**Expedited Bioethics Review Form (2)**

For a Proposed Research Study on Human

**Part I: Form Suitability Checklist:**

**Your answers to items of this checklist review assess whether the "Expedited Assessment Form 2" is appropriate for the proposed research study.** To assure the suitability of the current Expedited Assessment Form 2 vs. the Comprehensive Assessment Form 3, complete the following checklist by ticking **"Yes", "No" or "Not Applicable"** boxes.

In case you answered "No" to any item of items numbered 9-13 or answered "Yes" to any item of items numbered 14-18, the current Expedited Assessment Form 2 is not appropriate for your research proposal. Therefore, you are requested to complete the Comprehensive Assessment Form 3.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Items** | **YES** | **NO** | **Not Applicable** |
| **1** | The proposed research is consistent with Sharia law and other regulations in the Kingdom of Saudi Arabia. | **[ ]**  |  |
| **2** | Participation is Voluntarily.  | **[ ]**  |  |
| **3** | Participants are adults and the study **Does Not** enroll vulnerable population group, e.g., pregnant women, fetus or the underage? | **[ ]**  | **[ ]**  | **[ ]**  |
| **4** | The proposed research **Does Not** disclose the identity of the participants or collect personal data. | **[ ]**  | **[ ]**  | **[ ]**  |
| **5** | The potential risks participants may be exposed to would not exceed the minimal. | **[ ]**  | **[ ]**  | **[ ]**  |
| **6** | The proposed research consists of observations, interview or surveys only on adult population. | **[ ]**  | **[ ]**  | **[ ]**  |
| **7** | Data analysis using demographic variables will be done. | **[ ]**  | **[ ]**  | **[ ]**  |
| **8** | No secondary analysis using prohibited data or identification will be done. | **[ ]**  | **[ ]**  | **[ ]**  |
| **9** | The drugs or other pharmaceutical agents used in the proposed research are according to licensure and health regulations in the Kingdom of Saudi Arabia.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **10** | The drug usage does not include increasing or decreasing of the recommended dosage that may lead to potential risks.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **11** | The medical device/instrument used in the proposed research is approved by regulatory body and is being used as licensed.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **12** | Biological samples for the proposed research are collected using noninvasive techniques (Urine, saliva, nails, hair, mouth wash, etc.). | **[ ]**  | **[ ]**  | **[ ]**  |
| **13** | Data will be collected using licensed medical equipment/instruments according to the related regulations. | **[ ]**  | **[ ]**  | **[ ]**  |
| **14** | The research proposal is to utilize X-ray, electromagnetic waves or inject radioactive agents.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **15** | One of the research aims is to introduce a new drug.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **16** | One of the research aims is to introduce a new medical device. | **[ ]**  | **[ ]**  | **[ ]**  |
| **17** | One of the research aims is to collect sample by invasive techniques and/or conduct invasive or interventional procedure.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **18** | The proposed research aims to discover previously unknown potential risks.  | **[ ]**  | **[ ]**  | **[ ]**  |

\* Participation in the current research is voluntarily and based on informed consent. Participants must be aware of all circumstances related to their participation and kept updated throughout the research process of any arising information that may otherwise affect their decision to continue participating in the study.

**Part II: Required Information:**

**\*The following information/documents must be included in the application:** Updated CVs/bibliographies of the university affiliated and unaffiliated investigator(s). The research protocol explaining previous national and international reports, hypothesis/rationale/reasons for conducting the investigations, innovation aspect of the project, research setting and methods that also explain sample description and size calculation, funding sources, conflict of interests (social, commercial or financial), and Gantt Chart of the project schedule. Investigators must pledge not to change any of the research plan/methods or use data and samples for other objectives or hand them to the others except after applying for an approval from the committee. If a survey questionnaire will be used, its language must be suitable for the targeted population, its source and permission for used must be stated, otherwise, its validation method must be stated. A copy of the questionnaire should be submitted. Similarity index of the project text must not exceed the allowable 25% (No more 10% from a single source). Investigators must sign all the submitted documents. Certificates of earning the electronic workshop for bioethics and other related mandatory training workshops must be attached (<http://bioethics.kacst.edu.sa/Register/register-resercher.aspx>).

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest

**Title of the study: ………………………………….**

**Objective of the study** (summary - do not exceed three sentences): ……………………………………………………………………………………..……………………………………………………………………………………………………………..………………………………………………………………………………………………

Application Type (specify all that apply): [ ]  New [ ]  Renewal for 3 years [ ]  Amendment of a previously approved application (Approval #):

Type of The Study: [ ]  Postgraduate Research [ ]  PhD Thesis [ ]  Master Thesis [ ]  Higher Diploma Project [ ]  University Degree graduation or Course-based Project [ ]  Other

Type of the Project: [ ]  Research [ ]  Educational (Course code: XXX) [ ]  Community service [ ]  Field study

Expected date for Project Start:

Date Experimentation on living organisms Starts (If different than the project start date):

Expected Date for Project Completion:

Type of Living Organisms Used:

Size of sample (no of participants/ subjects) Required:

**Part III: Information of the Primary Investigator and Co-Investigators:**

|  |
| --- |
| **Name and Qualifications of the Primary Investigator (Research Supervisor):**  |
| **College / Department:**  |
| **Email:**  |
| **Postal Address:**  |
| **Telephone No / Extension:**  |
| **Emergency contact # (Mobile phone):**  |
| **Co-Researchers** | **Co-Investigator 1** | **Co-Investigator 2** | **Co-Investigator 3** |
| **Full Name** |  |  |  |
| **Qualifications** |  |  |  |
| **College / Dept.** |  |  |  |
| **Postal Address** |  |  |  |
| **Mobile/Landline Tel.#/Ext.** |  |  |  |
| **Email** |  |  |  |

**I certify that all data provided in this form are correct, and by signing below, I agree to abide by the university bioethics standards.**

**Signature of Primary Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Part IV: The Committee Decision for the Expedited Assessment Application:**

**For Committee Use Only**

Approval (\_\_\_\_\_\_\_\_\_\_\_\_) Rejection (\_\_\_\_\_\_\_\_\_\_\_\_)

**Reasons for Rejection:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **18** | **17** | **16** | **15** | **14** | **13** | **12** | **11** | **10** | **9** | **8** | **7** | **6** | **5** | **4** | **3** | **2** | **1** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Committee's Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**