Evidence Based Medicine, SAGE journals online, and Cochrane Database of Systematic Reviews), and Google Scholar (to access books, book chapters, older articles, and articles from journals not indexed through major database platforms), 101 articles were identified in the 2018 literature review and 36 articles were selected for full-text review after applying inclusion and exclusion criteria. In the 2023 literature review update, an additional 12 articles were identified and 3 were selected for full-text review. Appendix 1A provides detail on the search strategy, including selected databases, key concepts, and inclusion and exclusion criteria.

Definition of Key Terms

One issue that complicates inquiry into this topic is the lack of a single, standardized term to describe the type of consent in which participants are informed of the study, and are considered to agree to participate unless they specifically decline to be included in the study. The summarized studies used a variety of terms, often without specifying exactly what was meant, including: "passive consent", "implicit consent", "implied consent", "negative consent", "parental consent", "informed dissent", "opt-out", and "proxy". We use the term "passive consent" as the preferred term in this literature summary. We compare it with "active consent" or the type of consent with the approach where participants indicate their willingness to participate by agreeing to a specific statement, and then are included in the study. Additional terms encountered in the reviewed research for the latter type of consent included "active consent", "express consent", "positive consent", "informed consent", and "opt-in". Given the variety of terms employed by researchers, a certain degree of flexibility with definitions was adopted in reviewing the literature.

Results

A total of 39 papers were reviewed, including empirical, cross-sectional, mixed-methods, ethnographic

⁴ Children (5 to 13 years of age) were the focus of the first literature review in 2018 and for the updated review in 2023, literature relating to passive consent in studies of adolescents (14 to 18 years of age) was also considered.

inquiry, qualitative reports, and reviews. With respect to assessment of active and passive methods for obtaining parental consent, three themes were extracted from the papers: 1) benefits of employing passive consent in studies involving children and capturing children's voices in research, 2) issues involving active parental consent in studies involving children, and 3) general context and protocol considerations regarding consent in research involving children and adolescents. A fourth theme is added to summarize points related to grey literature involving Canadian health and behavior surveys in children and adolescents.

1) Benefits of employing passive consent in studies involving children

Passive consent is reported to lead to higher participation rates and more representative samples without compromising data quality.¹⁹⁻²² Passive consent can also enable greater access to children's views.²³ Carroll-Lind et al. (2006) report that with passive consent it is possible to gain direct access to children's perceptions of issues such as violence which can be extremely important.²³ Guided by Article 12 of the United Nations Convention on the Rights of the Child, the findings support the ethical decision to adopt a passive consent procedure and demonstrated children's competence to express the ways in which violence has affected them.²⁴ In older research, Grover (2003) claimed that proxy consent for children's involvement in research is justifiable only when given for and on behalf of the child in his or her best interest to enhance the child's well-being³¹ and Ellickson and Hawes (1989) suggested that passive consent can provide a viable alternative to active consent when supplemented by appropriate backup and privacy safeguard measures.³²

Heath et al. (2007) state that in respect of the rights of children and young people,²⁵ they should be able to opt in and out of research on their own behalf.²⁶ Abramovitch et al. (1991) concluded that children between the ages of 5 and 12 have the capacity to meaningfully assent to participation in research, but that there are substantial problems in guaranteeing that they are able to make this decision freely.³³ Coyne (2010) notes that there may be instances where it is not necessary or appropriate for parents to give consent, for example, in the case of minimal risk research.²⁷ Hallett and Prout (2003) propose that children's voices should be heard much more strongly in the process of policy formation at all levels.³⁴ Strategies researchers can use to help young children understand the research process and be better able to give informed consent are discussed.³⁴ Dockett et al. (2013) report an approach to engaging with children in research, emphasizing strategies to facilitate their informed, and ongoing, assent.²⁸

2) Issues involving active parental consent in studies involving children

Active parental consent has been reported to influence study participation, response rates, and sample characteristics. In a large study which employed active parental consent, researchers have found that high student mobility and larger school size are associated with lower form return and lower participation rates.³⁵ Surveying in the fall or spring (as opposed to winter) significantly decreased form return and participation rates, while being surveyed by internal staff (versus external screeners) significantly increased form return and participation rates.³⁵ Various researchers have concluded that subject selection bias may represent a threat to the validity of studies using a written parental consent procedure.^{12, 36, 37} In Frame and Strauss' grade-school student study of active parent consent, social withdrawal and poor academic performance were the best independent predictors of non-consent.³⁸ In a large sample (n=4500) of middle school students, Esbensen et al. (1999; 1996) indicated that active consent procedures produced deleterious effects on participation rates and lead to an underrepresentation of at-risk children in the sample.^{39, 40}

Jelsma et al. (2012) concluded that the high non-response rate and associations between response and

parental interest and gender indicate that some bias may be introduced through the need for active consent.⁴¹ In a weight-related survey of children, Mellor et al. (2008) reported that parents of children who are overweight or at risk for being overweight are significantly less likely to give active consent. In addition, parents of children enrolled in lower grades are more reluctant to consent to participate.⁴² White et al. (2007) reported that active consent leads to increasing difficulty in obtaining an acceptable response rate with an associated increase in administration costs.²⁹ Ellwood et al. (2010) reported that the requirement for active consent for population school-based questionnaire studies can impact negatively on response rates, particularly English language centres, thus adversely affecting the validity of the data and ethics committees need to consider this issue carefully.²¹

