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HML Ethics Review Board

Research Ethics Review Feedback Template

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

This template serves to meet UNICEF ethical standards for research, evaluation, data collection and analysis, and is the 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, adult and child 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. **This template serves as the official record of the ethics review for the project named below**.

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 protection 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. Research Protocol / Inception Report, containing, e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plan. 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 US Office for Human Research Protections within the US Department of Health and Human Services (IRB 00001211) 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, Chair & Human Subjects Protections Director
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UNICEF Human Research Subjects' Protections Ethics Review

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

Project Title:	***Real Time Evaluation of UNICEF'S Response to the COVID-19 Outbreak Crisis in Malawi***
HML IRB Research Ethics Review ID#:	306EMAL20
Initiating UNICEF Official, CO, & RO	Mussarrat Youssuf, Chief, Research, Evaluation & Knowledge Management UNICEF Malawi, ESARO
Principal Investigator/Project Manager name, degree(s), organization, & address:	Ricardo Sole/ Team Leader DARA
Other key personnel:	Chrissie Thakwalakwa, National Team Member-Public health specialist Julia Durand, Team Member - Evaluator
Contracting Firm	DARA Calle Felipe IV, 9 28014 Madrid SPAIN
Primary study site(s):	Lilongwe, Blantyre and Mzuzu (high-risk districts) plus 26 additional lower risk districts, Malawi
Project duration (dates from -- to):	September 2020 – January 2021 Correct? Yes correct
Duration of human subjects' participation (dates from -- to):	September – November 2020 Yes correct
Thematic Area/Areas:	Health Choose an item. Choose an item.
Target population:	COVID-19 at-risk population, Malawi

Date of ERB Request	03 November 2020
Date(s) ERB Comments Returned	06 November 2020, 09 November 2020
0Date Final Documents Received	12 November 2020
DATE OF ERB APPROVAL	13 November 2020

→ PROCESS: HML Ethics Review Board will conduct a research ethics review of submitted materials and make comments in red below under *Additional Information Needed*. We will then return this template for responses from investigators.
Please respond reply to our comments on this form, in another colour, directly under each comment. Please provide any revised documents and please note where any revisions to your documents may be found by page or paragraph number.
Once we have agreed on the safely of your research subjects, we will issue a letter of approval. This document and approval letter will be retained by UNICEF and HML ERB as a record of this review.

	Ethics Review Board Criteria of Interest	**Additional Information Needed → Investigators: Please respond to ERB info requests in another color below the request in the same box as the request**	**X** or **NA** equal **PASS** (for IRB use)
Section 1	***ERB Submission:*** **Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:**		
1.1	Research Protocol or Inception Report, containing, e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plan	Please keep us informed of any subject protection protocol or research design changes that need to occur in adaptation to the COVID-19 pandemic The situation in Malawi now allows for the local evaluation team member to visit the districts, taking the appropriate measures ensuring personal protection and social distance, and a do no harm approach. See 2.4 Methodology in IR.	**X**

1.2	Informed Consent documents	The informed Consent Form states that "*participants have been chosen in 6 districts*" whereas elsewhere you state there will be three high-risk and 26 lower risk districts. Why is there a discrepancy? We've corrected the different statements. We propose to carry out FGD in 6 districts refer, since this has been made possible by the evolution of the pandemic and the waiving of restrictions of movements in the country. For the sampling, from the initial 28 that were initially stated in UNICEF planning documents, we've retained the 12 districts that were prioritized in the second phase of the response financed by DFID. See 2.5. Sampling in IR.	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		X
1.8	Have informed consent and data collection instruments been pre-tested?		X
1.9	Are all submitted documents final versions?		
1.10	Additional comments or suggestions		X
Section 2	***Research Design:*** **Do submitted materials describe the proposed research? This includes:**		
2.1	Background and rationale		X
2.2	Description of methodology	What does the *observation in field sites* (p. 17-18) include? Is there a data collection tool? If so, please provide. If there are individuals contacted or in some way recorded, consent is required. We had initially left this in case the situation changed. However, no observation in the field has been considered given mobility restrictions in the country. Therefore, we haven't developed	X

