



HML Ethics Review Board

Research Ethics Review Document

Review of UNICEF Research Project Materials for the Protection of Human Subjects

v.2023.2

This document serves to meet UNICEF ethical standards in research and is the official record of an ethics review. It is designed to ensure effective processes and accountability for ethical oversight and to ensure the protection of, and respect for, child and adult rights within all research, evaluation, and data collection processes undertaken or commissioned by UNICEF. It conforms with the [UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection and Analysis](#); Document Number: CF/PD/DRP/2015-001; Effective Date: 01 April 2015, Issued by Director, Division of Data, Research and Policy.

The Purpose of Research Ethics Review

The purpose of an Ethics Review Board (ERB) or Institutional Review Board (IRB) is the protection of human research subjects' rights. These rights include *Respect* for individuals to make free decisions, *Justice or equity* regarding distribution of the burdens and benefits of research, and *Beneficence* or the obligation to do good and avoid harm.

ERBs review research protocols that involve the collection and analysis of data from human subjects to ensure that ethical standards are upheld. This is to protect the rights and welfare of subjects and to ensure that:

- subjects know the purpose of the study and are not placed at undue risk;
- participation is voluntary and confidential;
- subjects are provided and agree to informed consent prior to their participation;
- relevant protocols are in place to assure subjects' protection and safety, and;
- data collection and analysis does not result in the violation of privacy or discrimination.

Before issuing approval, the ERB must determine that the following requirements are satisfied:

- informed consent is sought from each subject or the subject’s legally authorized representative;
- the proposed research design is scientifically sound and that risks to subjects are minimized;
- any risks to subjects are reasonable in relation to anticipated benefits;
- subject selection is equitable;
- safeguards are included for subjects likely to be vulnerable to undue influence or coercion;
- subjects’ safety, privacy, and confidentiality are maximized.

Materials Requested for Review:	Also, please include:
<ol style="list-style-type: none">1. Inception Report / Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, subject recruitment, subject protection and data protection plans.2. Copies of all Informed Consent documents.3. Copies of all data collection instruments.	<ol style="list-style-type: none">4. Written protocols to ensure subjects’ safety.*5. Written protocols for the protection of human subjects’ identities.*6. Written protocols for the protection of data.*7. Other relevant documents. <p>*These may be statements incorporated into research plans and/or embedded in a single protection protocol.</p>

HML IRB is an autonomous committee authorized by the United States Department of Health and Human Services, Office for Human Research Protections (IRB #1211, FWA #1102, IORG #850), to review and approve research involving human subjects before the start of research, and to conduct annual reviews of that research independent of affiliation with the research organization submitting materials for review.

Please submit your materials in English for review to:
D. Michael Anderson, PhD, MPH, HML IRB Chair & Human Subjects Protections Director
and Penelope A. Lantz, JD, HML IRB General Counsel
unicef@hmlirb.com

HML IRB
1101 Connecticut Avenue, NW
Suite 450
Washington, DC 20036 USA
+1.202.246.8504 www.hmlirb.com

UNICEF Research Ethics Review for Human Subjects' Protections

→ **INVESTIGATORS:** Please confirm your project information and any additional information requested below.

Section 1	Project Overview Please provide any requested information	
1.1	Project Title:	<i>Evaluation of children's skills at the enrollment in primary schools</i>
1.2	HML IRB Research Ethics Review ID#:	697TUNI23
1.3	Initiating UNICEF Official: Name, office, email	Sarra Ben Miled, Programme & Planning Specialist, Tunisia CO, MENARO sbenmiled@unicef.org
1.4	Principal Investigator/Project Manager: Name, degree(s), organization, & address	Dr Yolaine Glèlè Ahanhanzo – Hessou Public health specialist, independent consultant
1.5	Other Key Personnel: Names & titles	Please provide: NA
1.6	Contracting Firm: Name & address	Please provide: NA
1.7	Primary study site(s): CO, RO, countries	Tunisia
1.8	Project duration: Dates from -- to	Please provide: NA
1.9	Duration of Subjects' Participation: Dates from -- to	Please provide (and revise your inception report section 5.2.2). Revised in section 5.2.2 October 2022 to March 2023
1.10	Thematic Area/Areas:	Education Choose an item. Choose an item.
1.11	Target population:	To define the results of the different policies, programs and interventions in preschool education in Tunisia on children's skills at the enrollment in primary education.

