For REC use only:

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Proposal No. \_\_\_\_\_

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| **Proposal Application for Research Involving Human Participants**  **Form # KSU-REC 002-E**  **SECTION I : GENERAL INFORMATION**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 1. **Title of Study:** | | | | | | | | | | English: |  | | | | | | | | | Arabic: |  | | | | | | | | | 1. **Contact information:** | | | | | | | | | | 1. **Principle investigator (PI)** | | | | | | | | | | Name |  | | | | | | | | | ID |  | Department/ College | | | |  | | | | Phone No. |  | Fax No. | | | |  | | | | E-mail |  | | | | | | | | | Status | □ Undergraduate student | | | | □ Hospital Staff | | | | | □ Graduate Student | | | | □ Post-Doctoral | | | | | □ Resident/Fellow | | | | □ Faculty | | | | | 1. **Are there Co-Investigators and Member of Research Team?** | | | | **□** Yes | | | | **□** No | | **Name** | **Email Address** | | **Department/College** | | | | **Role in Project** | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | |  |  | |  | | | |  | | | **Study expected start date (Day/Month/Year)** | | | --/-- /-- H --/--/--G | | | | | | | **Study estimated end date (Day/Month/Year)** | | | --/-- /-- H --/--/--G | | | | | | | **Study completion date (Day/Month/Year)** | | | --/-- /-- H --/--/--G | | | | | | | **Submission date (Day/Month/Year)** | | | --/-- /-- H --/--/--G | | | | | | |  |  |

**SECTION II: COLLABORATING INSTITUTIONS/FACILITIES AND OTHER REC REVIEWS**

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| Will the research be conducted only at KSU/KKUH with no involvement of a collaborating institution? | | | | | | |
| **□** Yes (if yes, skip to section III) | | | | **□** No | | |
| If you are collaborating with other sites, provide the name of each institution/facility and describe the type of involvement of each institution (e.g. recruitment, enrollment, consenting, study procedures, follow-up, and data analysis). Indicate if REC approval/site permission is attached | | | | | | |
| **Institution Name** | | **Describe Involvement** | | | **REC Approval/Site Permission Attached?** | |
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| **International Research:** | | | | | | |
| Will any aspect of the study take place outside the Kingdom?  If yes, complete the table below. | | | | | **□** Yes | **□** No |
| **Country** | **Address**  **(not more than 500 words)** | | **Name of Collaborating Institution/Facility** | | **Describe Involvement** | **REC/Ethics Approval and/or Site Permission Attached?** |
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**SECTION III: FUNDING INFORMATION**

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| --- | --- | --- | --- |
| 1. Is this research being funded? | | **□** Yes | **□** No |
| 1. If yes, please specify: | | | |
| **Funding agency** | | | |
| □ Governmental funding within the kingdom | | | |
| □ Private sector funding within the kingdom | | | |
| □ International government funding | | | |
| □ International private sector funding | | | |
| □Under graduate / post graduate student funding | | | |
| **Total budget of the project**: |  | | |

**SECTION V: DRUGS/BIOLOGICAL PRODUCTS/DEVICES, BIOLOGICAL SAMPLES, GENETIC TESTING, VULNERABLE GROUPS, STEM CELLS, ZYGOTES, GAMETES AND FETUSES, RADIATION and RADIOISOTOPES, AND EXPERIMENTAL ANIMALS**