		a tool for this. The team does not record remote interviews. However, given the evolution of the situation in Malawi, the team and UNICEF has decided to do Focus Group Discussions taking the appropriate measures ensuring personal protection and social distance.	
2.3	Does study involve an intervention or treatment group?		**X**
2.4	Does study involve a comparison or control group?		**X**
2.5	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……X g. case study…….. h. physical measurements …….. i. biological specimen ……..…… j. other……..X Humanitarian Performance Monitoring (HPM) indicators		**X**
2.6	Number of Data Collections: a. one-time (no follow-up) ……X b. two or more (follow-up) ……	This is a one-time, no follow-up data collection, correct? Correct	**X**
2.7	Sample size: Total *n* or approximate *n* =	Please provide an estimated total sample size. For KII no sampling is applied: we reach out to all programme and management staff of UNICEF MCO (50 persons), to specific officers at GoM level engaged in UNICEF supported activities (Min. of Education, Min. of Health, Min. of Gender and Welfare, Min of Agriculture, Department of Disaster Management). We also included KII with all IP and with the two HoM of the UN agencies UNICEF has financial agreements with (UNFPA and WHO).	**NR**

		In addition, we will attempt to contact by telephone the district COVID-19 focal points of the 12 districts targeted by UNICEF. This will be a voluntary interview with a verbal introduction informing of the possibility of opting out and requesting official consent. We will also conduct FGD, please see 3.2 below.	
2.8	Are any subjects children (<18 years old)? None	You site ethical concerns regarding child subjects. Will you have child subjects? If so, what are their ages? We intend to include FGD with youth 18-25 age. Consent will be required to their custodians or parents if advisable. This has been adapted in both section 2.6 Ethical standards in IR and in all guides and consent forms (annexes)	**X**
2.9	Additional comments or suggestions	You will note that we have several questions below regarding participation of children. Please clarify if there will be any subjects less than 18 years old. As above.	**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 project *Minimal Risk* Only?: This means the probability and magnitude of anticipated harm or discomfort is not greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests.		**X**
3.2	By their participation, are subjects vulnerable to any of the following?: a. physical risk …….. b. psychological risk ……..... c. social risk ……	Please describe any COVID-19 risks to both subjects and research staff. No risk related to the evaluation is foreseen. Travel to the country by international team members has been ruled out. Risk of	**X**

	d. economic risk …….. e. legal risk …….. f. political risk …….. g. employment risk…… h. academic risk…….. i. religious risk…….. j. other……	contracting or disseminating COVID-19 by local team members will be controlled, local team and participants will be distributed masks and hand sanitizer for al FGD. Local team members will follow recommendations in force on protective equipment and social distance to minimize risk of infection. When will you know whether or not you will conduct FGDs remotely or in-person? Jointly with UNICEF MCO and the evaluation team in the field, the decision has been taken to carry out in-person FGD starting next week, in six districts of the 12 retained by UNICEF as priority districts. This sample includes 2 districts per region (3 regions).	
3.3	Does the study request information or opinions where public disclosure may result in danger, limitations to future freedoms and access to services?		X
3.4	In event of any of the above risks, do protocols describe and outline clear strategies to mitigate risks?	Please respond (re Item 3.2). Protocols as issued by local authorities and UN on protective measures, social distance and use of protective equipment. New protocols have been added to ensure mitigation risks are detailed. The field team has been instructed on how and when to use them (for FGD). New protocols have been added in annex and the field team was instructed on how to use them.	X
3.5	Do study objectives show that risk is reasonable in relationship to expected gains? Are benefits clearly articulated?		X
3.6	Do gender, ethnicity, or other pertinent demographic characteristics, -- or grouping of subjects by any of these characteristics -- increase subject risk?		X

