

# Consent Procedures and Participation Rates in School-Based Intervention and Prevention Research: Using a Multi-Component, Partnership-Based Approach to Recruit Participants

Jessica Blom-Hoffman · Stephen S. Leff ·  
Debra L. Franko · Elana Weinstein ·  
Kelly Beakley · Thomas J. Power

Published online: 4 November 2008  
© Springer Science+Business Media, LLC 2008

**Abstract** Evaluations of school-based interventions and prevention programs typically require parental consent for students to participate. In school-based efforts, program evaluators may have limited access to parents and considerable effort is required to obtain signed consent. This issue is particularly salient when conducting research in under-resourced, urban schools, where parent involvement in the school setting may be somewhat limited. The aims of this article were to (a) examine the published school-based prevention and intervention literature to assess the state of the field in terms of consent procedures and participation rates; and (b) describe two examples of health promotion studies that used multi-component, partnership-based strategies in urban schools to encourage communication among children, their parents, and researchers. The purpose of the case studies was to generate hypotheses to advance the science related to school-based participant recruitment for research studies. Of nearly 500 studies reviewed, only 11.5% reported both consent procedures and participation rates. Studies using active consent procedures had a mean participation rate of 65.5% (range: 11–100%). This article highlights the need for researchers to report consent procedures and participation rates and describes partnership-based strategies used to enroll students into two urban, school-based health promotion studies.

**Keywords** Partnership · Recruitment · Participation rates · School-based research · Prevention · Intervention

There are many challenges students face when striving to meet educational and social-emotional goals within the school system. In fact, some have argued that educators need to appreciate children's interactions within their family, neighborhood, and community to support their academic and social-behavioral learning (Masten, 2003). One way to support the healthy development of students is through school-based health promotion programs that are based on partnerships with representatives from the school and community (Power, Manz, & Leff, 2003). The reality is that these programs often require the support of extramural research grants to be implemented and evaluated. One of the main challenges in conducting research with children is obtaining parental consent. Research has the potential to be misunderstood by parents and the local community (Fantuzzo, Coolahan, & Weiss, 1997), and low rates of participation can reduce the impact of these programs and threaten the external validity of many potentially strong school-based intervention efforts (Anderman et al., 1995). High participation rates are important in prevention and intervention research to reduce sampling bias and to increase representativeness (Frye et al., 2003). Therefore, it is important that researchers and educators work together to establish acceptable, feasible, and cost-effective ways to promote clear communication among students, teachers, parents, and researchers.

Due to the importance of reporting participation rates in prevention and intervention research, the extent to which participation rates have been reported in the health

---

J. Blom-Hoffman (✉) · D. L. Franko  
Department of Counseling and Applied Educational Psychology,  
Northeastern University, 203 Lake Hall, Boston,  
MA 02115, USA  
e-mail: j.blom-hoffman@neu.edu

S. S. Leff · E. Weinstein · K. Beakley · T. J. Power  
The Children's Hospital of Philadelphia, The University  
of Pennsylvania School of Medicine, 34th Street and Civic  
Center Boulevard, Philadelphia, PA 19104, USA

promotion literature was investigated in three separate studies (Dzewaltowski, Estabrooks, Klesges, Bull, & Glasgow, 2004; Estabrooks, Dzewaltowski, Glasgow, & Klesges, 2003; Glasgow, Bull, Gillette, Klesges, & Dzewaltowski, 2002). These investigations reviewed nutrition, physical activity, and smoking cessation intervention studies published in leading health behavior journals. Dzewaltowski et al. found that 88% of studies conducted in community-based sites reported participation rates. Estabrooks et al. found that 59% of school-based studies reported participation rates. Finally, Glasgow et al. reported that 69% of studies conducted in healthcare settings reported participation rates. The purpose of this article is two-fold: (a) to examine the types of consent procedures used and the extent to which participation rates are reported across the broad range of school-based prevention and intervention programs, and (b) to describe two case examples that illustrate the use of multi-component, partnership-based strategies to improve study participation rates.

Although there are times when the requirement for informed consent is waived, most of the time Institutional Review Boards require signed parent/guardian consent for children to participate in research studies (U.S. Department of Health and Human Services, 2005). When these studies are based in schools, most school districts also need to approve the study. Parental consent can be either active or passive. Studies that use active consent procedures require parents to sign a consent form indicating permission for their child to participate. Parents who do not return forms or who indicate on the form that they do not wish for their child to participate are considered “parental refusals” (Ellickson & Hawes, 1989). Studies that use passive consent (or notice) procedures only require parents to respond if they do *not* want their child to participate in the study. In passive consent procedures it is assumed that a lack of parental response is considered parental agreement that the child can participate in the study. There is a concern that parents’ rights may be violated when using passive consent procedures because they may not have received proper notification about the study (Esbensen et al., 1996). For example, if a child loses or misplaces a consent form, the parent will never see the description of the research study, and the researcher will conclude that the parent allows the child to participate.

The primary advantages of active consent procedures are that they increase the likelihood that parents have information about a research study and make an informed decision about whether or not they wish for their child to participate, and they represent a more respectful means of communicating with parents than passive notice procedures. Nonetheless, it is possible for parents to sign active consent forms without reading or fully understanding the

study. Disadvantages of using active consent procedures are that they typically yield considerably lower participation rates than passive procedures (Esbensen et al., 1996), are more costly for researchers (Ellickson & Hawes, 1989), and may result in biased samples if the consent rate is low and/or not representative of the participating schools. These latter concerns have serious implications for a study’s validity (see Anderman et al., 1995).

With school-based studies, researchers may have limited access to parents and considerable effort may be required to obtain signed, active parental consent. These issues are particularly salient when conducting research in under-resourced, urban schools, where parent involvement in the school setting may be more limited (National Center for Education Statistics, 2004). Lack of parental involvement in urban schools has been shown to be related in part to the lack of congruence between the culture of schools and the cultures represented by the diverse families who reside in neighboring communities (Christenson & Sheridan, 2001; Power & Bartholomew, 1987). For example, language barriers can prevent families who speak limited English from communicating effectively with school staff. Further, some parents may not feel comfortable interacting with school staff, which may be interpreted as a lack of parental interest or investment in their children’s educational success (Moles, 1993). With regard to research participation, parents of ethnic minority background may not trust researchers and may be skeptical about having their children participate in studies (Fantuzzo et al., 1997). In their study examining differences between students whose parents provided written consent for their students to participate in a health survey and those who did not return the consent form, Anderman et al. (1995) found that students who returned signed consent forms were more likely to be White and live in two-parent households. However, another study found higher participation rates among Black students relative to their White peers (Frye et al., 2003). Parental skepticism about research may be related to language differences, cultural mismatch between the researchers and the potential participants, and cultural beliefs about the research relevance (Rodríguez, Rodríguez, & Davis, 2006) or it may be rooted in part in the history of mistreatment of minority participants, such as the Tuskegee experiment (Hatchett, Holmes, Duran, & Davis, 2000).

