

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, human 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 (DRP). 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.,: research plan, 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. |

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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**Washington, DC 20036 USA**

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##### UNICEF Request for Human Subjects Protections Ethics Review

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

|  |  |
| --- | --- |
| **Project Title**: |  |
| HML IRB Research Ethics Review ID#: |  |
| Person & Office submitting ERB request: |  |
| Principal Investigator(s) name, degree(s), & address: |  |
| Other key personnel: |  |
| Primary study site(s): |  |
| Project duration (dates from -- to): |  |
| Duration of human subjects’ participation (dates from -- to): |  |

|  |  |
| --- | --- |
| Date ERB Request Received: |  |
| Dates ERB Request Processed: |  |
| **DATE OF ERB APPROVAL:** |  |

→ **PROCESS: HML IRB will conduct a research ethics review of submitted materials and make comments in red below. We will then return this template for responses from investigators. Please reply to our comments under *Additional Information Needed*, and we will issue a letter of approval or ask for further clarification.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 and materials provided separately or incorporated in text?**  |  |  |
| 1.1 | Research protocol / inception report, with necessary requisites as described above  |  |  |
| 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 | Comments, amendments, additions, or revisions |  |  |
| Section1. **2**
 | 1. ***Research Design:* Do submitted materials describe the proposed research?**
 |  |  |
| 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 | Gender, ethnicity, or other pertinent demographic characteristics of subjects |  |  |
| 2.9 | Comments, amendments, additions, or revisions |  |  |
| Section3 | ***Minimal Risk*: Do submitted materials address potential risks of participation?** |  |  |
| 3.1 | Minimal Risk Only: 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 | If the study or sampling and recruitment procedures have potential for greater than minimal risk, is it described? |  |  |
| 3.3 | If there is potential for greater than minimal risk, are mitigating procedures described? |  |  |
| 3.4 | Comments, amendments, additions, or revisions |  |  |
| Section**4** | ***Recruitment:* Do submitted materials describe subjects and the recruitment process?** |  |  |
| 4.1 | Are sampling strategy & subject recruitment procedures adequately described? |  |  |
| 4.2 | Subject identification:1. subjects’ names are recorded ……………..….
2. names recorded on separate informed consent (IC) 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................
 |  |  |
| 4.3 | If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses? |  |  |
| 4.4 | Do recruitment procedures show any indication of coercion, intimidation, compulsion, pressure, or force? |  |  |
| 4.5 | Are any subjects children (<18 years old)? |  |  |
| 4.6 | If subjects are children, do materials adequately describe ages and why these ages are appropriate? |  |  |
| 4.7 | If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) appropriate based upon age? |  |  |
| 4.8 | If subjects are paid, compensated, or provided a gift for participation, is the incentive described and justified as being non-coercive? |  |  |
| 4.9 | If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond? |  |  |
| 4.10 | Comments, amendments, additions, or revisions |  |  |
| Section**5** | ***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.**  |  |  |
| 5.1 | Type of Informed Consent:1. written & signed ………………………...…….…
2. written not signed ……………………………..…
3. verbal & signed …………………………….…….
4. verbal not signed ………………………………..
 |  |  |
| 5.2 | Are the process for obtaining IC adequately described? |  |  |
| 5.3 | Does the IC include a clear and simple invitation to participate, an explanation of what the subject will do and why they are being recruited? |  |  |
| 5.4 | Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language? |  |  |
| 5.5 | Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions, or may withdraw without consequences? |  |  |
| 5.6 | Does IC include a description of any risks or benefits to subjects? |  |  |
| 5.7 | Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality? |  |  |
| 5.8 | Does IC include the expected duration of the subject's participation (hours/minutes)? |  |  |
| 5.9 | Does IC provide identity and contact info of investigators? |  |  |
