# Appendix 2: Application to Involve Human Participants in Research

**INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)**

**THE AGA KHAN UNIVERSITY - KENYA**

**ETHICS REVIEW APPLICATION**

**Please refer to the Research Committee’s Letter of research/grant approval\_\_\_\_\_\_\_\_\_\_\_\_\_(Ref No). If you have questions about this form, please contact the Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Full Names) at**

**P.O. Box \_\_\_\_\_\_\_\_\_\_\_\_Code\_\_\_\_\_\_\_\_, Tel. \_\_\_\_\_\_\_\_\_\_\_\_\_ ext. \_\_\_\_\_\_\_\_\_Mobile\_\_\_\_\_\_\_\_\_\_**

**Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Date:**  |

**SECTION A – GENERAL INFORMATION**

1. **Title of the Research Project:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Key Words:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study Area:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(e.g Service delivery (Maternal health, Child health, nutrition, hygiene, sanitation, HiV, non-communicable diseases conditions etc). Medical products, vaccines and technologies. Health systems financing. Leadership and governance. Health information system. Human Resources for Health. Health Infrastructure, equipment. etc**)**

2. **Investigator Information (***Include the PI, Co-PIs and students/Trainees involved***)**

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|  | **Name & position** | **Dept./Address**  | **Phone No.**  | **E-Mail** |
| **Principal Investigator** |  |  |  |  |
| **\*Co-Investigator (1)**  |  |  |  |  |
| **Co-Investigator (2)** |  |  |  |  |
| **Student (1)** |  |  |  |  |
| **Student (2)** |  |  |  |  |

\*Add rows as necessary

3. **Proposed Date**

a) of commencement:\_\_\_\_\_\_\_\_\_\_\_\_ b) of completion:\_\_\_\_\_\_\_\_\_\_\_\_

(Note*: The commencement date is the date the researcher expects to actually begin interacting with human participants (including recruitment). The completion date is the date that the researcher expects that interaction with human participants, including follow-up, will be complete*.)

4. **Location/s** where the research will be conducted:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. **Other Research Ethics Committee/Board/IRB Approval**

1. Is this a multi-centred study? [ ]  **Yes** [ ]  **No**
2. Has any other institutional Ethics Committee/Board approved this project?

[ ]  **Yes** [ ]  **No**

If **Yes**, please provide the following information:

Title of the project approved elsewhere: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Name of the Other Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the Other Board: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of the Decision: \_\_/\_\_\_/\_\_\_\_\_\_

Attach copy of the clearance certificate / approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Will any other Research Ethics Board be asked for approval? [ ]  **Yes** [ ]  **No**

If **Yes**, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. **Level of the Project**

 Faculty [ ]

 Staff Research  [ ]

PhD Thesis  [ ]

Masters Thesis [ ]

[ ]  Undergraduate research [ ]

Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. **Funding of the Project**

* 1. Is this project currently funded? [ ]  **Yes**  [ ]  **No**
	2. Period of Funding: \_\_\_\_\_\_(dd/mm/yy) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to: \_\_\_\_\_\_\_\_\_\_(dd/mm/yy)\_\_\_\_
	3. Agency or Sponsor (funded or applied for): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	4. Amount: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. **Conflict of Interest**

1. Will the researcher(s), members of the research team, and/or their partners or immediate family members:
	1. Receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, etc.) as a result of or connected to this study? **Yes** **[ ]  No** **[ ]**
	2. If **Yes**, please describe the benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the general conduct of research.)

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1. Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor has placed on the investigator(s).

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1. Discuss the possibility of commercialization of the research findings., in any

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**SECTION B – SUMMARY OF THE PROPOSED RESEARCH**

9. **Rationale**

Describe the purpose and background rationale for the proposed project, as well as the hypotheses (is)/research questions to be examined.

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| **Synopsis:** **Aims/objectives:** **Significance/justification:** **Research questions:**  |

10. **Methodology**

Describe sequentially, and in detail, all procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements etc.)

***Note: Attach a copy of all questionnaire(s), interview guides or other test instruments.***

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| **Study Design****Subject Selection****Intervention****Methods of Data Analysis** |

11. **Experience**

What is your experience with this kind of research?

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12. **Participants**

Describe the number of participants and important characteristics (such as age, gender, location, affiliation, inclusion/exclusion etc.)

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13. **Recruitment**

1. Describe how and from what sources the participants will be recruited, including any relationship between the investigator(s) and participant(s) (e.g., instructor-student; manager-employee).

***Note: Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.***

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1. How and where will you contact these participants?

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1. Time required of participants: on occasion(s).

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1. Are participants proficient in the language in which the survey is being conducted?  Yes **[ ]** No **[ ]**

If not, is translation available? [ ]

 Yes **[ ]** No **[ ]**

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| If **No** to either of above, please provide details.  |

14. **Compensation**

1. Will participants receive compensation for participation?
	1. Financial[ ]   [ ]  **Yes**  [ ]  **No**
	2. Non-financial  [ ]  **Yes**  [ ]  **No**

If **Yes** to **either** i) or ii) above, please provide details.

