



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 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
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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>Summative evaluation of the UNICEF-supported child protection programme in Madagascar - 2015 to 2021 (Évaluation sommative du programme de protection de l'enfance soutenu par l'UNICEF à Madagascar - 2015 à 2021)</i>
1.2	HML IRB Research Ethics Review ID#:	832MADA23
1.3	Initiating UNICEF Official: Name, office, email	Salma LAYOUNI, Monitoring and Evaluation Officer, Madagascar CO, ESARO slayouni@unicef.org
1.4	Principal Investigator/Project Manager: Name, degree(s), organization, & address	Katherine Tredinnick, Project Manager, Associate at Genesis Analytics, Genesis Analytics (Pty) Ltd South Africa Office 3, 50 Sixth Road Hyde Park, Johannesburg
1.5	Other Key Personnel: Names & titles	Ian Macuslan, Team Leader Corinne Boulet; Deputy Team Leader; Loubna Marfouk, Researcher; Joanna Roger, Child Protection Expert; Daniel Rakotoarison, National Consultant; Kanto Razafimandimby, National Consultant.
1.6	Contracting Firm: Name & address	Genesis Analytics (Pty) Ltd South Africa Office 3, 50 Sixth Road Hyde Park, Johannesburg
1.7	Primary study site(s): CO, RO, countries	Madagascar: Analamanga, Androy, Atsimo Andrefana and Diana
1.8	Project duration: Dates from -- to	July 2023 to May 2024

1.9	Duration of Subjects' Participation: Dates from -- to	January 2024 to February 2024
1.10	Thematic Area/Areas:	Child Protection Choose an item. Choose an item.
1.11	Target population:	The child protection programme (2015-2021) implemented by UNICEF in collaboration with the Government of Madagascar.

Date of ERB Request	05 January 2024
Date(s) ERB Comments Returned	11 January 2024
Date Final Documents Received	17 January 2024 (Please see additional comment in Item 7.14.)
DATE OF ERB APPROVAL	19 January 2024

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 confidential 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.

	Ethics Review Board Criteria of Interest	Additional Information Needed → Investigators: Please respond to ERB info requests in another color directly below the request	X or NA equal PASS (for ERB use)
Section 2	ERB Submission: Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:		
2.1	Inception Report or Research Protocol.....X e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans		X
2.2	Informed Consent documents.....X	Please see Item 7.16. Please find the informed consent documents in the addendum.	X
2.3	Surveys and data collection instruments.....X	Your data collection tools appear to be in draft form. Please provide the final versions of the data collection tools for each subject (UNICEF staff, government partners, members of institutes, NGOs, service providers, care givers and programme target populations) and data collection type (KIIs, interviews & FGDs). Please provide age-appropriate guides for child subjects. The data collection tools for each subject have been sent as an addendum. Please note that institutes and NGOs have been regrouped in the category of partner entities “NGOs, CSOs, and non-governmental institutes” given that the nature of their engagement with the programme is similar. Also, please note that these tools remain subject to minor language adaptations, given the KIIs and FGDs will be conducted in the relevant regional dialects.	X

		Child protection expert, Joanna Rogers, has revised the guides for child subjects such that they are more age-appropriate. Please also these documents in the addendum.	
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		X
2.8	Is <i>UNICEF Procedure for Ethical Standards</i> cited? Cited		X
2.9	Have informed consent and data collection instruments been pre-tested? a. yes..... b. no.....X c. NR.....	Please respond. We did not want to consider pre-testing in advance of receiving ethical clearance. The research team is made up of members with extensive experience and expertise in child protection, and these experts have reviewed and approved the instruments and consent forms.	X
2.10	Are all submitted documents final versions? a. yes..... b. no..... c. NR.....X	Please respond.	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? Yes, we are happy to include the final protocol and instruments within an internal UNICEF searchable database.	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: a. survey questionnaire..... b. subject interview..... c. key informant interview (KII).....X d. focus group discussion (FGD).....X	On p.21 you mention field visits and observations. If these will be conducted, please describe what they will entail and provide the data collection tools. In December 2023, we discussed with UNICEF Madagascar the feasibility and usefulness of an	X

