

# Obtaining active parental consent for school-based research: a guide for researchers

## Abstract

**Objective:** Schools increasingly require researchers to obtain active parental consent for students to participate in health research. We sought to identify effective strategies for the recruitment of child research participants through schools.

**Method:** A search of Medline, PsycINFO, Educational Resources Information Center, ProQuest 5000 and the Cochrane Library electronic databases was conducted for the period 1988 to 2008.

**Results:** The review found evidence that the following strategies may be effective in enhancing participation rates:

- 1) promotion of the research to school principals, teachers, parents and students;
- 2) dissemination of study information using methods allowing direct contact with parents (i.e. telephone or face-to-face);
- 3) provision of incentives to teachers, students and at a class level;
- 4) making reminder contacts; and
- 5) having a member of the research team co-ordinate and closely monitor the recruitment process.

**Conclusion and Implications:** Application of these strategies should reduce the risk of non-response and other biases that result from selective non-participation. Further randomised controlled trials of these and other strategies are required to strengthen the evidence base.

**Key words:** methods, schools, child, data collection, active consent.

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To conduct paediatric research through schools, institutional review boards and research ethics committees usually require researchers to obtain signed parental consent, that is, active consent. This requirement presents a number of challenges for researchers,<sup>1,2</sup> and typically results in research participation rates between 30% and 60%.<sup>3</sup>

Methodological studies suggest that the risk of non-response bias in surveys increases substantially once participation rates fall below 80%.<sup>4</sup> The effect of non-response on the validity of inference from health research varies by study aims and design. In surveys, where the aim is to estimate the prevalence of a problem or risk behaviour, selective non-response can bias estimates. In cohort studies, if participants fail to complete follow-up assessments, relative risk ratios can be biased (attrition bias); and in intervention trials, loss-to-follow-up, particularly if differential by group, can result in biased estimates of effect. The presence of such biases has been documented in a number of school-based studies with low participation rates or high

rates of participant attrition. For example, students who truant, are from minority groups, of lower socio-economic status, or who engage in risky health behaviours<sup>3,5-7</sup> have been found to be less likely than their peers to participate in research requiring active parental consent, resulting in biased estimates from research studies among groups with the poorest health status.

In Australia, the utility of data collected through a number of recent large school-based health surveys requiring active parental consent has recently been questioned because of poor participation rates.<sup>8</sup> In order to provide guidance for researchers seeking to recruit study participants through schools, a literature review of published studies examining the effectiveness of strategies for obtaining active parental consent was conducted.

## Method

Initially, a systematic review of randomised controlled trials of school-based recruitment strategies was conducted, however, a search of Medline, PsycINFO, Educational Resources

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Information Center, ProQuest 5000, and the Cochrane Library electronic databases for research published between 1988 and 2008, identified just three randomised controlled trials (RCTs). The inclusion criteria was therefore extended and findings of other relevant quasi experimental, cohort and case studies published after 1995 identified during the literature review were included. A selective narrative synthesis of research was therefore performed to provide guidance for researchers on the following aspects of recruitment within schools: promotion of research to school staff, parents and students; dissemination of study materials; use of incentives; follow-up recruitment contacts; and oversight of the recruitment process.

## Findings

Table 1 presents the study design and the key findings of studies included in the review. All studies were primarily conducted in the US, one of which was an international study that also included the recruitment of Australian school students. Studies varied considerably in the reporting of outcome measures, including assessments of consent form return rates (regardless of whether parent consent was provided), consent rates (where parent permission was provided), and participation rates (where consent was provided and students participated).

### *Promotion of the research project*

#### *School staff*

Consent from the school principal is required for research to be conducted in schools, and their support for the research project is likely to be influential in parent decisions to allow their children to participate, and in school staff efforts to facilitate recruitment.<sup>9,10,11,12</sup> In interviews with school personnel responsible for recruiting students to a drug and alcohol survey, principals were rated as having more influence on parent decisions regarding their child's participation than were superintendents, school boards or the local mayor.<sup>12</sup> Direct contact with the school principal and school staff to secure their support and endorsement has been recommended by several authors.<sup>10,13-15</sup> During such contacts, it is suggested that researchers outline the following: the importance of the study and any benefits of participation to the school, students and staff; specific staff roles and responsibilities; possible barriers to the recruitment of students; and procedures for contacting the research team.<sup>13</sup>