Date of ERB Request	24 February 2023
Date(s) ERB Comments Returned	02 March 2023
Date Final Documents Received	07 March 2023
DATE OF ERB APPROVAL	07 March 2023

UNICEF Ethics Review Process

HML Ethics Review Board (UNICEF LTAS 42107154) will conduct a research ethics review of submitted materials and make comments below under **Additional Information Needed**. We will then return this template for responses from investigators.

Please respond to **our comments** in **another colour**, directly under each comment.

- Please provide any requested or revised materials, and please note where revisions to your materials may be found by page or paragraph number.
- Please do not alter ERB comments or the format of this document.

This HML ERB review document serves as the official record of the ethics review for the project named below. This document, including all comments and responses, will be retained by UNICEF and HML ERB as a record of this review. Once you and we have agreed on the ethical rights of your research subjects, we will issue a letter of approval.

	<p style="text-align: center;">Ethics Review Board Criteria of Interest</p>	<p style="text-align: center;">Additional Information Needed → Investigators: Please respond to ERB info requests in another color directly below the request all pages mentioned are for French version</p>	<p style="text-align: center;">X or NA equal PASS (for ERB use)</p>
<p>Section 2</p>	<p>ERB Submission: Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:</p>		
<p>2.1</p>	<p>Inception Report or Research Protocol.....X e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans</p>	<p>Please note that the table of contents in the IR refers to several items in the appendices that are not in the version provided. The missing elements were available and were sent for translation. Apparently there was a problem either with the translators or with the transmission of the translated files. The table has been updated after the corrections</p>	<p style="text-align: center;">X</p>
<p>2.2</p>	<p>Informed Consent documents.....X</p>	<p>Please provide: 1. the informed consent for the focus groups and principal survey; See page 85 (IC for focus group) page 80 (IC for principal survey) 2. the principal consent for the student survey; and See page 81 3. the child assent for the survey Apart from the consent of the director, there is only an unsigned verbal consent from the children for the tests to be carried out.</p> <p>Will there be a survey or questionnaire? See 3.2 below. If so, please provide questionnaire-specific IC document</p>	<p style="text-align: center;">X</p>

		I don't quite understand the question. Maybe it will be answered in the rest of the file. If not, thank you for being more precise.	
2.3	Surveys and data collection instruments.....X	<p>Please provide:</p> <ol style="list-style-type: none"> 1. pupil survey; 2. principal survey; 3. FGD guide for mothers, and 4. FGD guide for teachers <p>All were available</p> <ul style="list-style-type: none"> • pupil survey; page (page 122-127) • principal survey; (page 128-135) • FGD guide for mothers, (page 116-121) • FGD guide for teachers (page 109-115) • <p>Annexes 7 and beyond are not in the provided document – this includes data collection tools. Please provide.</p> <p>This is a problem with the translation, the translated versions will be made available</p>	X
2.4	Written protocols to ensure subjects' safety		X
2.5	Written protocols for protection of subjects' identities		X
2.6	Written protocols for protection of data		X
2.7	Other relevant documents	<p>In Section 4.4 you mention an information note to be provided to subjects in advance. Is that the same document as the consent form?</p> <p>If not, please provide a copy of the information sheets.</p> <p>Information notes are provided by target in Appendix 6. They are followed by the informed consent forms for each target</p> <ul style="list-style-type: none"> • Keys Informants (page 76) • FGD guide for mothers, (page 82-84) • FGD guide for teachers (page 82-84) 	X

