



HML Ethics Review Board

## Research Ethics Review Document

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

This document serves to meet UNICEF ethical standards for research, evaluation, data collection and analysis, 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.

<b>Materials Requested for Review:</b>	<b>Also, please include:</b>
<ol style="list-style-type: none"><li>1. Inception Report / Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, subject recruitment, subject protection and data protection plans.</li><li>2. Copies of all Informed Consent documents.</li><li>3. Copies of all data collection instruments.</li></ol>	<ol style="list-style-type: none"><li>4. Written protocols to ensure subjects’ safety.*</li><li>5. Written protocols for the protection of human subjects’ identities.*</li><li>6. Written protocols for the protection of data.*</li><li>7. Other relevant documents.</li></ol> <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 for review to:  
D. Michael Anderson, PhD, MPH, HML IRB Chair & Human Subjects Protections Director  
and Penelope A. Lantz, JD, HML IRB General Counsel  
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<b>Date of ERB Request</b>	10 January 2022
<b>Date(s) ERB Comments Returned</b>	17 January 2022
<b>Date Final Documents Received</b>	24 January 2022
<b>DATE OF ERB APPROVAL</b>	25 January 2022 (Please see note in Item 5.1.)

## 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.

	<b>Ethics Review Board Criteria of Interest</b>	<b>Additional Information Needed</b> → Investigators: <b>Please respond to ERB info requests in another color directly below the request</b>	<b>X or NA</b> equal <b>PASS</b> (for ERB use)
<b>Section 1</b>	<b><i>ERB Submission:</i> Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:</b>		
1.1	Inception Report or Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans	<b>Please keep us informed of any subject protection protocol or research design changes that need to occur in adaptation to the coronavirus pandemic in the sites of your study.</b> No adaptation required so far, as all interaction takes place online. If any changes occur, we will keep you informed.	<b>X</b>
1.2	Informed Consent documents		<b>X</b>
1.3	Surveys and data collection instruments		<b>X</b>
1.4	Written protocols to ensure subjects' safety		<b>X</b>
1.5	Written protocols for protection of subjects' identities		<b>X</b>
1.6	Written protocols for protection of data		<b>X</b>
1.7	Other relevant documents		<b>X</b>
1.8	Do protocols include a section identifying ethical issues and measures to mitigate ethical problems as required by UNICEF Procedure?		<b>X</b>
1.9	Have informed consent and data collection instruments been pre-tested?	These instruments were designed, used and pre-tested before during other evaluations involving very similar interviewing schemes for comparable groups of rights holders (evaluation of UNICEF Contribution to the normative policy framework of the social care services reform 2013-2019 in Albania; evaluation of UNICEF / UNFPA / UNDP project "Promoting kyrgyzstan's youth cohesion and interaction towards Uzbekistan" (2019-2020)). On these occasions, the informed consent and data collection instruments had been tested, and	<b>X</b>

		approved by the Ethical Review Board. In addition, for the current evaluation, informed consent and data collection instruments were submitted for comment and validation to all UNICEF country offices (Child Rights Monitors and ECD specialists) through the ERB review. Note that the informed consent forms are only applicable to rights holders (parents of children with disabilities and parents from Roma communities).	
1.10	Are all submitted documents final versions?	Please respond. Yes.	X
1.11	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 We understand that this includes the instruments and protocols as per the inception report – not the interview minutes.	X
1.12	Additional comments or suggestions		X
<b>Section 2</b>	<b>Research Design: Do submitted materials describe the proposed research? This includes:</b>		
2.1	Is the study's background, rationale, and study design scientifically sound?		X
2.2	Does study involve intervention, treatment, comparison, or control groups?		X
2.3	Type of data collection: a. survey questionnaire..... b. subject interview.....X c. key informant interview (KII).....X d. focus group discussion (FGD)..... e. document (desk) review.....X f. on-site observation..... g. case study..... h. analysis of secondary data..... i. physical measurements ..... j. biological specimen .....	You mention FGDs on pgs.44-45 and in your request for ethical review but you do not provide any FGD materials or protocols. Will you be conducting FGDs?  If so, please provide the data collection tools, informed consent and protocols for this type of data collection.  No FGDs envisaged. This was kept as an option in case several interviewees from the same institutions requested to have an FGD instead of individual	X

	k. other.....	interviews – but this did not materialize. Report amended accordingly.	
2.4	Number of Data Collections: a. one-time (no follow-up) .....X b. two or more (follow-up) .....		X
2.5	Sample size: Approximate total $n = 90$		X
2.6	Are any subjects children (<18 years old)? None	No	NA
2.7	Additional comments or suggestions		X
Section 3	<b>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?</b>		
3.1	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
3.2	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 knowledge? If so, are mitigating procedures described?		X
3.3	Do study objectives show that risks are reasonable in relationship to expected gains and benefits are clearly articulated?		X
3.4	By their participation, are subjects vulnerable to any of the following?: a. physical risk ..... b. psychological risk .....X c. social risk ..... d. economic risk .....	Please describe the potential for psychological risk. This applies only to rights holders (parents of children with disabilities/belonging to the Roma community). It does not apply to duty bearers, CSOs or UNICEF staff.	X

