**Comprehensive Bioethics Review Form (3)**

For a Proposed Research Study on Human

**\*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>).

**Section I: General Information:**

**Nature of the Study:** Tick (√) in the right place.

|  |  |  |  |
| --- | --- | --- | --- |
| Higher diploma research Project | [ ]  | Faculty staff member research Project | [ ]  |
| Graduation or Course-Based Research Project | [ ]  | PhD Thesis Research Project | [ ]  |
| Research Project for Others Parties (Specify): | [ ]  | Master Thesis Research Project | [ ]  |

\***The Study Title:**.......................................................................................................................................

**Aim of the study:** (No more than three sentences).

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**Personal and Contact Information of the Principal Investigator and Co-Investigators:** (In case co-investigator(s) is/are student, provide their information only in case they proposed the project idea).

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Principal Investigator** | **Co-Investigator 1** | **Co-Investigator 2** |
| Full Name: |  |  |  |
| Department and College: |  |  |  |
| Postal Address: |  |  |  |
| Mobile/Landline Tel.#: |  |  |  |
| Emergency Contact Number:  |  |  |  |
| E-mail: |  |  |  |

**Checklist to determine Bioethics assessment type**

Answer Yes or No for each item in the table below. If you answer **Yes** to any of the following items, you must then continue completing this Comprehensive Review Form (3), as your proposal does not qualify for the Expedited Review (Form 2).

|  |  |  |
| --- | --- | --- |
| Item | Yes | **No** |
| Does the proposed research conflict with any Sharia law and other regulations in the Kingdom of Saudi Arabia? | [ ]  | [ ]  |
| Does the project enroll vulnerable population groups, e.g., pregnant women, fetus or minors?\* | [ ]  | [ ]  |
| Does the proposed research disclose the identity of the participants or collect personal data? | [ ]  | [ ]  |
| Does the potential risk to which the participants are subjected to exceeds the minimum risk level?  | [ ]  | [ ]  |
| Is any of the project's procedures or methods designed on bases other than the acceptable conventional scientific methods that may endanger human participants? | [ ]  | [ ]  |
| Will any drug be used in this research in ways and quantities that are inconsistent with the approved license for the drug use and dosage? | [ ]  | [ ]  |
| Will any medical device/instrument be used in this research in ways that are inconsistent with the approved usage license for the medical device/instrument? | [ ]  | [ ]  |
| Will any of the collected biological sampling be taken through invasive means? **\*\*** | [ ]  | [ ]  |
| Does the methods increase or decrease drug dosage than conventional that may aggravate the damage? | [ ]  | [ ]  |
| Does the research being undertaken to identify potential new risks? | [ ]  | [ ]  |
| Does the project apply X-rays or micro-electromagnetic waves or inject radioactive materials to participants? | [ ]  | [ ]  |
| Does the project introduce a new drug? | [ ]  | [ ]  |
| Does the project introduce a new medical device/instrument? | [ ]  | [ ]  |
| Does the project apply a surgical or interventional procedure? | [ ]  | [ ]  |
| Does the proposal employ observations, interviews, questionnaires or surveys to collect data relevant to special needs, demographic, community or ethnic groups? | [ ]  | [ ]  |

\*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.

\*\* Does not include urine, faces, saliva/mouth wash, mucosal scraping, nail clippings, hair, etc.



**Section II: Collaborating Parties and Facilities and Required Approvals:**

Will the research procedures be done only within the premises if Jouf University? Yes (\_\_), No (\_\_). If Yes, move to Section III. If No, continue filling the following table.

**Collaborating Parties through Agreements with Jouf University:**

The university has formal agreements with the Directorate of Health Affairs of Al-Jouf, Camels and Pastures Research Center, Al-Jouf District Police, Water Directorate, and some other parties to facilitate conducting vital researches. However, the research approval from the Permanent Jouf University Bioethical Committee does not waive securing the required research approvals from the other parties. For more information, contact the committee.