#### *Parents*

Informing parents about research projects prior to requests for active consent has been suggested as a useful strategy to facilitate child participation.<sup>1</sup> Promoting the study through usual parent communication channels (e.g. school newsletters), a form of pre-notification, is a common strategy employed by researchers prior to seeking consent.<sup>1,12,13,16-18</sup> Overt endorsement of the study by the school principal, such as through a signed letter to parents, is a key component of efforts to recruit child participants.<sup>12,18</sup> In addition, research staff attendance at school open days, orientation nights

or parent teacher meetings, is reportedly effective in promoting study participation to parents and provides an opportunity for parents to question the researchers.<sup>1</sup>

#### *Students*

Sufficiently informing students of the research and participation requirements can encourage those interested in participating to request consent to do so from their parents.<sup>1,2</sup> As with promotion of the research to parents, the endorsement and support of school staff (e.g. during school assembly), may positively predispose children toward participation. Face-to-face interaction between research staff and students during visits to schools, and increasing recognition of the research project through the development of an appealing project name and brand, has also been recommended.<sup>10,19,20</sup> In the interests of protecting children, government departments and research ethics committees will require that all research staff have the appropriate police clearances.

### *Dissemination of study material*

Effecting direct contact with parents is important for obtaining consent.<sup>11,18</sup> For example, Stein and colleagues, in their survey of primarily African American and Latino students, reported that an explanation of the research and the distribution of consent forms with other enrolment documents to parents during an orientation meeting, yielded a significantly higher rate of return of consent forms than a strategy where class-based incentives were offered and consent forms were sent home with students (90% vs 53%).<sup>18</sup> Other contact strategies, such as telephoning parents or guardians to explain the study and participation requirements, are also likely to be effective.<sup>12,13</sup> It should be noted, however, that institutional review boards, research ethics committees and schools typically do not approve requests for access to parental contact details to permit direct telephone or mailed contact.<sup>14</sup>

The most common method of distributing consent forms to parents is via students. Integrating the consent process into other school activities which engage parents has been recommended as an effective means of maximising consent rates via student delivered methods.<sup>12</sup> For example, a return rate of 85% was achieved in a study by Pokorny and colleagues where the consent procedure was combined with school requirements for a parent signature on school reports.<sup>17</sup> The integrated method even appeared to be superior to a procedure in which forms were mailed directly to parents.

### *Provision of incentives*

Several studies show that school, class (peer) and individual incentives are a particularly potent strategy for encouraging student return of consent forms.<sup>10,12,19,21-24</sup> A randomised trial examining consent form return as part of a vaccination program found that return rates were greater in schools which received class incentives (pizza or ice cream coupons) than for an identical procedure without class incentives.<sup>21</sup> Incentives do not have to be extravagant to influence student response rates, but should be appropriate and relevant to the target population.<sup>10</sup> For example, in a group of low

