

COMMENT

# On conducting a study among institutionalised adolescents in Kerala, India: legal and ethical challenges

TS SUMITHA, RAVI PRASAD VARMA

## Abstract

We report the dilemmas faced by the investigators while conducting a study on the social and environmental factors for protection of the mental health of adolescents placed under State protection in Kerala, India. The proposal received counsel and directives from the Integrated Child Protection Scheme authorities, under the Social Justice Department of Kerala state and the Institutional Ethics Committee of the host institution. The investigator faced and had to reconcile conflicting directives and antithetical field realities, with respect to seeking informed consent from the study participants. The physical act of adolescents signing the consent form, rather than the actual process of assent, received disproportionately more scrutiny. The authorities also questioned the privacy and confidentiality requirements raised by the researchers. Of the 248 eligible adolescents, 26 chose to dissent from participating in the study, demonstrating that choices would be made if they are offered. There is a need for more discourse on achieving steadfast adherence to the principles of informed consent, particularly in research on vulnerable groups such as institutionalised children.

**Keywords:** adolescents under state protection, informed consent, assent, privacy, confidentiality

## Background

The Integrated Child Protection Scheme (ICPS) was introduced in India in 2009 to protect children at risk and thereby reduce vulnerabilities. The Kerala state government began implementing the scheme and, as envisaged by the central

government, it brought all existing child protection programmes under the ICPS [1]. Children's home residents are children (up to 18 years) determined by the Child Welfare Committees — the competent authority formed by the State at the district level — to be in need of care and protection. We used a child rights lens and considered institutionalised children as especially vulnerable. Article 5 of the United Nations Convention on the Rights of the Child recognises the increasing capacities of children to make their own choices. Article 6 calls for facilitating development of the child to its full potential. Article 7 states that children have the right to know and be cared for by their parents [2]. The circumstances leading to institutionalisation meant that the fundamental right pertaining to Article 7 had ceased to exist, at least temporarily. The mental wellbeing and resilience of such children is extremely important if they are to fulfil their true potential as affirmed in Articles 5 and 6. We had undertaken an earlier exploratory study to understand the individual and context-specific (social and environmental level) protective factors for mental health of all the institutionalised adolescents (12–18 years) [3]. This paper describes the ethical dilemmas and related constraints faced by the researcher in the process of conducting that cross-sectional study covering all government-run children's homes in Kerala state, India, in 2016.

## Methods used in the main study

The study was conducted primarily to describe individual level and context-based (institutional and social) protective factors for the mental health and resilience of institutionalised children in Kerala [3]. The study was conducted in 2016, when there were totally eight government-run children's homes in seven districts in the state. Of these, two are dedicated to girl children. All adolescents of 12 to 18 years of age residing in these homes were approached to participate in the study. Children who had arrived at the institution within one month prior to the data collection were not approached. Such children would still have been adapting to their new environment and would not have fully experienced many aspects of their new living circumstances. We chose to do a mixed methods study with a structured data collection tool for the quantitative cross-sectional survey, and interview guidelines for exploring the narratives relevant to mental health and resilience and future perspectives of a few selected participants who were on the verge of leaving home on reaching the age of majority. The proposal was submitted to

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the concerned authority of the Integrated Child Protection Agency, under the Social Justice Department of Kerala State for the requisite permissions and clearances. The Institutional Ethics Committee of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum (IEC/915/MAY-2016), Kerala, reviewed the proposal and tools and provided recommendations, and then cleared the study. The study and the experiences shared here occurred before the Indian Council for Medical Research (ICMR) released the National Ethical Guidelines for Biomedical Research Involving Children, 2017 (hereinafter ICMR Guidelines, 2017) [4]. So, our findings should be read in that light.

## **Ethical dilemmas faced in securing consent and response**

### ***Written informed consent and assent: to sign or not to sign***

ICPS was functioning under the Social Justice Department (SJD) of the state at the time the study was envisaged (at present under the Department of Women and Child Development). Hence, permission to undertake the study was obtained from the Director of SJD. There was a clause in the initial permission order issued by the SJD that the identification details of children interviewed should not be revealed. This contradicted the conventional procedure at the time of having the participant's name and signature in informed written consent and assent forms. The relevant ethical guidelines were very new for the officials in the SJD. After a month of repeated representations and assurances that family or school identification details of children would not be collected as part of the study, the officials were convinced about the importance of both informed consent and assent in a research project.