Depending on the sample size of the study, the participant recruitment process can take months and be very costly. In one study comparing active and passive consent procedures, passive consent procedures were successful in recruiting a 93% participation rate and active consent procedures were successful in securing a participation rate of 86% only after multiple follow up attempts using several different costly strategies (i.e., first class mailings, post card

reminders, two telephone calls, two special parent meetings, and daily teacher requests; Ellickson & Hawes, 1989). The cost of these efforts would be prohibitive for most researchers. When researchers are employed by institutions external to the school (e.g., universities and hospitals), there may be additional barriers to follow up efforts such as school policies that do not permit the release of parental contact information. Therefore, the consent process is typically a major challenge and this difficulty may be heightened for researchers working in schools with large numbers of students from lower socio-economic levels, where parent involvement in school can be more limited (Grolnick, Benjet, Kurowski, & Apostoleris, 1997). Nonetheless, researchers should not assume difficulties when recruiting participants from ethnic minority backgrounds (Rodríguez et al., 2006); researchers need to work conscientiously to utilize respectful procedures to ensure that parents are informed and can ask questions about the study.

Recruitment into school-based studies that are initiated by researchers external to the school typically begins with a series of meetings with school administrators and teachers. When approval for the project has been granted, the next step is for project information to be sent from the school to the home. There are numerous opportunities for breakdowns to occur in the “school-to-home-to-school” consent form process. For consent forms to be signed and returned in a timely manner, teachers must remember to send the consent forms home; children must remember to give the form to a parent to sign; children and parents must remember to put the form in the child’s folder or backpack to be returned to school; teachers must ask the children for the forms; and then teachers must keep them in a safe, organized place for the researcher to pick up. These same steps are required any time signed communication must pass via children from school to home and back to school (e.g., signed report cards, emergency contact forms, school-home notes). However, what is different in the case of a research study is that the consent forms require effort that exceeds teachers’ typical responsibilities. Further, communication with parents in under-resourced schools, in particular, is often constrained by additional factors that may affect students’ ability to bring back signed consent forms, including low literacy levels among parents and distrust between the community and university-based researchers (Fantuzzo, McWayne, & Bulotsky, 2003; Hatchett et al., 2000).

### Use of Partnerships to Enhance the Meaningfulness of School-Based Research

In order to conduct research that is socially meaningful, it is important for researchers to take time to understand and

appreciate the culture of the school and the surrounding community, and to incorporate this information into each stage of the research process (Fantuzzo et al., 2003; Ho, 2002; Tucker & Herman, 2002). The process of using empirically-based interventions and combining them with relevant psychological theory and then infusing feedback from key school and community stakeholders has been called “participatory action research” (PAR; Leff, Costigan, & Power, 2004; Nastasi et al., 2000). The advantages of utilizing PAR approaches are that resulting interventions are culturally sensitive and community-responsive, and are more likely to provide meaningful information and lead to sustainable gains within the relevant school or community settings (Hughes, 2003). The use of partnership-based research methodologies in urban, under-resourced schools where school and community members may be skeptical of the research process is critical (Fantuzzo et al., 1997). This article adds to the literature base by exploring how a participatory approach can be used in the initial stages of the research process to build communication among researchers, parents, and teachers, thereby facilitating a deeper understanding of the research process. This appreciation of the research process by parents may result in higher rates of parental permission.

### Purposes of the Article

The first purpose of this article is to describe the recruitment procedures and participation rates used in school-based intervention and prevention research studies that have been described in the published literature. The second purpose is to describe two case examples that used multiple strategies to recruit racially and ethnically diverse students attending under-resourced, urban schools to participate in evaluations of school-based prevention studies. In both illustrations, multiple strategies for building communication and trust between researchers and the school communities were employed. Participation rates and resources required to implement these multiples strategies are described. The case studies incorporated qualitative research methods (see Yin, 2003) to describe rates and quality of participation in two school-based research projects. The case examples suggest directions to advance the science related to school-based participant recruitment in research studies.

### Systematic Literature Review: Method

In order to review the status of participation rates and recruitment procedures in the school-based prevention and intervention literature, a PsychInfo search was conducted

in January 2007 using the following keywords: school-based prevention studies/programs, school-based intervention studies/programs. A total of 665 studies were identified and access to the full text of 481 studies was obtained (72% of the studies). Due to available resources, an a priori decision was made to review only studies available electronically for recruitment procedures and participation rates. The studies were published between 1977 and 2006. A research assistant (RA) reviewed the methods section of each article to determine (a) type of consent used (i.e., active, passive, or other) and (b) consent rate. When the article did not explicitly state that active consent was used, but used action verbs to describe the consent process (e.g., secured, received, requested, attained, required, provided, and obtained), it was assumed that active consent procedures were in place.

In order to assess inter-rater agreement, a second rater (RA) examined 124 studies (26% of total studies). Percent agreement between these two raters was 85% for consent type and 76% for participation rate. For cases in which there was disagreement between the two raters, a third rater (the first author) independently rated the article. In these cases, responses for which there was agreement between two of the three raters were used in the analyses. In this manner all discrepancies between coders were resolved. Following this initial review, a more detailed analysis of the articles reporting participation rates was conducted to examine the types of recruitment strategies used.

## Literature Review: Results and Discussion

Of the 481 studies reviewed, 10 were eliminated because they did not include children as participants or were not intervention or prevention studies. Of the remaining 471 studies, only 124 (26.3%) reported information related to whether consent procedures were utilized. As seen in Table 1, of these 124 studies, 75% reported using active

consent procedures and only 43.5% ( $n = 54$ ) of studies that included information about consent procedures reported the participation rate. Therefore, of the total school-based intervention and prevention studies that included child participants, only 11.5% reported consent procedures and participation rates. For studies using active consent procedures and reporting consent rates, the average consent rate was 65.5% (range: 11–100%), and for studies using passive consent procedures and reporting consent rates, the average consent rate was 89.1% (range: 74–99%). This last finding should be interpreted with caution, given that there were only four studies that used passive consent procedures to report participation rates.

