

Distr.
LIMITED
LC/CEA.11/6
5 November 2021
ENGLISH
ORIGINAL: SPANISH
21-00605

Eleventh meeting of the Statistical Conference of the Americas
of the Economic Commission for Latin America and the Caribbean

Virtual meeting, 23–25 November 2021

**PROTOCOL FOR THE COLLECTION AND DISSEMINATION OF DATA
ON CHILDREN AND ADOLESCENTS PARTICIPATING IN STUDIES**

SUMMARY



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INTRODUCTION

This document summarizes the main elements of the “Protocol for the collection and dissemination of data on children and adolescents participating in studies”, which was prepared by the working group to develop a protocol for the collection and dissemination of data on children and adolescents participating in studies of the Statistical Conference of the Americas of the Economic Commission for Latin America and the Caribbean (ECLAC). The working group was coordinated by El Salvador (Department of Statistics and Censuses (DIGESTYC)) and Panama (National Institute of Statistics and the Census (INEC)).¹

Its preparation was framed by the objectives set by the working group to provide the region’s statistical offices with an instrument that facilitates the collection and dissemination of data on children and adolescents participating in studies, while respecting ethical research principles. The instrument considers regional specifics and the effect of local cultural and gender norms; and it anticipates possible responses to sensitive situations (based on the identification of situations in which children are at risk).

A qualitative and quantitative diagnostic assessment of research with children and adolescents in Latin America and the Caribbean was used as the basis for designing this proposal. A questionnaire was sent to 25 of the region’s national statistical offices; 21 of them responded, and their representatives were subsequently interviewed.

Ten countries stated that they apply specific ethical research protocols for children and adolescents. In the other countries, the same protocols are used for both adults and children under 18 years of age.

The most widely researched topics are employment, education, health and nutrition, gender violence and, to a lesser extent, migration.

The diagnostic study reveals that some of the procedures described in the various international guidelines on ethical issues in research with children and adolescents are not being applied by the region’s national statistical offices. The procedures that are less frequently applied by the countries include: analysis of the harms and benefits that the research may entail for the participating children and adolescents (which is usually done before starting the research process); a review of the research design by an external ethics committee; the lifting of confidentiality when rights violations are detected during the fieldwork (which require protective actions, without these actions necessarily being associated with a complaint); and, lastly, the containment or mitigation of risky or sensitive situations.

This document is organized in three parts: the first part justifies the relevance of the ethical aspects included in the protocol; the second presents a simplified flow chart on the ethical issues that must be considered in research involving children and adolescents; and the third and last part presents the protocol, to check whether the basic requirements for the proper conduct of research involving children and adolescents have been met.

The protocol has two sections. The first seeks to verify the appropriateness of conducting the research with children. The second aims to ensure that each stage of the research—design, fieldwork and analysis and dissemination—adequately considers the four major ethical areas: analysis of harms and benefits, informed consent, privacy and confidentiality, and payments and compensations.

¹ The authors are grateful to the agencies of the various countries of the region and United Nations entities which provided valuable collaboration for the preparation of this document.

Lastly, annex 1 presents the table of contents of the full document, which addresses in greater depth the theory underlying the ethical aspects of the protocol. It also contains more detailed diagrams and includes various practical applications of the tool.

A. MAIN ETHICAL ISSUES TO BE CONSIDERED IN RESEARCH WITH CHILDREN AND ADOLESCENTS

1. Evaluation of harms and benefits

The initial stage of the research design process should ask what benefit, direct or indirect, the children and adolescents will receive as a consequence of their participation in the study and the possible harms that could be caused to them.

Consideration should be given to the physical harm that the child or adolescent might suffer as a direct consequence of his or her participation in the research; the retaliation, punishment or physical harm that might be inflicted on the child by others for his or her participation; and the emotional impact that this might entail.

This exercise should be carried out in all research in which children and adolescents participate, even if it is not child-focused.

The team must be certain that the required information cannot be obtained without interviewing children and adolescents directly or by collecting information about them through other primary sources, and that the information in question is absolutely necessary to achieve the research objectives.

The researchers must be prepared to detect and address such situations in the field, and build specific measures into the research design to guarantee the protection and care of children.

2. Informed consent

The request for consent entails due respect for the dignity of the participants and their right to make decisions on matters affecting them, as enshrined in the Convention on the Rights of the Child.

The request recognizes that the participants are best placed to assess the risks of their participation, including the right to desist or withdraw, irrespective of the wishes of their parents.

