Recruiting pupils for a school-based eye study in Nigeria: Trust and informed consent concerns

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Abstract
School-based research presents ethical challenges, especially with respect to informed consent. The manner in which pupils and their parents respond to an invitation to participate

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in research is likely to depend on several factors, including the level of trust between them and the researchers. This paper describes our recruitment and consent process for a school-based eye study in Nigeria. In the course of our study, a particular governmental incident helped to fuel public mistrust in governmental programs and posed a potential threat to our recruitment efforts. The recruitment and consent process included series of advocacy visits to stakeholders in the education sector, highly interactive briefing and health talk sessions in schools, use of telephone services as a medium for information dissemination, age-appropriate study information, parental consent, and pupil assent. Of the 6598 pupils provided with study information, 5723 returned parental consent forms. There were 69 cases of pupils who dissented despite having parental consent. The two leading concerns for the parents/guardians were the rumors regarding a military/governmental-sponsored health campaign and the side-effects of the dilating eye-drops. Nevertheless, our high level of recruitment suggests our recruitment and consent process was successful in assuaging fears for the vast majority of pupils and their parents.

**Keywords**
Recruitment, eye survey, trust, Nigeria, pupils, informed consent

**Background**

School-based research presents some unique ethical challenges, especially with respect to informed consent (Felzmann, 2009). In addition to seeking consent from parents/guardians, most established pediatric research ethics guidelines also require assent from the children for participation in research, even in low income countries (Cheah and Parker, 2014). It is expected that this should be undertaken to the degree that the target population of children are regarded as being capable of providing assent, taking into account the child’s age, maturity, and psychological state.

One significant complication for consent in the school setting is the involvement of other stakeholders such as the teachers, school principals/head teachers, and the school management boards, thereby adding further complexity to the decision-making process (Felzmann, 2009). In order to promote informed consent/assent, researchers are expected to develop suitably customized information that children can understand, since young children may not have the same cognitive capacities as their parents/guardians. However, existing studies on child capacity to understand information about research give no clear pointers about the age from which assent must be absolutely obtained in pediatric research (Waligora et al., 2014).

The manner in which children and their parents/guardians respond to the possibility of participating in health research is likely to depend on a number of factors. These include: the nature and scope of the research; the existing knowledge
and attitude of the parents/guardians to research in general; the relationship between the parents, children and the researchers; and finally, the quality of communication between them. Full parental/guardian understanding of the core components of a proposed research project is essential for obtaining informed consent when enrolling children in such studies (Ossemane et al., 2018).

Many obstacles can undermine full understanding of the contents of a study information thereby adversely influencing voluntariness for participation in research. For instance, public distrust of the research enterprise/researchers/institutions or their perceived/known sponsors can have a strong bearing upon how information is interpreted. Trust in researchers is crucial to the success of the research enterprise (Horn et al., 2011; Kerasidou, 2016), especially with respect to recruitment. In Nigeria, there has been a crisis of confidence in authorities at all levels in recent times; mistrust and lack of transparency are increasingly more visible (Roelofs, 2019). In the course of our Refractive Error Survey of School Children aged between 5 and 15 years in the South-Eastern Region of Nigeria (Maduka-Okafor et al., 2021), a particular incident helped to fuel public mistrust in governmental health programs. Rumors circulated at the commencement of our survey that people dressed in Army uniforms were forcefully vaccinating pupils and injecting them with an unknown disease (Tomori, 2018). Social media was agog with these rumors that the campaign was a ploy by the Federal government to infect the children of the region, and ultimately wipe out the people of the region. These rumors caused massive panic and even led to the withdrawal of some pupils from schools and the temporary closure of some schools in the South-East Nigeria. Coincidentally, the military was conducting special training exercises in some of these regions and a health campaign in one of the South-Eastern states. These factors threatened initial recruitment for a significant period.

Despite the extensive conduct of school-based research in Nigeria, there is a paucity of documented information on recruitment and best practice for consent. This paper, therefore, seeks to highlight our experiences and details lessons learnt in the recruitment of the research participants for the study, especially with respect to trust and informed consent issues. It is intended as an account of good practice in seeking consent against the backdrop of this complex situation.

