Research Ethics Approval

11 June 2024

Asmat Ali Gill
Evaluation and WASH sector expert (International)
The KonTerra Group
700 12th Street, NW | Suite 700
Washington, DC 20005

RE: Ethics Review Board findings for: *End-Cycle Independent Evaluation of the Nigeria-UNICEF WASH Country Programme Cooperation (CPC 2018-2022)* (HML IRB Review *912NIGE24*)

Dear Asmat Ali Gill,

Protocols for the protection of human subjects in the above study were assessed through a research ethics review by HML Institutional Review Board (IRB) on 30 May – 11 June 2024. This study's human subjects' protection protocols, as stated in the materials submitted, received **ethics review approval.**

You and your project staff remain responsible for ensuring compliance with HML IRB's determinations. Those responsibilities include, but are not limited to:

- ensuring prompt reporting to HML IRB of proposed changes in this study's design, risks, consent, or other human protection protocols and providing copies of any revised materials;
- conducting the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to mitigate hazards to subjects;
- promptly reporting any unanticipated problems involving risks to subjects or others in the course of this study;
- notifying HML IRB when your study is completed.

HML IRB is authorized by the United States Department of Health and Human Services, Office of Human Research Protections (IRB #1211, IORG #850, FWA #1102).

Sincerely,

D. Michael Anderson, Ph.D., MPH
Chair & Human Subjects Protections Director, HML IRB

cc: Fridah Karimi Mwirigi, Donatien Tameko, Benjamin Idoko Makolo, Orji Kenneth Ibezim, Stanley Omobude, Augustine Ohashiegbulam, Diana Chikuwa, Penelope Lantz, JD

Health Media Lab, Inc.
1101 Connecticut Avenue, NW Suite 450
Washington, DC 20036 USA
+1.202.246.8504
unicef@hmlirb.com www.hmlirb.com

HML Ethics Review Board

Research Ethics Review Document

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

v.2024

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:**
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.	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. *These may be statements incorporated into research plans and/or embedded in a single protection protocol. .

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:**	***End-Cycle Independent Evaluation of the Nigeria-UNICEF WASH Country Programme Cooperation (CPC 2018-2022)***
1.2	**HML IRB Research Ethics Review ID#:**	912NIGE24
1.3	**Initiating UNICEF Official:** Name, office, email	Diana Chikuwa, Supply Specialist, Nigeria CO, WCARO dchikuwa@unicef.org
1.4	**Principal Investigator/Project Manager:** Name, degree(s), organization, & address	Asmat Ali Gill: Evaluation and WASH sector expert (International) Please provide organization and address Organization; The KonTerra Group Address: 700 12th Street, NW | Suite 700, Washington, DC 20005
1.5	**Other Key Personnel:** Names & titles	Mariam Fagbemi: Qualitative Researcher / National Project Manager (Yuka Consulting) Ibitola Omotayo: National Evaluation / WASH Sector expert Covadonga Canteli: Senior Statistical Expert (International) Jane Burke: KonTerra's external quality assurance advisor
1.6	**Contracting Firm:** Name & address	The KonTerra Group1 https://www.konterragroup.net/home/ 700 12th Street, NW | Suite 700, Washington, DC 20005
1.7	**Primary study site(s):** CO, RO, countries	Nigeria, national
1.8	**Project duration:** Dates from -- to	Nov 6, 2023 – August 30, 2024

1 https://www.konterragroup.net/home/

1.9	**Duration of Subjects' Participation:** Dates from -- to	Please provide From July 5, 2024 – to – August 5, 2024
1.10	**Thematic Area/Areas:**	Health Education Gender
1.11	**Target population:**	The Programme also seeks to reinforce communities' roles in advancing access, quality and uptake of WASH services, with a specific focus on addressing inequalities within the sector.