**Does the Proposal involve the use of any of the following? Check all that apply:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. **Drugs/ Device Use** | | | | | | |
| * A SFDA approved drug or medical device | **□** Yes | | | | **□** No | |
| * An investigative/unapproved drug, supplement, chemical, biological products, or controlled substances | **□** Yes | | | | **□** No | |
| * A medical or non-medical device | **□** Yes | | | | **□** No | |
| * A proprietary product | **□** Yes | | | | **□** No | |
| * A placebo | **□** Yes | | | | **□** No | |
| If “Yes” to any of the previous points, please fill the KSU-REC forms # KSU-REC 010E for the use of Devices; AND the KSU-REC form # KSU-REC 011E for the use of drugs and/or biological products in research. | | | | | | |
| 1. **Biological Samples** | | | | | | |
| Blood, Urine, Tissue, Saliva, etc. (**Either banked or prospectively obtained)** | **□** Yes | | | | **□** No | |
| If “Yes”:   * Confirm that all relevant personnel have been trained and have an experience in dealing with biological samples. * Confirm that all relevant personnel have completed a “Blood borne pathogen training and immunization”. | **□** Yes  **□** Yes | | | | **□** No  **□** No | |
| 1. **Genetic Material Testing** | | | | | | |
| |  | | --- | | Genetic testing of biological samples (Blood, Urine, Tissue, Saliva, etc. , or the use of recombinant DNA/Human gene transfer (including use of vectors) | | **□** Yes | | | | **□** No | |
| If “Yes”:   1. Specify the genetic testing to be done on these samples. |  | | | | | |
| 1. Will the genetic sample be sent outside the Kingdom? | **□** Yes | | | | **□** No | |
| If “Yes”, approval from the Local Research Ethics Committee, King Saud University should be obtained before sending the genetic samples outside the Kingdom. Please attach the approval letter. | | | | | | |
| 1. Will results of genetic testing be reported to subjects? | **□** Yes | | **□** No | | | **□** NA |
| If “Yes”, the following conditions must be met:   1. A specific genetic test is being performed and subjects are notified at the time of the consent what the test is and how the results might affect them. 2. Specify who will transmit the results of the study. 3. Specify whether genetic counselors will be available to subjects. | | | | | | |
| 1. **Stem Cells, Zygotes, Gametes and Fetuses** | | | | | | |
| The Research project involves the use of stem cells, zygotes, gametes, or fetuses | **□** Yes | | | **□** No | | |
| If “Yes”, please fill the KSU-REC form # KSU-REC 009E for the use of Stem Cell, Zygotes, Gametes and Fetuses | | | | | | |
| 1. **VULNERABLE GROUPS** 2. **Prisoners (including those sentenced to death)** | **□** Yes | | | **□** No | | |
| **If “Yes”, please answer the following points:** | | | | | | |
| * The researchers agree that: Prisoners are treated like other persons as regards conducting research on them | **□** Yes | | | **□** No | | |
| * The researchers agree that: Inmates may not be subject to clinical research whether by coercion or inducement or for any purposes other than those set forth by the National Committee of BioEthics and stated in the Implementing Regulations of the Law of Ethics of Research on Living Creatures | **□** Yes | | | **□** No | | |
| * The research aims include: Study the criminal behavior of inmates, provided the research does not expose them to more than the minimal potential risk | **□** Yes | | | **□** No | | |
| * The research aims include: Study conditions of prisons and inmates as well as prevailing diseases and identify the circumstances leading to crime | **□** Yes | | | **□** No | | |
| * The research aims include: Study administrative rules and operational procedures applicable in prisons, so as to improve health and living conditions of inmates | **□** Yes | | | **□** No | | |
| 1. **Minors, incompetent, or disabled persons** | **□** Yes | | | **□** No | | |
| * The researchers agree that: an "Informed Consent" will be obtained from parents or the legal guardians in accordance with conditions set forth in the Law and Regulations, provided they are informed of the level of risk and its probability as well as the person's assent. | **□** Yes | | | **□** No | | |
| * The researchers agree that: either the parent or the legal guardian who grant the "Informed Consent" on behalf of minors, incompetent or mentally disabled persons is aware that his/her decision is based on the fact that the minor, incompetent or mentally disabled person is subject to no harm and may benefit from the research. | **□** Yes | | | **□** No | | |
| * The researchers agree that: after granting the "Informed Consent", either parent or the guardian may withdraw the consent at any phase of the research if he finds that the research conflicts with the interests of the minor, incompetent or mentally disabled person or if the research deviates from the objectives upon which the consent was granted. | **□** Yes | | | **□** No | | |
| If research includes any of the vulnerable group mentioned above, please sign the following statement: | | | | | | |
| * It is not possible to conduct the research on a competent person; * The interest of the minor, incompetent or mentally disabled person requires subjecting him to the research, provided he is not exposed to more than the minimal potential risk; * The research protocol includes clear and appropriate measures to minimize potential risk as much as possible; * Evaluation of potential risk and expected benefit from the research shall indicate type, nature, degree and possibility of risk as well as the direct benefit for the minor, incompetent or mentally disabled person subject of the research and for similar persons; | | | | | | |
| **Principle Investigator Name: Signature:** | | | | | | |
| 1. **Radiation or Radioisotopes** | | | | | | |
| The research project involves the use of Radiation or Radioisotopes | **□** Yes | | | | **□** No | |
| If “Yes”: | | | | | | |
| * Please specify where the radiation will be used (College, and building / room no.): | |  | | | | |
| * Please specify Name(s) of approved radioisotope permit holder, and the duration of permit: | |  | | | | |
| * Please specify methods of special handling and disposal of radioactive waste: | |  | | | | |
| 1. **Experimental Animals** | | | | | | |
| The research project involves the use of Experimental Animals? | **□** Yes | | | | **□** No | |
| If “Yes”, approval from the Local Animal Facility and from the Local Research Ethics Committee, King Saud University should be obtained before the use of experimental animals is initiated. Please fill the KSU-REC form #KSU-REC 008E for Experimental Animal Use in research. | | | | | | |

