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.

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 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.

Project Title:	***Evaluation of Cholera Rapid Response Teams (RRT) Program in Four Governorates in Yemen***
HML IRB Research Ethics Review ID#:	540YMEN22
Initiating UNICEF Official: Name, CO, & RO	Emmanuel Saka, Evaluation Specialist/Regional Evaluation Section MENARO, esaka@unicef.org
Principal Investigator/Project Manager: Name, degree(s), organization, & address	Dr. Ngozi AKWATAGHIBE Evaluation Team Lead Oversee Advising Group **Cameroun** - Rue 5N.414 Bloc L, Maképé-Douala **Belgique -** Rue De Wand 146 boîte 3 - 1020 Bruxelles **Canada** - 6390 Rue des Noyelles, Montréal – Québec
Other Key Personnel: Names & titles	Natalie Bockel, Wash Specialist Awny Amer, Data analyst Hubal Pfumtchum, Quality Assurance, Project Coordinator Cedrix Bamio, Quantitative Adviser
Contracting Firm: Name & address	Oversea Advising Group 5N.414 Road Bloc L, Maképé-Douala, Cameroon
Primary study site(s): (e.g., country, province, region)	Sana'a, Hajjah, Aden, and Ad Dali' Governorates, Yemen
Project duration: (Dates from -- to)	December 2021 – June 2022
Duration of Subjects' Participation: (Dates from -- to)	June 2022 to September 2022

Thematic Area/Areas:	Health Child Protection Social Policy
Target population:	People in Yemen lacking access to potable water or adequate sanitation and hygiene facilities, especially children, particularly those malnourished and with weakened immune systems

Date of ERB Request	21 March 2022
Date(s) ERB Comments Returned	25 March 2022
Date Final Documents Received	13 June 2022
DATE OF ERB APPROVAL	14 June 2022

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.

	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 1	***ERB Submission:*** **Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:**		
1.1	Inception Report or Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans	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. Given the current security situation in Yemen and restrictions in access, as well as COVID-19, the evaluation has been kept small in geographical scope, focusing on few governorates instead of covering the whole county. Where appropriate and possible, KIIs will take place virtually to reduce physical contact.	X
1.2	Informed Consent documents		X
1.3	Surveys and data collection instruments		X
1.4	Written protocols to ensure subjects' safety		X
1.5	Written protocols for protection of subjects' identities		X
1.6	Written protocols for protection of data		X
1.7	Other relevant documents	Yes	X
1.8	Do protocols include a section identifying ethical issues and measures to mitigate ethical problems as required by UNICEF Procedure? Included		X
1.9	Have informed consent and data collection instruments been pre-tested?	Please respond. Not Yet. Pre-testing of tools will be carried out after the approval of the inception report and tools.	X
1.10	Are all submitted documents final versions?	Please respond.	NR

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. Yes. Include	X
1.12	Additional comments or suggestions		X
Section 2	***Research Design:*** **Do submitted materials describe the proposed research? This includes:**		
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……..……..X b. subject interview……..…….. c. key informant interview (KII)……..……..X d. focus group discussion (FGD)……..……...X e. document (desk) review……..……X f. on-site observation…… g. case study…….. h. analysis of secondary data…….. i. physical measurements …….. j. biological specimen ……..…… k. other……..	Types of data collection include: Survey questionnaires Key informant interviews Focus Group Discussions Document (Desk) Review	X
2.4	Number of Data Collections: a. one-time (no follow-up) ……X b. two or more (follow-up) ……	One-time data collection, correct? Yes	X
2.5	Sample size: Approximate total *n* = 350	KII=37-39 FGD=120-240 Survey= please provide. Please provide approximate total *n.* **KIIs= 50-70** 10 KIIs with National government (MWE and MoPHP officials) 6 KIIs with UNICEF and WHO staff 20 KIIs with Health and Nutrition stakeholders (e.g., school staff, health staff, etc.) 6 KIIs with selected UNICEF RRT Team Leaders 10 KIIs with health and WASH cluster partners	X