	<ul style="list-style-type: none"> e. secondary document (desk) review.....X f. on-site observation..... g. case study..... h. physical measurements i. biological specimen j. other..... 	<p>observation activity. At the end of this meeting, we agreed that we would no longer carry out observations, given the evaluation does not focus on case studies and case management, but rather on strengthening the child protection system.</p> <p>Thus, the mention of field visits and observations should have been omitted from the inception report. We have now amended this.</p>	
3.3	Is the type of data collection appropriate for this study design?	<p>You state that you will conduct interviews if subjects do not want to participate in focus groups. When and how will this be determined?</p> <p>Will all subjects be offered the individual interview option?</p> <p>If not, please explain how it will be offered and to whom. While the 'default' data collection method for programme 'beneficiaries' is focus groups discussions, participants who present at the collection site will be reminded of their right to opt out of the FGD, to opt for an individual interview instead or to withdraw from the study entirely. This approach aligns with our ethical considerations of voluntary participation and caters to the comfort and specific needs of each participant.</p> <p>We have taken the possibility of participants opting for separate interviews into account in our planning. Our plan includes deploying 5 to 6 interviewers per region, working in small teams of two or three. This setup allows for individual interviews if a participant withdraws from a group and prefers a private interview.</p>	X
3.4	Are secondary data (desk review including documents, reports, publications):	Please select.	X

	a. publicly available.....X b. not publicly available containing personally identifiable information (PII)..... c. not publicly available containing no PII.....X	A 'publicly available' and C 'not publicly available containing no PII'	
3.5	Are types of data and variables in the secondary data set described?	Please respond. Yes, the secondary data is specified within the research framework.	X
3.6	Is how investigators' access to the secondary data described?	Please respond. Regarding investigators' access to secondary data, which was not detailed in the protocol: UNICEF securely stores this data in a Microsoft SharePoint repository and manages access to these documents tightly. Access has been granted to each primary member of our research team (and no one else) via our email addresses. For added security, we are required to enter a code when accessing the data.	X
3.7	If the secondary data contained subject records, did subjects consent to reuse of their data?	Please respond. The secondary data does not contain any identifying subject records.	X
3.8	Does study involve intervention, treatment, comparison, or control groups? a. intervention.....X b. comparison..... c. control..... d. none.....	Please select. a. Intervention Our study focuses on intervention groups, specifically 'beneficiaries' of the 2015-2021 UNICEF Child Protection Programme, identified by UNICEF regional officers. Additionally, we include interviews with partner organisations involved in the programme's implementation or evaluation.	X
3.9	Number of Data Collections: a. one-time only.....X b. two or more (e.g., pre-post)		X
3.10	Sample size: Approximate total $n = 410$	150, correct?	X

		<p>The approximate sample size of each group of the study's participants is as follows:</p> <p>Children $n =$ approx. 117 Primary care givers $n =$ approx. 141 Community members $n =$ approx. 112 Partner organisations (including government officials) $n =$ approx. 40</p>	
3.11	<p>Are any subjects children (<18 years old)?....8 – 17 yo</p> <p>a. 0 – 2.....</p> <p>b. 3 – 7.....</p> <p>c. 8 – 12.....X</p> <p>d. 13 – 17.....X</p>	<p>Please provide the ages of your child subjects.</p> <p>For children under 18, we have the following age groups: 8 to 12 and 13 to 17.</p>	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 knowledge? If so, are mitigating procedures described?		X
4.3	Do study objectives show that risks are reasonable in relationship to expected gains and benefits are clearly articulated?		X

4.4	<p>By their participation, are subjects vulnerable to any of the following?:</p> <ul style="list-style-type: none"> a. physical risk b. psychological riskX c. social risk d. economic risk e. legal risk f. political riskX g. employment risk..... h. academic risk..... i. religious risk..... j. other..... k. none..... 		X
4.5	<p>In event of any of the above risks, do protocols describe clear strategies to mitigate risks?</p>	<p>Please respond.</p> <p>Our risk mitigation strategies are outlined in our data collection protocol, and provided below for your information:</p> <p>*Physical risk mitigation strategy: To ensure the safety of our participants data collection will occur during daylight hours. This timing is chosen to minimise risks associated with travel, such as early morning or late evening insecurities, and to avoid heavy traffic conditions. Additionally, we will closely monitor weather conditions. Should severe weather occur, exceeding simple rain, we will adhere to public advisories from the National Office for Risk and Disaster Management and cancel data collection sessions as necessary. This strategy is in place to prioritise the physical well-being of participants and staff during the data collection process.</p> <p>*Psychological risk mitigation strategy: Our FGD and KII questions have been carefully developed to focus on the evaluation of services received and future improvement expectations, rather than probing into any personal challenges or traumatic experiences. These</p>	X