**The eye study and how consent was sought**

Using the Refractive Error Study in Children (RESC) protocol (Holden, 2007; Negrel and Ellwein, 2000; World Health Organization/National Institutes of Health, 2007), a school-based eye study with pupils aged 5–15 years was conducted in the South-Eastern Region of Nigeria in 2017/2018 (Maduka-Okafor et al., 2021). The study aimed to generate evidence for school-based eye health care. The South-East region has an adult literacy level of 74.5% which is slightly
higher than the national level of 71.6% (National Bureau of Statistics, 2010: 23). Using a multi-stage cluster sampling method, a minimum sample size of 5400 was derived for the study. Following clearance by the Health Research Ethics Committee of the University of Nigeria Teaching Hospital, preliminary approval was obtained from the respective State Ministries of Education/Health, school management boards, and authorities of the selected public and private schools (primary and secondary). Face-to-face delivery of the initial invitation letters to the school authorities was followed up by telephone calls and multiple on-site advocacy visits to obtain the co-operation of the schools. The interactions involved discussions about the study objectives, study procedures, data collection timetable, study information leaflets, parental consent forms, the study questionnaire and the provision of free spectacles to pupils who are identified as having uncorrected refractive errors. Simplified study information leaflets and consent forms were distributed by the school authorities to age-qualified pupils for transmission to their parents/guardians at least a month before the designated screening period for the respective schools within the five states of the South-Eastern region. These materials were prepared to be understood by anyone with at least 6 years of formal education in Nigeria. Following adequate briefing by the respective head teachers or principals of the schools, pupils were instructed to hand over the forms to their parents/guardians for the purpose of obtaining written consent. The core contents of consent forms included: identities and institutional (government) affiliations of the researchers, name and contact details of the principal investigator, information on the type and purpose of the research, the study procedure, voluntary participation, requirement for assent by the children, risks (minimal risk research), benefits, right to withdraw at any time without repercussions/consequences, use of a topical dilating agent that could cause temporary blurring of vision, confidentiality of data, the plan for the provision of free spectacle corrections, treatment of minor eye conditions for needy pupils, and a clause requesting the telephone number of parents/guardians who may require further information/clarification. The pupils were instructed to submit the consent forms (whether signed or not) to their respective teachers on a designated date, prior to the actual screening visits by the research team. Arrangements were made to study the submitted forms in preparation for the study. Telephone contact was made with parents/guardians who requested further clarification before granting consent. Consent was considered valid once both parents, or either parent, if they were the head of the household (irrespective of gender), signed the form prior to the actual screening day. Though a largely male-dominated society with prevailing gender norms that restrict mothers’ agency in health care decision-making, we readily accepted forms signed by just the mother if the mother was a single parent, household head or where the husband was not physically present to sign. In few instances where one parent
would grant consent and the other parent would not, concerted efforts were made to resolve the differences, with the purpose of ensuring a more inclusive participation of both parents in the decision-making.

Recruitment involved three broad stages: (1) Distribution and return of signed consent forms; (2) Follow-up calls with some parents; (3) Seeking assent from the pupils on the screening days. Eye health education was provided to the entire school at specially arranged assemblies. A brief talk on the appropriate use of spectacles was usually given by a trained ophthalmic nurse and, at certain times (when possible), by an adolescent member of the team who wore spectacles. Out of respect for the pupils as developing persons, they were provided with age-appropriate information and each was asked whether or not they wished to participate in the research. This was conducted at the beginning of each screening day by the principal investigator and facilitators with training/experience in communicating with children. Opportunities were provided for the pupils to ask questions during the briefing sessions by the team members with consideration given to the issue of power imbalance between the youth participants and adult researchers. For the interactive sessions, we requested that the most popular school teachers (usually selected by the School authorities) were also in attendance. At strategic locations within the screening venues, we also displayed large picture posters of Nigerian pupils undergoing various forms of eye examinations and eye drop instillation. Only those pupils who granted verbal assent and had submitted signed parental consent forms were recruited for the study.

Prior to recruitment, the research team had been trained on protecting the agency and well-being of young participants, and how to recognize and handle cases of distress and dissent among the pupils. Dissent, as expressed verbally or non-verbally, by any child was respected at any stage of the research. This included refusal to cooperate, out-rightly saying “NO,” becoming unduly apprehensive, constantly turning away in the course of the examinations, crying or displaying some other form of distress. On completion of the study in each school, all the children identified with uncorrected or poorly corrected refractive error were provided with free spectacle corrections. As part of the service delivery component of the project, all non-participating pupils, and teachers who requested were examined with torchlight/ophthalmoscopes without dilatation, and treated/referred as required.