Dear Researcher, if you are collaborating with one of the parties mentioned in the table below or you have one or more approval form their side to conduct research within their premises, highlight it. Mark with (√) in the right place and complete the table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TheFacility Name | Its affiliation | Nature of their participation (%, registration, approval of the research, etc.) | Approval Information | √ |
| King Abdulaziz Specialist Hospital |  |  |  | [ ]  |
| Prince Metab bin Abdul Aziz General Hospital  |  |  |  | [ ]  |
| Maternity and Child Hospital |  |  |  | [ ]  |
| Clinics of the Faculty of Dentistry |  |  |  | [ ]  |
| Al-Qurayat General Hospital |  |  |  | [ ]  |
| Dumat Al-Jandal General Hospital |  |  |  | [ ]  |
| Tabarjal General Hospital |  |  |  | [ ]  |
| Sowair General Hospital |  |  |  | [ ]  |
| Al-Jouf Mental Health Hospital |  |  |  | [ ]  |
| Al-Jouf Rehabilitation Center |  |  |  | [ ]  |
| Children with Disabilities Center |  |  |  | [ ]  |
| The primary Health Unit of ………………………… |  |  |  | [ ]  |
| The primary Health Center of …………………… |  |  |  | [ ]  |
| Al-Jouf Camels and Pasture Research Center |  |  |  | [ ]  |
| Water Directorate |  |  |  | [ ]  |
| Police Department  |  |  |  | [ ]  |
| Others (specify): …………. |  |  |  | [ ]  |

Add additional information as needed.

If the Principal Investigator is a student or is affiliated to other parties than Jouf University, please specify: …………………………………………..

**Other Collaborating Parties:**

If you're collaborating with other parties than those listed above, specify the name of the entity/ establishment (e.g., other universities, tribal aggregations, factories, farms or private institutions): ........................

Explain how the party will participant (e.g., recruitment of participants, securing the approval, conducting the study procedures, follow-up, data analysis, etc. ...). The research approval from the Local Committee of Bioethics does not eliminate the need to obtain ethical clearance from the other parties.

|  |  |  |
| --- | --- | --- |
| Name of the Institution | Nature of their participation | Research Approval/Their Approval is Attached |
|  |  |  |
|  |  |  |

Add additional information as needed.

If the Principal Investigator is a student or is affiliated to the other party, please specify: …………………………………………..

**International Research proposals:**

Will any of the research procedures be conducted outside the Kingdom? Yes (\_\_), No (\_\_). If Yes, complete the table below. Note: the research approval from the Local Committee of Bioethics does not necessarily replace the need to obtain the required bioethical clearance from the other parties.

|  |  |  |  |
| --- | --- | --- | --- |
| Address (Country, City) | Name of the collaborating party/Institution | Nature and methods for participation | The approval for the research (attached?) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Add more details if required. If the principal investigator is a student or is affiliated to the external institute, please explain.



**Section III: Research Funding:**

**Funding Sources**\***:**

Tick (√) for whatever applies.

|  |  |  |  |
| --- | --- | --- | --- |
| Research is funded by the Deanship for Students Affairs | [ ]  | Research is funded by the Deanship for Scientific Research | [ ]  |
| Research is funded by Charitable Organizations | [ ]  | Research is funded by the Department or College | [ ]  |
| Research is funded through a scientific award | [ ]  | Research is funded by King Abdulaziz City for Science and Technology | [ ]  |
| Research is funded by a scientific chair (Name: ……….) | [ ]  | Research is self-funded | [ ]  |
| Research is funded by other parties (Name: ……….) | [ ]  | Research does not need funding | [ ]  |

\*The Principal Investigator is responsible for reporting to the Bioethics Committee of the University in the event of any changes to the research funding sources through requesting an amendment for the original approval or the re-approval form.