We examined the possibility that researchers may be reporting participation rates more frequently in recent years and found this not to be the case. Although 76% of the studies that reported consent procedures and participation rates were published between 2000 and 2006, 71% of the studies that did not report this information were also published between 2000 and 2006. These data indicate there has been a proliferation of school-based prevention and intervention published research in recent years; however, researchers do not appear to be reporting participation rates any more frequently in recent years than in the past.

We attempted to examine ways in which demographic variables such as school location (e.g., urban, suburban, rural), participants' race/ethnicity, and percent receiving free or reduced price lunch may have impacted participation rates among the 54 studies that reported participation rates. Unfortunately, due to the small sample size and inconsistency in the reporting of demographic information across studies, we were unable to compare similarities and differences in participation rates across these potentially important variables.

Of the 54 studies that reported participation rates, nearly half ( $n = 24$ ; 44%) described specific recruitment procedures. A qualitative analysis indicated that the following procedures were used: (a) letters sent home via backpacks

**Table 1** Type of consent procedures used and participation rates reported in the school-based prevention and intervention literature ( $n = 124$ )

Consent procedure	Percent ( $n$ )	Percent ( $n$ ) of studies reporting participation rate	Mean participation rates (range)
Active consent	75% (93)	46.8% (43)	65.5% (11–100%)
Passive consent	5.6% (7)	57% (4)	89.1% (74–99%) <sup>a</sup>
Other (teacher, principal, adolescents only)	2.4% (3)	0	–
Both passive and active procedures used	3.2% (4)	75% (3)	– <sup>b</sup>
Not specified	13.7% (17)	23.5% (4)	–

<sup>a</sup> This mean participation rate should be interpreted with caution due to the small sample size

<sup>b</sup> Participation rates for the two studies that used both passive and active procedures were incorporated into the mean participation rates for the active and passive categories, respectively

**Table 2** Participation rate by recruitment strategy for articles that described recruitment procedures ( $n = 54$ )

Strategy	Number of studies	Participation rate <i>M (SD)</i>
Letters only	12	60.2% (30.6)
Phone calls home	2	67.5% (29)
Home visit only	1	60.5%
Contingency only	1	80%
Letter + school presentation	2	76.5% (24.7)
Letter + contingency	1	67%
Phone calls + home visit	1	72%
Letter + phone calls + contingency	2	50.45% (33.3)
Letter + presentation + contingency	1	97%
Letter + word of mouth + presentation	1	46%
Not described	30	74.4% (17.3)

or the mail, (b) phone calls made to the home, (c) home visits, (d) contingencies, (e) school presentations made to students or parents, and (f) a combination of strategies. As can be seen in Table 2, the majority of the studies that reported recruitment procedures described only one strategy (67%), and the most common strategy was sending letters home. Unfortunately, the sample size was too small to explore differences in participation rates as a function of the number or type of strategies used. One study that achieved a 99% participation rate (Mathews et al., 2005) held evening meetings for parents to ask questions and to obtain information about the research, translated all documents into the families' native language, described the research to students in their native language, made repeated classroom visits to explain the research and consent process to students and to hand out extra copies of consent forms, sent follow-up letters home to parents, and made

follow-up phone calls and home visits to request consent if parents/guardians did not have a telephone. Although these approaches are admirable, they may not be feasible for most research teams.

Overall, our review of the school-based prevention and intervention literature indicates that most school-based studies did not provide information on both consent process and resultant participation rates. In addition, most of the studies that were highly successful in recruiting participants did not report the strategies used to achieve these results. Thus, determining which strategies lead to higher permission rates is challenging. For the few successful studies that did report consent rates, the types of strategies employed might not always be feasible for researchers to conduct outside the context of a large, funded initiative. Overall, these findings are concerning. Given the lack of information regarding participation rates, it is difficult to establish if there are differences between those children whose parents allowed them to participate in a study and those who did not. This lack of information limits the ability to generalize research findings to broader groups of students (Anderman et al., 1995).

The two case examples that follow describe multiple recruitment efforts conducted in large, urban public school districts. The average active consent participation rate (65.5%) obtained from the systematic literature review described earlier was used as a benchmark to assess the success of the multi-component strategies used in the two case studies. As illustrated in Table 3, the multiple components included (a) establishing a need for the research project at the schools; (b) identifying key stakeholder groups in the school community; (c) finding optimal ways of communicating with teachers, parents, and students; (d) meeting with key stakeholder groups to explain the project and to listen to concerns; (e) developing a classroom-based incentive plan collaboratively to encourage home-school

**Table 3** Multi-component strategies for promoting home-school communication to recruit participants

Strategy	Brief description
1. Establish a need for the research project at participating school	1. Developing a shared vision for the research project is a crucial ingredient of partnership-based research paradigms
2. Identify key stakeholder groups	2. Identifying both formal and informal groups who understand and contribute to the school culture is extremely important
3. Find optimal ways to communicate with teachers, parents, and students	3. Establishing multiple ways for informing teachers, parents, and students about the study helps to establish support for and excitement about the research project
4. Meet with teachers, parents, and students to explain the project and to understand their needs/concerns	4. Clarifying the research process, what information will be shared with the community, and how consent will be obtained helps in building trust
5. Jointly decide upon an incentive plan to promote positive communication	5. Enlisting support of key stakeholders in establishing incentive plans helps to ensure its success
6. Provide reminders to students and teachers to encourage return of forms	6. Providing reminders in a consistent and respectful manner is often viewed positively by school staff

communication; and (f) providing reminders to students and teachers to encourage the return of consent forms. Whereas these recruitment strategies took effort to build relationships between the researchers and the school communities and financial resources, they were made without obtaining parents' personal contact information.

### **Case Example 1: The Athletes in Service 5 a Day Program**

This first case example required students to have signed consent forms to participate in the outcome evaluation of a school-based fruit and vegetable promotion program. The goals of the multi-component, universal program, called Athletes in Service 5 a Day (AIS), were to increase children's fruit and vegetable consumption, particularly during school lunch. Components of the nutrition education program included school-wide, classroom, lunchroom, and family activities, based on social learning theory (see Blom-Hoffman, 2008, for a description of the program). The multi-year program was implemented entirely by school staff. Initial data indicate the program was able to be implemented with fidelity, was perceived as highly acceptable by students, lunch monitors, teachers, and parents, and was associated with improvements in students' and parents' knowledge and increased fruit and vegetable consumption in the school lunch with more pronounced and enduring effects on fruit consumption (Blom-Hoffman, 2008; Blom-Hoffman, Wilcox, Dunn, Leff, & Power, 2008; Blom-Hoffman et al., 2007).