		<ul style="list-style-type: none"> pupil survey; page (page 79-80) principal survey; (page 78-79) 	
2.8	Is UNICEF Procedure for Ethical Standards cited? Cited	Cited on page 13 and page 69 FR version (see footnotes) Referenced in the list of references under numbers 59 and 61 (page 33)	X
2.9	Have informed consent and data collection instruments been pre-tested? a. yes.....X b. no..... c. NR.....		X
2.10	Are all submitted documents final versions? a. yes..... b. no..... c. NR.....	Please respond. Yes	X
2.11	May the final protocol and instruments be included in an internal UNICEF searchable database for colleagues to learn from your work?	Please respond: INCLUDE or OMIT? INCLUDE	X
2.12	Additional comments or suggestions		X
Section 3	Research Design: Do submitted materials describe the proposed research? This includes:		
3.1	Is the study's background, rationale, and study design scientifically sound?		X
3.2	Type of data collection: d. survey questionnaire.....X e. subject interview.....X f. key informant interview (KII).....X g. focus group discussion (FGD).....X h. secondary document (desk) review.....X i. on-site observation..... j. case study..... k. physical measurements l. biological specimen m. other.....	Table 13 references direct observations. But you have decided not to include classroom observations, correct? This was an error in Table 13 that has been corrected. After discussion with the EDC section team, the originally planned observations were removed from the protocol given the limited time. In some places in your protocol you refer to subject interviews, while in others you refer to questionnaires and surveys. Will there be a questionnaire or survey? Data will be collected from:	X

		<p>- Key informants with interview guides through interviews</p> <p>- Principals with questionnaires through a survey</p> <p>- Students with questionnaires including competency test items. Students will not be interviewed to provide personal information, but will complete activities that will lead to the completion of a questionnaire.</p> <p>If so, please provide the tool as well as a questionnaire-specific informed consent.</p> <p>Data collection tools are available</p> <ul style="list-style-type: none"> • pupil survey; page (page 122-127) • principal survey; (page 128-135) <p>IC</p> <ul style="list-style-type: none"> • pupil survey; page (page 81) • principal survey; (page 80) 	
3.3	Is the type of data collection appropriate for this study design?	<p>In Section 4.4 you mention photos and video. Will you be taking photos or video? If so, please explain the purpose and content.</p> <p>There is no mention of photos or video in section 4.4. These elements were mentioned in section 4.6 for aspects related to data security in general. For this study, no specific photo or video is planned. Photos will be taken in the field for illustrative purposes to possibly confirm information gathered from school principals (example of insufficient resources). No photos showing people will be taken and no videos will be made.</p>	X
3.4	<p>Are secondary data (desk review including documents, reports, publications):</p> <p>a. publicly available.....X</p> <p>b. not publicly available containing personally identifiable information (PII).....</p>	<p>Please describe for activity, performance, study and survey reports.</p> <p>Desk review is based solely on documents, reports and publications made available to the consultant team by the sponsor team and those</p>	X

	c. not publicly available containing no PII.....	retrieved from the Internet. These are only public and open access documents, without personal data.	
3.5	Are types of data and variables in the secondary data set described?	Please describe. These are essentially statistics on the performance elements of preschool in Tunisia: number of students, utilization rate, etc. The documents from which these data are taken are specified on page 15.	X
3.6	Is how investigators' access to the secondary data described?	Please respond. Specified page 15 end of section 4.2.1.	X
3.7	If the secondary data contained subject records, did subjects consent to reuse of their data?	Please respond. Non applicable	X
3.8	Does study involve intervention, treatment, comparison, or control groups? a. intervention..... b. comparison..... c. control..... d. none.....X		X
3.9	Number of Data Collections: a. one-time only..... b. two or more (e.g., pre-post)	In Table 12 in Section 5 you mention follow up. Will there be any follow up with subjects? Translation issue. It's not a follow up « Suivi de la collecte des données sur les écoles/élèves de l'échantillon et de saisie des données » It's data collection supervision as task for the consultant If so, how will that be done if you don't collect names or PII? Non applicable	X