**Researches Funded by Sources other than the University:**

For each of the funding sources of the study, please specify the following:

|  |  |
| --- | --- |
| Name of Funding Source |  |
| Name of the Funded Researcher: |  |
| The Research Title (if different from the title of this application): |  |
| Registration Number of the Research or Proposal: |  |
| Funding Status: Granted or under processing |  |

**Notes:** In case the grantee or the external funding support is not the principal investigator for this study, you must provide his personal and communication information. In case the research is fully or partially funded by sources other than the university, you must provide the proof that.In case there are more than one funding source for the study, duplicate the above table and provide relevant information for each of them.

Is the funding party aware of using humans in this study? Yes (\_\_), No (\_\_). If Yes, attached the proof for that. Add any additional information: ………………………….

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**Section IV: Conflict of Interest:**

Do all or one of researchers in this study have a personal interest (financial or moral), with a particular party concerned about the research? Yes (\_\_), No (\_\_). If Yes, please specify the name (s) of all that apply and explain the nature of the relationship: ………………………………. (In case the committee discovered different information, the researcher will be subjected to the provisions of Article 44 of the Bioethical Punishment Regulations).



**Section V: The Participating Human Subject:**

**How many persons enrolled in this research study? …………………………………….**

In case there are more than one category (gender, ethnicity, age, occupation, type/stage of the disease, etc.), explain the number of participants in each category: …………………..

Note: A person should not be considered as a participant except after signing the informed consent.

**In cases of survey studies**, specify how many persons will be surveyed and examined.

During the survey and examination stage for inclusion, you should calculate number of persons excluded and reason for the exclusion.

**Method of recruiting Participants:**

Explain how do you recruit participants to the study. Attach copies of any advertising materials or recruitment forms used. In case that the volunteering participants belong to parties other than the university, you must attach the approval for the study from that other party.

**Vulnerable population:**

Mark (√) the category(s) of participants enrolled in the research study.

|  |  |  |  |
| --- | --- | --- | --- |
| Needy people | [ ]  | Minor | [ ]  |
| Illiterates | [ ]  | Prisoners/Detainees | [ ]  |
| Military Personnels | [ ]  | Pregnant/Newborns | [ ]  |
| Non-Arabic Expatriates  | [ ]  | Persons with special needs | [ ]  |
| Individuals with infectious diseases, specify: ………………. | [ ]  | University Students (complete the item for university student participants) | [ ]  |
| Others, specify: ………… | [ ]  | University staffs (Complete the item for university staff participants) | [ ]  |

**Participation of Jouf University students or staff in research study:**

Will this study enrol Jouf university students whom you teach, mentor, or evaluate? Yes (\_\_), No (\_\_).

Will this study enrol Jouf university staff whom you are a superior to evaluator? Yes (\_\_), No (\_\_).

If Yes, explain the importance of enrolling this category of participants, how you would convince them to participate, and, how would you avoid any conflict of interest with them.



**Section VI: Medications, Medical Devices/Instruments, Radiation/Radioactive materials, Gene Testing, and Biological Sampling:**

**The Use of Medication and/or Medical Devices/Instruments:**

Will the study use a licensed drug or medical device/Instrument approved by an appropriate authority (e.g., Saudi FDA, etc.)? Yes (\_\_), No (\_\_).

Will the study use an unlicensed drug or experimental medical device/Instrument? Yes (\_\_), No (\_\_).

Will the study use non-medical devices? Yes (\_\_), No (\_\_).

Will the study be used as a product subjected to intellectual property rights? Yes (\_\_), No (\_\_).

Will the study employ a biomarker? Yes (\_\_), No (\_\_).

If yes, please describe and attach supplementary material(s) relevant to the used medication, device, product with intellectual property rights, or biomarker, and, how you would secure permission for their use.

**Biological samples:**

Will the study use biological samples (archival/retrospective and/or prospective)? Yes (\_\_), No (\_\_).

If yes, you need to fill out and attach the biosafety form before starting the study.

Will study collect biological samples by non-invasive methods (they include; urine and faeces, saliva, mouth wash, smears/scraping of mucus membranes, semen, nail or hair clips, etc.?