#### **Participants and Setting**

The multi-component strategy for obtaining consent was used in 12 kindergarten classrooms in four elementary schools during the spring 2005, and an abbreviated approach was used in the same classrooms the following school year (fall 2005). Because AIS was a universal program, all kindergarten students ( $n = 231$  in the spring 2005;  $n = 230$  in the fall 2005) were eligible to participate. Most of the students attending the schools were African-American (42%) or Hispanic (42%). Between 76 and 100% of students at the schools were eligible to receive free or reduced-price lunch and 20% were enrolled in bilingual education. Physical activity promotion elements of the AIS program operated within the schools for several years prior to the outcome evaluation and were viewed positively by the school principals. The addition of nutrition components to the program, a focus on younger students, and the inclusion of an outcome evaluation were new. Participation in the program evaluation required signed parental consent.

#### **Establishing School-Based Partners**

The AIS 5-a-Day program was conducted in collaboration with Northeastern University's Center for the Study of Sport in Society through the Urban Youth Sports (UYS) division. UYS had prior relationships with each of the four schools, was well regarded by principals, and facilitated the principal investigator's (PI) access in these schools. Multiple strategies were used to develop partnerships between the PI and the schools. An initial meeting was held at each school with the PI, the AIS program director, and the principal to discuss adding the nutrition components to the program and conducting a program evaluation. A subsequent meeting at each school involved teams of teachers, other school-based stakeholders (i.e., nurses and cafeteria managers), and the researcher. The purpose of these meetings, which lasted approximately 15 min and were set up by the school principal, was to discuss the program's goals and importance, how it met health education curricular objectives and could be incorporated into the existing school ecology, the program evaluation components, and the need for written parental consent. At these meetings a group reinforcement system for improving participation rates, which had been effective in a prior study (Angelucci, Grossman, Power, & Leff, 2004), was discussed to determine its relevance for use in this context.

#### **Materials**

##### *Consent Forms*

Consent forms, approved by the Institutional Review Board at Northeastern University and by the school district's research office, were translated from English into five languages by native speakers employed at a professional translation company. On the consent form, parents were asked to indicate whether or not they wanted their children to be included in the program evaluation. Teachers were given a brightly labeled envelope to collect returned consent forms. In the fall 2005, a brief (i.e., one paragraph) cover letter from the building principal was stapled to the front of the consent form.

##### *Interdependent Group Contingency*

In the spring 2005, an incentive system that arranged for reinforcers to be provided contingent upon communication between parents and researchers (as opposed to being based upon rates of parent consent) was established. Posters, which became known as Bring Back Boards (BBBs), were constructed from foam board and illustrated to include the name of the group reinforcement and the criterion for the

group contingency (i.e., 80% of the consent forms returned signed and marked either “yes” or “no”). Small pieces of Velcro were placed all over the board. Laminated cartoon pictures of boys and girls being physically active with Velcro on the back were given to the teacher. Upon return of their consent form, the students placed a figure on the board. A special structured recess period for the class organized by the AIS program was used to motivate children to bring back the signed forms. Students also received water bottles filled with a jump rope and teachers received a “health and wellness” gift bag.

### Procedures

In the spring 2005, the group contingency was discussed initially with the school principals to obtain feedback for designing this portion of the recruitment process and again at the teacher meetings. At all of the teacher meetings at least one teacher expressed concern about the lack of parental involvement in the school and doubt regarding the likelihood that consent forms would be signed and returned. In response to this concern, the BBB strategy was described as a way of encouraging children to remind their parents to complete the forms. An 80% return rate criterion for class-wide reinforcement was established in collaboration with teacher input based on a desire to encourage the majority of students to return the permission forms with clear communication from parents, while being realistic about the return rate. Important characteristics of the initial teacher meeting were (a) having principal attendance, (b) engaging the teachers in a brief discussion regarding the relevance of the program and the importance of the program evaluation, (c) emphasizing that the program and evaluation would not take a lot of time, and (d) providing attractive materials to the teachers (i.e., the BBBs) and explaining the contingencies for goal attainment.

Following the teacher meetings, the investigator and an RA went into each classroom and made a 10-min presentation to the students. Students were shown the consent forms, the BBB, and the laminated figures. Students were told they needed to bring back the letter signed with a decision by one of their parents/guardians. They were informed that if they reached the group criterion, they would receive a special recess and take-home prize.

Following the class presentation, the BBB was placed in a prominent location in each classroom, and teachers put the consent forms into the students’ take-home folders. The RA coordinated with the teachers a time to pick up the signed consent forms the following week. Teachers were given additional consent forms in case a student needed a replacement. When possible, several teachers spoke with parents about the importance of the program and the need

for the signed forms. The RA returned weekly for 3 weeks to collect the forms. As soon as possible after the classes met the criterion, the structured recess was held.

Because the required sample size was not obtained from the spring 2005 recruitment efforts, recruitment into the study continued in the fall 2005 with the new class of kindergarten students in the same 12 classrooms. In the fall 2005, consent forms with a cover letter from the principal were handed to the same classroom teachers, who agreed to distribute and collect the signed forms from their students. Unlike the spring 2005, in the fall 2005 the PI did not meet with the students to describe the project and the group contingency system was not used.

### Case Example 1: Results and Discussion

In the spring 2005, 90% of the consent forms were returned (range from 83 to 100% per school), and 64% of the parents provided consent for their child to participate in the research study (range from 59 to 75% per school). Eleven classrooms met the group contingency goal. Although the rate of returned consent forms was high (90%), the rate of parents who agreed to allow their child to participate in the outcome evaluation was lower (64%). The participation rate was consistent with the average participation rate (65.5%) for the very few studies using active consent procedures and reporting this information. In contrast, return and participation rates in the fall 2005 were substantially lower than those obtained the previous spring. In the fall 2005, the same classroom teachers were asked to send permission forms home. At this time classroom visits were not made by the research team and the group contingency was not used. In comparison with the spring 2005, where 90% of consent forms were returned, 11 of the 12 classrooms met the group contingency goal, and 64% of parents provided permission for their child to participation, in the fall 2005, only 69% of the consent forms were returned (range from 52 to 78% per school), only 3 of the 12 classrooms reached or exceeded an 80% return rate, and the average participation rate of 48% (range from 36 to 70% per school) was much lower. Together these findings suggest the potential importance of the investigator introducing the project to students and using a group contingency system.

