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
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UNICEF Research Ethics Review for Human Subjects' Protections

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

Project Title:	***Investir dans le Capital Humain des Enfants grâce à un Système de Protection Sociale durable et inclusif – MAS/UNICEF – Tunisie***
HML IRB Research Ethics Review ID#:	388TUNI21
Initiating UNICEF Official: Name, CO, &RO	Valentina Prosperi, M&E Specialist, Evaluation, MENARO, vprosperi@unicef.org
Principal Investigator/Project Manager: Name, degree(s), organization, & address	Yosr Abid Fourati, National Expert PhD in Economics Vision Development 21 Avenue des Etats-Unis, Immeuble les Jasmins, 7ème étage 1002 Tunis Belvédère
Other Key Personnel: Names & titles	Thais De Alcântara Peres, Team leader Fabrizio Rigout, Expert backstopping and quality Pauline Mauclet, Project Manager (Plan Eval) Solène Coma, Project Manager (Vision Development)
Contracting Firm: Name & address	Plan Eval 2/2.2 Rue du Fond Cattelain 1435 Mont Saint Guibert Belgium Vision Development 21 Avenue des Etats-Unis, Immeuble les Jasmins, 7ème étage 1002 Tunis Belvédère
Primary study site(s): (e.g., country, province, region)	Tunisia

Project duration: (Dates from -- to)	April 2021 – October 2021
Duration of Subjects' Participation: (Dates from -- to)	May – August 2021
Thematic Area/Areas:	Social Policy Child Protection Health
Target population:	Children made vulnerable by the socio-economic impacts of COVID 19.

Date of ERB Request	24 May 2021
Date(s) ERB Comments Returned	27 May 2021
Date Final Documents Received	18 June 2021
DATE OF ERB APPROVAL	18 June 2021

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 adaptation to the coronavirus pandemic, we have chosen to conduct a great part of the data collection activities remotely. The qualitative interviews with a sample of the target beneficiaries will consist of telephone interviews. Some KIIs will be carried our remotely as well. Regarding focus group discussions, we	**X**

		wish to conduct them in-person, if UNICEF and the MAS allow. Doing so, we will make sure that the strictest health protocol is implemented to protect both respondents and interviewers: limited number of participants per FGD, good room ventilation, provision of sanitary gel, wearing of face masks. (see last paragraph of annex I).	
1.2	Informed Consent documents	Please provide the IC for the quantitative telephone survey. A consent request is provided with the interview guide for the telephone interviews with families (annex IV of the inception report). This is the format we chose to use because of the remote nature of the interviews and following our meeting with ISTIS which carried out the quantitative component of the study.	X
1.3	Surveys and data collection instruments	Please provide the data collection tool for the quantitative telephone survey. Kindly find the interview guide for the telephone interviews with families in Annex IV of the inception report. Please provide the FGD guides for social workers and persons involved in the money management of transfers (p.14). Kindly find the FGD guide for social workers and persons involved in the money management of transfers in Annex VI of the inception report.	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	Do protocols include a section identifying ethical issues and measures to mitigate ethical problems as required		X

	by UNICEF Procedure? NF		
1.9	Have informed consent and data collection instruments been pre-tested?	Please respond. They will be pre-tested during the training of enumerators prior to data collection. The data collection instruments and consent request will, then, be revised accordingly.	X
1.10	Are all submitted documents final versions?	Please respond. The data collection instruments are the final versions devised prior to the pre-test. They may be revised after the pre-test. All revisions will need to be submitted to and approved by UNICEF and the MAS.	X
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. 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……..…….. b. subject interview……..……..X c. key informant interview (KII)……..……..X d. focus group discussion (FGD)……..……...X e. document (desk) review……..…… f. on-site observation…… g. case study…….. h. physical measurements …….. i. biological specimen ……..…… j. analysis of secondary data……...X	Are FGDs the only data collection to be completed in-person? Some KIIs may also be completed in-person. Subject interviews will be conducted by telephone.	X