**Table 1: The design, recruitment strategies and key findings of studies included in the review.**

Reference	Design/participants	Recruitment strategy	Findings
Unti et al. 1997.	RCT. 429 7th grade students from 4 schools in the U.S. Schools randomly assigned to recruitment strategies for consent to participate in a school vaccination program.	Strategy 1: Study presentation at school assembly; consent forms sent home and returned with children; individual incentives (extra scholastic credits). Strategy 2: Strategy 1 plus peer incentives if all students in class returned forms (pizza/ice cream party).	Strategy 2 schools had higher five day return rates than strategy 1 schools (91% and 98% v.s 82% and 86% respectively).
McMorris et al. 2004.	RCT. 1,058 5th, 7th and 9th grade students from 46 schools in Australia and the U.S. Schools randomly assigned to recruitment strategies for consent to participate in the International Youth Development Study.	Strategy 1: Consent forms mailed to parents; parents returned forms via mail in postage paid envelope; mailed replacement packs and telephone calls to parents who had not returned forms. Strategy 2: Consent forms sent home and returned to school via student; individual incentives (pen) in Australian schools; peer incentives in U.S. schools (\$100 class gift certificate) if 90% returned forms; mailed replacement packs and telephone calls to parents who had not returned forms.	Strategy 2 schools had higher return rates than strategy 1 schools (90% v.s 58%, $p<0.001$ ). Strategy 2 schools had higher consent rates than strategy 1 schools (78% v.s 52%, $p<0.001$ ).
MacGregor et al. 1995.	RCT. 482 7th and 8th grade students from one school in the U.S. Home rooms were randomly assigned to recruitment strategies.	Strategy 1: Consent forms sent home and returned to school via student; and individual incentive (entry in a lottery). Strategy 2: Same as strategy 1 however parents returned forms via mail in a postage paid envelope.	The overall initial return rate was low (6.4%). The number of forms returned using strategy 2 was greater than strategy 1 ( $p<0.05$ ).
Stein et al. 2007.	Quasi experimental. More than 1,500 6th grade student, primarily African American and Latino, approached to participate in the Cognitive-Behavioral Intervention for Trauma in Schools (CBITS) program in the U.S.	Strategy 1: Cover letter signed by principal and CBITS clinician; telephone contact for parents to call if they required further information; consent forms distributed with other school forms during a parent orientation meeting; weekly reminders to teachers to collect consent forms. Strategy 2: Cover letter signed by principal and CBITS clinician; telephone contact for parents to call if they required further information; clinicians visited homerooms to distribute consent forms and explain the program; peer incentives (ice cream party) if 90% of students in homerooms returned consent forms; weekly reminders to teachers to collect consent forms.	Strategy 1 yielded higher return rates than strategy 2 (90% vs 53%, $p<0.05$ ). Strategy 1 yielded higher consent rates than strategy 2 (70% vs 28%, $p<0.05$ ).
Pokorny et al. 2001.	Cohort study. Approximately 6,000 6th-8th grade students from 23 schools approached to participate in a tobacco alcohol and drug survey in the U.S.	Schools used various recruitment strategies. Strategy 1: (used in 7 schools): Consent materials sent home via students attached to student report cards (which required parent signature); consent form returned by student; teacher follow up of unreturned report cards/ consent forms. Strategy 2: (used in 13 schools): Consent materials mailed directly to parents but returned to school with students; teacher follow-up of unreturned consent forms. Strategy 3: (used in 1 school): Consent materials mailed directly to parents and returned via mail in a self addressed envelope that was provided.	For schools implementing strategy 1 the participation rate was 85%. For schools implementing strategy 2 the participation rate was 82% in 9 of the 13 schools and 55% in the remaining 4 schools. For the school implementing strategy 3 the participation rate was 66%.
Tung et al. 2005.	Cohort study. 8,918 5th and 6th grade students from 75 low socioeconomic schools approached for consent to participate in a vaccination program in the U.S.	Recruitment strategies were at the discretion of individual schools.	Return of consent forms was more likely in schools where nurses reported that teachers helped in publicity/ promotion, consent pack distribution, and consent form collection ( $p<0.05$ ).