**SECTION V: RESEARCH PROTOCOL AND SIGNIFICANCE**

1. **Please provide the proposed project abstract including the following subheadings: Background, objectives, and methods (not more than 500 words).**

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1. **Please describe briefly how this study will contribute to existing knowledge in the field (not more than 500 words).**

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1. **Please attach/upload the detailed Research Proposal Form (Form # KSU-REC 003E-A).**

**Study protocols should be formatted using Times New Roman font, size 12, double-spaced.**

**SECTION VI: RISKS AND BENEFITS OF THE PROPOSED RESEARCH**

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| --- | --- | --- |
| 1. **POSSIBLE RISKS** 2. **Indicate if the participants might experience any of the following risks:** | | |
| 1. Physical risk (including any bodily contact or administration of any substance)? | **□** Yes | **□** No |
| **If you checked yes for any questions please describe the risk(s / describe how each of the risks will be managed or minimized and please include an explanation regarding why alternative approaches cannot be used.** |  | |
| 1. Psychological risks (including feeling demeaned, embarrassed, worried or upset)? | **□** Yes | **□** No |
| **If you checked yes for any questions please describe the risk(s / describe how each of the risks will be managed or minimized and please include an explanation regarding why alternative approaches cannot be used.** |  | |
| 1. Social risks (including possible loss of status, legal risk, privacy and/or reputation as well as economic risks)? | **□** Yes | **□** No |
| **If you checked yes for any questions please describe the risk(s / describe how each of the risks will be managed or minimized and please include an explanation regarding why alternative approaches cannot be used.** |  | |
| 1. Are any possible risks to participants greater than those the participants might encounter in their everyday life? | **□** Yes | **□** No |
| **If you checked yes for any questions please describe the risk(s) in the space below/ describe how each of the risks identified above will be managed or minimized and please include an explanation regarding why alternative approaches cannot be used.** |  | |
| 1. **Misrepresentation/Trick: Is there any Misrepresentation/Trick involved in this research?** | **□** Yes | **□** No |
| 1. **If Misrepresentation/Trick is to be used in your methods, describe the details of the Misrepresentation/Trick (including what information will be withheld from participants) and justify the use of Misrepresentation/Trick.** | | |
| 1. **POSSIBLE BENEFITS:** | | |
| Discuss any potential benefits to the scientific community/society that justify involvement of participants in this study. ***(Please Note: Benefits should not be confused with compensation or reimbursement for taking part in the study).*** | | |

**SECTION VII: PRIVACY AND CONFIDENTIALITY**

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| 1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? **□** Yes **□** No 2. If yes, select all that apply: | |
| □ Name | □ IP Address |
| □ Date of Birth | □ Biometric Identifiers |
| □ Mailing or Email Address | □ Photos/Images/Audio Recording |
| □ Phone or Fax Numbers | □ Signatures, handwriting samples |
| □ National ID | □ Any unique identifiers not mentioned above |
| □ License, Certificate or Vehicle ID |  |

**SECTION VIII: CONSENT PROCESS**

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| 1. **Informed Consent:** |
| * Will you use a written informed consent document?   **□** Yes  **□** No, I am asking a waiver of written informed consent  **□** Not applicable |
| 1. **Written parental permission** |
| * Will you obtain written parental or guardian permission for children, individuals under 18, prisoner and incompetent?   **□** Yes  **□** No, I am asking a waiver of written informed consent  **□** Not applicable |
| 1. **Please attach/upload Arabic consent form using the forms provided by the KSU-REC (Form no. KSU-REC 005A, OR KSU-REC 006A)**   **An English consent form might also be attached/uploaded (Form no. KSU-REC 005E, OR KSU-REC 006E)** |