Date of ERB Request	30 May 2024
Date(s) ERB Comments Returned	06 June 2024
Date Final Documents Received	11 June 2024
DATE OF ERB APPROVAL	11 June 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 (IR) or Research Protocol……..…..X** e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans		X
2.2	**Informed Consent (IC) documents……X**	Please provide the IC for observations at health facilities and schools. **Provided –** please see the revised attachment *(2. Consent Forms_Nigeria CPC WASH Evaluation V2 AG) [Page# 14-16]* Please provide the IC for photographs during transect walks (Research Protocol p.56). **Provided –** please see the revised attachment *(2. Consent Forms_Nigeria CPC WASH Evaluation V2 AG) [Page# 16-17]*	X
2.3	**Surveys and data collection instruments……..…X**		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		X
2.8	Is *UNICEF Procedure for Ethical Standards* cited? NC		X
2.9	Have or will informed consent and data collection instruments be pre-tested? a. yes……..……..X b. no……..…..……. c. NR……..……..	Please respond. The informed consent forms, and all data collection tools will be pre-tested before starting the fieldwork. Before this, comprehensive training for all field staff will be conducted. During the training, all informed consent	X

		forms and all data collection tools will be tested by role-playing exercise between training participants (survey enumerators, and FDGs moderators). After the training, a separate pre-testing of all IC forms and tools will also be conducted (by the national data collection partner firm).	
2.10	Are all submitted documents final versions? a. yes……..……..X b. no……..……. c. NR……..……..	Please respond. Yes (all submitted documents have been reviewed and approved by UNICEF and the Evaluation Reference Group (ERG). The data collection tools may undergo any further refinement after the pre-testing (or field testing) before starting the actual data collection. The final pre-tested tools will be shared again with UNICEF team before the actual field work for their final endorsement and record.	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 (post completion of the evaluation – UNICEF Nigeria will upload all final/approved deliverables (Inception Report including tools, informed consents, and final evaluation reports) on UNICEF's global evaluation database namely "The Global Evaluation Reports Oversight System (GEROS)". It is an online database of UNICEF's evaluations from all countries that aims to support strengthening of the evaluation function.	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……..……..…..X b. subject interview (IDIs)……...……..X c. key informant interview (KII)……..……..X d. focus group discussion (FGD)……..……..X e. secondary document (desk) review……..		X

	f. on-site observation……X g. case study……X h. physical measurements …….. i. biological specimen …… j. other……..		
3.3	How will data be collected and recorded (paper, tablets, online, in-person, remote, etc.)?		X
3.4	Is the type of data collection appropriate for this study design?		X
3.5	Are secondary data (desk review including documents, reports, publications, social media): a. publicly available?..... b. not publicly available containing personally identifiable information (PII)?…… c. not publicly available containing no PII?..... d. none……..X	Please respond. d. None	X
3.6	Are types of data and variables in the secondary data set described?		X
3.7	If the secondary data contained subject records, did subjects consent to reuse of their data?	Please respond. N/A; (no secondary data will be reused/reproduced after the evaluation contract closure)	X
3.8	Does study involve intervention, treatment, comparison, or control groups? a. intervention……..……..X b. comparison……X c. control…… d. none……		X
3.9	Number of Data Collections: a. one-time only……..……X b. two or more (e.g., pre-post) ……..…	This is an end-cycle evaluation. Was there any pre-cycle data collection? a. One-time only (no pre-cycle data collection was done under this evaluation contract)	X
3.10	Sample size: Approximate total *n* = 4,080	Please provide a total estimated sample size. • Household survey sample size n = 3456	X