**Table 1: The design, recruitment strategies and key findings of studies included in the review. Continued.**

Reference	Design/participants	Recruitment strategy	Findings
Ji et al. 2004.	Cohort study. 21,123 7th-10th grade students from 41 schools approached to participate in a tobacco alcohol and drug survey in the US.	Methods to recruit students varied between participating schools but included: project staff discussions with parents during student school enrolment; student incentives (extra-credit) for returning consent forms; peer (pizza party) and teacher incentives (gift certificate) if all students returned forms; inclusion of consent forms with school forms or report cards; mailing consent forms directly to parents; providing stamped envelope for form return; assigning teaching staff responsibility for distribution and collection.	Procedures where the consent form was attached to a school form that parents had to sign and return to school yielded the highest return rate.  Middle schools had significantly higher average return rates than high schools ( $p < 0.05$ ).
Harrington et al. 1997.	Case study. 2,456 3rd grade students from 28 schools approached to participate in the High 5 Alabama child nutrition project in the US.	District nutritionist were enlisted to serve as advocates and facilitated recruitment of schools; research personnel held information sessions with teaching staff; consent forms distributed to parents and returned to school via students; student incentives (erasers) for return of forms; reminders letters; teachers encouraged to implement their own ideas to increase consent form return.	Overall, active parental consent was obtained for 67% of students.
Johnson et al. 1999.	Case study. 2,331 8th, 10th and 11th grade students from 16 schools approached to participate in a alcohol, tobacco and other drug prevention program in the US.	Letter of support from school superintendent; consent forms distributed to parents via student, mailed directly to parents or included as part of orientation packs (method determined by schools); reminders letters via students or mail (method determined by the school); students incentives for participation (lottery for \$50 gift certificate); additional strategies at the discretion of schools not meeting set benchmarks.	Overall 74% of students returned consent forms, of which 72% provided active parental consent.
Cline et al. 2005.	Case study. 4,273 5th - 12th grade students from schools participating in the Princeton City (Ohio) School District Study examining the development of obesity, insulin resistance and diabetes in US. adolescent students.	Not specified.	No specific return or consent rate provided. Authors recommend: a letter of support from the superintendent; research staff attendance at school open days researcher classroom visits; incentives for student participation; phone contact with parents of children interested in participation.
O'Donnell et al. 1997.	Case study. 3,253 7th grade students from 3 socio-economically disadvantaged schools approached to participate in the Reach for Health program targeting risks associated with drug abuse, violence and early sexual behaviours in the US.	Field coordinator, responsible for overseeing recruitment and meeting with teachers; regular coordinator visits to classrooms; consent materials distributed to parents via students; telephone number for parents if they required further information; school (\$250 gift certificate) and teacher incentives (\$25 gift certificate) if >90% return rate; student incentive for form return (t-shirts).	The overall return rate of consent forms was 89-95%.  The overall consent rate was 73-84%.
Leahey et al. 2004.	Case study. Approximately 4,000 7th and 8th grade students from 20 schools approached to participate in a smoking prevention trial (SPLASH) in the US.	Project staff co-ordinated the recruitment process and kept in contact with principals and teachers; support letter signed by the principal; consent materials sent home and returned to school via students; project staff visited participating classrooms; peer incentives (pizza party) for classes returning at least 90% of consent forms.	The overall return rate of consent forms was 90%, of which 93% provided active parental consent.
Esbensen et al. 2008.	Case study. Over 4,500 6th and 7th grade students from 29 schools approached to participate in the Gang Resistance Education and Training (GREAT) school based violence prevention program in the US.	Face-to-face meetings held between research staff, principals and teachers; consent materials sent home and returned to school via students; reminder letters; teacher financial incentives for each returned consent form (\$2) plus financial bonus for meeting return rate benchmarks (\$10-30); student incentives (FM radio) for returned consent forms.	The overall return rate of consent forms was 90%.  Overall rate of consent was 79%.

**Table 1: The design, recruitment strategies and key findings of studies included in the review. Continued.**

Reference	Design/participants	Recruitment strategy	Findings
Ladin L'Engle et al. 2004.	Case study. 5398 7th and 8th grade students from 14 schools approached to participate in a media (and subsequently a health) study in the US.	Recruitment into the health survey involved a two step process: 1. Recruitment into the media study incorporated face-to-face information sessions with up to 100 students to seek interest in participation and obtain contact details; consent materials mailed to parents of interested students; student incentives: \$1 (not contingent on return of forms), \$20 for participation, and prize draw (basketball tickets and gift certificates up to \$100); reminder letters and emails; additional reminder telephone calls and mailings for lower responding groups.  2. Students participating in the media survey were then mailed an information letter for a health survey. Consent to participate was then sought via telephone or home visit.	Approximately 85% of students expressed an interest in participating in the media study and were mailed study material, of which 65% participated in the survey.  Of the media survey participants 90% participated in the health survey.
Ji et al. 2006.	Case study. 811 3rd grade students from 14 socio-economically disadvantaged schools approached to participate in a prevention program (unspecified) in the US.	Research staff distributed consent forms and a letter of support from the principal to students in class; research staff visited classrooms to collect student returned forms daily; peer incentives (pizza party) and teacher incentives (gift certificate) if 90% of students returned forms.	Overall 98% of students returned consent forms, of which 79% provided consent to participate.
Elder et al. 2008.	Case study. Sixth, 7th and 8th grade female students from 36 schools across 6 sites approached to participate in the Trial of Activity for Adolescent Girls in the US.	For each of the six sites, participation rates were compared at baseline to two follow-up data collection periods. Recruitment methods varied across sites, schools within sites and between follow-up periods. Recruitment strategies included soliciting the support of principals; in school presentations; attendance at school open days; incentives; and follow-up telephone reminders.	Overall recruitment rates were 80% at baseline, 85% at follow-up 1 and 89% at follow-up 2.
Fletcher et al. 2003	Case study. 877 3rd grade students from nine schools approached to participate in a study investigating friendship in the US.	Principals designated specific school staff to facilitate recruitment; Research Assistants coordinated the recruitment process; consent forms distributed to parents via students; consent forms were designed to be easy to read and printed on colour paper; teacher incentives (\$5 gift certificate to spend on class resources for every returned form); Research Assistants at different schools implemented additional strategies at their discretion including class incentives for meeting benchmarks (candy); reminder letters with additional consent forms distributed to parents who had not returned forms; telephone follow-up of parents who had not returned forms.	Overall 95% of parents returned consent forms.  Overall 85% of parents provided consent.
Dent et al. 1997.	Case study. 2799 students from 21 continuation high schools (for students with academic difficulties) and traditional high schools approached to participate in a drug abuse prevention project in the US.	For both school types, consent materials were sent home and returned to school via students; students not returning forms within 1 week were telephoned by research staff to request verbal consent.	For the continuation schools, 39% of students returned forms and a further 39% provided verbal consent when telephoned by the researchers, compared with 61.6% and 28.3% respectively for traditional high schools.