		20 KIIs with community leaders and community water management committees FGD=8 (8 -10 participants each) **Household Survey: 100 households** **RRT Survey: 100**	
2.6	Are any subjects children (<18 years old)? None	What are the ages of subjects under 18 years old? No	**NA**
2.7	Additional comments or suggestions		**X**
Section 3	***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?**		
3.1	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.	Yes	**X**
3.2	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**
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 …….... c. social risk ……..…… d. economic risk ……...		**X**

	e. legal risk ……..……..... f. political risk …….. g. employment risk…… h. academic risk……..... i. religious risk……..…. j. other……		
3.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?		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?		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?	Please discuss. In terms of the field work safety protocols, all field researchers will be trained on how to collect quantitative and qualitative data and apply the humanitarian principles of "Do No Harm" and "Light Footprint'' when they collect data in the field. Our researchers/enumerators have ensured that informed consent clearly highlights the aims and methods of the assessment, including its intended and possible outcomes, and provides an opportunity to decline participation. Confidentiality and privacy are of utmost importance in our data collection. Participant safety and security are considered of paramount importance by OAG and AFCAR. As a result, all possible considerations are taken to ensure evaluation activities do not put participants at risk. This is achieved through logistical considerations, e.g. choice of interview locations and research design tools, ensuring key informants/participants are not targeted as a result of their participation. Furthermore, AFCAR teams will ensure maintaining the anonymity of participants to encourage them to speak openly and frankly, with questionnaires designed in-house to ensure appropriate	X

		questions. Participant safety will be discussed in depth during the training workshop and all security protocols will be included in the fieldwork manual.	
3.9	Is reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	Please respond. We will not interview minors	X
3.10	Additional comments or suggestions		X
Section 4	***High Risk:* When subjects are vulnerable to heightened risk have additional safeguards been included to protect their rights and welfare?**		
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		X

	could damage health or safety; removal of organs for exploitation? If yes, are study-specific protection protocols provided?		
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	***Recruitment:* Do submitted materials describe subjects and the recruitment process?**		
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 ..…… d. other personally identifiable information (PII) is recorded…… e. no PII is recorded …… f. subjects are given a unique identifier..... g. other……	Names will be recorded separate from responses	X
5.2	If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?		X
5.3	Are subject recruitment procedures & sampling strategy adequately described?	How will adolescents be recruited? We will not interview adolescents	X
5.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?	How will privacy be maintained during recruitment of subjects, particularly for the FGDs? FGDs will be carried out with community women and men and school boys and girl's beneficiaries in the selected communities. Female and male participants will be grouped separately to promote open and active participation. The selection of participants for FGDs will be made using purposive sampling methods (the evaluation team in collaboration with AFCAR Consulting will develop some clear eligibility criteria contextualized to Yemen for the participation in FGDs; also with the support of UNICEF stakeholders. The	X

		FGDs will be audio-recorded and transcribed. To maintain anonymity, the respondent's name will only be captured on an attendance sheet and will not be mentioned during the FGDs and therefore will not be captured by the audio-recorder. Upon transcription, findings will be also be presented in structured template. FGD with female participants will be organised separately from FGD with male participants. This will enable us to create safe spaces for the participation of women and prevent reticence in their answers.	
5.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?	Will a separate FGD guide be used for the adolescent FGDs? If not, why not? No longer relevant	X
5.6	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?	Please respond. We will not interview children. However we will ensure privacy and confidentiality of all the subjects including vulnerable groups such as people with disabilities who may be interviewed.	X
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?	Please respond. No, When administering any interview, the research team and assistants will seek and obtain consent from participants. We will provide potential participants with appropriate information about the purpose and nature of the evaluation, so they can make an informed choice. The community and participants will be made ware of the sample selection cariteria. All potential participants will be made aware that their participation is voluntary and does not affect their eligibility to receive services from any programs now or in the future. All	X

		participants will be informed that the data collected will be held in strict confidence. The respondent will be made aware at the outset that he/she is free to terminate the interview at any point and to skip any questions that he/she does not wish to respond to. All potential participants will be made aware that their participation is voluntary and does not affect their eligibility to receive services from any programs now or in the future. All participants will be informed that the data collected will be held in strict confidence. The respondent will be made aware at the outset that he/she is free to terminate the interview at any point and to skip any questions that he/she does not wish to respond to. The conduct of the evaluation will be informed by Humanitarian Principles of "do-no-harm": - The purpose of humanitarian action is to protect life and health and ensure respect for people (Humanity); - Not taking sides in hostilities or engage in controversies of a political, racial, religious or ideological nature (Neutrality); - Analysis of information will be carried out on the basis of assessed need and will make no distinctions on the basis of nationality, race, gender, class or political opinions (Impartiality); and - Is autonomous from political, economic, military, or other objectives that any actors may hold with regard to areas where humanitarian action is being implemented (Operational Independence).	
5.9	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have		X