**Participation in the study**

Out of 6598 pupils provided with study information leaflets, we ultimately received 5723 signed consent forms from the assenting pupils who formed the sample. The remaining forms (875) were either not returned at all by the pupils or were not signed by parents/guardians. Sixty-nine pupils dissented despite their parents/guardians having given their consent. The overall consent rate for the study was 86.7%. Only
179 parents/guardians called to seek further information about the research prior to giving their consent. Fifty-five parents were recorded as having visited the school to witness the study procedure before providing consent for their children’s participation. In 372 cases, parents/guardians returned unsigned consent forms but provided their telephone numbers as an indication of interest and were called by members of the research team. Within this category, 335 (90.1%) ultimately provided consent following telephone interaction with the principal investigator. The two primary concerns of the parents/guardians were about the potential side-effects of the dilating eye-drops, and rumors regarding the Military/Government-sponsored health campaigns in the region.

We encountered various challenges during the consent process. Some parents refused to sign but then called by phone or appeared in person on the screening day to give approval. Some parents signed but indicated that they did not want any medication to be administered in their child’s eyes. In few cases, parents granted consent, but the pupil rejected the instillation of dilating drugs, thereby failing to complete the examination. There were numerous cases of children being absent from school on the screening days, perhaps as a result of truancy, fear/apprehension about the procedures, being deliberately kept back at home by their parents, or some other unidentified reason. After the first round of recruitment in each state, four states had a response rate above 75% which went on to exceed 85% by the end of the study. The remaining state, in which the military-organized exercises and health campaigns occurred, initially registered a low response rate below 60%. Following intensive advocacy and community engagement activities, this improved to approximately 81% by the completion of the study. In one school in this state, there was an emergency Parents-Teachers Association meeting to afford us the opportunity of articulating and disseminating appropriate information about the research. No attempt was made to determine whether there were differences in the pattern of recruitment between rural and urban settings or between private and public school settings.

Discussion

Trust concerns and recommendations

Lack of trust can be a barrier to consent and participation in research (Horn et al., 2011; Kerasidou, 2016) and this is something we had direct experience of in our study. Nevertheless, we ultimately achieved a very high recruitment rate, a good indication that trust was developed over time. Presentations at assemblies and the delivery of eye health talks probably helped stimulate interest, persuade the pupils and convey a sense of professionalism. We believe that ongoing engagement with the parents, pupils, school authorities, and other stakeholders assisted in achieving this high rate. Given the challenges presented by the governmental incident in one
of the states, the response rate is an indication that our recruitment method was acceptable to the study communities. When preparing the study information leaflets, maybe we could/should have specifically addressed the rumors associated with the Nigerian military activity. Overall, the response rate is reflective of the level of trust that the parents placed in the researchers and their affiliated research institution (Guillemin et al., 2018). One major lesson from this experience is that stakeholders in the research enterprise must strive to build and sustain trust through a number of mechanisms, including the building of relationships. They must demonstrate a track record of accountability, professional integrity, shared interests, and a concern for the best interests of the participants (Horn et al., 2011). Regardless, trust comes from listening, from dialog and understanding, as much as from providing the required information. Other studies have suggested that personal communication with the researchers has a positive effect on students’ willingness to participate (Testa and Coleman, 2006). There must be open and transparent, two-way communication between the researchers and communities (schools, parents, pupils) to build and foster trust.

**Informed consent concerns and recommendations**

Our study adds to the growing body of evidence related to the need for tailored informed consent processes in developing country contexts (Ossemene et al., 2018; Addissie et al., 2014). It must be noted that the contractual documentation of the informed consent process is probably insufficient for building trust and should be considered a minimum effort toward that end (Tomori, 2018). Though the principle of the autonomy is central in research ethics (Friesen et al., 2017), complete voluntary choice is illusory in pediatric research because decision-making by these children is usually influenced by their parents’ point of view (AAP Committee on Bioethics, 2016). Parents are presumed to make decisions in the best interests of the child (AAP Committee on Bioethics, 2016; Cheah and Parker, 2014). At times, these may really be in the best interests of the parents and not necessarily the child.

One of the main concerns regarding consent in school-based research is the form that parental consent should take; whether it should be active consent/opt-in (as adopted in our study), passive consent/opt-out, or institutional standing parental consent in which the school principal or head teacher acts as in loco parentis (Felzmann, 2009). In favor of the opt-out approach, it might be argued that in school settings parental consent is at least supplemented by the consent of the school principal.