socio-economic and ethnically diverse elementary school students, a recruitment strategy incorporating a pizza party for students and gift vouchers for teachers who met agreed recruitment benchmarks achieved a consent form return rate of 98%.<sup>22</sup>

### Parent reminders

High return rates (70-100%) can be achieved with multiple follow-up contacts and reminders,<sup>7,12,20,24</sup> especially via methods which permit personal follow-up contact with parents, such as the telephone.<sup>7,20</sup> Reminders and follow-up contacts are particularly important to ensure sufficient representation of minority groups who may be least likely to respond to invitations to participate

in research.<sup>20</sup> However, investment in more than three or four reminder contacts, is unlikely to substantially increase consent form return.<sup>11</sup>

### Recruitment oversight

Having a dedicated study co-ordinator to oversee the recruitment process appears to assist in eliciting parental consent, and it may be critical to ensuring study integrity.<sup>24</sup> Studies in which recruitment was the primary responsibility of teachers report poor compliance with consent procedures, such as teachers distributing consent forms late or not at all, misplacing returned forms, and providing incorrect instructions.<sup>14</sup> Accordingly, investigators should employ

strategies to: solicit buy-in from teachers and inform them of the benefits of the research to their students or the community; provide them with ongoing support and resources; undertake any aspects of recruitment that can be effected without teachers' help; and finally, they should closely monitor the recruitment process.<sup>1,13,19</sup>

## Discussion

We found surprisingly few randomised controlled trials examining the effectiveness of strategies for obtaining active parental consent for participation in school-based research. Including non-randomised studies, the findings of the review suggest that, to maximise participation rates, researchers should 1) promote the research to school principals, teachers, parents and students; 2) disseminate study information using methods allowing direct rather than mediated communication (i.e. telephone, face-to-face); 3) offer incentives to teachers, peers and individual participants; 4) provide three follow-up reminder contacts to parents who have not made a decision regarding participation; and 5) ensure that a dedicated member of the research team co-ordinates and closely monitors the recruitment process. This advice addresses an identified need among paediatric researchers, and should reduce the risk of non-response and therefore biases resulting from selective non-participation.

Given evidence of the effectiveness of direct rather than passive strategies found in the review, innovative recruitment approaches that are potentially more acceptable to Institutional Review Boards and ethics committees, but which allow direct contact with parents, warrant investigation. For example, McMorris and colleagues reported that direct telephone contact with parents to request consent for research participation was permitted following a passive consent procedure where parents notified schools if they did not wish to be approached by researchers.<sup>23</sup> Similarly, information regarding the impact of specific aspects of research, such as the demand characteristics of participation (e.g. requirement for a biological specimen) or the appearance of information sheets and consent forms (e.g. design or colour); and information regarding the effectiveness of novel recruitment methods, such as web-based strategies, may help researchers improve participation rates.

The primary limitation of this review is the necessary reliance on non-experimental studies which may have been biased by incomplete control of potential confounding variables, and the dearth of research outside of the US. Randomised controlled trials conducted in Australia and other countries' school systems are required to more robustly test the appropriateness of strategies identified here for researchers internationally. The findings of this review offer a guide for research practice in the meantime.

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