3.10	Sample size: Approximate total $n = 2187$	<p>Is this correct? 1600-1920 pupils (student questionnaire) 160 directors (director questionnaire) 27 KIIs Yes</p> <p>8 FGDs – how many people in each FGD? mentioned in section 4.3.3 (page 20). 7 à 10 people per groupe.</p> <p>Please provide your total estimated sample size. Added under table 10 sampling synthesis (page 21)</p>	X
3.11	Are any subjects children (<18 years old)?.....5 – 6 yo a. 0 – 2.....X b. 3 – 7.....X c. 8 – 12..... d. 13 – 17.....	What are the ages of students in your study? These are children entering the new primary school in 2022-2023. Most of them are around 5-6 years old, which is the age range of 3-7 years old	X
3.12	Does study include the use of technologies (e.g., on-line data collection or intervention, <i>U-Report</i>)?		X
3.13	Additional comments or suggestions		X
Section 4	Subject Risks: Are risks reasonable in relation to any benefits to subjects and to the importance of knowledge that may be expected to result from the research?		
4.1	Is the research <i>Minimal Risk Only</i> ?: This means the probability and magnitude of anticipated harm or discomfort is no greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests.		X
4.2	Does the research involve <i>greater than minimal risk</i> , but where risks are justified by anticipated benefits; where the relation of the anticipated benefits to risks is at least as favorable as available alternative approaches; and where the intervention or procedure is likely to yield generalizable		X

	knowledge? If so, are mitigating procedures described?		
4.3	Do study objectives show that risks are reasonable in relationship to expected gains and benefits are clearly articulated?		X
4.4	By their participation, are subjects vulnerable to any of the following?: a. physical risk b. psychological risk c. social risk d. economic risk e. legal risk f. political risk g. employment risk..... h. academic risk..... i. religious risk..... j. other..... k. none.....	Are there any of these risks to your subjects? NO	X
4.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?	Please describe as needed. Non Applicable	X
4.6	Does the study request information or opinions where public disclosure may result in danger, limitations to future freedoms, or access to services?		X
4.7	Do gender, ethnicity, or other demographic characteristics - or grouping of subjects by any of these characteristics, especially in FGDs -- increase subject risk?		X
4.8	If a subject discloses or is suspected to be at risk outside the study, are procedures in place to address or report risk and refer subject for relevant support?		X
4.9	Is local reporting abuse of children mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	Is there a form for reporting to UNICEF? No incident report form however, it is expected that page 71 and also on page 73 to : Report any case or suspected case of risk outside the study (violence on minors or gender-based violence): the lead consultant will report the case	X

		<p>in writing to UNICEF, while respecting the identity and dignity of the persons concerned. UNICEF, in collaboration with the relevant government authorities, will follow up on the case</p> <p>Who is the designated contact at UNICEF for reporting? The reference person is the person in charge of the evaluation, Mrs. Salma Layouni, as mentioned on all the documents provided</p>	
4.10	Additional comments or suggestions		X
Section 5	High Risk: When subjects are vulnerable to heightened risk have additional safeguards been included to protect their rights and welfare?		
5.1	Can subjects be perceived as vulnerable, including: children, especially unaccompanied or separated (UASC); lacking WASH, food, shelter, or medical care; refugees in conflict or post conflict; those in natural, ecological, or disaster settings; mothers & pregnant women; forced migrants and illegal or undocumented immigrants; prisoners or persons in institutions including orphanages or juvenile justice systems; gang members; those with mental or physical illness or disability; those with HIV/AIDS; those at economic or educational disadvantage; persecuted minority groups, or under high familial, peer, or social pressure? If yes, are study-specific protection protocols provided?		X
5.2	Does the sampling strategy target people at risk for issues such as: violence, torture, abuse, kidnapping; sexual exploitation, harassment, prostitution or pornography, female genital mutilation or cutting, reproductive or sexual issues; sexual orientation; child, early or forced marriage; suicide? If yes, are study-specific protection protocols provided?		X