		<p>questions have been reviewed by the UNICEF Madagascar team and our child protection specialists. Our research team will also ensure that our interviewers are thoroughly briefed to avoid questions that could evoke psychological distress, such as feelings of shame, sadness, or anger. Additionally, prior to each session, participants will be informed about the nature of the questions and reassured that they have the option to abstain from answering any that might cause discomfort. This approach is designed to safeguard the psychological well-being of all participants.</p> <p>‘Confession of an illegal act’ strategy: We will inform participants at the outset that should they disclose any illegal or criminal acts during the course of the interview, we are obligated to report such confessions. This policy ensures that participants are aware and in control of the potential consequences of the information they choose to share. Participants will be reminded of this protocol before the interview begins, allowing them to make informed decisions about their disclosures</p> <p>.</p>	
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?	<p>You mention seeking subjects that include: <i>“one or more of the following vulnerability criteria: economically disadvantaged, young girls, rural areas, people with disabilities, families vulnerable to emergency situations, single-parent families, children from reception centres, street children.”</i> How will you stratify these various groups for FGDs?</p> <p>We discussed this section with the UNICEF focal points, who weighed up with us the different stratifications to be taken into account when forming the FGD. As we do not organise thematic groups, there is a high level of</p>	X

		<p>heterogeneity in the constitution of the groups. However, we did take into account the power dynamics when forming the groups – for example we have separated the groups based on gender, given gender hierarchies are rife in this context. In addition, the focus group discussions of community members will be separated by ‘perceived status’ to ensure participants feel comfortable in sharing openly. For example, members of security forces and village chiefs tend to be feared and will therefore be grouped separately from those who do not share the same ‘status’.</p> <p>We ensure inclusivity for participants with disabilities by collaborating with UNICEF, who informs us in advance if individuals with disabilities will be joining the group. We then provide reasonable accommodations during the sessions, making them inclusive and accessible to everyone.</p>	
4.8	<p>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>	<p>Please describe the procedures to be used by the study team and UNICEF.</p> <p>Yes, these procedures are outlined in the data collection protocol, and included below too:</p> <p>We have established a rigorous reporting system for high-risk cases during data collection. Our Interviewer training emphasises mandatory reporting protocols. Participants will be informed that any disclosed abuse or risk exposure will be reported to the Ministry of Population for appropriate action, with a focus on maintaining confidentiality. Consent will be obtained for reporting; if declined, anonymised case information, marked as "does not wish to be reported," will be shared with UNICEF and the Ministry. In cases of imminent danger or distress, the session will be halted, and</p>	X

		immediate action coordinated with the Ministry and UNICEF.	
4.9	Is local reporting abuse of children mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	Please respond. Yes, reporting is mandatory. However, as outlined above, if individuals want to remain anonymous, their case will be reported to UNICEF and Ministry of Population without identifying information.	X
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;		X

	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?		
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 responsesX b. names recorded separate from responses..... c. no names are recorded d. other PII is recorded.....X e. no PII is recorded f. subjects are given a unique identifier..... g. other.....		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?	Please describe how and by whom all subjects are selected and recruited. We collaborated with UNICEF regional focal points to ensure ethical participant recruitment. While we don't directly recruit participants, the process is carried out by relevant ministerial departments and UNICEF focal points. Our research team provided the inclusion criteria and conducted a recruitment briefing on ethical considerations, including voluntary participation, distinction between focus groups and individual interviews, and protection of vulnerable individuals with the UNICEF team.	X

		<p>Based on the above, UNICEF and the relevant ministerial departments have recruited participants based on the outlined inclusion criteria, and the participants' willingness to participate. Consent is prioritised, and participants can opt for individual interviews if they prefer.</p> <p>The selection and recruitment process is conducted by trained social workers from the Ministry of Population and under their discretion, respectful of each person's needs. Public posting or community meetings for recruitment are not employed.</p> <p>Overall, our recruitment procedure prioritises participant privacy, choice, and other ethical considerations throughout the process.</p>	
6.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?	<p>Please describe if you will enlist local partners to support recruitment.</p> <p>The recruitment of participants was a collaborative process between the Genesis Research Team, UNICEF and the relevant Ministries, as described in 6.3 above. We confirm that the selection and recruitment process ensures privacy of the 'subject's throughout.</p>	X
6.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?	<p>Please respond.</p> <p>Yes, the instruments were drafted by Madagascar Child Protection expert, Daniel Henintsoa Rakotoarison, and reviewed by global child protection expert, Joanna Rogers.</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.</p> <p>Participant recruitment is the responsibility of UNICEF and relevant ministries. Our research team have shared ethical considerations with UNICEF and provided additional recruitment guidelines. These guidelines</p>	X

