**Application for ERC Approval Contact Information of Applicant & PI Project / PI / Applicant / Team Information**

|  |  |
| --- | --- |
| Date: | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |
| Short Title of Study: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Full Title of Study: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. | **Principal Investigator details:** | | | **Remarks** |
|  | Title |  | |  |
|  | First Name: |  | |  |
|  | Surname |  | |  |
|  | Department |  | |  |
|  | Designation |  | |  |
|  | Campus |  | |  |
|  | Country |  | |  |
|  | Telephone |  | |  |
|  | Ext. |  | |  |
|  | Email |  | |  |
|  | Please attach your basic biomedical research certificate from CITI “Collaborative Institutional Training Initiative” OR the certificate of GCP training program conducted by AKU. |  | |  |
|  | Expiry date of certification | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ | |  |
| 2. | **Departmental Coordinator/Representative details:** | | |  |
|  | Title | |  |  |
|  | First Name: | |  |  |
|  | Surname | |  |  |
|  | Department | |  |  |
|  | Designation | |  |  |
|  | Campus | |  |  |
|  | Country | |  |  |
|  | Telephone | |  |  |
|  | Ext. | |  |  |
|  | Email | |  |  |
|  | Please attach your basic biomedical research certificate from CITI “Collaborative Institutional Training Initiative” OR the certificate of GCP training program conducted by AKU. | |  |  |
|  | Expiry date of certification | | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 3. | **Team Member details:** | |  |
|  | Title |  |  |
|  | First Name: |  |  |
|  | Surname |  |  |
|  | Department |  |  |
|  | Designation |  |  |
|  | Campus |  |  |
|  | Country |  |  |
|  | Telephone |  |  |
|  | Ext. |  |  |
|  | Email |  |  |
|  | Please attach your basic biomedical research certificate from CITI “Collaborative Institutional Training Initiative” OR the certificate of GCP training program conducted by AKU. |  |  |
|  | Expiry date of certification | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |  |
|  | (certificate question repeat with all members) | |  |
| 4. | Is this study a part of students/resident synopsis? | Yes 1  No 2 |  |
| 5. | If yes, Program  (Exclude resident, fellow and faculty research from) | Resident 1  Fellow 2  PhD. 3  MSc. 4  MScN 5  Med. 6  MHPE 7  MPhil 8  MMed 9  MA 10  Faculty Research 11  Others.(Please Specify) 98 |  |
| 6. | Is the study: (Choose option) | Non-Funded 1  Funded or sponsored, please select (dropdown list) 2  URC 3  Seed Money 4  HEC 5  Department Fund 6  External / 7  Others please specify: 98 |  |
| 7. | If Funded or sponsored, Please select | Received 1  In process 2 |  |
| **Page # 1 - Conflict of Interest** | | | |
| 1. | Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have: | |  |
| a. | A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? | Yes 1  No 2 |  |
| b. | A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project? | Yes 1  No 2 |  |
| c. | A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? | Yes 1  No 2 |  |
| d. | A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project? | Yes 1  No 2 |  |
| 2. | Has the University or has a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team? | Yes 1  No 2 |  |
| 3. | Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project? | Yes 1  No 2 |  |
| **Type of ERC Approval** | | | |
| 1. | Please indicate whether you are applying for ERC exemption or full committee review or your study has already been approved by the previous ERC? | Exemption 1  Full review (If select Exemption) 2  Approved by Previous ERC 3  4 |  |
| a. | If check Exemption | Experimental drug(s) 1  Radioactive agents 2  Non-therapeutic research 3  Non-approved use or non-approved dose for approved drugs 4  Experimental surgical procedures 5  Fetal research 6  Behavioral research 7  Gene molecular cloning 8  Nutritional Research/survey 9  Observational research 10  Registry 11  Clinical Trial 12  (If Clinical Trial: please upload the approval from CTU)  Other (please specify) 98 |  |
| 2. | Is the activity a systematic investigation designed to contribute to generalizable knowledge? | Yes 1  No 2 |  |
| 3. | Does the research involve obtaining information about living individuals? | Yes 1  No 2 |  |
| 4. | Does the research involve intervention or interaction with the individuals? | Yes 1  No 2 |  |
| 5. | Is the information individually identifiable? | Yes 1  No 2 |  |
|  | (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) | | |
| 6. | Is the information private? | Yes 1  No 2 |  |
|  | (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public) | | |
| 7. | Does the research involve collection or study of existing data, documents, records, or pathological or diagnostic specimens? | Yes 1  No 2 |  |
| a. | Are these sources publicly available? | Yes 1  No 2 |  |
| 8. | Does this research involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior? | Yes 1  No 2 |  |
| 9. | Does the research involve children? | Yes 1  No 2 |  |
| 10. | Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects? | Yes 1  No 2 |  |
| 11. | Does the research involve studying, evaluating, or examining public benefit or service programs? | Yes(if yes go to Q 11 a) 1  No (if no page end) 2 |  |
| 11a | (a) Is the research or demonstration project conducted or approved by the Government Department or Agency Head? |  |  |