| 5.10 | Do IC materials advise subjects of their obligation to keep information confidential in focus group discussions? |  |  |
| 5.11 | Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type? |  |  |
| 5.12 | Where data collection differs by method (e.g.: survey, FGD, interview), do IC materials cover each method? |  |  |
| 5.13 | For child subjects, is there provision for obtaining consent from parent, guardian, caregiver, or responsible person?  |  |  |
| 5.14 | For child subjects, is their role in the study described adequately for them to provide written or verbal assent? |  |  |
| 5.15 | If IC is written, is a copy left with subjects or there is explanation for not doing so? |  |  |
| 5.16 | Comments, amendments, additions, or revisions |  |  |
| Section**6** | ***Subject Protections:* Do submitted materials clearly identify protection against risk?** |  |  |
| 6.1 | Do materials describe the use of information collected? |  |  |
| 6.2 | Are subjects given a clear indication of who will have access to their responses and in what form? |  |  |
| 6.3 | If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for their safety or protections? |  |  |
| 6.4 | If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive? |  |  |
| 6.5 | Have personnel collecting data from subjects had ethical training specific to the target group? |  |  |
| 6.6 | Are personnel collecting data aware of ethical issues that may arise and their mitigation strategies? |  |  |
| 6.7 | Comments, amendments, additions, or revisions |  |  |
| Section**7** | ***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?** |  |  |
| 7.1 | 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………………………………….
 |  |  |
| 7.2 | In event of any of these risks, do protocols describe and outline clear strategies to mitigate against these risks? |  |  |
| 7.3 | Do study objectives show that risk is reasonable in relationship to expected gains? |  |  |
| 7.4 | Does study deliver potential benefits to subjects through provision of information or services? |  |  |
| 7.5 | If a subject discloses or is suspected to be at risk outside of the study, are procedures in place to address or report risk?  |  |  |
| 7.6 | Comments, amendments, additions, or revisions |  |  |
| Section**8** | ***Vulnerability:* When subjects are vulnerable to heightened risk have additional safeguards been included to protect their rights and welfare?** |  |  |
| 8.1 | Can subjects be perceived as vulnerable, including: children, especially unaccompanied or separated (UASC); women (especially pregnant women); 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; refugees in conflict, post conflict, transition or disaster settings, illegal or undocumented immigrants; persecuted minority groups, or under high familial, peer, or social pressure? If so, are study-specific protection protocols provided? |  |  |
| 8.2 | Does sample target people at risk for issues such as: violence, torture, or abuse; sexual exploitation, harassment, or abuse including prostitution or pornography, female genital mutilation, reproductive or sexual issues; sexual orientation; suicide, elder abuse? If so, are study-specific protection protocols provided? |  |  |
| 8.3 | Are subjects involved in any of the following: slavery, including the sale and trafficking of children; forced labour, war or armed conflict; illegal activities, production or trafficking of drugs; work that could damage health or safety? If so, are study-specific protection protocols provided? |  |  |
| 8.4 | Does the study request information perceived as sensitive within social, religious, or political context, or opinions where public disclosure may result in danger, limitations to future freedoms and access to services? If so, are study-specific protection protocols provided? |  |  |
| 8.5 | If children or other vulnerable groups are subjects, is recruitment done in a manner sensitive to potential vulnerabilities or weaknesses (real or perceived) subjects may have?  |  |  |
| 8.6 | Comments, amendments, additions, or revisions |  |  |
| Section**9** | ***Data Protection:* Do data collection and storage protocols adequately ensure subject & data safety?** |  |  |
| 9.1 | Are data collection tools appropriate and constructed to assure subject confidentiality or anonymity? |  |  |
| 9.2 | Do data collection procedures and environment ensure subject safety and data security? |  |  |
| 9.3 | Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type? |  |  |
| 9.4 | Do protocols describe chain of custody of data and protections for data transfer or transmission, analysis, storage, de-identification, and destruction? |  |  |
| 9.5 | Is future contact with subjects, if any, planned in a way that ensures data security? |  |  |
| 9.6 | Comments, amendments, additions, or revisions |  |  |