Consent from parents/guardians does not, however, abrogate the need for assent from children. In pediatric research, informed consent is an active process comprising parental informed permission and childhood assent, normally from around age
7 years when children are assumed to have developed reasoning skills but these are somewhat limited (AAP Committee on Bioethics, 2016; Waligora et al., 2014). However, this is a contentious issue. Research that reflects a participatory rights perspective, and is respectful of children’s agency, must be based on children making informed decisions about their participation (Dockett and Perry, 2011). In our opinion, therefore, assent should be a means of recognizing the wishes of young children in relation to research participation. It involves more than passive acceptance or non-refusal on the part of the children. As advocated in other circles (Cocks, 2007; Vitiello, 2003), our approach to assent in our study was that of an ongoing process of discussion and engagement which involved a clearly-demonstrated affirmation by the child to participate (not merely the absence of objection) and required the researcher to take an interest in the child, and be vigilant to both verbal and non-verbal responses. Assent requires familiarity and established trust between the researcher and child.

When a child is found to possess the capacity and maturity to understand the various implications of research or medical treatment, including the risks and benefits, such a child can provide consent. It is important that researchers and health workers are able to determine whether young people have the required “Gillick competence” to make the decision (Griffith, 2015). Children and research communities might, on the other hand, not be fully appreciative and aware of the risks associated with participation in the research (Maglio and Pherali, 2020). It is thus important that efforts be made to provide age or developmentally appropriate information to children while engaging meaningfully, especially since there are no universally accepted age for providing assent or consent. Apart from the high literacy rate in the study area, it is thus likely that the high recruitment rate in our study may also be a reflection of the easy readability and comprehensibility of the information leaflets and consent forms distributed.

One outcome we experienced in this survey (which prospective school-based researchers should take cognizance of) was of some children wishing to participate but their wish being overruled by the parents. There can be conflicts between parental permission/refusal and assent/dissent by the children, especially those with capacity for rational decision-making. Against this backdrop, one must also appreciate the practical challenges inherent in applying and effectively invoking the doctrine of Parens Patriae within the Nigerian socio-cultural context; this is a society in which child dissent is regarded as a mark of utmost disrespect to one’s parents or seniors. The magnitude of discordant responses between parents and children in this study reinforces the importance of obtaining the permission and cooperation of young participants.

Against this backdrop, risk-benefit ratio assessment may have been a consideration for consenting parents. The high response rate may also be associated with issues related to reciprocity, whereby the parents/guardians granted consent in
anticipation of prospective health benefits such as provision of free spectacles and free treatment of minor eye conditions. Closely related to this is the possibility of the failure of societal members to distinguish between a health research activity and a free community medical outreach activity. Considering the research was situated in a resource-limited country, this factor cannot be totally overlooked. The perception of direct benefit to the child (free eye examination by a team of eye specialists and the possibility of being provided with free spectacles, if found necessary) vis-a-vis minimal possibility of harm may have facilitated and promoted consent.

Nevertheless, healthcare service provision to the participants (ancillary care obligations), and other members of the school community who may have been excluded from participation in the research, must be taken into account. Fair distribution of benefits should be inherent in the research design as a matter of principle but the perception of fairness in research will also increase peoples’ willingness to engage with it.

**Conclusion**

Establishing appropriate communication and engagement with parents, pupils, and other stakeholders, and building trust relationships, especially between researchers and parents/children, is paramount for the successful recruitment of participants in school-based research. Additionally, age and/or developmentally appropriate information about the research is necessary for ensuring their assent/consent is truly informed. It is imperative that adequate time and opportunities be provided for parents/guardians and pupils to explore and discuss their concerns with the researchers, and to appreciate the fundamental difference between research activities and free community health programs. Participant recruitment in research can also be strengthened by taking into account prevailing local socio-cultural contexts in the design and administration of the consent forms, study information leaflets and the implementation of the consent process, especially in determining appropriate age limits for childhood assent and in resolving conflicting parental/child decisions for research participation. School-based research programs should also take into consideration the possibility of incorporating a service-provision component for all within the school setting, including those who do not participate as well as teachers and support staff. The observations from this study suggest that the recruitment practices adopted facilitated a high participation level, albeit a minimal risk study.

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