	k. other……..		
2.4	Number of Data Collections: a. one-time (no follow-up) …… b. two or more (follow-up) ……X	You will follow up with 100 of the quantitative survey respondents to conduct a qualitative interview, correct? We will follow up with 50 of the quantitative survey respondents. This sample will be interviewed a first time in the coming weeks and a second time at the end of the intervention.	**X**
2.5	Sample size: Approximate total *n* = 2680	20 KIIs, 100 interviews, 2440+ telephone surveys & 12 FGDs correct? This is correct. The 100 (50+50) interviews will be conducted in two data collection phases with a sample of 50 respondents extracted from the quantitative survey sample.	**X**
2.6	Are any subjects children (<18 years old)?	On p.38 you state the FGDs will include young beneficiaries. Will you have any subjects under age 18 years? We will not conduct FG discussions with young beneficiaries on their own, however, they may be present with their parents at the FG.	**X**
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.		**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		**X**

	as favorable as available alternative approaches; and where the intervention or procedure is likely to yield generalizable knowledge? If so, are mitigating procedures described?		
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 ……... e. legal risk ……..……..... f. political risk ……..…….. g. employment risk…… h. academic risk…….... i. religious risk……..…. j. other……	You ask beneficiaries in FGDs to share what monetary support they get. Is that appropriate? Could it be embarrassing for subjects? In fact, as we have the data from the quantitative survey for much of the families, we will not ask these questions, but we will have the answers in mind when interviewing the family member. I suggest to still keep them in the questions guide, in case we don't find the response in the associated quantitative responses. We can give them the choice to answer or not. As one of the questions of the evaluation is about the effectiveness of the aid, it is very important to understand what categories of the cash transfers they receive and the amounts. Do you anticipate any other of these risks to subjects especially in FGDs? No, but we anticipate participants may be worried about the consequences of their responses for their future eligibility to such program. This is a risk we addressed in section 13 "Limitations et gestion du risque".	**X**
3.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?	If so, please discuss This is a risk that weighs more on the quality of the data collected than on respondents. Measures have been described to mitigate these risks in section 13 "Limitations et gestion du risque".	**X**
3.6	Does the study request information or opinions where		**X**

	public disclosure may result in danger, limitations to future freedoms, or access to services?		
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 describe. Yes, in accordance with the ToRs, a “plan de soutien” has been devised, shared with enumerators and FG moderators during the training in order to support subjects who are at risk and refer them to relevant support. The plan de soutien is provided in annex VII of the inception report.	X
3.9	Is reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	Please describe. Yes. Following our discussions with people from the MAS at the Comité de Pilotage meeting, it was agreed that any type of abuse should be reported and families referred first of all to the social workers.	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		X

	familial, peer, or social pressure? If yes, are study-specific protection protocols provided?		
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 could damage health or safety; removal of organs for exploitation? 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	To what extent are subjects identified: a. names are recorded with responses……X b. names recorded separate from responses….. 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……	The inception report indicates that FGD and beneficiary participants in semi-structured interviews will not be identified by name or other PII (p. 35). However, the FGD and semi-structured interviews do request the participant's name and information about their family. Why ask for names and PII? We suggest you use pseudonyms FGD. In fact, we don't need to ask the names, each respondent is already identified in the quantitative survey by a code, we will use the same codes.	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?		
5.3	Are subject recruitment procedures & sampling strategy adequately described?	What are the selection criteria for beneficiaries in FGDs and qualitative interviews? See annex I, paragraph “groupes de discussion” When relevant, and if the quantitative data allows for it, we can select some families “monoparentales”. We cannot attest this for the moment because we need to check the quantitative data first, which is planned in the next phase with the sample choice. As the selection of the 50 families for the qualitative survey will be chosen from the quantitative survey sample, we will do a random selection. How will be people be contacted for FGDs? People will be contacted through UNICEF as the UNICEF has the institutional legitimacy to do so along with the necessary contact information.	**X**
5.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?	Yes, families will be identified by codes.	**X**
5.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?	Please provide an age-appropriate FGD guide for child participants. We will not have a FG only with children.	**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 discuss regarding information on family problems and financial strain, especially for child subjects. The subjects targeted for both phone interviews and FGDs are vulnerable groups. The nature of phone interviews will help ensure privacy for this aspect of data collection. With regard to FGD, every effort will be undertaken to safeguard subjects’ privacy. Personal information will be asked only when paramount to the objectives of the study. No information will be shared	**X**