		• Observations sample size; 72 schools and 72 health facilities • Sample size (KIIs/interviews) = 64 respondents • Sample size (FGDs) = 52 FGDs (estimated number of participants will be 52*8 = 416)	
3.11	Are any subjects children (<18 years old)?....8 – 17 yo a. 0 – 2……..……..……..…….. b. 3 – 7…….. c. 8 – 12……..X d. 13 – 17……X e. None……	Please clarify the ages of child subjects. In the Research Protocol you state 13 to 16. In the consent forms you state both 13 to 18 and 15 to 18. • In Schools, students of higher classes/grades (between 8-10) in the age range of 13-16 years will be consulted). • At the community level, children/adolescents (between 13-18 years of age) will be allowed to participate in group discussions. • We corrected the age (13-18) in the consent forms.	X
3.12	Does study include the use of technologies (e.g., on-line data collection or intervention, *U-Report*)?		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 *Minimal Risk* Only?: 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 *greater than minimal risk*, 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	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……X	Do you think there may be any political risk for subjects? No – There will not be any political risk for subjects as the UNICEF's WASH programme is aligned with Government's priorities around social service delivery and the evaluation does not involve any analysis of political affiliations of the subjects. Hence, their political participation and opinions will not be explored during the discussions. Moreover, all subjects' safety, convenience, respects/dignity, compliance to local cultural and gender norms, and strict compliance to 'do no harm' will be demonstrated during all stages of the data collection. Instead, their participation will benefit them with enhanced knowledge on the topics under discussion, as well as empower them a sense of proud feelings for their contributions to inform the evaluation findings.	X
4.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?	If so, please discuss mitigations. The study execution does not pose any potential risks to subjects for their participation in the study. Moreover, the evaluation protocols include clear strategies to mitigate any unforeseeable risks that may arise during the data collection process. The mitigation strategies involve immediate actions such as contacting other family members, engaging local authorities, providing emergency medical aid, and transferring individuals to nearby hospitals if necessary. Additionally, the protocols outline procedures for offering social and psychological support on-site to ensure the well-being of participants. Furthermore, the evaluation team is trained to identify and respond promptly to any potential risks, ensuring the safety and welfare of all involved throughout the evaluation process.	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?	Will all be FGDs stratified by gender? • All FGDs will be conducted in compliance to local gender norms and adherence to local cultural and social practices, and therefore • It is anticipated that some FGDs may be executed with mixed groups (with both male and female participation) if local social norms and gender considerations will allow this approach. • Where mixed group discussion would not be feasible – separate FGDs with male and female participants will be conducted.	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?		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		X

	familial, peer, or social pressure? If yes, are study-specific protection protocols provided?		
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 recorded ..……..…… d. other personally identifiable information (PII) is recorded……..…….. 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?	How and by whom will FGD subjects be selected and recruited, including inclusion and exclusion criteria for FGDs, observations, and KIIs. By whom: FGD subjects will be recruited by a separate team (comprising one male and female staff) of the national data collection firm. How: This team will visit the selected/sample community 2-3 days in advance of the actual day of the FGD event and will recruit participants for FGDs with support and facilitation from the local leader of the community. Inclusion criteria: • FGDs: Only those subjects will be recruited who will be willing to participate on volunteering basis, who will give their consent/assent, and who will fall within the defined age ranges (please see in previous responses). • For KIIs, respondents/subjects will be selected in consultation with UNICEF team, based on their knowledge, engagement/role in WASH programme design/implementation, and/or their position within some programme related organization (implementation partner, Govt. organization). Exclusion: • All children below the age of 13, and adults (male/female) above the age of 60 years will not be included in the discussion considering potential limitations of their recall capacity as well as their physical comfort due to age-factor effects. • No subject will be included who will be ill or sick or not feeling well/healthy at the time of FGD execution to limit the risk of any infection spread.	X

6.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?		X
6.5	Will recruitment be done by anyone outside the study team? If so, please describe who they are, what role they will have, and how the study team will supervise them to ensure subject safety and security during recruitment.	Please respond. • Subjects will be recruited by a separate designated team (comprising one male and female staff) of the national data collection firm. • They are called 'FGD/KIIs organizers/facilitators. They are part of the study field team. • All designated staff of the national firm are considered part of the study/evaluation team. • How: This team will visit the selected/sample community 2-3 days in advance of the actual day of the FGD event and will recruit participants for FGDs with support and facilitation from the local leader of the community. • Supervision: The subjects recruitment team will work under the direct supervision and guidance of the national manager for all field work (or primary data collection). She (Ms. Mariam) is the head of the national data collection firm. The recruitment team will also receive a comprehensive training to ensure subjects safety, security, and comfortable logistics.	X
6.6	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?		X
6.7	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?		X
6.8	Do recruitment procedures show indication of bribery, coercion, intimidation, compulsion, pressure, or force?		X
6.9	Is recruitment of some members of the population and not others likely to result in resentment for either	Could there be any issues within the community or school for subjects who are not selected?	X