Monetary and personnel costs associated with the participant recruitment in the spring 2005 were as follows. Approximately \$100.00 was spent constructing the boards, \$3.40/student was spent on student incentives and \$5.40/teacher was spent on teacher incentives. A structured recess, which was part of the group reinforcement, was provided in kind by the AIS program. Additionally, an RA spent approximately 30 h designing the boards, attending teacher and classroom meetings, and following up with teachers.

In most cases, these recruitment costs would not be feasible outside the scope of a grant-funded project. In the absence of recruitment funds, creative, less expensive alternatives could be substituted for the tangible incentives (e.g., mystery motivators, Jensen, Rhode, & Reavis, 1994). Also, the second case example provides a less costly alternative.

Given the high percent of returned consent forms in the spring 2005 (90%), we were disappointed with the lower percent of parents (64%) who agreed to allow their child to participate in the program evaluation. Subsequent conversations with teachers revealed that the length of the consent form (i.e., four single spaced pages) might have been overwhelming to some parents. This highlights the importance of working with Institutional Review Boards to determine ways to communicate appropriate information about school-based prevention studies concisely without overwhelming families. This is a challenge given the ethical responsibility of psychologists to provide specific information to potential participants, including limits to confidentiality (American Psychological Association, 2002; see Rodríguez et al., 2006, for a more in-depth discussion).

One teacher reported that a parent confided in her that she did not want to participate for fear that her government food stamp benefits may be taken away. Rodríguez et al. (2006) found that word of mouth recruitment from trusted community members was the most successful method in recruiting a group of Spanish-speaking, Latino families in a rural community. In schools, parent coordinators can partner with researchers to assist with recruitment efforts by using word of mouth to dispel fears associated with participation. Also, including a place where parents can request more information about the study before deciding if they want their children to participate (Belzer, McIntyre, Simpson, Officer, & Stadey, 1993) may be helpful. The next case example illustrates how relationship-building efforts at multiple levels helped to create strong partnerships and a responsive context for research.

### Case Example 2: The Friend to Friend Program

This case example describes how a research team used a multi-component partnership-based process to establish a relational and physical aggression intervention research program in three inner-city elementary schools. The intervention, called Friend to Friend (F2F), is a social cognitive small group intervention that helps girls recognize different forms of aggression, become better problem-solvers, and exhibit less aggression in potential conflict situations. F2F is based upon three theoretical models including a social information processing (SIP) model of aggression (Crick & Dodge, 1994), a developmental-ecological systems paradigm (Bronfenbrenner, 1986;

Kazak & Simms, 1996), and social learning theory (e.g., Bandura, 1973; Dishion, Capaldi, Spracklen, & Li, 1995). The program used intervention techniques derived from two empirically supported interventions for physical aggressors (e.g., Hudley & Graham, 1993; Lochman, 1992) and was designed specifically for urban African-American third and fourth grade girls by partnering with culturally diverse students, teachers, and playground/lunchroom supervisors over the course of several years (see Leff et al., 2007, for a review of the design of this program). Preliminary results of the F2F program suggest that it is viewed as highly acceptable by participating girls and teachers, and that it may help to reduce relationally aggressive girls' levels of relational and physical aggression, hostile attributions, and feelings of loneliness (Leff et al., *in press*).

Even though F2F is a targeted intervention program for relationally and physically aggressive girls, part of the screening process included having all students (boys and girls) complete initial measures. As such, all students in the third through fifth grades from the three schools were given the opportunity to participate if consent forms were signed by parents/guardians and returned to the teacher.

### Participants and Setting

All students attending 28 general education classrooms from three inner-city elementary schools were eligible for participation in the F2F research project. The three schools were drawn from a large, urban, public school district. The majority of students attending these schools were African-American (>95%), and most received free or reduced price lunch (83%). Many teachers and playground/lunchroom supervisors were skeptical and/or had an incomplete understanding of the research process based upon prior negative experiences when collaborating with researchers from local academic institutions (see Fantuzzo et al., 1997). Further, school officials reported that they had variable levels of parental involvement in their schools with tension sometimes occurring between teachers and parents. As in the first case example, it was clear that the school expected to have low parent consent rates, and it was unclear how motivated teachers would be able to encourage parents to complete needed forms.

### Establishing School-Based Partners

The research team spent considerable time meeting with key school and community personnel to understand school needs and to build support for the research project. Schools were chosen for inclusion in the research study on the basis of several factors: (a) an expressed interest by school administration, (b) the lack of a systematic and/or ongoing



aggression/bullying prevention or social skills promotion program, and (c) an identified point person to work with the research team. Despite administration support, each school made it clear that it would be a challenge to obtain strong teacher and parent buy-in for the study because of past negative experiences with researchers.

1. *Establish need for research project.* An initial step in a partnership process is to ensure that the proposed research study will meet the needs of the particular schools and surrounding communities. All three schools struggled in developing strategies to address the common types of conflicts among girls and wished to provide more consistent programming in social skills/anger management.
2. *Identify key stakeholder groups.* Meetings were held with various representatives from key stakeholder groups including administrators, teacher grade-group leaders, playground and lunchroom staff, and parents/community members to understand concerns with aggression and bullying (see Leff et al., 2004, and Leff, Power, Costigan, & Manz, 2003, for a more detailed description of the partnership process with paraprofessionals across these unstructured school contexts).
3. *Explore optimal ways with which to communicate with parents, teachers, and students.* Parents/community members helped the researchers to design a range of strategies to become better known at the school and to let parents and teachers know about the study. These included making flyers that were handed out at the school, sending a brief letter home to parents signed by the PI, school principal, and a parent representative describing the study in general terms, attending and presenting the study briefly at Back to School Night and a parent–teacher organization meeting, and being available each week at the school to answer questions or concerns.
4. *Meet with teachers and students to explain the project and understand their needs/concerns.* These procedures were consistent with the first case example. However, it is noteworthy that *all* 28 teachers indicated agreement with all study procedures and allowed their students to be given consent forms despite the fact that the active intervention would only be provided in randomly selected classrooms. Therefore, teachers needed to agree with consent and screening procedures *before* knowing whether or not they would be involved in the active part of the intervention program. Also, the research team arranged a time to stop by each classroom twice—first to introduce themselves to students and to have a general discussion about peer relationships and the importance

of finding ways to solve friendship making problems, and a second time to tell students more about the research project.