5.3	Are subjects involved in any of the following: slavery, including the sale and trafficking of children; forced labour, servitude, forced recruitment to armed groups; war or armed conflict; illegal activities, production or trafficking of drugs; economic exploitation; work that could damage health or safety; removal of organs for exploitation? If yes, are study-specific protection protocols provided?		X
5.4	Does the study request information relating to illegal activities? If yes, is an MOU in place with government to ensure that no participant is prosecuted? Have participants been notified of this agreement?		X
5.5	Additional comments or suggestions		X
Section 6	Recruitment: Do submitted materials describe subjects and the recruitment process?		
6.1	To what extent are subjects identified: a. names are recorded with responses..... b. names recorded separate from responses.....X c. no names are recordedX d. other PII is recorded..... e. no PII is recorded f. subjects are given a unique identifier..... g. other.....	No names or other PII are collected for any subjects, correct? Indeed, no names are mentioned or recorded as specified in the main document, in the safety protocols, information notes, consent forms and collection tools	X
6.2	If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?		X
6.3	Are subject recruitment procedures & sampling strategy adequately described?	How will you select the dozen students from each school? Students are selected randomly as mentioned in the protocol for administering the questionnaires (page 79). The precision has now been added in section 4.3.1..	X
6.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?	How will you maintain privacy of child subjects during the recruitment process? The survey is done during part of the day, morning or evening. Students are in a classroom	X

		where they are tested and then return to their classroom with their teacher. The first and last names of these children are not kept and are not included in the data analyses (page 74-Protocol for the Protection of the Identity of Respondents)	
6.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?	<p>Please describe for the survey with children. The content of the material is adapted to children of the targeted age since it is about testing the skills they are supposed to have already acquired. Details are given on pages 16 and 17 and the tool is available on pages 122-127.</p> <p>How and by whom will it be administered? Is it completed by the students independently or administered by a data collector?</p> <p>It is a test of children's skills. The questionnaire including the different items will be completed by the interviewer who is an experienced and trained primary school inspector.</p>	X
6.6	If subjects are children or other vulnerable groups, or if subject matter is sensitive, is recruitment sensitive to subjects' potential vulnerabilities (real or perceived) and does it ensure privacy throughout recruitment?	<p>Please describe for children selected within each school.</p> <p>The sample defined to conduct the assessment survey is stratified. The important stratum is the preschool formula first (8 formulas in the Tunisian context), then it will be necessary to seek 10 children newly enrolled in the primary cycle having done such type of preschool. The diversity on which the sample was based, the preschool formulas, their distribution by region and geographical area. What concerns the children is their pre-school history (yes or no, if yes, which formula, for how many years,...). All these information are gathered in section 4.3.</p>	X

6.7	Do recruitment procedures show indication of bribery, coercion, intimidation, compulsion, pressure, or force?		X
6.8	Is recruitment of some members of the population and not others likely to result in resentment for either inclusion or exclusion? Have strategies to address this been adequately described?	Please describe for children in schools. This issue was studied. The test was constructed in such a way that no child felt excluded. All parents of the first grade classes were informed of the survey and the number of students selected in the sample, for a collective understanding of the purpose of this research.	X
6.9	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have strategies to address this been adequately described?		X
6.10	If subjects are paid, compensated, provided a gift, or provided other benefits or services for participation, is the incentive described and justified as non-coercive? a. cash or gift card..... b. refreshment..... c. travel cost..... d. phone or internet credit..... e. small gift..... f. other..... g. none.....X h. no response.....		X
6.11	Additional comments or suggestions		X
Section 7	Informed Consent: IC is a negotiation whereby subjects are informed about the study and their rights, and they agree to participate voluntarily. IC must be sought from each subject or the subject's authorized representative confirming this process.		
7.1	Type of Informed Consent: a. written & signedX b. written not signed c. written & signed by authorized representative.....X d. written with online checkbox..... e. verbal & signed or recorded.....	Please describe how consent will be recorded for each subject type. Consent is collected in written and signed form for all targets • Key informants: written & signed • Mothers focus group: written & signed	X