	inclusion or exclusion? Have strategies to address this been adequately described?	No – the recruitment of some members of the population and not others will not result in any resentment for either inclusion or exclusion. Yes – clear strategy is defined to ensure avoidance of any resentment is to do recruitment of subjects through ethical channels such as through teachers or school administration for school children/adolescents, and at the community level through involvement of local leaders or community elders. Moreover, we will ensure that the decision to participate or decline remains voluntary and will not affect participants' access to any benefits or services as well as to ensure avoidance any form of coercion or pressure. The other key strategies will be maintaining transparent communication and feedback Mechanisms, provision of adequate guidance, and ensuring privacy, confidentiality, and compliance to 'do no harm principle' during the recruitment and execution of study.	
6.10	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have strategies to address this been adequately described?		**X**
6.11	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……X c. travel cost…… d. phone or internet credit…… e. small gift…… f. other…… g. none…… h. no response……	Any compensation? If so, what and how much? During the recruitment, and before starting the FGD event, complete informed consent will be secured from each participant (study subject) while emphasizing and ensuring they understand their volunteer participation, right to withdraw from the study anytime, and that 'no monetary compensation' will be provided. Transparent and clear communication and feedback on this aspect will be ensured. Instead, other forms of non-monetary compensation such as (awareness and knowledge sharing on study purpose, and benefits for them in the future, providing them two-way comfortable logistics from their residence	**X**

		to the FGD event, and offering them refreshments (tea, coffee, biscuits or snacks) before or after the FGD event.	
6.12	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. ICs must be sought from each subject or the subject's authorized representative confirming this process.**		
7.1	Type of Informed Consent: a. written & signed ……..……X 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…. g. verbal not signed or recorded……..……. h. active…… i. passive…….. j. other …….	You have standalone consent forms for KIIs and FGDs and you also have consent text at the start of each data collection guide. Please explain how these will both be used with each subject. • With study subjects, only one IC form, labelled for KIIs, and FGDs will be used which each subject. • The standalone consent forms are for internal use by the evaluation team to be used for field teams training, and for general reference purposes within the team. Why do you have two consent forms for parents of FGD child subjects? Child subjects may be interacted in two settings – one at school level, and the other at the community level. Therefore, two IC forms for parents are inserted. During this revision, we also edited the titles of both types of parental IC forms to make it clearer and more explicit.	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?	Please include in the survey IC that the data collector may ask to see their WASH facilities. Yes – we included this statement in the Survey IC form. *'Please note that during the survey interview, we may ask your permission to observe water, sanitation and*	X

		hygiene facilities (Toilet, handwashing place/station, and water points, and storage containers) at your home'. We also provided the survey IC form in Attachment#2 of Ethical Application materials (it was missing here in the previous version).	
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)?		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 include in all ICs. Yes - description of any risks or benefits included in all IC forms. Please see the revised/updated Attachment#2 of this ethical package.	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 in a form that is useful like name, phone, and email?	Please provide to survey respondents. Yes – the identity and contact information of investigators added to Survey IC form. Please see the revised/updated Attachment#2 of this ethical package.	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?	Please clarify when, how and by whom parental consent will be obtained. • For all child subjects, informed consent (IC) will be obtained (by the FGD recruitment team initially) from	X

		their teachers in schools, parent, guardian, caregiver, or authorized representative as appropriate at the first step (before the FGD event day). This will be followed by taking IC directly from the participating children/students (by the discussion moderator) before starting the discussion in a friendly and gender sensitive manner. • This two-stage IC process will ensure that consent will be secured from individuals who are legally responsible for the children and can make informed decisions on their behalf. • In situations where the children or students are considered mature enough to provide consent independently – they will be informed properly about all IC content to seek their voluntary participation. Please replace 'you' or 'your' with 'your child' in the parental consent. **Yes – Replaced** (necessary edits done at all relevant appearances)	
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*?		**X**
7.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	Please include in all ICs for FGDs. We included the below statement in all IC forms for FGDs. - The confidentiality of your data is important to the evaluation team. We (The evaluation team) advise you to avoid sharing discussion information with anyone outside the group members. This will ensure confidentiality of individual opinions is maintained by everyone after the FGDs.	**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?		X
7.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Will you provide a copy of their IC to each subject? If not, why not? • To avoid the creation of any extra burden for subjects to store and handle these IC forms. • This is one-time data collection; subjects will not be contacted again for data collection so there is no advantage or reasoning available to provide IC forms to subjects. • Moreover, IC forms will not be provided to subjects because before starting any data collection event (survey interview, FGDs, observations, KIIs) all subjects will be provided with clear and comprehensive information about the purpose of the evaluation, the data collection procedures, and their rights as participants. Written consent will be obtained from each participant before any data is collected, ensuring that they understand and agree to the terms of their participation.	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?	Will female data collectors conduct data collection with women and girls? Yes, each field team comprising both male and female data collectors. Based on the social norms, and cultural preferences, dedicated female staff will be available to interact with women, and girls during data collection.	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?	You assign unique IDs to subjects on the consent/assent forms. Who oversees creating the crosswalk that has the subject name that corresponds to each ID? Filed supervisor followed by the quality assurance manager will be responsible for managing the cross-referencing of the unique IDs and names of the subjects during data processing. How is that data stored and protected? All data types (survey datasets, paper-based field notes, KIIs/FGDs audios) will be transformed into electronic data including the field notes (taken during KIIs, and FGDs), and will be stored in computers (secure server, and/or Google Drive of the national firm (Yuka Consulting, and Konterra Group – the evaluation contract holder firm). For data protection, all electronic data will be handled by the authorized staff (quality assurance manager, data analyst and project manager) of the national partner and the core evaluation team members.	X

