

HML Ethics Review Board

**How to Request a Research Ethics Review**

The purpose of Ethics Review Board (ERB) or Institutional Review Board (IRB) approval is the protection of human research participants’ rights, including *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.
1. MATERIALS REQUESTED - To request ERB approval for evidence generation, please provide the following:

1. **Inception Report** or **Research Protocol**, containing, e.g.,: specific aims or objectives, research questions, study design, subject recruitment, subject protection and data protection plans.

2. **Informed Consent** documents.

3. **Data collection** instruments.

**B. BACKGROUND INFORMATION** **- Please provide the following:**

|  |  |
| --- | --- |
| **Project Title:** |  |
| **HML IRB Research Ethics Review ID#:** | For HML IRB use - please leave blank |
| **Initiating UNICEF Official:**Name,CO, & RO |  |
| **Principal Investigator/Project Manager:** Name, degree(s), organization, & address |  |
| **Other Key Personnel:**Names & titles |  |
| **Contracting Firm:**Name & address |  |
| **Primary study site(s):**(e.g., country, province, region) |  |
| **Project duration:**(Dates from -- to) |  |
| **Duration of Subjects’ Participation:** (Dates from -- to)  |  |
| **Thematic Area/Areas:**Choose up to three that most closely match | Choose an item. Choose an item. Choose an item.  |
| **Target population:**Primary beneficiaries of your study |  |

## RESEARCH DESIGN - Please provide the following:

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| --- |
| Type of data collection: (Please attach for each type marked)1. survey questionnaire………………..………..…..
2. subject interview………………………..………..
3. key informant interview (KII)………..……….…..
4. focus group discussion (FGD)…………..….…..
5. secondary document (desk) review……………
6. on-site observation………………………………
7. case study………………………………………..
8. physical measurements ………………………..
9. biological specimen ……………….….…………
10. other..……………………………………………..
 |
| Number of Data Collections: 1. one-time (no follow-up) …………………………
2. two or more (follow-up) …………………………
 |
| Sample size: Approximate total *n* =  |
| Are any subjects children (<18 years old)?If yes, please provide ages: |

**D. SUBJECT RISKS - Please provide the following:**

|  |
| --- |
| 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…………………………………..….
10. other………………………………………………
 |

|  |  |
| --- | --- |
| **In our review we will ask you to describe:** | Please cite page references in documents |
| Procedures for mitigating subject risks |  |
| How you will protect subject safety throughout data collection, analysis, storage, and dissemination. |  |

##### E. SUBJECT RECRUITMENT

|  |  |
| --- | --- |
| **We will also you to describe:** | Please cite page references in supporting documents |
| How your subjects are recruited |  |
| How their names and PII are recorded and how they are protected |  |
| How you will provide special protections for children and other vulnerable subjects |  |
| Any incentives you will provide. |  |

**F. INFORMED CONSENT**

**Informed consent must be obtained** and should address the following in easy to understand statements:

* an explanation of the purpose of the study,
* a statement that participation is voluntary,
* an explanation of risks and benefits even if there are neither,
* a description of privacy and confidentiality procedures,
* the duration of subject’s involvement,
* permission to record audio, video, or notes, and
* your contact information for subjects with questions or concerns.

*For subjects younger than 18 years, informed consent from parents or guardians must be obtained.*

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| *Click here for a sample informed consent statement.* [*https://www.healthmedialabirb.com/informed-consent*](https://www.healthmedialabirb.com/informed-consent) |

***Please attach a copy of each informed consent document for IRB review****.*

|  |
| --- |
| **Plea Please respond here:** |
| Type of Informed Consent (Mark X all that apply):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……………..…….
7. active……………………………………………….
8. passive……………………………………………..
9. other ………………………………………….……
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|  |  |
| --- | --- |
| **In our review we will ask you to describe:** | Please cite page references in supporting documents |
| How, when, and where you will obtain consent from your subjects |  |
| How parental consent will be obtained for subjects under age 18 years |  |
| Informed consent for each subject and data collection type  |  |

#### G. SUBJECT & DATA PROTECTIONS

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| --- |
| To what extent are subjects identified: (Mark X all that apply)1. names are recorded with responses………….
2. names recorded separate from responses…..
3. no names are recorded ..………………………
4. other personally identifiable information

(PII) is recorded …………………………………1. no PII is recorded ………………………….……
2. subjects are given a unique identifier...............
3. other……………………………………….………
 |

|  |  |
| --- | --- |
| **We will also ask you to describe:** | Please cite page references in supporting documents |
| The environment to maintain subject’s safety and confidentiality throughout your study |  |
| Your staff’s training in research ethics  |  |
| Your staff’s experience working with children and vulnerable subjects |  |
| The chain of custody and destruction of your data |  |

Once you and ethics reviewers agree on safety protocols for your research participants, we will issue an approval letter.

Please submit your materials for review to:

D. Michael Anderson, PhD, MPH

HML IRB Chair & Human Subjects Protections Director

dma@hmlirb.com

and

Penelope A. Lantz, JD

HML IRB General Counsel

plantz@hmlus.com

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 subsequent reviews of that research independent of affiliation with the research organization submitting materials for review.