	<p>e. legal risk .....</p> <p>f. political risk .....</p> <p>g. employment risk.....</p> <p>h. academic risk.....</p> <p>i. religious risk.....</p> <p>j. other.....</p>	<p>Parents will not be asked about their or their children's personal history. Instead, they will be asked to share their experience of accessing improved services and their opinion about these services. However, in the course of describing this experience, they may want to share their history or compare their recent experience of accessing services, with other/past experiences when they did not have access to such services. These memories may be painful because they could be associated with feelings of injustice or neglect from the part of duty bearers.</p>	
3.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?	<p>Please describe how you will mitigate the risk of psychological harm.</p> <p>Section 6, pages 45-47 of the inception report.</p>	X
3.6	Does the study request information or opinions where public disclosure may result in danger, limitations to future freedoms, or access to services?		X
3.7	Do gender, ethnicity, or other demographic characteristics -- or grouping of subjects by any of these characteristics, especially in FGDs -- increase subject risk?	<p>Please describe if you will conduct FGDs.</p> <p>N/A</p>	X
3.8	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?	<p>Please describe.</p> <p>This was already specified in the inception report, Section 6, p. 47: "If an interviewee discloses or is suspected to be at risk outside of the study, the interviewer will acknowledge the risk, address this by reporting the risk to the project team, and appropriately refer the interviewee for relevant support, specific to the situation at hand (e.g. providing the phone number of a specialized association, police, local service provider)."</p>	X
3.9	Is reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	<p>Please describe.</p> <p>Not mandatory.</p> <p>The rights holders interviewed have been engaged with parental ECD services for a significant period of time. As</p>	X

		users of these services, any sign of abuse of minors should have been identified and addressed long ago by the duty bearers and/or CSOs providing these services. Besides, the interview questions are unlikely to reveal abuse of minors. Therefore, there is no obligation for the evaluation specialists to report abuse which is unlikely to be detected and which, if existing, was almost certainly identified and addressed already by the relevant institutions. Should abuse of minors surface during an interview, the interviewer will first ask whether this has been a part of the issues addressed through the services accessed. If not, the interviewees will exercise judgement and due diligence, in consultation with the team leader, to consider the duty to report it to the CSO which has put the evaluation specialist in touch with the interviewee. Any further referral will be done by the CSO.	
3.10	Additional comments or suggestions		X
Section 4	<b>High Risk: When subjects are vulnerable to heightened risk have additional safeguards been included to protect their rights and welfare?</b>		
4.1	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

4.2	Does the sampling strategy target people at risk for issues such as: violence, torture, abuse, kidnapping; sexual exploitation, harassment, violence or abuse; prostitution or pornography, female genital mutilation, reproductive or sexual issues; sexual orientation; child, early or forced marriage; suicide? If yes, are study-specific protection protocols provided?		X
4.3	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
4.4	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
4.5	Additional comments or suggestions		X
Section 5	<b>Recruitment: Do submitted materials describe subjects and the recruitment process?</b>		
5.1	To what extent are subjects identified: a. names are recorded with responses..... b. names recorded separate from responses.....X c. no names are recorded .....X d. other personally identifiable information (PII) is recorded.....X e. no PII is recorded ..... f. subjects are given a unique identifier..... g. other.....	Please describe how you will collect and store information required for snowball sampling.  This applies to rights holders, whose name will not be collected. Duty bearers', UNICEF staff's and CSO representatives' names will be collected, as they speak in their official capacities.  We will not collect and store any information for snowball sampling beyond the phone number of potential interviewees from among rights holders. The CSOs working with rights holders already have the data of their service users (rights holders). Based on their knowledge	X

		<p>of the rights holders, they will propose to some (2 to 3 in each country) to participate in the evaluation. For those who agree, they will (1) provide them with the written consent form to sign (without stating their name or any personal information) and (2) share their phone number exclusively with the relevant Evaluation specialist, who will contact them directly, arrange the interviews without recording name, and delete their phone number upon completion of the interview.</p> <p>In your request for ethical review you state that no names are recorded. But your data collection tools in Annex 5, 6 and 7 begin by collecting interviewee name, Please reconcile. Specified in the data collection tool for rights holders.</p> <p><b>You have provided this at the bottom of the IC: “Signature (no name).” What does this mean?</b></p>	
5.2	If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?	<p>You will have subject contact information for recruitment, please describe how it is stored.</p> <p>Please describe for IC and Annexes 5, 6 and 7.</p>	<b>X</b>
5.3	Are subject recruitment procedures & sampling strategy adequately described?	How will you recruit subjects (email, phone, letter, etc...)?	<b>X</b>
5.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?		<b>X</b>
5.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?		<b>NA</b>
5.6	If subjects are children or other vulnerable groups, or if subject matter is sensitive, is recruitment sensitive to		<b>NA</b>

