Prince Sultan University

PSU Institutional Review Board

**Application for Human Participants Review**

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| **Note:** * Before completing application, investigators must consult guidance available at [National Committee of Bioethics (NCBE), King Abdulaziz City for Science and Technology (KACST), Saudi Arabia]:

http://bioethics.kacst.edu.sa/Document/Regulations/Ethics-Rugl-English.aspxhttp://bioethics.kacst.edu.sa/Document/Bioethic-Rgl-fin-bks.aspxhttp://bioethics.kacst.edu.sa/Researchers/Rules-and-regulations/Conducting-research-on-humans.aspx * This form serves as both a decision-making tool and application for PSU IRB approval of research projects involving human subjects.
* All items must be completed, and the form must be typed and submit electronically (with signature) to the PSU Institutional Review Board (irb@psu.edu.sa).
* Submission of this application indicates that the Principal Investigator (PI) and Faculty Advisor (if student PI) acknowledge they are responsible for ensuring that all personnel comply with National Committee of Bioethics (NCBE).
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**Expedited Review (Article (10.18 of Royal Decree No. (M / 59) - National Committee of Bioethics)**

**Article (10.18)**

The local committee may approve certain research by using the expedited review procedure in the following cases:

1. If the risk that the human subject may be exposed to does not exceed the minimal risk level;

2. If the research does not reveal the identity of the human subject;

3. If the research deals with clinical studies on drugs or medical equipment, provided:

a. The drug is used in accordance with its licensing and dosages approved by the concerned party, and does not entail any increase in potential risk for the human subject;

b. The medical equipment in use has originally been licensed by the concerned party and has already been utilized accordingly.

4. If taking biological samples for research purposes is carried out via non-invasive methods such as analysis of urine, saliva, nail or hair clippings, etc.

5. If research data is to be collected by using medical equipment approved by the concerned party, such as:

a. Sensors which are directly applied on body surface or at a close distance thereto and which do not expose the body to a significant amount of energy and do not violate the privacy of the human subject;

b. Weight taking or audiometry devices;

c. Magnetic resonance imaging (MRI) or ultrasonography imaging devices;

d. Electrography (ECG & EEG), Thermal Imaging, normal nuclear radiation rate measuring, infra-red imaging, blood flow measurement with ultrasound imaging (Doppler sonography), and echocardiography devices;

e. Moderate exercise, muscle strength, body ratios (such as body fat ratio) and measurement of joint and muscle flexibility devices, provided these tests are deemed appropriate after taking age, weight and health condition into account;

f. Search for information, records or samples that were previously collected or will be collected in the future for non-research purposes;

g. Collect information via audio or video taping (static or moving) for the purpose of looking for the attributes or behavior of an individual or group without violation of privacy of the human subject.

However, excepted from these devices is the use of X-ray or electromagnetic microwave devices.

**Exemptions from PSU IRB Review (Article (10.23, 10.32 and 10.33 of Royal Decree No. (M / 59))**

**Article (10.23)**

1. If the principal investigator wishes to amend the research proposal approved by the local committee, he shall submit the matter to the local committee to obtain its approval prior to proceeding with the amendment.

2. The following may be exempted from local committee review:

a. Amendment of advertising material used for inviting human subjects, provided said amendment does not disrupt the content of such material;

b. Amendments that only include providing administrative support to the study;

c. Enrolling samples or cases brought from outside the establishment with the same terms.

3. In all cases, the principal investigator shall furnish the local committee with a detailed report on the amendment he has carried out.

**Article (10.32)**

The local committee may exempt the following research projects from the periodic follow-up:

1. Research involving study of information and data previously collected, provided one of the two following terms is fulfilled:

a. If the information is generally and publicly available;

b. If the information is recorded in a manner that does not reveal the identity of the source person.

2. Research including educational tests, surveys, interviews or public behavior monitoring, except in the two following cases:

a. If the information is recorded in a manner that reveals the identity of the source person.

b. If participation in the research should bring a person outside the scope of research to be subject to criminal or civil liability or jeopardize his financial position or career.