		<p>emphasise voluntary participation, distinguishing between FGDs and individual interviews, protection of vulnerable individuals, personalised arrangements, and participant choice regarding the data collection method. Recruitment is conducted by trained social workers (from the Ministry of Population) on a case-by-case basis, respecting individual needs. Public posting or meetings are not used for recruitment. This approach ensures a personalised and ethical recruitment process.</p> <p>How will you screen for the following vulnerability criteria: economically disadvantaged, young girls, rural areas, people with disabilities, families vulnerable to emergency situations, single-parent families, children from reception centres, street children?</p> <p>As discussed above, recruitment is managed by UNICEF regional focal points and relevant ministry focal points. Selection is conducted by applying our inclusion criteria to their database of past beneficiaries of the programme. Our training of interviewers takes into account gender, disability, age and various vulnerabilities. The groups formed in the FDG have a high level of heterogeneity; however, power relations will be taken into account and avoided in the constitution of the groups, as described in 4.7</p>	
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?		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	<p>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?</p> <ul style="list-style-type: none"> a. cash or gift card..... b. refreshment..... c. travel cost.....X d. phone or internet credit..... e. small gift..... f. other..... g. none..... h. no response..... 	<p>Any compensation planned? If so, what, and how much?</p> <p>Yes, c (travel costs) are paid for. Data collection will not take place in participants' homes. Instead, UNICEF have identified central, neutral and distinct locations for the data collection in each region. Each participant (in the child, primary caregiver and community groups) will be compensated their travel expenses (Ar 5000) per person. In addition, all participating children will be provided with water and a snack. Even if someone withdraws from the research process, they will still be reimbursed for their travel costs.</p>	X
6.11	Additional comments or suggestions		X
Section 7	<p>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.</p>		
7.1	<p>Type of Informed Consent:</p> <ul style="list-style-type: none"> a. written & signedX b. written not signed c. written & signed by authorized representative....X d. written with online checkbox..... e. verbal & signed or recorded.....X f. verbal & signed by authorized representative....X g. verbal not signed or recorded..... h. active..... i. passive..... j. other 	<p>Please see Item 7.16.</p> <p>A</p> <p>Informed consent will be written and signed.</p>	X
7.2	Are the processes for obtaining each IC adequately described?		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?	<p>Please include a brief explanation of what the subject will be expected to do, and why they are being recruited in each IC.</p> <p>Yes, please see revised consent forms in the addendum provided.</p>	X

7.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?		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?		X
7.6	Does IC include the expected duration of the subject's participation (hours/minutes)?	Please include in each IC. Yes, please see revised consent forms in the addendum provided.	X
7.7	Are subjects given a clear indication of who will have access to their responses and in what form?		X
7.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?		X
7.9	Does IC include a description of any risks or benefits to subjects?	Please briefly include in each IC, even if to say there is none. Yes, please see revised consent forms in the addendum provided.	X
7.10	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?		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?		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?	When, how, and by whom will parental consent be obtained for child subjects under 18 years of age? The parental consent form should be clear on what type of data collection the child is participating in (interview or focus group). We have specified in our ethical considerations for recruitment purposes that participation in this activity is voluntary. We have also submitted a schedule detailing that the activity to be held is an FDG or an individual	X