		with any third party. A few sentences have been added in the interview guide and FGD targeting the programme beneficiaries, section " presentation et consentement".	
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?		X
5.9	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have strategies to address this been adequately described?	Is this a potential issue, especially because subjects are beneficiaries? Yes, it is. This is an issue that ISTIS encountered while conducting the quantitative survey. Measures to mitigate this risk have been described in section 13 "Limitations et gestion du risque" of the inception report.	X
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? None		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. verbal & signed or recorded……..X e. verbal & signed by authorized representative…. f. verbal not signed or recorded……..…….. g. active……	Will verbal consent be recorded? How? Verbal consent will be recorded and so will the qualitative phone interviews. Written and signed consent will be asked for all in-person FGDs and interviews.	X

	h. passive…….. i. other ……..…		
6.2	Are the processes for obtaining each IC adequately described?	Data collectors should confirm that subjects consent, not just if they have any questions. Yes, this has been modified accordingly.	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?		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. This has been included in the section “Présentation et consentement”, a sentence has been added for more clarity.	X
6.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?		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?	In your ICs you state that “*responses will remain anonymous and confidential*.” However, anonymity is not possible in these types of data collections. Please revise. This has been revised accordingly. Please include a statement on the limits of confidentiality	X

		in regard to mandated reporting of abuse or neglect. This has been revised accordingly.	
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?	Please provide to every subject. Contact information will be provided at the end of the discussion/interview. Data collection instruments have been modified accordingly. Access to phones have been adressed as a potential risk in section 13. With regard to FGD, efforts will be undertaken to hold them so that they are easily accessible to respondents.	**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?	Please provide a consent form for the parents or guardians if you have child subjects. This has been added accordingly (see annex VIII).	**X**
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*?	Please provide. Yes, it is but we will not have a FG only with children. See 6.12.	**X**
6.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	Please include in ICs for FGDs. Yes this is clearly stated in the verbal IC as well as the written form.	**X**
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 include in the IC if you are recording. This has been added accordingly.	**X**
6.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Please offer to provide a copy. Change has been made accordingly (annex VII).	**X**
6.18	Additional comments or suggestions		**X**
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	Please describe COVID-19 precautions to be used for in-person data collection?	**X**

	dissemination?	See last paragraph of annex I.	
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?	Please describe for quantitative survey respondents. Only one additional contact is planned. All contact information will be destroyed after the validation of the final report, Will you need to link answers from the quantitative survey to the qualitative interview? Yes. The quantitative survey will provide us with information and data about the families, we will only ask complementary questions in the qualitative survey and much less detailed, If so, how will you protect subject identity and data? We will use data from the quantitative survey because it is necessary but it will not be shared, it will just serve the interviewers to know the family better before interviewing it.	X
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?	Please discuss Yes they have. Detailed instructions will be, however, given during the training and in the interviewers guide which will be submitted to the client. .	X
7.6	Have personnel collecting data from subjects had ethical training specific to the target group?		X
7.7	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?		X
7.8	Additional comments or suggestions	Will data collector training occur in-person or remotely? It will occur in-person.	X

		If in-person, please describe COVID-19 protections. See last paragraph of annex I.	
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?		**X**
8.2	Do data collection procedures and environment ensure data security?		**X**
8.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?	Please describe. Yes recordings will be destroyed for audio data and written consent forms for written data. This procedure is clearly stated both in the consent forms as well as the verbal IC (annex III to VIII).	**X**
8.4	If data will be shared with partners, is there a clear agreement or NDA?		**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. Yes. No data transmission or transfer will be permitted as declared in the verbal IC and consent form. There will be a single copy of each data file so that if data destruction by request of UNICEF is necessary after a retention period, the destruction will be definitive. Additionally, all members of the team with access to data files will have to state by the end of the contract that they have no local copies of it. All sharing privileges of these files will be undone at that stage.	**X**
8.6	Additional comments or suggestions		**X**