A strong conclusion by Shaw et al. (2015) on parental consent was: *“Active only parental consent leads to biased samples and biased estimates of associations between outcomes of interest, which could lead to miss-targeted behavioural policies and interventions. Strategies to boost response rates to levels sufficient to warrant the conduct of the research are labour-intensive and costly, and the obtained samples are still likely to be biased. For low risk research, such as bullying surveys, rigorous active–passive consent procedures which result in higher participation rates, lower costs and reduced burden on teachers and schools, are recommended.”*¹²

Gallagher et al. (2010) on active consent: *“...we highlight problems of information, understanding, authority, capacity and voluntariness. We conclude that informed consent is more problematic than is generally admitted, and that researchers would benefit from more openly acknowledging its limitations.”*⁴³ Echoing this, Strugnell et al. (2018) concluded in their research on passive consent that better scientific outcomes will emerge through use of passive consent in prevalence, monitoring and community intervention studies on childhood obesity.¹¹

In a review by Hollmann and McNamara (1999) on issues associated with the use of active and passive parental consent procedures, they concluded that active consent procedures satisfy legal and ethical requirements but include problems such as low response rates, non-representative samples, and costly implementation. Passive consent, however, has been questioned regarding its ability to adequately inform parents.⁴⁴ Studies that employ good communication strategies with parents can assist in informing parents adequately.

3) General context and protocol considerations regarding consent in research

Protocol considerations include such aspects as ensuring that parents have sufficient information about the study, consent forms are translated into home languages, children are informed of their research rights, responses are confidential, etc. With respect to ethics and research protocol to prevent harm and ensure that studies are in the best interest of children participating, much of what is reported on protocol is drawn from studies involving active consent. For example, Lambert and others⁴⁵⁻⁴⁷ have suggested information to provide to children in order for them to decide on participating such as:

- State that they are being invited to take part in a research project
- Outline what you are doing and why this research is being undertaken
- Explain what will happen to them if they decide to take part
- Explain to them that they do not have to take part, it is up to them to decide to participate, or not
- If they do not wish to take part reiterate that this will not affect the services they receive and no one will be upset about the refusal
- Explain that information they provide is private unless they disclose that they or someone else is at risk of harm.

Felzmann (2009) discusses the complexity of the school setting and how it has implications for the management of the informed consent process, including the decision at what point and in which manner each stakeholder group (researchers, parents, children, school principals, teachers and children's peer group), needs to be involved in the process. The presence and divergent roles of multiple stakeholders in school settings also have implications for addressing issues of confidentiality.⁴⁸

Finch (2016) explores some of the assumptions underlying 'informed consent' and the notion of 'consent pedagogy'.⁴⁹ David describes the process of providing children 'information' through leaflets and classroom activities in order for them to make 'choices' about participation.⁵⁰

In a U.S. social policy report, Fisher et al. (2013) note that parents, child and youth participants, at times, cannot understand IRB-required consent forms and urge revisions that allow for modification of the consenting process.⁵¹ Yazejian (2013) states "*They [Fisher et al., 2013] reiterate the point that the current IRB process has been based on a biomedical model and is ill-fitted for social and behavioral research.*"⁵² Powell and Smith (2006) make suggestions to enhance children's participation in research and demonstrate a respect for their participation rights.⁵³

Priest et al. (2012) planned to review active versus passive parental consent for improving participant recruitment and outcomes in studies targeting children, however due to lack of funding this work did not proceed.⁵⁴

Crane and Broome (2017) conducted a review of twenty-three empiric studies to examine ethical issues in research with children and adolescents. They reported that "*Even young children demonstrated the ability to understand essential elements of research, although there is variability in children's level of understanding. Trust was a significant contributing factor to children's and adolescents' participation in research, and also shaped their assessments of risk. Incentives were mainly viewed positively, although concerns of possible undue influence were expressed.*"⁵⁵

4) Grey literature

Of Canadian health and behavior surveys involving children, the ages of individuals included in the study populations vary, making direct comparisons challenging with respect to participation rates and method of consent. Nonetheless, it appears that those studies involving passive consent have higher participation rates.⁵⁶⁻⁶⁰ Clearly, where active consent was required for the Kindergarten Parent Survey (Offord Centre for Child Studies)⁶¹ the participation rate was far lower and researchers note the issue of sample bias as a result. In studies of youth,⁶²⁻⁶⁴ the Compass study (designed to facilitate multiple large-scale school-based data collections similar to the Early Development Instrument⁵⁶ and Middle Years Development Instrument studies^{56, 60}) published a technical paper on consent emphasizing that passive consent is critical in its design such that there is an appropriate sample to answer the research questions and to protect the confidentiality of participating students.⁶⁴

In a pre-print (considered grey literature in this review), van Woudenberg et al. (2023) reported on their study to ascertain parents' perceptions of parental consent procedures for school-based research.¹⁶ They used an online survey in which parents were exposed to video vignettes of multiple types of research in the classroom and were asked to indicate how they rate active and passive parental consent in terms of appropriateness. In half of the research methods (observation, focus group, co-creation, surveys, and longitudinal surveys), passive parental consent scored on average above the midpoint of the scale.^{16, 17} Passive consent was rated comparably appropriate for some types of research, particularly for secondary school children.