Yes (\_\_), No (\_\_).

Will the study collect biological samples by invasive means? Yes (\_\_), No (\_\_). If yes, you need to fill out and attach the biosafety form before starting the study.

**Gene investigation:**

Will the study carry out any gene investigation using the collected biological samples?

Yes (\_\_), No (\_\_). If yes, you need to fill out and attach the genetic testing form before you start your study.

**Radiation and Radioisotopes:**

Will the study be using ionizing radiation, X-rays, high frequency electromagnetic rays, radioactive isotopes or other radiolabelled chemicals? Yes (\_\_), No (\_\_). If yes, you need to fill out and attach the radiation biosafety form before you start your study.

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**Section VII: Research Plan:**

* The research proposal should consider the following points:
* The design of the study should be appropriate for fulfil its objectives.
* Balance the designed goals and the potential risk to the participants.
* Suitability of the research resources and emergency plans.

**The Study Objective:**

Describe the study hypothesis and objectives: Describe their relationship.

**Introduction:**

Mention previous studies on human or experimental animals that drove you to hypothesize the current study; with proper referencing.

**Study Setting/Design, Procedures, Materials and Methods:**

Describe the study design and setting with time schedule for each point. Describe the time schedule for the whole study from the beginning to its end, mentioning the target endpoint biomarker/clinical outcomes/achievements. In clinical studies disclosing personal information of the participants, all related procedures should be described in details and specify individuals how will be see and collecting such data. In case of using deception in the treatment (e.g., placebo treatment, etc.), you should justify its use (reasons and importance) in the study.

In case clinical studies using audio and/or video recording for participants, describe how it will be done, justify its use with model recordings, along with diary cards and questionnaires prepared. If the study will provides a treatment for the participants, fill and attached the medication form with the application.

**Statistical methodology and justification of sample size assigned:**

Describe the statistical methods used including sample size calculation procedures, making sure to reaching meaningful results with the minimum number of participants possible. Describe statistically how you calculate and circumvent the attrition bias. All methods should be properly referenced.

**Inclusion and Exclusion Criteria of participants:**

Describe the characteristics of the study population. List the criteria for inclusion and exclusion for participation. Describe and justify any special exclusion criteria that are based on gender (females, multiparous, etc.), age, religion, or ethnicity. Explain the circumstances where the investigator can terminate the participation of a participant (e.g. incompliance with the study criteria, termination of the study, etc.). Describe the initial contact and selection procedures. Describes the means by which you will provide all information for the study to potential participants and/or their Guardians.

**Risks and Inconveniences:**

Describe any potential risk or inconvenience participants could be exposed to and explain measures taken to minimize it. The risks considered should include; physical, psychological, social, legal, occupational, and financial risks, and, any potential inconveniences they may suffer (time spent, fasting, etc.).

# Estimate the probability of occurrence of risk, and in case it is realized, determine how bad its effect on the participant will be.

Justify the use of any procedure, instrument or device that is not conventionally used.

Explain how you would mange dangerous/critical citations.

Explain the plan to get rid of the remaining of biological samples.

Explain the plan to get rid of all of the remaining of study.

In case the study requires stopping previously prescribed medication for the participant, explain risk participant could be exposed to and justify the procedure.

**Benefits:**

State the direct and indirect benefits participants could receive from the study. Explain how the study would benefits the community at large (e.g., new information, etc.), or specific category of people (e.g., athletes, children with autism, etc.). Do not mention any compensation in this section.

**Analyzing and balancing benefits vs. Risks:**

Describe the risks in proportion to the benefits of the study and explain how benefits to participants and/or the community outweigh the risks. Describe each potential risk vs. its potential benefit(s) for participants and/or community.

**Economic considerations**

Are there any costs for participation and/or payment or other ways of compensation will be given to participants. Describe how the amount and method of compensation has been negotiated and reached. If the compensation is fractioned, please explain the details. For any additional procedures and investigations, the economic considerations should be taken into account.