5. *Jointly decide upon an incentive plan to promote positive communication.* Teachers in schools involved with the F2F study developed the BBB strategy, as described in the previous case example.
6. *Provide reminders to students and teachers to encourage the return of consent forms.* These procedures were similar to those described in the first case example.

## Materials

### *Consent Forms*

Three-page consent forms were accompanied with a one-paragraph cover letter signed by the PI, school principal, and point person from each school. The cover letter described the primary goals of the study in basic terms, what was required of participating students and parents, and the PI's contact information. The cover letter and the consent form were approved at the second author's university and the school district's research office. To help facilitate parents' understanding of where to mark and sign the consent form, sections of the signature page were highlighted. In addition, space was provided for parents to write their phone number if they had any questions and wished for the research team to call them to clarify aspects of the study. Teachers were given a folder to collect returned consent forms.

### *Group Contingency*

A small poster board was designed for each classroom with an animated cartoon character holding a large, unfilled cookie tray. "Bring back your consent forms and help your class win a party" was written on the poster. Each teacher was given small paper cookie cutouts for students to tape to the cookie tray once each signed consent forms were returned. An 80% return rate contingency was established for students to receive reinforcement, which was a 20-min cookie party planned in conjunction with the teacher. No specific reinforcers were given to the teachers.

### Procedures

The same procedures described in the first case example were used to introduce teachers and students to the group contingency system, to follow up with the teachers each week, and to schedule the group reward once the classroom contingency was met.

## Case Example 2: Results and Discussion

Overall, the procedures used to encourage strong home–school communication about the research project were successful. In total, 87.5% of the signed consent forms were returned by parents with an indication of whether or not they wished for their child to participate (range from 64 to 100% per classroom), and 81% of the consent forms were returned with parent/guardian permission for the student to participate in the study (range from 54 to 97% per classroom). This participation rate was much higher than the average rate among the small number of studies in the published literature that used an active consent procedure and reported their participation rates (65.5%).

With regard to monetary and personnel costs associated with participant recruitment, approximately \$50 was spent on constructing and copying the boards, and \$0.30/student was spent on incentives. No money was spent on teacher incentives. Additionally, an RA spent approximately 15 h attending meetings, following up with teachers, and organizing the collection of the consent forms.

The majority of teachers took an active role in reminding their students to bring back the consent forms and providing positive encouragement when forms were returned quickly. Not surprisingly, the classrooms that had the lowest consent form return rates also had teachers who appeared to the research team to be less invested and less enthusiastic about the research project. Thus, it appears that successfully engaging teachers is a key factor in establishing strong parent–teacher–researcher communication. A number of teachers expressed that they found the partnership process and group contingency system to be an acceptable and respectful way in which to establish and encourage communication in the context of a research project. In fact, several teachers discussed using a similar strategy in the future to focus on improving home–school communication for important classroom events.

## General Discussion

This article highlights the lack of information pertaining to recruitment procedures and participation rates in the published literature. It was surprising that so few studies reported information regarding consent, participation rates, and recruitment procedures. Unfortunately, due to the small number of studies reporting participation rates and recruitment procedures and inconsistency in the reporting of demographic information across these studies, we were unable to explore similarities and differences in participation rates across recruitment procedures and contextual variables.

The importance of using multi-component, culturally sensitive, relationship-based approaches when recruiting participants from ethnic minority backgrounds into research studies has been articulated in the literature (May et al., 2007; Rodríguez et al., 2006). Both of the case examples were conducted in large, urban school districts with primarily African-American and Latino children, and all students in the target classrooms were eligible for participation. The strategies included relationship-building between researchers and school staff at multiple levels, a visit to the class by the PI to explain the study, and implementation of a group contingency program with reinforcement. The purpose of the strategies was intended to engage schools in the earliest phases of the recruitment process, to encourage communication about the study with school staff, students, and parents, and to facilitate trust between the research team and the children's school and family. Important elements of these strategies may have included (a) gaining administrator support, (b) communicating clearly with stakeholder groups, (c) utilizing procedures that required minimal teacher time, (d) including reminder materials that were visually appealing and attractive, (e) including a group contingency, (f) taking time to develop relationships, and (g) implementing the procedures in the context of socially meaningful intervention programs.

The second case example may have had higher participation rates than the first case example for a number of reasons including the length of the consent form, additional strategies for communicating with parents, procedures for selecting participating schools, and administrator support at the schools. First, the consent form in the second case example was one page shorter than the form used in the first example. Second, the research team was present at parent events to discuss the study with families, and the consent form included a place where parents could request more information about the study. Third, different approaches to school selection were used in the two case examples. Whereas schools that had a prior relationship with the university because they were already participating in the highly regarded Athletes in Service program were selected for the first case example, schools in the second case example were selected based on administrator interest in bullying prevention and the lack of this type of programming at the schools. Principals in the second case example may have seen a greater need for the study at their school and may have communicated this in some way to their teachers.

## Considerations and Directions for Future Research

Considerations regarding the systematic literature review included the following. First, given resource constraints, an

a priori decision was made to review only those studies that were available electronically via a university library. As such, 72% of the studies ( $n = 481$ ) identified through the PsychInfo search were reviewed. However, there is no reason to believe that there would be any differences between the studies that were available electronically versus those that were not. A second, more important limitation is the possibility that the average participation rates described in Table 1 are not representative of participation rates in published studies because so few studies report participation rates. If not required to report participation rates, researchers may be more inclined to report this information when the rates are higher, and thus the results from the current study may be higher than those obtained across all studies conducted. A third limitation is that the literature review only included school-based prevention and intervention studies included in the PsychInfo database. A PubMed or ERIC search may have revealed different findings. Finally, because so few studies report consent procedures and participation rates, it was not possible to examine differences in participation rates as a function of consent procedures, thus highlighting the importance of reporting consent procedures and participation rates in the literature.