### ***So, who should sign the consent forms? Not my job***

Experiences from each Children's home were different and the main point raised was on the question of their signature in the informed consent and assent forms. In most of the homes, the authorities refused to give their consent in writing, explaining that they wanted to avoid problems that may arise for them. They admitted that many researchers had approached the homes for data collection and never asked for informed consent or assent. While they could not deny permission, due to the order from the SJD, it took hours of negotiation to make the authorities understand the processes endorsed for informed consent and assent to participation in the study, and reassure them that this was not a fault-finding mission.

Some staff members in the Children's homes blamed ICPS officials in the state for giving us permission to fulfil the requirement for written consent and assent. Staff in permanent employment in the Children's homes were unwilling to sign the consent forms. They pressurised the caretakers, employed on a temporary basis, to give informed consent to avoid any risk to themselves. Obviously, temporary staff in Children's homes agreed, but repeatedly asked whether they would face any problems arising from this. In some homes, the staff did

not cooperate and created hurdles by not allowing the children to participate in the study. In one home, the staff raised the issue of legality of the children's signature because they were minors. ICPS officials intervened and convinced the officials in this home, but it took several visits to collect the data. Another home did not allow children to write their names along with their signatures in assent forms. They, however, did allow the names to be written in a separate sheet.

### ***Maintaining confidentiality while under paternalistic scrutiny***

Permission was granted on the condition that the children would be interviewed in the presence of the Superintendent of the concerned Children's home, or of an officer authorised by the Superintendent. The ethical approach calls for a gatekeeper's permission without sharing of information provided by the research participants and after taking precautions to avoid jeopardising the relations between the gatekeeper and the participant. In order to overcome this hurdle, the data collection strategy was finalised as a self-administered questionnaire. The information sheets for both consent and assent clearly included the condition that the questionnaire filled by the participants would not be shared with anybody other than the researcher and the research guide.

### ***Executing the consent process: beyond the signature***

The actual execution of the consenting process did not face the same scrutiny or challenges as the process of affixing signatures. The State level authorities and authorised gatekeepers of children's homes were willing to permit data collection once convinced of the official approval given to the study, and when all issues on the question of the signature were resolved. At the assent level, many children asked if they were actually permitted to sign or write their names in assent forms. Interestingly, the assent process revealed that given a choice to exert their autonomy and take a decision regarding participation, responses would be varied. Some children may choose to opt-out of the study while others would assert their identity and right to make a statement. There were 248 adolescents in the eight Children's homes at the time of the study, of which 26 declined to participate, despite the informed consent being signed on their behalf.

### ***Navigating nuanced vulnerabilities and confused personhood***

Successfully negotiating the conflicting regulatory tenets did not mean that ethical concerns were automatically addressed once all procedural requirements were met. An unanticipated challenge was that nearly a fifth of the children were unable to read or write fluently in any language. The investigator, thus, had to read out the questions and possible responses to groups of children who could then fill the responses that they felt appropriate.

Choices were available for most of the questions, and children were asked to put a tick mark against the choice they preferred for each question.

They were reassured that they could choose to hand in blank forms should they wish to, and that anything they submitted would remain confidential. An investigator-guided questionnaire being administered in groups yielded several advantages. First, the mandated requirement of a staff member's presence was easily achieved without the risk of harm should the child share any sensitive information. Second, this offered a sense of security to children as they were not singled out for data collection. Third, some degree of self-determination was provided to them, as the option of returning blank forms was made very clear. Lastly, the option of walking up to the researcher with a query offered moments of privacy for the children when they wanted to say something confidential.

During the interactions for assent and data collection, some participants voiced concerns about how their identities were regulated by the system in general. One child shared an invitation letter to an upcoming children's play that had a photo of the children on stage, but with their faces blurred (de-identified), and asked: "why should we not show our faces to the public?" Children also pointed out some deficiencies in the available facilities and services, and negative attitudes on the part of some programme officers. We maintained the anonymity and confidentiality of such children and submitted a consolidated set of findings to the State-level programme officials.