Discussion

Of the studies involving active and passive consent with children, passive consent is reported to increase response rates and representativeness of samples, and maintain data integrity. Passive consent can also enable greater access to children's views. For low risk research, passive consent is well supported and can be less problematic for population-based study. The informed consent process can be complex, with multiple stakeholder groups. Multi-level strategies are recommended to boost participation and achieve wider samples although this can add time and expense to research. Study confidentiality may be harder to maintain with active consent. Providing additional study information and translated consent forms can be beneficial, particularly where the home language is not English.

Strengths and Limitations of Evidence Base

The wide range in type of studies, consent, sample sizes, and participant ages challenge the literature synthesis but themes emerged that provide guidance on this topic. Ethics review board requirements for studies vary from country to country so comparisons are complicated.

Appendix 1A: Literature Search Strategy

A.1 Selected Databases

- Academic Search Complete; CINAHL; Medline; and PsycInfo (accessed via EBSCO); Cochrane Database of Systematic Reviews; Evidence Based Medicine; SAGE journals online, and Elsevier Science Direct (accessed via OvidSP); the Science Citation Index and Social Science Citation Index (accessed via Web of Knowledge); and Google Scholar.

A.2 Search Concepts and Keywords

Two principal topic domains were identified for use in the databases described above: 1) method of consent and 2) social science surveys/studies involving children. To capture the first domain, keywords included: "passive consent" OR "implicit consent" OR "implied consent" OR "parental consent" OR "negative consent" OR "informed dissent" OR opt-out OR proxy as well as "active consent" OR "express consent" OR "informed consent" OR opt-in. In order to locate studies involving children or the process of ethical review, terms included: children OR bias OR ethics OR "institutional review board" OR IRB OR gatekeeper. Boolean logic was integrated to combine the two constructs and to avoid the inclusion of irrelevant results. Specific Google Scholar searching involved limiters such as "intitle:consent" and exclusions (e.g., -clinical -vaccination).

A.3 Inclusion and Exclusion Criteria

Articles published in non-English languages were excluded due to a lack of resources available for translation. In terms of study design, reviews, surveys, cohort studies, case-control studies, ethnographic inquiry, longitudinal, and linkage designs were all eligible for inclusion. Chapters and articles with context or process information related to consent were included. Commentaries, editorials, and studies reported solely as abstracts (such as conference proceedings) were excluded. Studies involving clinical or health care were excluded as were those involving youth or adolescents rather than children between 5 and 13 years of age in the first literature review in 2018, however adolescents were included in the population of interest in the 2023 review. No geographic limitation was placed on the search and the papers included are representative of various countries, for example, Canada, US, Australia, New Zealand, Ireland, Scotland, UK, Scandinavia, and South Africa.

A.4 Literature Organization and Storage

Bibliographic details and links to electronic versions of all 39 articles selected for full-text review were maintained in an Endnote citation management database.

Further references for considering ethical issues are:

Anderson P, Morrow V, editors. **The ethics of research with children and young people: A practical handbook**. New York, NY: Sage; 2011. Available from: <http://methods.sagepub.com/book/ethics-of-research-with-children-and-young-people>.

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Slee PT, Campbell M, Spears B. The ethics of research involving young people. In: Slee PT, Campbell M, Spears B, editors. **child, adolescent and family development**, 3rd ed. Cambridge, UK: Cambridge University Press; 2012. Available from: <https://www.cambridge.edu.au/academic/companion/development/>.

Spriggs M. Understanding consent in research involving children: The ethical issues a handbook for Human Research Ethics Committees and Researchers: Parkville, Vic, Australia: Murdoch Children's Research Institute; 2010. Available from: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.542.6712&rep=rep1&type=pdf>.

Note:

Unable to review: Rees R, Garcia J, Oakley A. Consent in school-based research involving children and young people: a survey of research from systematic reviews. *Research Ethics Review*. 2007;3(2):35-9. Available from: <http://eprints.ioe.ac.uk/3704/>.

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The Human Early Learning Partnership is situated within the traditional, ancestral and unceded territory of the x^wməθk^wəyəm (Musqueam) People.

https://earlylearning.ubc.ca/app/uploads/2023/08/HELP-Technical-Report_Passive-Consent.pdf

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Michele Wiens, Senior Manager
(Knowledge Management)
Email michele.wiens@ubc.ca

Faculty of Medicine, SPPH
2206 East Mall, UBC
Vancouver, BC V6T 1Z3
Phone 604. 822. 1278
Email earlylearning@ubc.ca
Web www.earlylearning.ubc.ca