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**Monitoring Ethical Compliance and Integrity in Research:**

**Self-Assessment tool**

**AKU- ERB**

**March 2021**

**Purpose:** This form is a tool for researchers to use as a self-assessment of their ERC approved study to ensure that the regulatory and institutional requirements for maintaining ethical compliance are met.

Principal investigators from all campuses are required to complete this mandatory self-assessment together with the annual progress report after receiving ERC approval.

The self-assessment is an institutional AKU requirement in order to achieve 100% monitoring of ethical compliance.

If you should have any questions or concerns regarding self-assessment, contact the respective Ethics Review Committees Offices.

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| --- | --- |
| Principal Investigator: |  |
| Title of Grant/Research Study:  |  |
| Co-Investigator(s): |  |
| Research Team: |  |
| Institution: |  |
| Department: |  |
| Sponsors/funding. (Select)  | **URC**/**Seed Money** □**External Funded**  *Local or* □ *Overseas* □**Self-Funded** □ |
| Date of ERC Approval: |  |
| ERC number: |  |
| Date of start of the project: |  |
| If the project has not commenced, or commencement delayed, advise when the project is expected to commence or whether the project is to be withdrawn or what is the reason for delay in starting the project work? |
| Date of Completion (If applicable) |  |
| Designated person for self –Assessment (If not PI) |  |
| Date of self-assessment/monitoring |  |
|  |  | **Date/Comments** |
|  | ERC approval for full review ( ) exemption ( ). | Yes | No |  |  |
|  | Any concerns/reservations from ERC addressed, in the process between submission and approval.  | Yes | No | NA |  |
|  | Approval/exemption from the national accreditation body (NBC/NACOSTI, IMRI) has been received. | Yes | No | NA |  |
|  | Progress report submitted to the ERC on time. (After One Year of the approval) *(If applicable)* | Yes | No | NA |  |
|  | ERC renewal obtained. *(If applicable)* | Yes | No | NA |  |
|  | ERC approval lapsed and research activities continued. | Yes | No | NA | If Yes, give reasons |
| **Comments:** |
| **Project Activities** | **Date/Comments** |
|  | The project is running in accordance, with the protocol approved by ERC | Yes | No | NA |  |
|  | Was there any protocol deviation? | Yes | No | NA |  |
|  | If yes for the Q 8- Action taken to avoid recurrence. | Yes | No | NA |  |
|  | If changes or deviation: ERC was informed for approval. | Yes | No | NA |  |
|  | Was ERC approval taken? | Yes | No | NA |  |
|  | Delegation of Authority (Responsibility) Log maintained \* | Yes  | No  | NA |  |
|  | Persons responsible to enroll study participants are qualified and have received the necessary training.  | Yes | No | NA |  |
|  | Persons responsible have full knowledge of the study protocol and risks associated with participation. | Yes | No | NA |  |
|  | Recruitment of participants has been duly supervised and was noted to be satisfactory with full disclosure. | Yes | No | NA |  |
|  | Well understood informed consent has been taken from every participant/surrogate according to the process described in the protocol | Yes | No | NA |  |
|  | Participants who want to withdraw from the study are facilitated to do so and their data has been removed | Yes | No | NA |  |
|  | Consent forms are appropriately signed by the participants. | Yes | No | NA |  |
|  | PI or delegated person has conducted a ***periodical*** review of all consent forms to ensure ethical compliance.  | Yes | No | NA | Daily/Weekly/Fortnightly/Monthly |
|  | Consent forms are stored securely and are available for audit. | Yes | No | NA |  |
|  | In the case of illiterate subjects, thumb impression was obtained in front of an impartial witness.  | Yes | No | NA |  |
|  | For the vulnerable participants consent from a surrogate in the presence of an impartial witness has been obtained.  | Yes | No | NA |  |
|  | In the case of children between 7 to <18 years of age: Parental consent and the child assent have been obtained. | Yes | No | NA |  |
|  | Healthcare waste produced in this research project is handled according to the established guidelines | Yes | No | NA |  |
|  | All necessary steps have always been taken to ensure the safety of the research team; especially during COVID pandemic. | Yes | No | NA |  |
| **Research Participants Safety.**  | **Date/Comments** |
|  | Risks to participants in the research have been identified and measures are taken to minimize them. | Yes | No | NA |  |
|  | Insurance/financial resource to cover adverse events/ harm is available and current during life of study. | Yes | No | NA |  |
|  | Compensation or medical treatment coverage is provided in accordance with the ERC approved consent form.  | Yes | No | NA |  |
|  | Reporting of adverse event (minor) was noted and ERC was informed. Was same reported within stipulated period? | Yes | No | NA |  |
|  | Reporting of the serious adverse event observed and immediately notified (within 24 hours) to respective ERC.  | Yes | No | NA |  |
| **Comments:**  |  |
| **Project related documents/Master folder** | **Date/Comments** |
|  | Study Master File (Investigator site file? ISF) containing signed protocol and amendments, regulatory approvals, delegation log, training logs, Study Specific SOPs, contracts and agreements, consent forms, data collection tools and complete record of correspondence with ERC. \*\* | Yes | No | NA |  |
|  | Documentation is up to date, accessible, clearly ordered and comprehensible for external monitors/sponsors review.  | Yes | No | NA |  |
| Comments: |  |
| **Integrity and safety of data** | **Date/Comments** |
|  | Physical security of data is adequately maintained. All consent forms, questionnaires and study-related documents are stored in a secure place. Only relevant persons can access the data.  | Yes | No | NA |  |
|  | Electronic data is secured, and password protected, and only relevant persons have access to electronic data. | Yes | No | NA |  |
|  | Ensured confidentiality and security of the data. | Yes | No | NA |  |
|  | The project is compliant with MTA and DTA.  |  |  |  |  |
|  | Disposal of residual biological material is in compliance with institutional policies. |  |  |  |  |
| **Comments:** |
| Principal Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

NA= Not Applicable

\* Delegation of Authority from PI- If applicable e.g. Clinical Trials, Clinical/Hospital Studies, Intervention Studies.

\*\*Master Folder includes,

* Protocol (All versions)
* ERC Correspondence including Letter of approval/Extension, Annual Report (if applicable).
* Approvals from National Accreditation Bodies.
* All CRFs
* Consent/Assent Forms.
* Questionnaire/s or any other data collection tool.
* Contract Agreements
* Training Logs and Certificate