**SECTION IX: CONFLICT OF INTEREST DISCLOSURE**

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| **The REC policy requires that members of the faculty conducting research involving human participants at King Saud University must disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict has to be managed prior to the faculty member’s engaged in the research with human participants.** | | |
| **□** Yes | **□** No | Are you, a family member, or spouse the inventor of any products, novel treatment under evaluation, or technology used in the research? |
| **□** Yes | **□** No | Do you, or does a family member, or spouse have fiduciary role or have an ownership interest in any entity that provides materials, novel treatment under evaluation, products, technology, or services in the research? |
| **□** Yes | **□** No | Do you or does any family member, or spouse receives income/payments from an entity that provides materials, novel treatment under evaluation, products, technology, or services in the research? |
| **□** Yes | **□** No | Is the research sponsored by a company for which you, and/or a family member consult, serve on its scientific advisory board, data safety monitoring board, or board of directors or have a paid position? |
| **□** Yes | **□** No | Is the research sponsored by a company for which you (or your spouse or your children) hold any ownership interest (stock, not including stock owned through a mutual fund) or from which you are entitled to receive royalties from a licensing agreement? |
| **□** Yes | **□** No | Is the research sponsored by a company? |
| **□** Yes | **□** No | The value of my remuneration or financial interest exceeds SR 20.000 |
| **□** Yes | **□** No | Are you, a family member, or spouse receive other remuneration (trips, gifts… etc.) |

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| **What is (are) the name(s) of the company or entity for which you will be engaging in the external activity (if applicable)?** |
| **Please provide a brief description of the nature of your relationship with the entity, and the amount of your expected remuneration from, or the value of your financial interest in the outside company or entity; if applicable (not more than 500 words).** |
| **Investigators must declare to the KSU-REC of any change in circumstances during the development of, or in the course of a project that would mean that they or their spouse, or family members would receive or hold any of the declarable items described above. Please check the following box if applicable.**  **I have read the above statement on conflicts of interest. I have nothing to declare now and I will immediately declare in writing to the KSU-REC of any future conflicts of interest** |

**SECTION X: PRINCIPAL INVESTIGATOR CERTIFICATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **I agree to:**  **Comply with the law of Research Ethics Committee on Living Creatures in the Kingdom of Saudi Arabia, and the Implementing Regulation of the Law of Ethics of Research on Living Creatures by the National Committee of Bioethics and the Local Research Ethics Committee on Living Creatures in King Saud University Institutional Review Board (KSU-REC)**  **I also understand the absolute need to:**   1. Design the study with the standards set by the University, the Saudi Food and Drug Administration and other sponsoring agencies. 2. Obtain prior approval from the KSU-REC before amending the research protocol or the approved consent form 3. Report to the KSU-REC in accordance with KSU-REC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants 4. Submit a progress report both annually and whenever requested by the KSU-REC. 5. Submit the Re-Approval form/Completion Form as needed 6. Ensure that each individual listed as study personnel in this application is knowledgeable of the study procedures described in the proposal 7. Include the KSU-REC approval no. in any published paper coming out of this study 8. Abide to the items and conditions listed in the attached files, including but not limited to the study proposal, informed consent, etc. 9. Abide timely with all the requested reports or forms, as failure to do so will entitle the KSU-REC to terminate the approval already granted to the study under progress.   ***Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.*** | | | | |
| **Principle Investigator (PI) Name**  **---------------------------------------------** | **PI Signature**  **----------------------------------------** | **Date**  **--------------------------------** |
| **Co-Investigator Name**  **---------------------------------------------** | **Co-Investigator Signature**  **----------------------------------------** | **Date**  **-----------------------------------** |
| **Co-Investigator Name**  **---------------------------------------------** | **Co-Investigator Signature**  **----------------------------------------** | **Date**  **-----------------------------------** |
| **Co-Investigator Name**  **---------------------------------------------** | **Co-Investigator Signature**  **----------------------------------------** | **Date**  **-----------------------------------** |
| **Co-Investigator Name**  **---------------------------------------------** | **Co-Investigator Signature**  **----------------------------------------** | **Date**  **-----------------------------------** |
| **Co-Investigator Name**  **---------------------------------------------** | **Co-Investigator Signature**  **----------------------------------------** | **Date**  **-----------------------------------** |

*For more information, please visit the website of the Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm\_Policies*)*