**Control of data integrity and protection**

The study should include a plan for insuring accuracy/integrity and protection of the collected data. Such plan, data, records and documentations should be reachable and assessable by the Bioethics Committee Bureau. Mostly the principal is the one in charge of such duty. If a student is a co-investigator, it is prohibited to be in charge of this duty.

Items included in the data integrity and protection plan are:

* + - 1. Frequency of examination.
1. Who is in charge of controlling and protecting the data?
2. Nature of the controlled data.
3. How will data be analyzed and interpreted?
4. What action(s) or procedure(s) will be taken at the specific stages or endpoints of the study?
5. How the person in charge of data control and protection will communicate with the Bioethics Committee?

The reaction of the participants to the minimal/higher than minimal risk they are exposed to during the study should be determined by a questionnaire and the results should dictate the procedure done for items 1-3 above. The questionnaire and the procedure done are the responsibility of the principal investigator with the help of the student co-investigator and need to be done biweekly. In case a consequent amendment for the study procedures ensues, a request for such change should be submitted to the Bioethics Committee.

**Privacy/Confidentiality**

Explain how the integrity of the personal privacy and interests of the participants will be insured during the study period. Describe the actions taken to protect the privacy of the data obtained and how it will be protected after finishing the study. Describe your control and security plan to protect electronic data.

If sensitive information is to be obtained (use of unauthorized drugs, criminal activities, etc.), please indicate whether you need to apply for a confidentiality approval. Make sure to determine confidentiality limits and specify external effector (Sponsors, FDA, etc.) who can access the data. In case the participants will be surveyed and/or examined, explain how you store or destroy the data that indicates the personality of the participant in case they will be excluded.

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**Section VIII: Informed Consent (enlightened agreement for participation):**

As a Principal Investigator, you are responsible for applying the proper procedures to ensure that obtaining the informed consent form participants in this study implement relevant roles and regulations. Although the study may not enrol specific category of people, they may be used for recruitment or hiring participants.

**Procedures for obtain the Consent:**

Description of the Consenting: It include; who is obtain the informed consent, and where, when, and how long time is required to obtain the consent from the participants. The consent must be clear so as participants understand that their consent indicates their acceptance to participant in the study, that they understand the nature of the study and nature of their participation, and explains potential risks and dangers, and that they have the freedom to withdraw from the study whenever they want (They may qualify to insurance in complicated studies, studies requiring devotion of extended period of time, or those studies exposing participants to risks higher than the minimum).

**Ability to Consent:**

Describe how to assess the ability of the participant to consent in cases with limited ability to decide or those with language and hearing disabilities. In such cases you need to obtain the consent from the f the participant is unable to give consent, you will need to obtain approval from the blood or legal guardian.

**Authorization and consent of guardian**

In case of children or persons with special needs participation, indicate how many guardians will give authorization and consent for participation andindicate whether you will obtain a consent from the child or the person with special needs. Is such consent will be oral or written? Provide copies of these authorization and consent forms in their final form.

**Documentation of the informed consent**

Specify the templates to be used for each category of participants (e.g., adult consent form, guardian consent form, child authorization/consent form (Type-written, hand-written, or oral) and/or providing an informative brochure of the study that include the consent form. Copies of all of these forms and documents in their final form must be attached to this application.

**Delay, waiving or amending the informed consent**

The Bioethics Committee may approve waiving or delaying the collection of consents or approve an amendment of some of its items in case of studies with the minimal potential risk. In case you plan to apply for a waiver of collecting consents from participant (e.g., in case participants did not condition their participant on signing the informed consent), for delaying participant signature on the consent (e.g., in case participants will not sign until they read the study brochure), or for replacing the consent with another one (e.g., in cases of using deception in treatment as in the placebo effect studies), based on the study design, please answer the following questions:

In cases of an application to waive consent collection, or, replacing the informed consent:

* Why did you consider yours study a minimum risk study?
* How this exemption will affect the rights and interests of the participants?
* Why is the exemption necessary for conducting the study?
* If applicable, how would you inform participants about emerging important data?