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1. If participants choose to withdraw, how will you deal with compensation?

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**SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH**

15. **Possible Risks**

* 1. Indicate if the participants might experience any of the following risks: **Yes No**
		1. Physical risk (including any bodily contact or administration of any substance)? [ ]  [ ]
		2. Psychological risks (including feeling demeaned, embarrassed worried or upset)? [ ]  [ ]
		3. Social risks (including possible loss of status, privacy and/or reputation)? [ ]  [ ]
		4. Is there any deception involved? [ ]  [ ]
		5. Are any possible risks to participants greater than those the participants might encounter in their everyday life? [ ]  [ ]
	2. If you answered **Yes** to any of points i) through v) above, please explain the risk.

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* 1. Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

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16. **Possible Benefits**

Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific community/ society that would justify involvement of participants in this study.

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**SECTION D – THE INFORMED CONSENT PROCESS**

17. **The Consent Process**

1. Describe the process that the investigator(s) will be using to obtain informed consent, including a description of who will be obtaining the informed consent. If there will be no written consent form, explain why.

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***Note: Attach a copy of the Project Information Sheet( if applicable), the Consent Form (if applicable), the content of any telephone script (if applicable) and any other material which will be used in the informed consent process.***

1. Will the information provided to the participants be complete and accurate?

**Yes** **[ ]  No** **[ ]**

If no, please describe the nature and extent of the deception involved. Include how and when the deception will be revealed, and describe the specialized training of the person who will administer this feedback. It is recommended that participants have the opportunity to sign a second consent form, following debriefing when the deception is revealed, to ensure a fully informed consent.

***Note: Attach a copy of the debriefing feedback and, if necessary***

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18. **Consent by an authorized party**

If the participants are minors or for other reasons are not competent to consent, describe the proposed alternate source of consent, including any permission / information letter to be provided to the person(s) providing the alternate consent.

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19. **Alternatives to prior individual consent**

If obtaining individual participant consent prior to starting the research project is not appropriate for this research, please explain and provide details for a proposed alternative consent process.

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20. **Participant feedback**

Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research).

 ***Note: Please provide a copy of the written information, if applicable.***

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21. **Participant withdrawal**

1. Describe how the participants will be informed of their right to withdraw from the project. Outline the procedures that will be followed to allow the participants to exercise this right.

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1. Indicate what will be done with the participant’s data and any consequences for the participant of withdrawing from the study.

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1. If the participants will not have the right to withdraw from the project, please explain.

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**SECTION E – CONFIDENTIALITY**

**22. Ensuring confidentiality**

1. Will all participants be anonymous? [ ]  **Yes** [ ]  **No**
2. Will all data be treated as confidential? [ ]  **Yes** [ ]  **No**

*(Please note the difference: Participants’ identity/data will be confidential if an assigned ID code or number is used, but it will not be anonymous. Anonymous data cannot be traced back to an individual participant.)*

1. Describe the procedures to be used to ensure anonymity of participants and/or confidentiality of data both during the conduct of the research and in the release of its findings.

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1. Explain how written records, video/audio tapes and questionnaires will be secured, and provide details of their final disposal or storage.

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1. If participant anonymity or confidentiality is not appropriate to this research project, explain, providing details of how all participants will be advised of the fact that data will not be anonymous or confidential.

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**SECTION F – MONITORING ONGOING RESEARCH**

23. **Adverse events** (unanticipated negative consequences or results affecting participants) must be reported to the IERC as soon as possible.

24. **Additional Information**

(Use an additional page if more space is required to complete any sections of the form, or if there is any other information relevant to the project that you wish to provide to the IERC)

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**SECTION G – BRIEF CURRICULUM VITAE (**All Investigators/ Supervisors/ Students Involved)

*(copy this page as required)*

**Surname: First name:**

For monitoring purposes only please indicate: Sex: Nationality:

 **EDUCATION/TRAINING**

|  |  |  |  |
| --- | --- | --- | --- |
| Institution And Location | Degree | Completion Date | Field Of Study |
| 1. |  |  |  |
| 2. |  |  |  |
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| 4. |  |  |  |

Most recent posts held

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Types of posts held** | **Institution** | **Period** |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |

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| Recent publications: list only five most important and relevant publications or presentations over the last five years (papers in press or submitted for publication are also acceptable). *Please give full bibliographic reference [authors, title, journal, volume, page numbers, and year].* |

**SECTION H – SIGNATURES**

**Principal Investigator Assurance:**

As a Principal Investigator/Primary Supervisor, I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ have the ultimate responsibility for the conduct of the study, including performance of the project and protection of the participants. I have read and am responsible for the content of this application. If any changes are made in the above arrangements of procedures, or adverse events are observed, I will bring these to the attention of the IREC.

**Signature of Principal Investigator/Primary Supervisor Date**