As a general rule, consent should be obtained for parents or legal guardians, and adolescents and children over eight years of age should also themselves give assent. When the research involves participation by children and adolescents who are at risk, more flexible solutions are required, which would include identifying an adult recognized by the child or adolescent to give consent. Each country's legislation should be considered as the basis of the ethical framework governing research with children and adolescents.

Consent should be explicit, informed (both adult and child participants must understand the objectives of the research), voluntary and renegotiable.

3. Confidentiality and privacy of information

Participant privacy means, first and foremost, respecting the fact that children may not want to share certain information with the researcher, and they should not be pressured to do so.

This concept also implies that the place where the interview is conducted should be safe and in full view; and it should enable child and adolescent participants to confide information without being overheard by outsiders or, in the case of written material, without their responses being seen by others.

Information confidentiality also extends to the stages of collection, storage, and dissemination of the research findings. The ethical principle of non-maleficence means ensuring that the research participants, and their families or communities, are not harmed by the dissemination of the research findings. This also includes the safeguarding and storage of information, and the maintenance of participant anonymity when databases are shared.

4. Payments and compensations

Payments to children and adolescents participating in a research project are of four possible types:

- (i) Payment as reimbursement, which compensates the children or their parents for any expenses incurred as a result of their participation (such as transportation, meals or lodging);
- (ii) Payment as compensation to the children or their parents for their time, effort and any inconvenience caused (such as loss of income);
- (iii) Payment in recognition of the child's participation in the research. This is an expression of appreciation to the participants for their collaboration, and usually takes the form of small gifts given at the end of participation; and
- (iv) Payment as an incentive to participate. This form of payment raises the most ethical issues, since it can be seen as a form of persuasion that contravenes the norms of the Nuremberg Code, under which potential participants should not be persuaded in any way to participate in research.

5. Ethics committee

It is recommended that ethics committees be set up to provide feedback on the research design and strategies to address the ethical issues involved. This committee is advisory in nature and should consist of at least three individuals who are external to the research, avoiding conflicts of interest. Each institution will be responsible for deciding whether approval by the committee will be a requirement to proceed with the research.

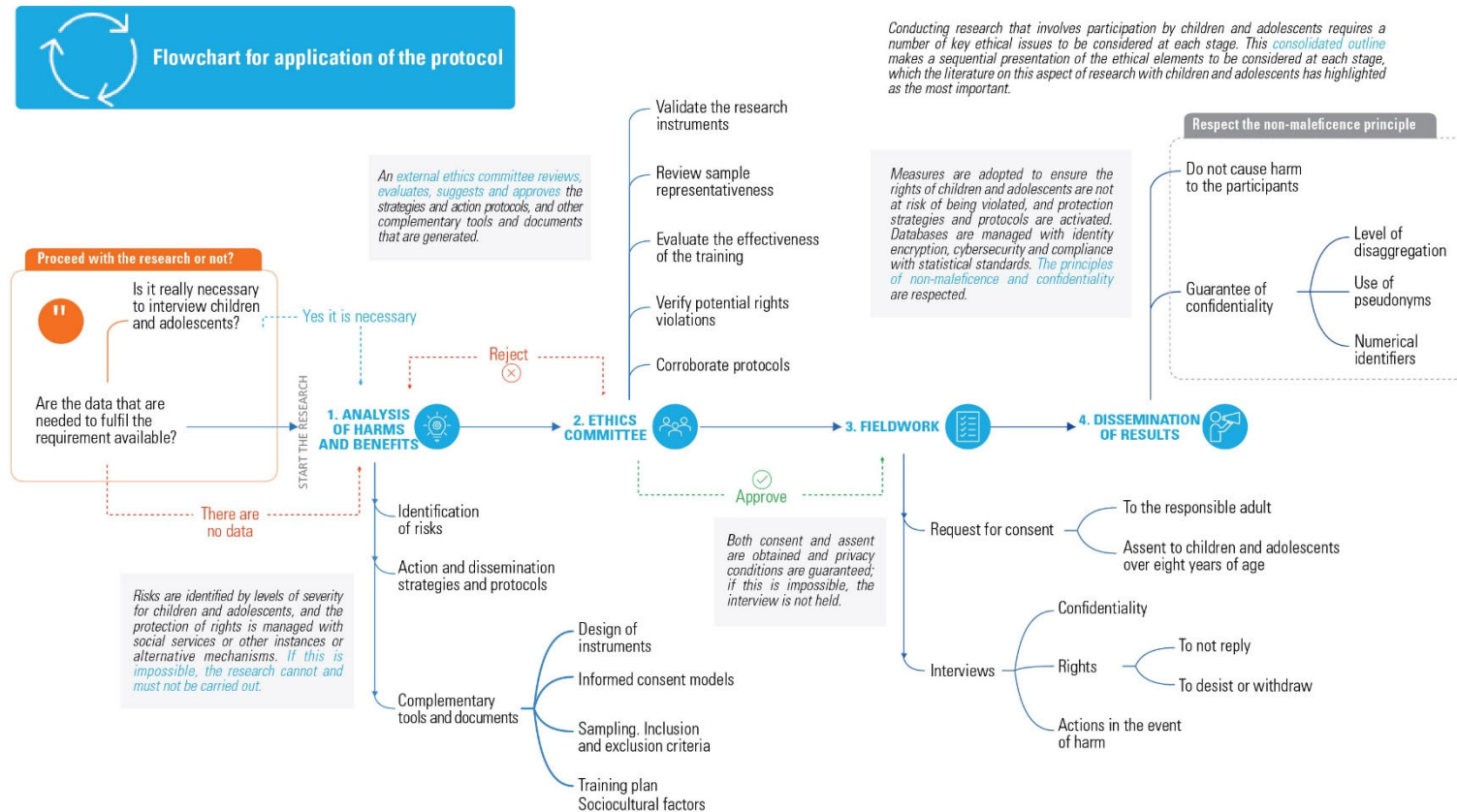
Alternatively, the ethics committee of a university or research centre can be used.