The two case examples were limited in that control groups were not included to test the effectiveness of the multi-component strategy. Additional research using a randomized, control group is needed to investigate the efficacy and acceptability of these methods in a more rigorous manner. It is important to consider the possibility that the multi-component strategies alone did not account for the findings described in the two examples. Contextual variables may have influenced the participation rates. In addition, both research studies involved providing students access to an intervention. Parents' interest in getting their children a service that appeared to be beneficial and was free of charge might have factored in to the consent/communication rates. However, recently a non-intervention study (i.e., Leff et al., 2006) that used the same multi-component strategies to obtain informed consent resulted in similarly high consent rates. Another limitation is the use of a food-based reinforcement in the second case example. Non-food alternatives to motivate students to return consent forms are preferable, given the obesity epidemic (U.S. Department of Health and Human Services, 2001) and the resultant wellness policies that are being developed in school districts nationally (Child Nutrition and WIC Reauthorization Act of 2004).

## Conclusions

There are several advantages that may be associated with using multi-component strategies involving partnership-

based and group contingency methods to increase participation rates in school-based research. First, the partnership-based approach is respectful of parents' right to receive pertinent information about a study and to decide at their own will if they would like their child to participate. Second, the contingency system was focused upon fostering communication between researchers and parents/guardians; the return of the consent forms with or without consent to participate was equally acceptable. These procedures help to ensure that there is no coercion in the consent process, which is particularly important among children who are poor (Frye et al., 2003). Third, our limited observations indicated that the procedures were acceptable and feasible for teachers and students. Fourth, teachers and principals appeared to appreciate the emphasis on improving home-school communication about the study.

Although it is difficult to know the extent to which the partnership-based approaches influenced participation rates in these two case examples, the efforts to build partnerships between the research team and key stakeholder groups in the schools seemed to be critical in communicating with the school community and families about the study (see Leff et al., 2004). For evidence-based health promotion programs to be implemented and sustained in school settings, it is important to have buy-in from key stakeholder groups. When signed parental consent is required in these settings, it is particularly important to invest in relationship-building efforts prior to and during the recruitment process, as well as in all subsequent stages of the research process. Future research can investigate the effects of the following variables on participation rates: (a) varying consent form length, (b) having a section on the consent form where parents can request more information about the study, (c) using group contingency components, (d) considering the perceived value of the research study to parents and school staff, (e) contextual and demographic variables, and (f) using a participatory approach to designing the consent process with school staff. Finally, future school-based intervention and prevention studies should report consent procedures, participation rates, and comparisons between participating and non-participating students to examine sample representativeness.

**Acknowledgments** The projects described were supported by three grants from the National Institute of Health (grant numbers: K23MH001728, K23HD047480, and R34MH072982). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Child Health and Human Development, and the National Institute of Mental Health. The authors are appreciative of the artistic creativity of Jannon Farkis and Kaila Wilcox, who collaborated in the design of the boards used in Case Example 1, and Michael Grossman, who collaborated in the design of the cartoon boards in Case Example 2.