3.7	If a subject discloses or is suspected to be at risk outside of the study, are procedures in place to address or report risk and appropriately refer subject for relevant support?	Mandatory reporting is referenced in consent form. Please elaborate on how staff is trained or what protocol will be followed in the event of a disclosure. UNICEF MCO has a specific referral mechanism in case of disclosure of risks affecting subjects. Being a RTE we rely on the system of referral established at district level, which involves local authorities. We have also added a form for FGD in annex.	**X**
3.8	Is reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	Please describe. As above, see new protocols	**X**
3.9	If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond?	Is there any follow up planned? No follow up with subjects is planned by the ET. We may recommend following up issues identified to UNICEF MCO.	**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?	Will anyone in these groups be participating? The FGD composition will include youth of 18-25 years, women, including mothers and pregnant women. We cannot rule out, for example, PLWHIV/AIDS, as the prevalence is high in the country, and persons with economic or educational disadvantage, given the socioeconomic situation in Malawi. UNICEF specifically targets those groups in the Country Porgramme and also in the Response to COVID-19. It is crucial for the evaluation to capture challenges for those groups in terms of access to services and support received.	**X**

		Consent forms will be requested, and the team will use UNICEF MCO referral systems in place if issues arise.	
4.2	Does the sampling strategy target people at risk for issues such as: violence, torture, or abuse; 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, 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? If yes, are study-specific protection protocols provided?		X
4.4	Does the study request information relating to illegal activities? If yes, is an MOU in place with government to ensure that no participant is prosecuted? Have participants been notified of this agreement?		X
4.5	Additional comments or suggestions		X
Section 5	***Recruitment:*** **Do submitted materials describe subjects and the recruitment process?**		
5.1	Are subject recruitment procedures & sampling strategy adequately described?	Please briefly describe how you will draw your sample. For the KII see above. For FGD, we sample 2 districts per Region, in total 6 districts, of the 12 UNICEF has prioritized in the COVID-19 response, through DFID/FCDO funding. To recruit participants, we rely on community committees and youth clubs in each location. For KII, sampling is explaining above, point 2.7. See 2.5 Sampling in IR.	X

5.2	Do recruitment procedures clearly describe ways and means to ensure privacy of potential subjects throughout the recruitment process?	Snowball and purposive sampling is referenced on p.20. Please describe how privacy will be ensured throughout this process. Privacy and confidentiality will always be ensured through the consent forms and protocols to be applied. The local team is familiar with adequate practice at community level. Names will be coded.	**X**
5.3	If subjects are children, do materials adequately describe ages and why these ages are appropriate?	Please describe. No children under 18.	**X**
5.4	If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?	Please provide. No children under 18.	**X**
5.5	If children or other vulnerable groups are subjects, or if subject matter is sensitive, is recruitment done in a manner sensitive to subjects' potential vulnerabilities or weaknesses (real or perceived) and does it ensure privacy throughout recruitment?		**X**
5.6	To what degree are subjects identified: a. subjects' names are recorded with their responses……..…….. b. names recorded on separate informed consent ..……..X c. no names are recorded ..……..... d. other personally identifiable information (PII) is recorded…….……..X e. no PII is recorded …… f. subjects are given a unique identifier..... g. other……..	You tell survey takers that name and position will not be associated with their answers, but then ask for their position and section (IR p.81). Why do you need position and section info? We request this information for a descriptive analysis of the responses obtained, in case there are differences between administrative, programmatic of managerial position. This will also allow to target recommendations for example.	**X**
5.7	If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?	Please describe. Each interview is coded; the information obtained is uploaded to the evaluation matrix and attributed to the code. PII is kept in an internal record, under custody of the TL and will be eventually destroyed once the exercise is	**X**

		validated (final report accepted). DARA also has a privacy policy that has been added as an annex.	
5.8	Do recruitment procedures show any indication of bribery, coercion, intimidation, compulsion, pressure, or force?		X
5.9	Is recruitment of some members of the population and not others likely to result in resentment for either inclusion or exclusion? Have strategies to address this been adequately described?		X
5.10	Are potential subjects likely to conflate evidence generation with potential or actual goods or service provision? Have strategies to address this been adequately described?		X
5.11	If subjects are paid, compensated, provided a gift for participation, or provided other benefits or services, is the incentive described and justified as being non-coercive?		X
5.12	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. verbal & signed or recorded……..... e. verbal & signed by authorized representative.…… f. verbal not signed or recorded…….…….. g. other ……	Please provide informed consent documents for survey, KII, and observation subjects. The IC you sent is for FGD participants only. It also appears to be for child subjects. This has been added. The consent form provided in Annex 8 is addressed to FGD participants only. Please provide informed consent statements for all subjects. Please refer to Items 6.5 through 6.12 for guidance. Thank you, added.	X