	subjects' potential vulnerabilities (real or perceived) and does it ensure privacy throughout recruitment?		
5.7	Do recruitment procedures show indication of bribery, coercion, intimidation, compulsion, pressure, or force?		X
5.8	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?		X
5.9	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have strategies to address this been adequately described?		X
5.10	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?		X
5.11	Additional comments or suggestions		X
Section 6	<b>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.</b>		
6.1	Type of Informed Consent: a. written & signed .....X b. written not signed ..... c. written & signed by authorized representative.. d. verbal & signed or recorded..... e. verbal & signed by authorized representative.... f. verbal not signed or recorded.....X g. active..... h. passive..... i. other .....	You state on p.45 you will obtain verbal consent for KII subjects but the written and signed consent form in Annex 3 is for all subjects. Please explain the process and materials to be used to obtain consent from each subject type. Corrected on page 45: only rights holders (approx. 4 interviewees in total) will receive a written consent form. Other interviewees, who speak in their official capacity, do not require a written consent form. Process and materials for rights holders' written consent forms described on pages 46-47 and in Annexes 5, 6, 7.  If you will use verbal consent for some subjects, please make sure to include text to ask for and record consent. Done – annexes 5, 6, 7.	X

6.2	Are the processes for obtaining each IC adequately described?	<p>Please review the IC with subjects before asking them to sign it and revise the text at the beginning of Annex 6 to reflect that the data collector is instructed to review the IC with subjects. Done (Annexes 4, 6)</p> <p>Please Revise Annex 7 to indicate how you will obtain consent and confirm that subjects understand the information contained in the consent form. No written consent form for duty bearers and CSOs (which are the subject of Annex 7). Only verbal consent, which is part of the introduction.</p> <p>How will the consent forms be signed and returned? See Annex 4</p>	X
6.3	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?		X
6.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?		X
6.5	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?		X
6.6	Does IC include the expected duration of the subject's participation (hours/minutes)?		X
6.7	Are subjects given a clear indication of who will have access to their responses and in what form?	<p>You state on p.58 that UNICEF will store the consent forms. Please advise subjects of this. Done (Annex 3)</p>	X
6.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?		X
6.9	Does IC include a description of any risks or benefits to subjects?		X

6.10	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?	<p>In Annexes 5, 6 &amp; 7, you have a line item labeled in confidence/shareable filled in as "In Confidence." For any subjects would that ever be changed to Shareable? No</p> <p>If so, what would be shareable and under what conditions? N/A</p> <p>You mention anonymity in several places including the IC. Given that you know who subjects are, your small sample size &amp; your variety of subject types, it is more appropriate to assure confidentiality. Amended, as applicable</p>	X
6.11	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 and/ or transport?		X
6.12	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?		NA
6.13	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 <i>assent</i> ?		NA
6.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	<p>Please include in ICs if you will be conducting FGDs. N/a</p>	X
6.15	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?		X
6.16	Where data collection differs by method (e.g.: survey, FGD, interview, audio recording), do ICs cover each method?		X
6.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?		X
6.18	Additional comments or suggestions		X

<b>Section 7</b>	<b>Subject Protections: Do submitted materials clearly identify protection against risk?</b>		
7.1	Do materials describe protocols for subjects' safety throughout data collection, analysis, storage, and dissemination?		X
7.2	Are all data collected necessary for the purposes of evidence generation?		X
7.3	Do data analysis and reporting procedures ensure subject confidentiality (or anonymity) and security?		X
7.4	If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond?	Any follow up? No	X
7.5	If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive?		NA
7.6	Have personnel collecting data from subjects had ethical training specific to the target group?		X
7.7	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?		X
7.8	Additional comments or suggestions		X
<b>Section 8</b>	<b>Data Protections: Do data collection and storage protocols adequately ensure subject &amp; data safety?</b>		
8.1	Are data collection tools appropriate and constructed to assure subject confidentiality or anonymity?	Why include names on data collection tool? They are not included for rights holders, but they are for UNICEF staff, duty bearers and CSOs, who speak in their official capacity. This, together with stakeholder analysis enables the team leader to understand which point of view is represented in which interview/quote: contextualizing statements is important to draw truthful findings.	X
8.2	Do data collection procedures and environment ensure data security?		X
8.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?		X

8.4	If data will be shared with partners, is there a clear agreement or NDA?	<p>You state on p.58 that you will share the consent forms with UNICEF. Will you share any of the data or other PII with UNICEF.?</p> <p>No</p>	X
8.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, storage, de-identification, and destruction?		X
8.6	Additional comments or suggestions		X