

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](https://www.unicef.org/supply/files/ATTACHMENT_IV-UNICEF_Procedure_for_Ethical_Standards.PDF); 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.

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| **Materials Requested for Review:**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. | Also, please include: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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**HML IRB**

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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**: |  |
| HML IRB Research Ethics Review ID#: |  |
| Initiating UNICEF Official, RO, & CO |  |
| Principal Investigator/Project Manager name, degree(s), organization, & address: |  |
| Other key personnel: |  |
| Contracting Firm |  |
| Primary study site(s): |  |
| Project duration (dates from -- to): |  |
| Duration of human subjects’ participation (dates from -- to): |  |
| Thematic Area/Areas: | Choose an item. Choose an item. Choose an item.  |
| Target population: |  |

|  |  |
| --- | --- |
| Date of ERB Request |  |
| Date(s) ERB Comments Returned |  |
| Date Final Documents Received |  |
| **DATE OF ERB APPROVAL** |  |

→ **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.**

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| --- | --- | --- | --- |
|  | **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 |  |
| 1.2 | Informed Consent documents  |  |  |
| 1.3 | Surveys and data collection instruments  |  |  |
| 1.4 | Written protocols to ensure subjects’ safety |  |  |
| 1.5 | Written protocols for protection of subjects’ identities |  |  |
| 1.6 | Written protocols for protection of data |  |  |
| 1.7 | Other relevant documents |  |  |
| 1.8 | Have informed consent and data collection instruments been pre-tested? |  |  |
| 1.9 | Are all submitted documents final versions? |  |  |
| 1.10 | Additional comments or suggestions |  |  |
| **Section****2** | ***Research Design:* Do submitted materials describe the proposed research?** **This includes:** |  |  |
| 2.1 | Background and rationale |  |  |
| 2.2 | Description of methodology |  |  |
| 2.3 | Does study involve an intervention or treatment group? |  |  |
| 2.4 | Does study involve a comparison or control group? |  |  |
| 2.5 | Type of data collection:1. survey questionnaire…………………….….…………..…
2. subject interview………………………………..………….
3. key informant interview (KII)…………..…………..……...
4. focus group discussion (FGD)……………..……………..
5. document (desk) review…………..………………………
6. on-site observation…………………………………………
7. case study…………………………………………………..
8. physical measurements …………………………………..
9. biological specimen ……………….…….…………………
10. other..………………………………………………………..
 |  |  |
| 2.6 | Number of Data Collections: 1. one-time (no follow-up) ……………………………………
2. two or more (follow-up) ……………………………………
 |  |  |
| 2.7 | Sample size: Total *n* or approximate *n* =  |  |  |
| 2.8 | Are any subjects children (<18 years old)? |  |  |
| 2.9 | Additional comments or suggestions |  |  |
| 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. |  |  |
| 3.2 | By their participation, are subjects vulnerable to any of the following?:1. physical risk ………………………………………………..
2. psychological risk …………………………………...........
3. social risk ………………………………………………….
4. economic risk ……………………………………………..
5. legal risk ……………………………………………..........
6. political risk ………………………………………………..
7. employment risk……………………………………………
8. academic risk………………………………………...........
9. religious risk………………………………………………..
 |  |  |
| 3.3 | Does the study request information or opinions where public disclosure may result in danger, limitations to future freedoms and access to services? |  |  |
| 3.4 | In event of any of the above risks, do protocols describe and outline clear strategies to mitigate risks? |  |  |
| 3.5 | Do study objectives show that risk is reasonable in relationship to expected gains? Are benefits clearly articulated? |  |  |
| 3.6 | Do gender, ethnicity, or other pertinent demographic characteristics, -- or grouping of subjects by any of these characteristics -- increase subject risk? |  |  |
| 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? |  |  |
| 3.8 | Is reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting? |  |  |
| 3.9 | If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond? |  |  |
| 3.10 | Additional comments or suggestions |  |  |
| 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? |  |  |
| 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? |  |  |
| 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? |  |  |
| 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? |  |  |
| 4.5 | Additional comments or suggestions |  |  |
| Section**5** | ***Recruitment:* Do submitted materials describe subjects and the recruitment process?** |  |  |
| 5.1 | Are subject recruitment procedures & sampling strategy adequately described? |  |  |
| 5.2 | Do recruitment procedures clearly highlight ways and means to ensure privacy of potential subjects throughout the recruitment process?  |  |  |
| 5.3 | If subjects are children, do materials adequately describe ages and why these ages are appropriate? |  |  |
| 5.4 | If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate? |  |  |
| 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? |  |  |
| 5.6 | To what degree are subjects identified:1. subjects’ names are recorded with their responses……………..…………………………………….
2. names recorded on separate informed consent only……...…………………………….……………………..
3. no names are recorded ..…………………………............
4. other personally identifiable information (PII) is recorded………………………………….………………….
5. no PII is recorded …………………………….……………
6. subjects are given a unique identifier.............................
 |  |  |
| 5.7 | If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses? |  |  |
| 5.8 | Do recruitment procedures show any indication of bribery, coercion, intimidation, compulsion, pressure, or force? |  |  |
| 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?  |  |  |
| 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? |  |  |
| 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?  |  |  |
| 5.12 | Additional comments or suggestions |  |  |
| 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:1. written & signed ………………………...…….……………
2. written not signed ……………………………..……..........
3. written & signed by authorized representative.…………
4. verbal & signed or recorded……………….………..........
5. verbal & signed by authorized representative….……….
6. verbal not signed or recorded…………………….……….
 |  |  |
| 6.2 | Are the processes for obtaining IC adequately described? |  |  |
| 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?  |  |  |
| 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*? |  |  |
| 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? |  |  |
| 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? |  |  |
| 6.7 | Does IC include the expected duration of the subject's participation (hours/minutes)? |  |  |
| 6.8 | Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?  |  |  |
| 6.9 | Are subjects given a clear indication of who will have access to their responses and in what form? |  |  |
| 6.10 | Does IC include a description of any risks or benefits to subjects? |  |  |
| 6.11 | Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality? |  |  |
| 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?  |  |  |
| 6.13 | Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group? |  |  |
| 6.14 | Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type? |  |  |
| 6.15 | Where data collection differs by method (e.g.: survey, FGD, interview), do ICs cover each method? |  |  |
| 6.16 | If IC is written, is a copy left with subjects or there is explanation for not doing so? |  |  |
| 6.17 | Additional comments or suggestions |  |  |
| 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? |  |  |
| 7.2 | Do data analysis and reporting procedures ensure subject confidentiality (or anonymity) and security? |  |  |
| 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? |  |  |
| 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? |  |  |
| 7.5 | Have personnel collecting data from subjects had ethical training specific to the target group? |  |  |
| 7.6 | Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies? |  |  |
| 7.7 | Additional comments or suggestions |  |  |
| 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? |  |  |
| 8.2 | Do data collection procedures and environment ensure subject safety and data security? |  |  |
| 8.3 | Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type? |  |  |
| 8.4 | Do protocols describe chain of custody of data and protections for data transfer or transmission, storage, de-identification, and destruction? |  |  |
| 8.5 | Additional comments or suggestions |  |  |