The committee should evaluate the risks and benefits of participation by children and adolescents, the methods and instruments to be used, the process of recruiting and training field workers, respect for gender differences, consent models, protection of the participants' privacy and confidentiality until the dissemination stage of the study, and protocols for providing protection and support if violations are detected during the field work.

B. FLOW CHART FOR INCORPORATING ETHICAL CONSIDERATIONS IN RESEARCH INVOLVING CHILDREN AND ADOLESCENTS

Diagram 1 provides a sequential view of the different procedures that need to be carried to incorporate the necessary ethical considerations in research involving children and adolescents.

Diagram 1
Flow chart for application of the protocol for the collection and disclosure of data on children and adolescents participating in studies



Source: Prepared by the author.

C. PROTOCOL FOR THE COLLECTION AND DISSEMINATION OF DATA ON CHILDREN AND ADOLESCENTS PARTICIPATING IN STUDIES

The protocol should be applied in two steps. The first step entails assessing whether having children and adolescents participate in the research is justified; and the second step must address the ethical issues or considerations that need to be taken into account at each stage of the research.

1. First step: evaluation of relevance and readiness

If your answer to any of the relevance and readiness questions is “No”, then children and adolescents should not participate in the research.

Review the objectives and reformulate your research before proceeding to the next stage, paying special attention to aspects identified as negative.

Step 1 questionnaire Evaluation of relevance and readiness

Relevance and readiness	Yes/No
1. Have you made sure the required information is not available in other research?	
2. Does the research require the direct participation of children because data cannot be obtained in other ways (such as by using secondary data or interviewing individuals aged over 18 about their experience in childhood or adolescence)?	
3. Do you have the technical knowledge and interpersonal skills to involve children in the research?	
4. Following careful review, are you sure that the research will not impose excessive costs or negative effects on participants (such as missed classes, monetary costs, extra work)?	
5. Following careful review, are you sure that the research takes account of gender differences, specific situations and risks to which children and adolescents may be exposed through their participation in the study?	
6. Are there protection services, or public or private institutions, which can provide adequate and timely care to child participants in the event of serious physical or psychological risks or harm identified in the fieldwork, while also taking gender differences into account?	

2. Second step: ethical aspects to be implemented at each stage

The questions must be answered before starting the research. The issues to be considered at each of the three stages—design, fieldwork, and analysis and dissemination—have been structured around four ethical domains: harms and benefits, informed consent, privacy and confidentiality, and payments and compensation. If you check more than one “No”, consider whether you can make adjustments to the research to reduce and control the level of harm that may be caused. If the eventual harms are insignificant, justify your decision in the methodological report.