		interview. At our meeting with the interviewees, we will remind them of the nature of the activity (FDG or Interview), and we will tell them that they can still choose whether they want to take part in an individual interview if they no longer wish to be part of the FDG. No justification will be asked of them. Once they have made their choices, the next line of our session is a line-by-line explanation of informed consent to the parent and child. We will remind parents that they can choose not to include their children in the activity if they wish to withdraw, or to sign the consent form if they wish to continue. Similarly, we will ask the child if they still wish to take part in the activity and that they can refuse even if the parents agree.	
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 <i>assent</i> ?	<p>The child assent form has a place for the parent's signature. It should record the child's assent.</p> <p>Children should be advised that even though their parent has provided consent, it is up to them whether or not they participate.</p> <p>Yes, please see revised consent forms in the addendum provided.</p>	X
7.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	<p>Please include in ICs for FGDs.</p> <p>Yes, please see revised consent forms in the addendum provided.</p> <p>Please include in IC for Community Member FGD.</p>	X
7.15	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?		X
7.16	Where data collection differs by method (e.g.: survey, FGD, interview, audio recording), do ICs cover each method?	<p>Please provide separate ICs for KIIs and observations.</p> <p>The consent forms are adapted for each group of participants (children, primary caregivers, community members etc) to match their level of understanding. All ICs request consent for audio recording. The consent</p>	X

		forms do not differ greatly based on the data collection method being a FGD or KII. However, within FGDs, the IC includes the request for discussions within the focus group to remain confidential, i.e., to not be shared with anyone outside the FGD.	
7.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Please offer a copy to all subjects. We will do 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?	.	X
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?		X
8.5	Are backgrounds and qualifications of data collectors adequately described?		X
8.6	Have personnel collecting data from subjects, especially child subjects, had ethical training specific to the target group?		X
8.7	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?		X
8.8	Additional comments or suggestions		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?		X
9.2	Do data collection procedures and environment ensure data security?	How will you decide between in-person and remote data collection?	X

		<p>How will remote data collection be conducted (Zoom, phone, etc.)?</p> <p>Where will in-person data collection take place? For Partners:</p> <p>In-person and remote data collection will be decided depending on the respondent's preferences and availability. In case of indifference, in-person interviews will be prioritised.</p> <p>Remote data collection will be conducted through either:</p> <ul style="list-style-type: none">(i) Gmail video/phone call(ii) Teams video/phone call(iii) Zoom video/phone call(iv) WhatsApp video/phone call. <p>These options will be presented to the respondent and we will let them their preferred option.</p> <p>Data will be collected from members of the community in the offices of the partner Ministries and CSOs. No data will be collected from the community remotely. We have submitted a timetable with the logistical requirements necessary for calm and secure data collection for the people interviewed in FDGs or in individual interviews. The ministerial departments and CSOs will make one or two rooms available to us for this purpose, so that we can welcome people discreetly. These places are, for example, the Maison des Jeunes (youth centre), non-stigmatising service centres frequented by various users</p>	
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		<p>at the town halls. For interviews with children, additional measures have been taken into account, such as sitting within sight of the windows or leaving the door open to ensure that the interviews are safe for the children. In the event that parents wish to attend the children's interview, without participating in the interview, we will not refuse them the right to remain in a corner of the room. Data is safely uploaded to a shared and secured cloud storage space, as described in more detail below.</p>	
9.3	<p>Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?</p>	<p>How will interview and focus group data be recorded? We would like the data collected to be recorded in audio form. In the event that the interviewee does not consent to being voice-recorded, our interviewers will transcribe the session live. In the transcriptions, we will ensure that the notes do not reveal the identity of the interviewees. For voice recordings, we will not mention the name of the person or persons.</p> <p>The system we have put in place for the audio recordings is as follows: The recordings will be made using a smart phone. This phone will be protected by a password and will be linked to an email address with a protected cloud backup account. The research team will ensure that each phone has sufficient internet data to remain connected. After each recorded collection session, the interviewer will immediately upload the recording to the cloud. Once the team leader has checked that the data has arrived in the cloud, he or she will instruct the interviewer to delete the recording from the phone immediately before moving on to the next session.</p> <p>In instances where notes have been taken, a photo of these notes will be uploaded to the cloud, and deleted</p>	X

		from the interviewer's phone upon confirmation from the team leader that the data is stored safely in the cloud.	
9.4	If data will be shared with partners, is there a clear agreement or NDA?		X
9.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, management, and de-identification?	How will data be shared with UNICEF? Relevant UNICEF personnel will be provided with access to the data within the secured Cloud storage.	X
9.6	Do protocols state length of retention and destruction of raw data (months, years)? a. destroyed at end of study.....X b. destroyed after three years..... c. retained indefinitely..... d. other..... e. NR	At the end of the study, correct? Correct.	X
9.7	Additional comments or suggestions		X