3. Research conducted for educational purposes.

**Article (10.33)**

2. As an exception from the provision of the preceding paragraph 1 hereabove, the local committee may exempt certain research projects that it has previously approved from periodic evaluation in either of the following cases:

a. If the only objective of research continuation is a long-term monitoring of persons who took part in the research and no additional risk emerged in the research;

b. If the research is nearly finished and only analysis of data and conclusion of results are remaining.

3. After the periodic assessment of the research is carried out, the local committee shall issue a decision including its approval or rejection of continuation of the said research.

**Full Board Review**

For certain kinds of research/project involving high level of risk, proposal is presented and discussed at a meeting.

For the research/project to be approved, it must receive the approval of a majority of the PSU IRB committee members present.

**SECTION 1: Types of Review *[to be completed by all applicants]***

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|  Expedited Review Full Board Review Exemptions from PSU IRB Review  |

**SECTION 2: General Information *[to be completed by all applicants]***

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| 1. **Title of proposal:**
 | **Click here to enter text.**  |

1. **Principal Investigator(s) details:**

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| --- | --- | --- | --- | --- | --- |
| NAME  | COLLEGE | ADDRESS | EMAIL ADDRESS | PHONE | ROLE |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text | Choose an item |

1. **Faculty Advisor\* details (if applicable):**

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| --- | --- | --- | --- | --- | --- |
| NAME  | COLLEGE | ADDRESS | EMAIL ADDRESS | PHONE | ROLE |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text | Choose an item |

\*Faculty Advisor: Details are needed for undergraduate and graduate students.

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| 1. **PI Status:** Faculty Undergraduate Student Graduate Student Staff Non-PSU
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 ***If Non-PSU****:* Will research be conducted outside of Saudi Arabia? Yes No

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| 1. **Project Type:** Faculty/Staff Research Thesis/Dissertation Other-specify:
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1. **Project timeline:** From **Click here to enter a date** To **Click here to enter a date**
2. **Source of Funding: (if applicable):**  **Click here to enter text.**
3. **Study Location:**  **Click here to enter text.**
4. **Data Collection timeline:** From **Click here to enter a date** To **Click here to enter a date**

**SIGNATURES:**

In signing this form the applicant confirms that:

1. This application represents an accurate and complete description of the proposed research;
2. The research will be conducted in compliance with the recommendations of and only after approval has been received the PSU IRB.
3. The PI is responsible for reporting any adverse events or problems to the IRB, for requesting prior IRB approval for modifications, and for requesting continuing review and approval.

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| Principal Investigator | **Click here to enter text.**  |  | **Click here to enter a date**  |
| typed name |  Signature |  DATE |
| Faculty Advisor (required for all student projects) | **Click here to enter text.**  |  | **Click here to enter a date**  |
| typed name  |  SIGNATURE |  DATE |

**PSU IRB Committee Use Only**

 Expedited Review Full Board Review Exemptions from PSU IRB Review

**DeCISION**: Approvals Approvals with Modifications DENIALS

REVIEW Committee CHAIR signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date

Period of approval: From **Click here to enter a date** To **Click here to enter a date**

**SECTION 3: Research Proposal *[to be completed by all applicants]***

**A. PURPOSE OF RESEARCH**

Explain 1) why this research is important and what the primary purposes are, 2) what research question(s) or hypotheses this activity is designed to answer, and 3) whether and how the results will be used or disseminated to others.

1) **Click here to enter text.**

2) **Click here to enter text.**

3) **Click here to enter text.**

**B. RESEARCH METHODS**

1. Check the research data collection that may be associated with your project:

 Paper questionnaires, surveys, or tests (attach instruments)

 Online questionnaires, surveys, or tests (attach instruments)

 In-person interviews or focus groups (attach initial questions)

 Phone or online interviews (attach initial questions)

 Collection of artifacts (e.g. photos, work samples or essays)

 Collection of analysis of biological samples

 Behavior observation/experiments

 Physical activities or interventions

 Review of existing datasets or records

 Others specify: **Click here to enter text.**

1. Summarize the methods you intend to use; setting and recruitment; data collection tools. State how data will be managed, i.e. statistical tests/coding of qualitative texts; use of software applications such as SPSS or NVivo.