In cases of an application to delaying participants' signature of the informed consent:

* Why did you consider yours study a minimum risk study?
* Is there a breach of confidentiality that poses a risk to the participants?
* Is the signed consent form the only document proving that the person is a participant in the study?
* Is the study procedures requires that the participant must sign an informed consent outside the study framework, i.e., not overseen by the Bioethical Committee?



**Section IX: Approvals:**

**Approval of the Application by the Principal Investigator:**

I agree and pledge to implement the regulations of Jouf University for studies conducted on humans.

1. I agree to comply with all regulations, decisions, and requirements of the Bioethics Committee.
2. This study is designed, to the top of my knowledge, so as to protect the participants by complying with the concerned regulations of Jouf University, the Ministry of Health, the Saudi Food and Drug Administration, the National Bioethics Committee and other protective agencies.
3. I must obtain the prior approval from the Bioethics Committee before commencing this study, amending the protocol or amending the informed consent/participation authorization forms that were previously approved.
4. I must inform the Bioethics Committee for any unexpected deviations in the path of the study, or emerging events or problems during the study that may endanger the participants.
5. I must submit reapproval request and/or end of the study report as required.
6. My and my research team participation in this study does not violate Jouf University regulations concerning conflict of interest.
7. The research team individuals got the required training necessary to conduct investigations on humans and they comprehend all of the study procedures.
8. The research team individuals have the required training and experience to conduct the research procedures assigned to each of them.

In addition to all of the statements above, my signature on this application conforms that I have the required facilities and resources necessary for conducting this study.

|  |  |
| --- | --- |
|  |  |
| The official hand signature of the Principal Investigator | Date |

|  |  |
| --- | --- |
|  |  |
| The official hand signature of the Student Researcher (only if he started the research idea) | Date |

|  |  |
| --- | --- |
|  |  |
| The official hand signature of the Clinical Supervisor (In case the study requires a participating physician as a clinical supervisor) | Date |

**Approval of the Application by the Head/Coordinator of the Department:**

I here by affirm that I have read this research application and the study procedures, and, I believe that it has a valid hypothesis and research questions and that answering these questions has a significant scientific/clinical value. And, to my knowledge, the investigator has the required time, facilities and experiences to conduct the study.

|  |  |
| --- | --- |
|  |  |
| The official hand signature of the Head/Coordinator of the Department (Is required for all studies, except in case of external grant applications/support, where, the contract must be attached to the application) | Date |

**Instructions for filling the Bioethical Approval Form 3 for conducting research on Humans**

**Important: The checklist for filling this form:**

* Review the forms and instructions stated in the homepage of the committee on the online university gate and fill a softcopy of the form for submission.
* Carefully read each item and prove correct and accurate information as requested.
* Notice the importance of answering; Yes/No and complete the requested information whenever apply. Replace the space (\_\_) with mark "√" beside the chosen answer.
* Hand filled forms are not acceptable.
* Do not modify or omit any of the parts of the form that apply or do apply to your study.
* Remove the instructions page from the application.

Contact the committee in case you need any help – 0146465329. LCBE@JU.EDU.SA

**The Principal Sections of the Form (3) are:**

Section I: General Information:

Section II: Collaborating Parties and Facilities and Required Approvals:

Section III: Research Funding:

Section IV: Conflict of Interest:

Section V: The Participating Human Subject:

Section VI: Medications, Medical Devices/Instruments, Radiation/Radioactive materials, Gene Testing, and Biological Sampling:

Section VII: Research Plan:

Section VIII: Informed Consent (enlightened agreement for participation):

Section IX: Approvals:

**Supplements:**

Amendment Forms.

Re-approval / Final report

List of the research team and other persons working in it

List of devices/drugs used in the study.

Gene investigations Form.

Description of the treatments apply.

Others.