6.2	Are the processes for obtaining IC adequately described?	How will you obtain IC for remote data collection? We start with a standard verbal introduction and clarify issues of confidentiality and optout. Interviews are requested through email, therefore ensuring voluntary participation of each interviewee. The survey has its own initial explanation and consent requests and is each participant can stop at any time. This has been further detailed and added in the KII, FGD and survey guides in IR annexes.	**X**
6.3	For child subjects, is IC being obtained from parent, guardian, caregiver, or authorized representative? If not, is an explanation provided as to why this is unnecessary?	Again, it is unclear whether children will be participating. While they are mentioned in the inception report and the Certificate of Consent makes allowance for parent/guardian to give consent for a minor, there is not a plan described to engage minors, nor materials tailored to them. Please explain. No children foreseen	**X**
6.4	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*?	Please clarify. No children foreseen	**X**
6.5	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 on each IC. Yes	**X**
6.6	Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions, or may withdraw without consequences?	Please include Yes	**X**
6.7	Does IC include the expected duration of the subject's participation (hours/minutes)?	Please include Yes	**X**

6.8	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?	Please include Yes	X
6.9	Are subjects given a clear indication of who will have access to their responses and in what form?	Please include Yes	X
6.10	Does IC include a description of any risks or benefits to subjects?	Please include Yes	X
6.11	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?	Please include Yes	X
6.12	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?	Please include on each IC and provide to each subject. We've added contact details of investigator. Please be sure to add this to your revised IC.	X
6.13	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?		X
6.14	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?		X
6.15	Where data collection differs by method (e.g.: survey, FGD, interview), do ICs cover each method?	Please provide an IC for each type of data collection method. We have a Consent Form for FGD. However, for KII the consent is verbal and asked at the beginning of each survey. There is also an introduction that states an informed consent and gives participants op-out option. The survey allows for participants to stop at any moment. We've added an introduction to the guides and forms.	X
6.16	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Will you leave a copy of the IC with each participant? If not, why not?	X

		Yes, a copy of the IC will be left with each participant.	
6.17	Additional comments or suggestions		X
Section 7	***Subject Protections:*** **Do submitted materials clearly identify protection against risk?**		
7.1	Are all data collected necessary for the purposes of evidence generation?		X
7.2	Do data analysis and reporting procedures ensure subject confidentiality (or anonymity) and security?	Please discuss protocols. As in 5.2	
7.3	If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for their safety or protection throughout the evidence generation including the dissemination and communication processes?	Please describe considerations if children will be included as subjects. No children below 18 years old	X
7.4	If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive?	Please describe if children will be included as subjects. No children below 18 years old	X
7.5	Have personnel collecting data from subjects had ethical training specific to the target group?		X
7.6	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?		X
7.7	Additional comments or suggestions		X
Section 8	***Data Protection:*** **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?		X
8.2	Do data collection procedures and environment ensure subject safety and data security?	How will subjects be divided for FGDs? Will they be same of mixed gender? What about interviewers and translators (if needed). The local team knows the local languages. Mix of gender is possible in some FGD (committee members and youth clubs), but we aim to have at least two gender specific FGD per district.	X

8.3	Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type?	Please explain how data will be collected for observations. No observation is planned due to mobility limitations for Covid19 How will surveys be implemented and collected? Web based survey to UNICEF staff.	**X**
8.4	Do protocols describe chain of custody of data and protections for data transfer or transmission, storage, de-identification, and destruction?	Please describe. Data will be kept in DARA's Drive that is secured with specific passwords only used by the three team members. Once the analysis is over, data will be stored in a password protected hard disk only accessible to DARA's Evaluation Manager. DARA ensures all information is deleted from Drive once the evaluation is finished. Please also see DARA's Privacy Policy, added as an annex.	**X**
8.5	Additional comments or suggestions		**X**