 **Click here to enter text.**

**C. EXISTING DATASET/SECONDARY DATA**

1. Are the data existing at the current time? Yes No Not Applicable
2. What/who is the source from which the data set was obtained? **Click here to enter text.**
3. Is it a public use data file (access is available without permission)?

 Yes  No

3a)***If no,* attach a letter** of cooperation or agreement for the data access.

**Click here to enter text.**

1. Future Use of data: Do you anticipate using these data for other studies in the future?

 Yes No

***If yes, please explain.***  **Click here to enter text.**

**D. PARTICIPANTS**

1. Number of participants: **Click here to enter text.**

2. Age(s)/Age Range of the participants: **Click here to enter text.**

1. Will children and/or adolescents (individuals 17 and under) be included in this research?

  Yes  No

**E. PARTICIPANT RECRUITMENT**

1. Describe how you will contact potential participants in order to seek permission to use their data. If you plan to contact them verbally, in person or over the telephone, you must provide a script of what will be said.

 **Click here to enter text.**

1. How will you protect participants’ privacy during recruitment?

 **Click here to enter text.**

1. What relationship, if any, is there between the potential participants and the PI and/or any other members of the research team?

 No relationship Personal friends or family Students Employees

 Others specify: **Click here to enter text.**

***If any relationship, please explain.*** what steps you will take during the recruitment process to minimize potential undue influence, coercion, or the appearance of coercion.

 **Click here to enter text.**

4. Will you give participants compensation (cash, gifts, payments, and/or services without charge)?

 Yes No

 ***If yes, explain****:* **Click here to enter text.**

**F. RISKS AND BENEFITS**

1. All research carries some potential for risk (e.g., social, economic, emotional, psychological, or physical risk). Check all potential risks that may be associated with your project at some level:

 Inconvenience or time (all studies have this)

 Emotional discomfort, stress, or distress

 Risks to privacy or dignity

 Risks to social reputation

 Legal risks

 Financial risks

 Other – describe: **Click here to enter text.**

1. Describe the nature and degree of possible risks associated with your study procedures.

  **Click here to enter text.**

1. Explain what steps you will take to minimize the risks of harm and to protect participants’ confidentiality, and rights.

**Click here to enter text.**

1. Describe the anticipated benefits of this research for individual participants. If none, state “None.”

**Click here to enter text.**

1. Describe the anticipated benefits of this research for the field or society, and explain how the benefits outweigh the risks.

**Click here to enter text.**

**G. CONFIDENTIALITY**

1. Will you record any demographic data or direct participant identifiers? **Choose an item.**

 Name

 Addresses

 Age

 Ethnicity

 Gender

 Income

 Job title/Name of Employer

 Marital Status

 Student ID

 Phone Numbers

 IP addresses (collected by online survey)

 Photographs or videos

 Audio recordings

 Other – describe: **Click here to enter text.**

1. Explain why it is necessary to maintain such identifiers and describe the coding system you will use to protect against disclosure.

**Click here to enter text.**

1. Will you retain participants’ direct identifiers after the data collection is complete?

 Yes  No

1. Describe what procedures will be used to ensure secure storage of data (e.g. survey responses, interviews etc.) during the course of the project. Specify who will have access to these materials.

**Click here to enter text.**

1. How long will you keep the study data?

**Click here to enter text.**

**H. CONSENT FORMS/PROCESS** (Check all that apply.)

 **Written Signed Consent** - Attach a copy of all consent forms.

 **Oral Consent** - Provide a) justification for not obtaining written consent

 **Click here to enter text.**

 **Elements of Consent Provided via Letter or Electronic Display** – Provide a) justification for not obtaining written consent, and b) the text for the letter of consent or the electronic display.)

  **Click here to enter text.**

**I. Application and Attachment Checklist**

1. All questions are answered Yes No
2. Data collection instruments (e.g. surveys/interview questions etc.) are attached.

 Yes No

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| If you have any questions or need assistance, please contact the PSU IRB Committee: |
| Dr. Mohammad Nurunnabi CMA, FAIA(Acad), SFHEA, FRSAChair, PSU Institutional Review Board (IRB)Phone: +966 11 494 8130 |
| Email: irb@psu.edu.sa |