	strategies to address this been adequately described?		
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	***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.**		
6.1	Type of Informed Consent: a. written & signed ……..……..…..X b. written not signed ……. c. written & signed by authorized representative.. 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 ……..…	Informed Consent will be Written and signed Verbal and signed or recorded Depending on the choice and convenience of the subjects	X
6.2	Are the processes for obtaining each IC adequately described?		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?	Please consider rephrasing the IC form for adolescents to be more direct about the purpose. Rather than focusing on "RRT Program", which may be obscure to a child, say something like, we want to hear what your experience was with the water you used for drinking or washing, and the access you had to use a private toilet. Use simpler language please. No longer relevant	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?	Please include in all IC forms. This has been done. In all the IC forms it has been noted that: The researchers will read the notes for analysis. The recordings/notes will be kept in secure digital locations and will be destroyed or deleted after all the information have been mined.	**X**
6.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?	Please include in all IC forms. This has been done. In all the IC forms it has been noted that: the data the interview will provide may give some important information to the policy makers and development partners to improve the RRT programme in the country	**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?		**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 *assent*?		**NA**
6.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	You state on p.11 that, "*Participants should also be made aware that they should not discuss the information*	**X**

		that is shared by other participants during the focus group once they leave the site." Please include this in all ICs for FGDs. Yes. This has been done	
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?	Please provide an IC form for survey subjects. IC has been provided for the RRT and household survey participants	**X**
6.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Please respond. A copy will be left with subjects	**X**
6.18	Additional comments or suggestions		
Section 7	***Subject Protections:*** **Do submitted materials clearly identify protection against risk?**		
7.1	Do materials describe protocols for subjects' safety throughout data collection, analysis, storage, and dissemination?	Please describe. Subjects' safety protocols are described in the protocol including the elements of privacy and confidentiality and who has access to data for analysis (researchers) and how data will be stored and disseminated.	**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?		**NA**
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?	Please discuss.	**X**

		The data collection team will be trained on ethical considerations such as informed consent, confidentiality and anonymity, humanitarian principles, etc.	
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
Section 8	***Data Protections:*** **Do data collection and storage protocols adequately ensure subject & data safety?**		
8.1	Are data collection tools appropriate and constructed to assure subject confidentiality or anonymity?	How will subject confidentiality be maintained for the online survey? They survey will be conducted face-to-face. When administering any interview, the research team and assistants will seek and obtain consent from participants. Consent and assent to participate will be verbal but documented by the interviewer with his/her signature, name, and date. We will provide potential participants with appropriate information about the purpose and nature of the evaluation, so they can make an informed choice. All potential participants will be made aware that their participation is voluntary and does not affect their eligibility to receive services from any programs now or in the future. All participants will be informed that the data collected will be held in strict confidence. The respondent will be made aware at the outset that he/she is free to terminate the interview at any point and to skip any questions that he/she does not wish to respond to.	X
8.2	Do data collection procedures and environment ensure data security?	Where will the FGDs take place? How will you ensure the environment is safe and private? FGDs will be conducted in a way to have women and men take part in group discussions separately, and implemented our safety, social distancing, and protection guideline to avoid COVID-19 risk.	X

8.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?	How will any written materials be managed? How will they be stored and kept secure? In term of mechanisms to ensure subjects' data protection, during the data collection phase, respondents will be told about the use of their personal data via the informed consent forms. In addition to processes put in place by AFCAR, OAG has a data manager who ensures that security and protection of data are assured. Only the project coordinator, the data manager and the evaluation core team will have access to the OAG ODK weblink and One Drive user name and password in which the data is stored.	X
8.4	If data will be shared with partners, is there a clear agreement or NDA?	Any data sharing planned? All raw data will be shared with UNICEF. The data will be collected using the KOBO platform where a technical team of UNICEF can have equal access during the evaluation period.	X
8.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, storage, de-identification, and destruction?	Please describe chain of custody through destruction of raw data. To ensure data protection, personal identifiers such as names will be removed during data processing (including transcription). Personal data will be anonymized by the researchers during data processing. The data will have codes that will indicate governorates, category of stakeholders, function and gender for the purposes of analysis. The anonymized data will be stored in the OAG internal server and managed by a Data Protection Officer in the organization. The password will also be managed by the Data Protection Officer. Data will be deleted on the submission and approval of the final evaluation products - UNICEF will be advised prior to the deletion.	X
8.6	Additional comments or suggestions		X