## References

- American Psychological Association. (2002). Ethical principles of psychologists and code of conduct. *American Psychologist*, *57*, 1060–1073.
- Anderman, C., Cheadle, A., Curry, S., Diehr, P., Shultz, L., & Wagner, E. (1995). Selection bias related to parental consent in school-based survey research. *Evaluation Review*, *19*, 663–674.
- Angelucci, J., Grossman, M., Power, T., & Leff, S. S. (2004, July). Partnering with girls to design a cartoon-based attributional measure. Poster presented at the annual meeting of the American Psychological Association, Honolulu, HI.
- Bandura, A. (1973). *Aggression: A social learning analysis*. Englewood Cliffs, NJ: Prentice-Hall.
- Belzer, E. G., McIntyre, L., Simpson, C., Officer, S., & Stacey, N. (1993). A method to increase informed consent in school health research. *Journal of School Health*, *63*, 316–317.
- Blom-Hoffman, J. (2008). School-based promotion of fruit and vegetable consumption in multiculturally diverse, urban schools. *Psychology in the Schools*, *45*, 16–27.
- Blom-Hoffman, J., Franko, D. L., Power, T. J., Stallings, V. A., Dai, J., & Thompson, D. R. (2007). Promoting fruit and vegetable consumption during school lunch. Poster presentation at the American Psychological Association Annual Meeting, San Francisco, CA.
- Blom-Hoffman, J., Wilcox, K. R., Dunn, L., Leff, S. S., & Power, T. J. (2008). Family involvement in school-based health promotion: Bringing nutrition information home. *School Psychology Review*, *37*.
- Bronfenbrenner, U. (1986). Ecology of the family as a context for human development: Research perspectives. *Developmental Psychology*, *22*, 723–742.
- Child Nutrition and WIC Reauthorization Act of 2004, Pub. L. No. 108-265, ±204. Retrieved 6 Nov 2007 from [http://www.fns.usda.gov/cnd/Governance/Historical/PL\\_108-265.pdf](http://www.fns.usda.gov/cnd/Governance/Historical/PL_108-265.pdf).
- Christenson, S. L., & Sheridan, S. M. (2001). *Schools and families: Creating essential connections for learning*. New York: Guilford.
- Crick, N. R., & Dodge, K. A. (1994). A review and reformulation of social information processing mechanisms in children's social adjustment. *Psychological Bulletin*, *115*, 74–101.
- Dishion, T. J., Capaldi, D., Spracklen, K. M., & Li, F. (1995). Peer ecology of male adolescent drug use. *Development and Psychopathology*, *7*, 803–824.
- Dzewaltowski, D. A., Estabrooks, P. A., Klesges, L. M., Bull, S., & Glasgow, R. E. (2004). Behavior change intervention research in community settings: How generalizable are the results? *Health Promotion International*, *19*, 235–245.
- Ellickson, P. L., & Hawes, J. A. (1989). An assessment of active versus passive methods for obtaining parental consent. *Evaluation Review*, *13*, 45–55.
- Esbensen, F. A., Deschenes, E. P., Vogel, R. E., West, J., Arboit, K., & Harris, L. (1996). Active parental consent in school-based research: An examination of ethical and methodological issues. *Evaluation Review*, *20*, 737–753.
- Estabrooks, P., Dzewaltowski, D. A., Glasgow, R. E., & Klesges, L. M. (2003). Reporting validity from school health promotion studies published in 12 leading journals, 1996–2000. *Journal of School Health*, *73*, 21–28.
- Fantuzzo, J. W., Coolahan, K., & Weiss, A. (1997). Resiliency partnership-directed research: Enhancing the social competencies of preschool victims of physical abuse by developing peer resources and community strengths. In D. Cicchetti & S. Toth (Eds.), *Developmental perspective on trauma: Theory, research and intervention*. Rochester, NY: University of Rochester Press.
- Fantuzzo, J. W., McWayne, C., & Bulotsky, R. (2003). Forging strategic partnerships to advance mental health science and practice for vulnerable children. *School Psychology Review*, *32*, 17–37.
- Frye, F. H. A., Baxter, S. D., Litaker, M. S., Thompson, W. O., Guinn, C. H., Baglio, M. L., et al. (2003). Differences in fourth-graders' participation rates across four school-based nutrition studies. *Journal of Child Nutrition and Management*, *27*, nihms6422.
- Glasgow, R. E., Bull, S. S., Gillette, C., Klesges, L. M., & Dzewaltowski, D. A. (2002). Behavior change intervention research in healthcare settings: A review of recent reports with emphasis on external validity. *American Journal of Preventive Medicine*, *23*, 62–69.
- Grolnick, W. S., Benjet, C., Kurowski, C. O., & Apostoleris, N. H. (1997). Predictors of parent involvement in children's schooling. *Journal of Educational Psychology*, *89*, 538–548.
- Hatchett, B. F., Holmes, K., Duran, D. A., & Davis, C. (2000). African Americans and research participation: The recruitment process. *Journal of Black Studies*, *30*, 664–675.
- Ho, B. S. (2002). Application of participatory action research to family-school intervention. *School Psychology Review*, *31*, 106–121.
- Hudley, C., & Graham, S. (1993). An attributional intervention to reduce peer-directed aggression among African American boys. *Child Development*, *64*, 124–138.
- Hughes, J. N. (2003). Commentary: Participatory action research leads to sustainable school and community improvement. *School Psychology Review*, *32*, 38–43.
- Jensen, W. R., Rhode, G., & Reavis, H. K. (1994). *The tough kid toolbox*. Longmont, CO: Sopris West.
- Kazak, A. E., & Simms, S. (1996). Children with life threatening illnesses: Psychological difficulties and interpersonal relationships. In F. W. Kaslow (Ed.), *Handbook of relational diagnosis and dysfunctional family patterns* (pp. 225–238). New York: Wiley.
- Leff, S. S., Angelucci, J., Goldstein, A. B., Cardaciotto, L., Paskewich, B., & Grossman, M. (2007). Using a participatory action research model to create a school-based intervention program for relationally aggressive girls: The Friend to Friend Program. In J. Zins, M. Elias, & C. Maher (Eds.), *Bullying, victimization, and peer harassment: Handbook of prevention and intervention in peer harassment, victimization, and bullying* (pp. 199–218). New York: Haworth Press.
- Leff, S. S., Costigan, T. E., & Power, T. J. (2004). Using participatory-action research to develop a playground-based prevention program. *Journal of School Psychology*, *42*, 3–21.
- Leff, S. S., Crick, N. R., Angelucci, J., Haye, K., Jawad, A., Grossman, M., et al. (2006). Understanding social cognitive development in context: Partnering with urban African American girls to create a hostile attribution bias measure. *Child Development*, *77*, 1351–1358.
- Leff, S. S., Gullan, R. L., Paskewich, B. S., Abdul-Kabir, S., Jawad, A. F., Grossman, M., et al. (in press). An initial evaluation of a culturally-adapted social problem solving and relational aggression prevention program for urban African American relationally aggressive girls. *Journal of Prevention and Intervention in the Community*.
- Leff, S. S., Power, T. J., Costigan, T. E., & Manz, P. H. (2003). Assessing the climate of the playground and lunchroom: Implications for bullying prevention programming. *School Psychology Review*, *32*, 418–430.
- Lochman, J. E. (1992). Cognitive-behavioral intervention with aggressive boys: Three year follow-up and preventive effects. *Journal of Consulting and Clinical Psychology*, *60*, 426–432.
- Masten, A. S. (2003). Commentary: Developmental psychopathology as a unifying context for mental health and education models, research, and practice in schools. *School Psychology Review*, *32*, 169–173.

- Mathews, C., Guttmacher, S. J., Flisher, A. J., Mtshizana, Y., Hani, A., & Zwarenstein, M. (2005). Written parental consent in school-based HIV/AIDS prevention research. *American Journal of Public Health, 7*, 1266–1270.
- May, D. E., Hallin, M. J., Kratochvil, C. J., Puumala, S. E., Smith, L. S., Reinecke, M. A., et al. (2007). Factors associated with recruitment and screening in the treatment for adolescents with depression study (TADS). *Journal of the American Academy of Child and Adolescent Psychiatry, 46*, 801–810.
- Moles, O. C. (1993). Collaboration between schools and disadvantaged parents: Obstacles and openings. In N. F. Chavkin (Ed.), *Families and schools in a pluralistic society* (pp. 21–49). Albany, NY: State University of New York Press.
- Nastasi, B. K., Varjas, K., Schensul, S. L., Silva, K. T., Schensul, J. J., & Ratnayake, P. (2000). The participatory intervention model: A framework for conceptualizing and promoting intervention acceptability. *School Psychology Quarterly, 15*, 207–232.
- National Center for Educational Statistics. (2004). *The condition of education*. Washington, DC: US Department of Education.
- Power, T. J., & Bartholomew, K. L. (1987). Family-school relationship patterns: An ecological assessment. *School Psychology Review, 16*, 498–512.
- Power, T. J., Manz, P. H., & Leff, S. S. (2003). Training for effective practice in the schools. In M. Weist, S. Evans, & N. Tashman (Eds.), *School mental health handbook* (pp. 257–273). Norwell, MA: Kluwer Academic/Plenum Publishers.
- Rodríguez, M. D., Rodríguez, J., & Davis, M. (2006). Recruitment of first-generation Latinos in a rural community: The essential nature of personal contact. *Family Process, 45*, 87–100.
- Tucker, C. M., & Herman, K. C. (2002). Using culturally sensitive theories and research to meet the academic needs of low-income African-American children. *American Psychologist, 57*, 762–773.
- U.S. Department of Health and Human Services. (2001). The Surgeon General's call to action to prevent and decrease overweight and obesity. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General.
- U.S. Department of Health and Human Services. (2005). Basic HHS policy for protection of human research subjects. §46.116 General requirements for informed consent, Title 45 Code of Federal Regulations.
- Yin, R. K. (2003). *Case study research: Design and methods* (3rd ed.). Thousand Oaks, CA: Sage.