## Discussion

At the time of the study, we were required to collect signed informed consent and assent forms from the gatekeepers and the children respectively. This study was conducted before the release of the ICMR Guidelines, 2017 [4]. A similar study conducted today may not have had the same approach to consenting. However, we feel it is useful to discuss our experiences in line with the emerging context of informed consent and assent, and implications for research among institutionalised children.

### **Consenting institutionalised children — regulatory context**

Our research questionnaire received expedited approval for implementation from the State agencies, probably because it was in line with the Child rights framework. The rights-based approach has also informed the Juvenile Justice (Care and Protection of Children) Act, 2015 (hereafter written as Juvenile Justice Act, 2015) [5], as well as the ICMR Guidelines, 2017 [4]. However, there are some differences in the way both these instruments operationalise child protection. The ICMR Guidelines, 2017, are mainly focussed on the praxis of individual researchers. The guidelines section 3.1.2 provides an option for waiver of consent in certain situations when confidentiality is warranted due to "the sensitivity of the research objective, for example, study on disease burden of

HIV/AIDS" [4]. The guidelines are, however, silent on children under the guardianship of the state, where the legally acceptable/authorised representative (LAR) is a gatekeeper on behalf of the state who is also bound to follow the relevant legislative guidelines.

The Juvenile Justice Act, 2015 is legally binding at an institutional level [5]. Given these anomalies the reactions we faced from the child protection officials were not surprising. The ICPS functions under the Juvenile Justice Act, 2015 which, in chapter IX, clause 74 (1) upholds the prohibition on disclosure of identity of children by stating that "no report in any newspaper or other forms of communication regarding inquiry or investigation or judicial procedure, shall disclose the name, address or school or any other particular, which may lead to the identification of a child in conflict with law or a child in need of care and protection." Clause 74 (3) lists the penalties for breach of this provision [5]. The provisions of this Act also do not permit audio or video recording or presence of an impartial witness for consenting of such children under the usual circumstances.

It is incumbent on Ethics Committees to decide whether a research question has this requirement. An aspect in support of waiver of consent and assent for institutionalised children is the hierarchy of laws in India. This hierarchy was laid down in *Gauri Shanker and Ors. vs State Of U.P. And Ors.*, 2005, and is as follows: (i) the Constitution of India, (ii) the statutory laws from the Parliament or State legislatures, (iii) the Rules or regulations under any Act, and (iv) administrative orders or executive instructions [6]. The Juvenile Justice Act, 2015, thus takes precedence over the ICMR Guidelines, 2017. However, waiver of informed consent by the Institutional Ethics Committees is still subject to evidence of privacy, confidentiality, and non-violation of the child's rights. Researchers would have to describe how these will be achieved. Based on our experiences, we describe the concept of informed consent and process below, which may help future researchers plan and disclose their approach to ensuring ethically appropriate recruitment of vulnerable study participants.

### **Obtaining consent of institutionalised children — reconciling anomalies**

The child protection officers, we dealt with, questioned signed assent on two aspects — protection of the child and validity of the signature. Unfortunately, the latter aspect drew more attention, thus potentially weakening the actual intended purpose of appointing the LAR. Extreme protective measures may make children see themselves as lacking or at fault, as suggested by Saleebey, whose account of Foucault's description of vulnerability designates "those who cannot name their situation, themselves, their group, or their past" as being vulnerable [7]. In our study, the vulnerability was nuanced, and not merely limited to the aspect of being institutionalised. The regulation of identities

alongside the conventional role of being school children may be disempowering and such persons may have less autonomy [8]. But it does not follow that those with diminished autonomy should have their autonomy further eroded [9]. As it happened, having children refuse to participate, although for reasons we do not know, was an indication of their ability to think independently and make a choice, and thus of their autonomy [10].

The ICPS functions under the Juvenile Justice Act, 2015, stipulates strict restrictions on disclosure of the identity of children [5]. However, the National Policy for Children, 2013, enshrines the rights of children to “be provided a conducive environment and the opportunity to express their views in any way they are able to communicate, in matters affecting them” [11]. All widely accepted standards too support seeking assent from those too young to give legal consent. The Council for International Organizations of Medical Sciences (CIOMS) guidelines suggest considering the assent of adolescents nearing the age of maturity as “co-consent” [12]. Sibley et al recommend assent as a process “to involve those children who are sufficiently able to participate in the decision-making process,” thus presenting an opportunity to protect the rights of the child, respect the child’s developing autonomy and play a pedagogical role with respect to decision-making [13].

