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:	***Evaluation of approaches to social protection programming in humanitarian situations, focusing on cash-based programming***
HML IRB Research Ethics Review ID#:	247EOHQ20
Initiating UNICEF Official, RO, & CO	Denis Jobin, M.A.P., M.A. Senior Evaluation Specialist, Goal Area 2&5, Evaluation Office, NYHQ
Principal Investigator/Project Manager name, degree(s), organization, & address:	Dr Michael Samson, EPRI's Director of Research, Co-team Leader Mr. Nard Huijbregts, EPRI's Lead Social Policy Advisor, Co-team Leader
Other key personnel:	Ms. Katharina Bollig, EPRI Social Policy Advisor Ms. Sandra Berger, EPRI's Quantitative Research Officer Ms. Lani Trenouth, independent humanitarian professional specialized in cash-based interventions in emergency settings
Contracting Firm	Economic Policy Research Institute (EPRI) 228 Main Street, No. 431 Williamstown, MA 01267 USA
Primary study site(s):	Yemen, Malawi, Dominica, Nepal
Project duration (dates from -- to):	55 weeks (23 October 2019 to 13 November 2020)
Duration of human subjects' participation (dates from -- to):	5 weeks (25 May 2020 to 19 June 2020)
Thematic Area/Areas:	Social Policy Child Protection Choose an item.
Target population:	Vulnerable populations affected by emergencies

Date of ERB Request	18 May 2020
Date(s) ERB Comments Returned	21 May 2020
Date Final Documents Received	05 June 2020
DATE OF ERB APPROVAL	05 June 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. Yes, we will.	**X**
1.2	Informed Consent documents	Please provide for online survey. Please see the online consent document for the online survey in the annex of the inception report. Page 159 and 160.	**X**
1.3	Surveys and data collection instruments	Please provide the online survey. At this point in time, this is not possible as the online survey	**X**

		is meant to validate the findings and recommendations of the primary data collection activities and the validation workshop. As such, data collection, analysis and drafting of findings and recommendations must be finalized, before the questions for the online survey will be drafted. Content-wise, the latter will focus on participants' views on key findings and recommendations and hence will not introduce any new topics to the evaluation. Please do provide once available.	
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?	Any plans to pretest instruments? Thus far, the instruments have been reviewed and adjusted based on comments received from UNICEF headquarters and country offices. Moreover, experts on the team in the areas of social protection and humanitarian work have reviewed the instruments independently. In addition, the first round of KIIs will serve to test the instruments and if EPRI finds that some questions are difficult to comprehend or to answer, they will be adjusted for further rounds of interviews.	**X**
1.9	Are all submitted documents final versions?	Please confirm. Yes, the documents attached to the email with which this document was sent are the final versions. **Update – the documents have been revised in light of comments received by the UNICEF**	**X**

		Evaluation Office. Please see page 52, the last paragraph of the Inception report and page 6 of the Protection Protocol, point 4f.	
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		**X**
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)……..…….. e. document (desk) review……..……X f. on-site observation…… g. case study…….. h. physical measurements …….. i. biological specimen ……..…… j. other..……secondary data…….. X	In the Annexes, the interview instructions include dismissing those who do not consent. Will any of these KIIs be done in a group format or all individually? All KIIs will be done individually and over skype, zoom or telephone. If for some reason the key informant cannot be contacted through these means, then EPRI will send the respective questionnaire via email. The key informant will then fill out the questionnaire and send it back to EPRI. See inception report page 35, paragraph 3.	**X**
2.6	Number of Data Collections: a. one-time (no follow-up) …… b. two or more (follow-up) ……X	There will be follow-ups, correct? There will be follow-ups with individuals that were interviewed during the inception phase that agreed to another interview during the evaluation phase in which EPRI will gather further in-depth and analytical information on the programme. However, these individuals are allowed to opt out of a follow-up survey if they do not wish to be interviewed again. Furthermore, during the evaluation phase, EPRI has asked participants whether or not they can be contacted if further clarification is needed on	**X**

		any responses provided. This was clarified in the consent forms. See the annex of the inception report. Paragraph one on pages 126, 130, 136, 142, 148, and 153.	
2.7	Sample size: Total *n* or approximate *n* = 136	106 KIIs and 30 CO online surveys, correct? Correct, 106 KIIs and one online survey sent out to a maximum of 30 COs.	**X**
2.8	Are any subjects children (<18 years old)? None	None, correct? Correct, no children.	**X**
2.9	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 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 ……. d. economic risk …….. e. legal risk ……..... f. political risk …….. g. employment risk…… h. academic risk……..... i. religious risk……..		**X**
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?		**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?		X
3.8	Is reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?		X
3.9	If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond?	Many of the stakeholders interviewed will be consulted again during the data collection phase, using the pre-developed data collection instruments in the Annex. If individuals were not identified, then how can you re-contact them? There may have been some confusion here. The individuals that are undertaking remote key informant interviews will be identified by the relevant UNICEF COs. As such, EPRI will have their name and contact details. However, during the inception mission, EPRI undertook less structured and less detailed interviews in order to get an initial understanding of the context and the programme. It was here that EPRI asked whether or not the participant would be willing to be re-contacted during the evaluation phase for a more structured and in-depth interview. Only the individuals that have consented to this re-contact will be interviewed again during the upcoming evaluation phase. However, if they have changed their mind, then upon re-contact, these individuals may also	X