	f. verbal & signed by authorized representative.... g. verbal not signed or recorded..... h. active..... i. passive..... j. other	<ul style="list-style-type: none"> • Focus group educators: written & signed • School principals: written & signed • Students: written & signed by authorized representative (school principal) 	
7.2	Are the processes for obtaining each IC adequately described?	How will IC be obtained in the case of virtual interviews? The consent forms will be sent by e-mail to the subjects who will return them filled and signed in pdf version.	X
7.3	Does the IC include a clear and simple invitation to participate, an explanation of what the subject will be expected to do, and why they are being recruited?	Please include in child subject IC, FGD IC, and questionnaire IC. Were available: pages 77, 80, 81, 85)	X
7.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?	Please include in all IC documents. Were available: pages 77, 80, 81, 85))	X
7.5	Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions or may withdraw anytime without consequences?	Please include in all IC documents. Were available: pages 77, 80, 81, 85)	X
7.6	Does IC include the expected duration of the subject's participation (hours/minutes)?	Please include in all IC documents. Were available: pages 77, 80, 81, 85)	X
7.7	Are subjects given a clear indication of who will have access to their responses and in what form?	Please include in all IC documents. Were available: pages 77, 80, 81, 85)	X
7.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?	Any re-use of data? If so please describe for subjects in each IC NA	X
7.9	Does IC include a description of any risks or benefits to subjects?	Please include in all IC documents. Were available: pages 77, 80, 81, 85))	X

7.10	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?	<p>Any limits to confidentiality? If so, please include in all IC documents.</p> <p>No limit to confidentiality</p> <p>All the ICs include a statement on confidentiality</p>	X
7.11	Does IC provide identity and contact info of investigators? Is the form of contact useful and appropriate given power dynamics and access to resources like phones or email?	<p>Please include in all IC documents.</p> <p>Were available: pages 77, 80, 81, 85)</p>	X
7.12	For child subjects, is IC being obtained from parent, guardian, caregiver, or authorized representative? If not, is a justification provided for why this is unnecessary?	<p>Is it appropriate in Tunisia to obtain consent from the principal to conduct a survey with children in the school?</p> <p>t is a national and multi-sectoral survey, the national team with whom the work was built is multi-sectoral. The information was passed on in a top-down manner. However, each elementary school director and each preschool director received a letter explaining the scope and objectives of the survey and that their collaboration is valuable for the success of the work.</p> <p>Please provide the information sheet/consent form to be used to obtain consent from the principal.</p> <p>Information sheet page 78-79</p> <p>IC from principal for children test administration page 81</p>	X
7.13	For child subjects, is their role in the study described adequately and in an age and culturally appropriate manner for them to provide written or verbal assent?	<p>What is the age of your child subjects?</p> <p>5-6 ans</p> <p>Please provide us with an age-appropriate statement that explains what they are being asked to do, and then read it to them.</p> <p>The test is purely pedagogical, the child is tested on activities related to the basic skills at the beginning of primary school, he has pictures and</p>	X

		he answers by pointing to what the investigator asks him, or to reproduce geometrical shapes or symbols (fine motor skills). The test is a set of educational and pedagogical exercises. No questions outside this aspect have been programmed.	
7.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	Please include in FGD IC document. Yes absolutely. Part highlighted in yellow in the document that was available on page 85	X
7.15	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?	Please provide. NA	X
7.16	Where data collection differs by method (e.g.: survey, FGD, interview, audio recording), do ICs cover each method?	Please obtain consent to audio record. In Section 4.4 you mention photos and video. If you will be taking photos or video please get signed consent. As mentioned in 3.3, no video is planned. It is specified that for those subjects who have given their consent for an audio recording, this recording will be made. This facilitates the analysis of the data but it is not a requirement and is not obligatory. A verbal consent can be considered here but we have added a consent form for audio recording as requested.	X
7.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?		X
7.18	Additional comments or suggestions		X
Section 8	Subject Protections: Do submitted materials clearly identify protection against risk?		
8.1	Do materials describe protocols for subjects' safety throughout data collection, analysis, storage, and dissemination?	Your protocol states that " <i>The identification of the place [the location of data collection] will be left to the respondent</i> ". Does this extend to child subjects? If	X