The important tenets of informed consent need to be upheld even if waiver of the standard procedure is allowed. As explained by the European Data Protection Board (EDPB), the requirements are that it should be — (i) clear (ii) concise (iii) specific (iii) granular (iv) freely given (v) revocable. Processes for actual implementation of these are needed if the rights of children participating in research are to be upheld. However, these tenets also call for proportionate reduction in information collected around these tenets when the participants are children. The EDPB prioritises parental authorisation and simple age determination procedures of the child. These were not challenges for us, as children had the state representatives and institutional gatekeepers as the LAR, and age documentation was already done during the institutionalisation process [14].

We acknowledge that the environmental factor (seeing other children filling up the form) might have influenced the child’s decision to fill up the form. However, we believe that the process was free of “undue influence or coercion” or of mere absence of objection being taken as assent, as mentioned by Tait and Geisser [15]. Debating the physical act of signing and not the actual essence of the consent/assent process reflects a lacuna. It is well recognised that the recording should not constitute the main process of assent [16]. The issue of government officials feeling threatened when asked to sign an informed consent form is beyond the scope of this manuscript; but it reinforces our understanding that the act of signing was perceived as the central issue in the consent/assent process. The concept of informed consent continues to be implemented as a procedural obligation in health research

on persons. However, conceptualisation and praxis of informed consent should uphold dignity, individual agency and autonomy while the processes of implementing these should be adapted to local contexts. By engaging with stakeholders early on, while still conceptualising the research, researchers may be able to identify broader contextual aspects (legislative, administrative, social, cultural, etc) that have to be accounted for. At this stage, researchers may also consciously explore the potential power relations and vulnerability levels that exist within the context that may have a bearing on individual agency and autonomy for consent. A set of processes may thus be proposed and reviewed by the ethics committees of the respective research organisations. Protection of children does not end with consenting or even data collection. Meticulous implementation of consent beyond the procedural aspects in ways suited to the research context will reflect the respect shown to the personhood of the participant. This will actually benefit research by building mutual trust between the researcher and the participant.

## Conclusion

Research among institutionalised adolescents was difficult to pursue due to conflicting directives from the systems and authorities enforcing legal and ethical protection. As a researcher and a law-abiding citizen, the principal investigator was constantly negotiating between the two throughout the research process. Whether strong protective measures may amount to suppression of identities in protected children and affect the child’s capacity for self-determination in the context of research needs to be explored further. The tenets of consenting or assenting should remain mandatory but institutional and federal requirements should encourage authentic engagement processes with potential participants rather than mere compliance with set guidelines.

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**Statement of similar work:** *A presentation based on the study was made at the 6th National Bioethics Conference, 2017. It is available online at <https://ijme.in/nbc-20140321/pdf/nbc6/sumitha-consent-assent-and-confidentiality.pdf> While the basis for both the presentation and the manuscript are the same, the description of the background, the organisation of the results and approach to the discussion of the manuscript are original.*

**Conflict of interest:** *None to be declared.*



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## COMMENT

## Learning to switch gears — Steering palliative care into emergency medicine

RACHANA BHAT, AKSHAYA RAMASWAMI, PRAVEEN AGGARWAL

## Abstract

Emergency care is largely seen as synonymous with resuscitation and saving lives. In most of the developing world where Emergency Medicine (EM) is still evolving, the concept of EM

*palliative care is alien. Provision of palliative care in such settings poses its own challenges in terms of knowledge gaps, socio-cultural barriers, dismal doctor-to-patient ratio with limited time for communication with patients, and lack of established pathways to provide EM palliative care. Integrating the concept of palliative medicine is crucial for expanding the dimension of holistic, value-based, quality emergency care. However, glitches in decision-making processes, especially in high patient volume settings, may lead to inequalities in care provision, based on socio-financial disparities of patients or premature termination of challenging resuscitations. Pertinent, robust, validated screening tools and guides may assist physicians in tackling this ethical dilemma.*

**Keywords:** emergency medicine, palliative care

The term Emergency Department (ED) paints a picture of a fast-paced setting, with patients of varied but severe illness. Emergency care is largely linked with resuscitation. As Emergency Medicine (EM) physicians, years of our training are focused on how fast we can think and act to save lives and reduce morbidity.

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