Step 2 questionnaire
Ethical matters to be considered at each stage

E1 STAGE OF DESIGN	
Stage 1 Domain 1 HARMS AND BENEFITS	Yes/No
1. The benefits, whether direct or indirect, that the participants will obtain from their participation in the study are clearly stated.	
2. The risks or possible harm that the research, in each of its stages, may cause to the study population or part of it, will be analysed.	
3. Specific measures have been considered to address the risks identified and to obviate or mitigate any harm or emotional impact that the research may cause to any participant. The measures in question consider the increased exposure of girls and adolescent women to sexual abuse and exploitation.	
4. If measures to prevent or reduce harm to a specific population or group cannot be guaranteed, consideration has been given to excluding the group or cases in question from the sample under study, or to cancelling or redesigning the study.	
5. Representative samples of the population are used, giving all groups an opportunity for representation, including those that are harder to reach. The criteria for inclusion in, and exclusion from, the sample are made explicit. Alternatively, their absence is justified, and a mitigation strategy is devised.	
6. Data collection will use methods that are appropriate to the age and stage of development of participating children and adolescents.	
7. Support is available for the children and adolescents during and after the research process, if necessary.	
8. There is a protocol for action when situations of child mistreatment, abuse or exploitation are detected. This will provide for support and referrals to specialized protection and support networks.	
9. The protocol of action to be applied when situations of child mistreatment, abuse or exploitation are detected considers the real chances that reporting such cases will activate a network of protection and support for the child in question, and that it will not cause him/her any harm.	
10. The data collection team will be trained in protocols for incorporating ethical aspects in research with children and adolescents, and will be sensitized to gender issues.	
11. If the research addresses issues such as gender violence, trafficking, sexual abuse or exploitation, the design prioritizes a female data collection team.	
12. The research design is reviewed by an ethics committee (academic or institutional), preferably external and independent. If this is not possible, a committee whose members are not directly involved in the study will be asked to review the design.	
13. If the research addresses issues such as gender violence, trafficking, sexual abuse or exploitation, the data collection team will be sensitized on these issues, taking account of the gender differences that exist between boys, girls and adolescents.	

E1 STAGE OF DESIGN		
Stage 1 Domain 2 INFORMED CONSENT		Yes/No
14.	The request for consent is based on the laws of the country in question.	
15.	The consent of mothers, fathers or guardians is considered.	
16.	The consent form provides information on: <ul style="list-style-type: none"> – the purposes and objectives of the research; – the potential benefits and risks to which the child will be exposed; – the methods and instruments to be used; – the confidentiality of the information provided by the child; – the privacy required for the interview; – the possibility of refusing the interview and of withdrawing at any time; – the procedures and channels for reporting possible abusive behaviour by the research team; and – focal points for asking questions about the research. 	
17.	The research design includes requesting assent from children and adolescents participating in the research. Assent should be requested from all children over 8 years of age.	
18.	The children’s assent request includes: <ul style="list-style-type: none"> – a clear and age-appropriate explanation of the research for each participant; – the objectives of the research; – the existence of potential risks, if any, and benefits associated with both the population participating directly in the fieldwork and the extended population (national, regional, specific or other); – assurances of complete confidentiality; and – an explanation of the possibility of refusing to participate before or after the study process has begun. 	
19.	The explanations and information on the research given to participants have been pre-tested to ensure that they are intelligible to the population of interest.	
20.	The research design has a clear protocol for how to proceed when children want to participate but their mothers or fathers do not, and vice versa.	
Stage 1 Domain 3 PRIVACY AND CONFIDENTIALITY		Yes/No
21.	Privacy conditions have been defined for the place where the information is collected.	
22.	The situations and conditions in which the privacy and confidentiality of the information could be waived have been made clear; for example, situations of abuse that require specialized intervention. Any lifting of the principle of confidentiality should always be justified in terms of the best interests of the child in question, and should be noted in the informed consent.	
23.	The processes through which the information and data collected will be anonymized are made explicit.	
24.	Security protocols are provided for the information collected and stored, and for the corresponding access authorizations.	

