THE AGA KHAN UNIVERSITY
NAIROBI

Applications for Scientific and Ethics Review

Principal Investigator

Are you the Principal investigator

- Yes
- No

Co-investigators

Co-investigator

Title

First Name

Surname

Organisation

Qualification

Address

Telephone

Email

Country

Please Select...

General Information

Short title of the Research Project.

The short title should be no more than 5 words

Sample Application Form

Full title of the Research Project

Key words

Principal Investigator Certificates

- ☐ CITI Courses (Specify)
- ☐ GCP
- ☐ GCLP
- ☐ Any other

Co-investigators certificates

- ☐ CITI
- ☐ GCP
- ☐ GCLP
- ☐ Any Other

What is the duration of the study?

Insert the duration in months

Proposed date of starting the study

Proposed date of completion

Funding for the study

Describe your source of funding for the study

Please Select...

Date when funding starts

Date when funding ends

State the location where the study will be conducted.

- [ ] Aga Khan University, Nairobi
- [ ] Other or additional

Level of the project

- ○ Faculty
- ○ Staff Research
- ○ PhD Thesis
- ○ Masters Thesis
- ○ Undergraduate Research
- ○ Other

Rationale

What are your study research questions and/or objectives?

What is the significance/justification for the study?

Methodology

Is your study prospective or retrospective?

- Prospective
- Retrospective
- Both prospective and retrospective

What is your study population?

What is your sampling strategy (Sampling frame)?

Explain your inclusion and exclusion criteria.

Describe your methods of data analysis.

What is your method for determining sample size?

What is your sample size?

Participants

Describe the participants (or your sample) and important characteristics (such as age, gender, location, affiliation, inclusion/exclusion e.t.c)

Approval by another Institutional Scientific Ethics Review Committee

Please indicate whether you are applying for a Full Committee Review (FCR), an Expedited Review, an Exemption from FCR or your study has been approved by a previous Kenya based ISERC.

Please Select...

Conflict of Interest

Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits?

- ☐ Yes
- ☐ No

The Consent Process

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.

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.

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

- ☐ Yes
- ☐ No

Attach a copy of the debriefing feedback if it will be provided.

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.

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.

Participant feedback

Explain what feedback/information will be provided to the participants and stakeholders 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).

Please provide a copy of the written information if applicable.

Transfer of Data emanating from the Research

What records, data or human biological specimens will you be using?

Please Select...

For each of the data sources, describe the methods you will use to uphold confidentiality

Will you require storage space for samples collected in this study? This may include refrigeration/freezer space or storage cabinets.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Will all the data be treated as confidential?

- ☐ Yes
- ☐ No

Describe the procedures to be used to ensure anonymity of participants or the data source.

Describe how Confidentiality of data collected will be maintained during the conduct of the research and in the release of its findings?

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

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

How will soft and hard data be transmitted among research personnel?

- ☐ Secure network
- ☐ Password access
- ☐ Data encryption
- ☐ Password protected files
- ☐ Automatic log-off
- ☐ Data de-identified by the research team
- ☐ Locked cabinet
- ☐ Data coded by the research team with a master list secured and kept separately
- ☐ Others

Will data be transferred outside the Aga Khan University Hospital - Nairobi?

- ☐ Yes
- ☐ No

Export of Biological Materials

Will human biological samples be transfered outside the Aga Khan University Hospital?

- ☐ Yes
- ☐ No

Are Material Transfer Agreements in Place?

- ☐ Yes
- ☐ No

Will subjects specimens be stored for future research?

- ☐ Yes
- ☐ No

Describe your plans for disposition of data and or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended.

Progress reports and Self assessment report

Upload your Annual Progress Report Form.

Upload your ERB Self Assessment Form

Serious Adverse Events Reporting

Upload a Serious Adverse Event report

Upload a SUSAR Report

Document submission

Please upload your study protocol

Please upload your study questionnaire available in any other language

Please upload the Materials Transfer Agreement - if any will be required in this study

Please upload the Data Transfer Agreement - if any will be required in this study

Please upload the NACOSTI permit (if applicable - If not, upload as soon as it is available

Please upload a brief curriculum vitae (upload for all Investigators, supervisors and students involved)

As a word document, upload a list of the most important and relevant publications or presentations over the last five years (papers in press or submitted for publication are also acceptable

Please upload your turn-it in report (anti-plagiarism report) for this study.

Please upload any other relevant document.

Signatures

Signature of the applicant

By signing this form I declare that all the information provided in this application form is correct and that all the details here-in are true to the best of my knowledge.

I agree to be held accountable for any false or plagiarized information that i have provided.

Once you have signed the form please remember to click the submit button on the left hand side.