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Ethical Issues in “ Written Parental Consent and the Use of Incentives in a Youth Smoking Prevention Trial: A Case Study From Project SPLASH”

Although the potential ethical issues associated with this specific research seem minor, “ worst-case scenario” risks to participants could include invasion of privacy, psychological trauma or emotional upset, embarrassment, stigma, peer pressure relating to the survey and discussion of confidential survey content and time costs.   
The research also raised questions about the potential for coerciveness of students. A very large percentage of students whose parents completed the consent form by assenting that their child could participate in the survey also assented themselves. These high rates could indicate that teachers and schools, through highly encouraging student participation, plus the use of incentives, were possibly coercing students. Assent incentives for the 8th grade students in the form of a pen for the baseline survey and candy for the follow-up survey did play a role in student decision-making, as the authors observed that offering an incentive resulted in previously-reluctant students opting to take the survey. The unhealthiness of the pizza and the candy accompanying the program also arguably pose a health risk.   
In certain parts of the procedure, teachers were given significant responsibility and played a large role, such as in the 8th grade when teachers were solely responsible for motivating students to return with the written parental consent. Giving the teachers this role without making it clear how teachers could or could not motivate students could potentially pose ethical issues or influence the signing of written consent forms.

## How were the ethical issues resolved?

Researchers addressed the potential ethical issue that completing the survey might have posed by distributing a fact sheet and parental consent form to students to have signed by their parent or guardian and returned to school, regardless of whether or not the parent agreed to allow that student’s participation. On the consent form, parents were given multiple options from which to choose.   
In addition to written parental consent, on survey days students also had to give their assent after project staff explained the study. By requiring both parental and student assent, the researchers ensured that the students were willingly participating in the survey and their parent or guardian was also willing.   
The researchers did not observe any harm to students through participation in the study and believed that the benefits of providing tobacco-prevention education to at-risk youth outweigh the “ unlikely and/or unknown” risks. The sole parental concern the researchers fielded related to the funding source for the study, which was clarified by modifying the fact sheet in the consent form packet.

## Were the subjects appropriately protected? How and why?

It did seem as though the researchers appropriately protected the subjects. Assuming that the project staff remained neutral, did not coerce students whose parents had consented but were hesitating themselves into taking the survey and did not upset, embarrass or pressure students into taking the survey or at any other time during the study, the subjects were appropriately protected thanks to the use of the parental consent form and the requirement that students assent on the day of the survey.   
The researchers acknowledged the potential for student coercion resulting from teachers, the school and incentives and suggested that having