

HML Ethics Review Board

**How to Request a Research Ethics Review**

The purpose of an 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.

A. MATERIALS REQUESTED

To request ERB approval for evidence generation, please provide the following:

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.

Also, please provide:

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 or embedded in a single protection protocol.

**B. BACKGROUND INFORMATION**

**Please provide the following:**

|  |  |
| --- | --- |
| **Project Title:** |  |
| **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 one or more of the closest matches | Choose an item.  Choose an item.  Choose an item.  |
| **Target population:**Primary beneficiaries of your study |  |

## C. RESEARCH DESIGN

**Please provide the following:**

|  |
| --- |
| **1. Type of Data Collection***Please X all that apply* |
| Survey questionnaire |  | On-site observation |  |
| Subject interview |  | Case study |  |
| Key informant interview (KII) |  | Physical (body) measurements |  |
| Focus group discussion (FGD) |  | Biological measurements (samples) |  |
| Document review |  | Other (please specify) |  |

|  |
| --- |
| **2. Number of Data Collections***Please X all that apply* |
| One-time only (no follow-up) |  |
| Two or more (follow-up) |  |

|  |  |
| --- | --- |
| **3. Sample Size***Provide approximate total sample size* | Total N =  |

|  |  |
| --- | --- |
| **4. Participation of Children***Are any of your subjects less than 18 years old? If so, please provide their ages:* |  |

**D. SUBJECT RISKS**

**Please provide the following:**

|  |
| --- |
| **1. By their participation, are subjects vulnerable to any of the following?:***Please X all that apply* |
| Physical risk |  | Political risk |  |
| Psychological risk |  | Employment risk |  |
| Social risk |  | Academic risk |  |
| Economic risk |  | Religious risk |  |
| Legal risk |  | Other |  |

|  |  |
| --- | --- |
| **2. We will also ask you to describe:** | Please cite page references in supporting documents |
| Procedures for mitigating subject risks |  |
| How you will protect subject safety throughout data collection, analysis, storage, and dissemination. |  |

##### E. SUBJECT RECRUITMENT

**Please provide the following:**

|  |
| --- |
| **1. Subject Identification***Please X all that apply* |
| Subjects names are recorded with responses |  | No PII recorded |  |
| Names recorded separate from responses |  | Subjects given an unique identifier |  |
| No names recorded |  | Other |  |
| Other personally identifiable information (PII) |  |  |  |

|  |  |
| --- | --- |
| **2. We will also ask 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 notification that participation is voluntary,
* an explanation of the risks and benefits,
* a description of privacy and confidentiality,
* the duration of subject’s involvement, and
* contact information for subjects with questions or concerns.

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

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

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

**Please provide the following:**

|  |
| --- |
| **1. Type of Informed Consent***Please X all that apply* |
| Written and signed |  | Verbal not signed or recorded |  |
| Written not signed |  | Active |  |
| Written & signed by parent or guardian |  | Passive |  |
| Verbal & signed or recorded |  | Other |  |
| Verbal & signed by parent or guardian |  |  |  |

|  |  |
| --- | --- |
| **2. We will also 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

**Please provide the following:**

|  |  |
| --- | --- |
| **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.