| 12. | What records, data or human biological specimens will you be using?  [Multiple answer] | Data already collected for another research study 1  Data already collected for administrative purposes (e.g. hospital discharge data) 2  Medical records 3  Electronic information from clinical database  4  Patient specimens (tissues, blood, serum, surgical discards, etc). 5  Other 98 |  |
| 13. | For each of the data sources describe the methods to uphold confidentiality. | Yes 1  No 2 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Details** | | | |
| 1. | Why are you doing this study (study rationale)? |  |  |
| 2. | What are your study objectives? |  |  |
| 3. | Brief Summary of Proposal including methodology (<100 words) |  |  |
| 4. | **Study Duration?** | |  |
|  | End date of study | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |  |
|  | End date of study | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |  |
|  | Total Duration (in days, weeks, months and year) | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |  |
| 5. | What is the sample size? |  |  |
| 6. | What is the source population? |  |  |
| 7. | What is the sampling strategy and enrolment method |  |  |
| 8. | What is the inclusion and exclusion criteria? |  |  |
| 9. | Is permission needed from any higher authorities for the study?  (school principals, facility directors, hospital or healthcare system administrators) |  |  |
| 10. | What is the study design? |  |  |
| 11. | What interventions / interaction will the research subject undergo if they enroll in this study? Please state in detail. |  |  |
| 12. | What is the duration of an individual subject's participation, including follow-up evaluation if applicable? Please include the number interactions with each participant. |  |  |
| 13. | Where will the interaction / intervention with the research participants take place?  Describe locations where subjects will be studied, both on and off the AKU/AKUH campus |  |  |
| 14. | What benefits, if any, are expected for the society from this study? |  |  |
| 15. | What benefits, if any are expected for the research subjects upon participation in this study? |  |  |
| 16. | What benefits, if any are expected for the University upon approval of this study? |  |  |
| 17. | Inducements for participation. Describe all inducements to participate, monetary or non-monetary. If monetary, specify the amount and schedule for payments and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it. For compensation in foreign currency, provide a US$ equivalent. Provide evidence that the amount is not coercive. |  |  |
| 18. | Direct or Indirect costs to be borne by subjects. Includes child care, travel, parking, clinic fees, diagnostic and laboratory tests, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this. |  |  |
| 19. | List all potential risks to the participants if they enroll in this study. |  |  |
| 20. | State all measures that you are taking to mitigate these risks. |  |  |
| 21. | Describe procedures for maintaining confidentiality of the data you will collect or will receive. |  |  |
| 22. | How will soft and hard data be transmitted among research personnel? | Secure network  Password access  Data encryption  Password protected file(s)  Automatic log-off  Data de-identified by research team  Locked cabinet  Data coded by research team with a master list secured and kept separately  Others please specify |  |
| 23. | With whom will the data be shared outside the immediate AKU research team? For each, explain confidentiality measures. |  |  |
| 24. | Will data be transferred outside this country? | Yes 1  No 2 |  |
| 24a. | **Are data transfer agreements in place?** | Yes 1  No 2  In process 3 |  |
| 25. | Will human biological samples be transferred outside this country? | Yes 1  No 2 |  |
| 25a. | **Are data transfer agreements in place?** | Yes 1  No 2  In process 3 |  |
| 26. | Will subjects' specimens be stored for future research? | Yes 1  No 2 |  |
|  | Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. |  |  |
| **Consent details** | | | |
| 1. | Describe the process of obtaining informed consent from subjects. |  |  |
| 2. | Are you applying for a waiver of written (i.e., signed) consent? | Yes 1  No 2 |  |
| 2a. | The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). Participants should be asked whether they want documentation linking them with the research and the participants’ wishes will govern whether they sign the form. Note: This justification cannot be used in FDA-regulated research. | Yes 1  No 2 |  |
| 2b | The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey). |  |  |
| 3. | Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope). |  |  |
| **Upload documents** | | | |
| 1. | Please attach your study protocol. | (Mandatory) 1  Upload Document 2 |  |
| 2. | Please upload your study tool/proforma (English). | (Non-Mandatory) 1  Upload Document 2 |  |
| 3. | Please upload you study questionnaire (Urdu or any other languages), if applicable. | (Non-Mandatory) 1  Upload Document 2 |  |
| 4. | Please upload your English Consent (Urdu or any other language, if applicable) | (Non-Mandatory) 1  Upload Document 2 |  |
| 5. | Upload any other documents if applicable. | (Non-Mandatory) 1  Upload Document 2 |  |
| **Principal Investigators Signature** | | | |
| 6. | Are you submitting this application as PI? | Yes 1  No 2 |  |
| 7. | Request Signature |  |  |
| 8. | Name of Departmental Research Committee (DRC) Chair |  |  |
| 9. | Request DRC chair Signature (mandatory) |  |  |