E1 STAGE OF DESIGN	
Stage 1 Domain 4 PAYMENT AND COMPENSATION	
25.	Provision has been made for disseminating the research findings to the participants (for example, through a child-friendly version of the final report).
26.	If gifts are given by way of thanks or recognition, this has been discussed with local experts or leaders so as not to generate conflicts between participants and non-participants.
27.	Monetary payments for children's participation are ruled out.
28.	Children and adolescents can participate in the research without incurring expenses or loss of important daily activities (such as school attendance).
E2 FIELD WORK STAGE	
Stage 2 Domain 1 HARMS AND BENEFITS	Yes/No
1.	The language used by the interviewer and in the data collection instruments will always be respectful, empathetic, inoffensive and non-disruptive with respect to the experiences and knowledge of participating children.
2.	The language used in the data collection instruments and the overall experience of participating in the study do not victimize, blame or affect the self-esteem or emotional integrity of children.
3.	The data collection team has been trained and has the necessary skills to work with the study population and has been sensitized on gender issues.
4.	Checks have been made to ensure that none of the members of the data collection team pose a threat to participating children (for example, by including individuals who are banned from working with children).
5.	The data collection team has been trained and has clear protocols and identified sources of support for taking care of children who suffer an emotional impact during the interview.
6.	The data collection team has been trained and has clear protocols and sources of support identified for action, if abuse or violation of the rights of any of the participants is detected. This will take account of gender differences and the greater exposure of girls and female adolescents to sexual abuse and exploitation.
Stage 2 Domain 2 INFORMED CONSENT	Yes/No
7.	The interviewing of children can only start once informed consent is obtained from their mothers, fathers or guardians, together with the assent of the participating child. The possibility of refusing to participate or withdrawing at any time, without any penalty, will be clearly stated.
8.	The information provided for assent will be checked to ensure that it is understood, in terms of both the benefits and risks of the research, and the possibility of desisting or terminating the interview at any time.
9.	The data collection team is trained to always ensure that the request for children's assent is made in a context that is free of pressures that could undermine or restrict the child's freedom to decide whether or not to participate. The voluntary nature of participation in the study must be emphasized.
10.	Once the information has been provided and explained, if mothers, fathers or guardians do not give their consent, or if the children do not give their assent, the interviewer should accept the wishes of the mothers, fathers or guardians, or of the children themselves, without trying to convince or persuade them otherwise.

E2 FIELD WORK STAGE	
Stage 2 Domain 3 PRIVACY AND CONFIDENTIALITY	Yes/No
11. The researcher or interviewer who interacts with the child shall ensure the privacy of the space in which the interview is held and the confidentiality of the information.	
12. The confidential nature of the information provided by the child will be made explicit when requesting consent from mothers, fathers or guardians.	
13. Younger participants —adolescents under the age of majority and younger children— will be offered the possibility of having an adult present during the collection and production of data.	
14. The methods and instruments used in data collection and production safeguard the participants' privacy.	
Stage 2 Domain 4 PAYMENT AND COMPENSATION	Yes/No
15. If, in the research design and following consultation with local leaders, it is decided to offer a gift or make a donation of educational material, the field team will deliver it individually, without this influencing the decision to participate.	
E3 ANALYSIS AND DISSEMINATION STAGE	
Stage 3 Domain 1 HARMS AND BENEFITS	Yes/No
1. To avoid biases or misinterpretations of the data that could distort the participants' voice, and hence their right to express themselves, the analysis for the official publication of the research will be performed by qualified professionals.	
2. In no circumstances will the dissemination of research findings allow, or lead to, identification of the participants, their family or their community.	
3. When presenting the findings and making the databases publicly available, steps will be taken to ensure that all indicators are presented with an age and gender breakdown.	
Stage 3 Domain 3 PRIVACY AND CONFIDENTIALITY	Yes/No
4. Databases of variables and transcripts should mask participant identification data; and the original identification data should be kept in separate folders.	
5. The consents given for children and adolescents participating in the study should be kept in separate folders from the variable and transcript databases.	
6. The databases, both those of participant identification and those of the variables and transcripts, should be adequately protected against hacking and cyber-attacks.	
7. Databases will only be shared through insecure means, such as e-mail, USB devices or laptops, if personal data are encrypted and anonymized.	
8. The information collected, especially data that makes it possible to individualize the participants, will be kept in folders of restricted access and clearly identified authorizations.	
9. Data that individualizes the participants will be kept (stored) for a maximum period of five years following publication of the study.	

Annex 1

GENERAL TABLE OF CONTENTS OF THE “PROTOCOL FOR THE COLLECTION AND DISSEMINATION OF DATA ON CHILDREN AND ADOLESCENTS PARTICIPATING IN STUDIES”²

Glossary and acronyms

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Bibliography

² The table of contents presented here is provisional.