		Please see more details under "Protocol for Safe Data Handling, and Protection, page#3" of the Attachment#5 of the Ethical package.	
9.2	Do data collection procedures and environment ensure data security?	Where will FGDs take place? FGDs will take place in settings or places which will be organized with support of the community focal person (local leader) by the FGD organizing team. These settings or places may include community gathering public places/buildings such as community hall, office of some organization). The key criteria for selection of these places are central location in the community, availability of a clean and spacious sitting arrangement, and safe and secure environment (inside and outside) in the chosen place to ensure subject's comfort and convenience.	**X**
9.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?	Please respond. How will FGD data be recorded (tablets, paper, audio)? • FGDs and KIIs data will be recorded on paper as rough discussion notes by the FGD notetaker and/or moderator of KIIs. Also, audio recordings will be done for KIIs and FGDs. These audios will be transcribed later for thorough analysis. • Survey and checklist-based observations data will be recorded through android devices and/or Tablets. • The evaluation team is completely cognizant of and will ensure that data safety and protection protocols cover all data types, including written field notes, audio recordings, (videos will not be done), and observational data to be recorded during field visits. • For written data, measures such as encryption and restricted access will be implemented. • Audio data will be securely stored and accessed only by authorized personnel.	**X**

		• Observation data will be anonymized to protect the identities of individuals. • The relevant SOPs of data protections (for each type of data) will be clearly explained to all field staff to safeguard confidentiality, privacy, and integrity. • By addressing each data type safety requirements comprehensively, the evaluation team will minimize risks associated with data collection, storage, and analysis, ensuring the ethical conduct of the evaluation process.	
9.4	If data will be shared with partners, is there a clear agreement for protection of subjects' and their data?		X
9.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, management, and de-identification?	Please describe. • The evaluation team has developed clear protocols for the chain of custody of data and will implement all protection measures for data transfer or transmission, management and de-identification throughout the data lifecycle. • These protocols or procedures ensure secure transfer or transmission of data, utilizing encrypted channels and access controls to prevent unauthorized interception or tampering. • Data storage will adhere to strict security measures, including encryption and access controls, with regular backups to safeguard against loss or corruption. • De-identification techniques will be employed to anonymize sensitive information, protecting the privacy of participants.	X
9.6	Do protocols state length of retention and destruction of raw data (months, years)? a. destroyed at end of study……..…… b. destroyed after three years…… c. retained indefinitely……	Please respond. Yes - The evaluation will also implement secure destruction of all forms of data after six months of the completion of the evaluation contract. The destruction of all materials and/or data will be applicable to all	X

	d. other……X e. NR	evaluation team members, and all staff of the national partner firm who have been involved in this evaluation. Konterra's project manager, evaluation Team Leader, and the national partner's project manager will ensure this aspect.	
9.7	Additional comments or suggestions	The evaluation team would like to request early approval of this ethical clearance. It will enable the evaluation team to compensate for a significant time loss on this process due to delays in administrative and procedural requirements at the UNICEF NCO to initiate this ethical approval package. The evaluation team plans to start field work by the first week of July 2024 after securing this Ethical Approval.	X