		<p>not, where will data collection take place? Will there be a chaperone or second data collector to accompany child subjects?</p> <p>This statement concerns adults, key informants and focus group participants, in order to maintain confidentiality during data collection (see data security protocol on page 75).</p> <p>For the children, everything takes place in their school with the accompaniment of their principal who attends all the tests. As these are tests, a large proportion of the items are administered in groups. Only a few items are administered individually (mentioned on page 18)</p>	
8.2	Are all data collected necessary for the purposes of evidence generation?		X
8.3	Do data analysis and reporting procedures ensure subject confidentiality (or anonymity) and security?		X
8.4	If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond?	<p>Any future contact? If so, please respond.</p> <p>NO</p>	X
8.5	Are backgrounds and qualifications of data collectors adequately described?	<p>Please describe.</p> <p>The surveyors are primary school inspectors, the only ones authorized to have access to the schools and to interview the principal, teachers and students. Their appointment was made by the authorities of the Ministry of Education (page 17)</p>	X
8.6	Have personnel collecting data from subjects, especially child subjects, had ethical training specific to the target group?	<p>Please describe.</p> <p>Ethical considerations are included in the content of the training of investigators. In addition, all consultants have been trained in ethical considerations in research. Mentioned in the personal safety protocol on page 75</p>	X

8.7	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?	Please describe. Issues addressed during interviewer training (see page 70)	X
8.8	Additional comments or suggestions	In Section 5, you state that two of the four consultants will be responsible for data collection. Which two? Corrected. The collection of qualitative data is the responsibility of the international evaluation consultant and the national consultant (possibly with the inspector supervising the school and its director). Also in Table 12 you mention that the international consultant will train supervisors and investigators. What does that mean? his is the training of the surveyors. Corrected Who will conduct data collection in each school? For the quantitative survey, primary school inspectors	X
Section 9	Data Protections: Do data collection and storage protocols adequately ensure subject & data safety?		
9.1	Are data collection tools appropriate and constructed to assure subject confidentiality or anonymity?	In Section 4.4 you state that subjects will be told their data is collected and processed anonymously. Focus groups by their nature cannot be anonymous especially when subjects know one another. The best you can assure is to keep data confidential and advise discussants to do so for the group. This was done in the briefing note and consent forms for the focus groups (page 84-85) Please provide data collection tools. Will they be electronic or paper? Done Annexe 7 Paper version	X

9.2	Do data collection procedures and environment ensure data security?	<p>Where will focus groups take place? n spaces identified in advance by the preschools or in the community by the local teams. These spaces should be out of sight to ensure confidentiality. This was mentioned on page 20 section 4.3.3. and on page 75 in the data safety protocol.</p> <p>Where and by whom will the survey for students be administered? Will students be removed from their classes or will it be administered to the entire class? The group of students to be surveyed has been removed from their class (group of 6 students), after one hour of testing, this group returns to their class and it will be the turn of the other group of 6. According to the ministerial authorities, it was considered better to leave the students in their class with their teacher and only those who will be surveyed in another room..</p>	X
9.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?	<p>Please describe for paper, digital and audio recordings (and photo or video if applicable). NA</p>	X
9.4	If data will be shared with partners, is there a clear agreement or NDA?	<p>Any data sharing? If so, please respond. NO</p>	X
9.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, management, and de-identification?	<p>Please describe for paper, digital and audio recordings (and photo or video if applicable). NA</p>	X
9.6	<p>Do protocols state length of retention and destruction of raw data (months, years)?</p> <p>a. destroyed at end of study.....</p> <p>b. destroyed after three years.....</p>		X

	c. retained indefinitely..... d. other.....X five years e. NR		
9.7	Additional comments or suggestions		X