		choose to not participate. This is their choice as indicated in the respective consent form provided in the annex of the inception report. A consent form for each group of interviewees is provided: Donors, Government, NGOs/IOs, UNICEF HQ, UNICEF RO and UNICEF CO. Information on a list of pre-interviewed individuals can be seen on page 34, paragraph 2 and the subsequent table in the inception report. A potential list of KIIs for the evaluation phase is also provided in the table on page 37 and 38 of the inception report. The KIIs for the evaluation phase are contacted by staff of the UNICEF CO. The exception to this is the UNICEF Malawi CO, who will identify the relevant KIIs and provide EPRI with the contact details as well as an introduction letter to aid in the setting of interviews.	
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, 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?	How will subjects be recruited? Subjects will be recruited based on an expert sampling technique as well as a chain referral approach. The latter encourages identified stakeholders to refer other individuals that should also be consulted. Page 36, paragraph 1 in the inception report describes both approaches.	X
5.2	Do recruitment procedures clearly highlight ways and means to ensure privacy of potential subjects throughout the recruitment process?	Please discuss. The chain referral approach encourages identified stakeholders to refer other individuals that should be consulted. In this process, it is ensured that the referred to individual will not know who has referred him if the original stakeholder does not wish to be identified. As such, the anonymity of the original stakeholder is ensured. Furthermore, the original stakeholder will also not be notified	X

		whether EPRI has contacted his reference or not. Under the expert sampling technique, EPRI relied highly on the UNICEF CO to identify individuals that would be able to successfully contribute to the evaluation. The UNICEF CO ensured that each key informant was contacted privately. No list of participation was shared with the key informants. The UNICEF COs shared the contact information of key informants in line with the protection protocol – through encrypted and password protected files.	
5.3	If subjects are children, do materials adequately describe ages and why these ages are appropriate?		**NA**
5.4	If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?		**NA**
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?		**NA**
5.6	To what degree are subjects identified: a. subjects' names are recorded with their responses……..……X b. names recorded on separate informed consent only……..…….. 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.....		**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 As the interviews will be conducted remotely, the subject's name or any other PII will be	**X**

		recorded using a digital recorder. This is the only place in which the name or any other PII will be stored. The information that the subject presents will be noted down in a word document that does not identify the subject's name. Instead, the recording will be saved under a numerical value. The same numerical value will be used to save the corresponding word document. As such, when analyzing the responses, no reference will be made to the real name of the individual. See the "Pre-discussion, consent and preparation" paragraphs on pages 125, 129, 135, 141, 147 and 152.	
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 ……..……..…… b. written not signed ……..……....		X

	c. written & signed by authorized representative…… d. verbal & signed or recorded…….....X e. verbal & signed by authorized representative…… f. verbal not signed or recorded…….…….		
6.2	Are the processes for obtaining IC adequately described?	Please describe for online survey. Please see page 159 and 160 of the inception report (annex). A consent script that will be placed as the first page of the online survey has been developed. This explains that the participation is voluntary and that responses will be confidential. In fact, the online survey will only ask for the country in which the UNICEF office resides. The respondent of the online survey will then be able to either consent to the online survey or not. If not, then the online survey will finish there with no further questions asked.	**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?		**NA**
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*?		**NA**
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?		**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?		**X**
6.7	Does IC include the expected duration of the subject's participation (hours/minutes)?		**X**
6.8	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?		**X**
6.9	Are subjects given a clear indication of who will have access to their responses and in what form?		**X**

6.10	Does IC include a description of any risks or benefits to subjects?		X
6.11	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?		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 provide to each subject. The IC does provide the identity and contact information of the investigators. When the written consent script is sent to the subject, it will also include the name and email address of the EPRI investigator that will undertake the interview. As such, the subject may contact EPRI with any questions in relation to the interview or the evaluation. For the online survey, the last page will include the name and email addresses of the investigators to which the UNICEF country offices can reach out if need be. This can be found in the second paragraph on pages 126, 130, 136, 142, 148, 153 and 160. In terms of power dynamics, EPRI relies on UNICEF COs to arrange the key informant interviews. The exception to this is the Malawi CO, which has asked EPRI to do the contacting. However, an introduction letter will be provided in order to facilitate contact. As most UNICEF CO's are initiating contact with the relevant key informants, EPRI is confident that the right mode of communication will be used given the status of the key informant. Furthermore, in terms of access to resources, EPRI ensured that the remote key informant interviews can be undertaken in three ways. First, via skype/zoom. If this is not possible, then EPRI will contact the key informant via phone. If these options are not possible, then	X

		EPRI will, as a last resort, send the tool to the key informant via email and ask him/her to fill it in and send it back.	
6.13	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?		**NA**
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?		**X**
6.16	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Will they receive a copy? Prior to the interview, participants receive a written consent form via email, with the instruction to read through it before the interview. At the beginning of the interview, EPRI will ask the participant whether he/she read through the consent form, fully comprehended the content and whether the participant consents to participating in the interview. The written consent form shared with the participant includes contact details of the interviewer from EPRI, should the participant wish to reach out to EPRI regarding any questions or clarifications. This was added to the inception report annex in the first paragraph on pages 125, 129, 135, 141, 147, and 152.	**X**
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?		**X**
7.3	If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for		**NA**

	their safety or protection throughout the evidence generation including the dissemination and communication processes?		
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?		**NA**
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?		**X**
8.3	Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type?	Please provide See the attached single protection protocol.	**X**
8.4	Do protocols describe chain of custody of data and protections for data transfer or transmission, storage, de-identification, and destruction?	Please provide. See the attached single protection protocol.	**X**
8.5	Additional comments or suggestions		**X**