**Proposal Application for Animals studies**

**Form # PSAU- BERC**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |  |
| **Co-Investigators responsible for the study if different from the PI.** |
| **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: FUNDING INFORMATION**

|  |  |  |
| --- | --- | --- |
| 1. Is this research being funded?
 | **□** Yes | **□** No  |
| 1. If yes, please specify:
 |
| Funding agency: |

**SECTION III: CONFLICT OF INTEREST**

|  |  |  |
| --- | --- | --- |
| Does any of the team members have a conflict of interest regarding project results? | **□** Yes | **□** No  |
| If yes, please specify: |

**SECTION IV: DRUGS/BIOLOGICAL PRODUCTS/DEVICES, BIOLOGICAL SAMPLES, GENETIC TESTING, RADIATION and RADIOISOTOPES.**

**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  |
| * Chemical, Natural Products or biological products
 | **□** Yes | **□** No  |
| Specify: |
| 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/ 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  |
| 1. **Stem Cells, Zygotes, Gametes and Fetuses**
 |
| The Research project involves the use of stem cells, zygotes, gametes, or fetuses | **□** Yes | **□** No  |
| **Specify:** |

**SECTION V: RESEARCH PROTOCOL AND SIGNIFICANCE**

1. **Please provide the proposed project rational/purpose and significance (no more than 500 words).**

|  |
| --- |
|  |

1. **Please describe briefly the general experimental design and procedure.**

|  |
| --- |
|  |

1. **Provide the rational for choice of the animal model.**

|  |
| --- |
|  |

1. **Justify the animal numbers**

|  |
| --- |
|  |

**SECTION VI: Animal treatment**

|  |
| --- |
| 1. **Will animals be physically restrained longer than one hour in a conscious state?**
 |
| **□** Yes **□** NoIf **Yes** describe below  |
|  |

|  |
| --- |
| 1. **Will you be administering a substance (including anesthetics)?**
 |
| **□** Yes **□** NoIf **Yes** specify dose, route of administration, frequency, volume and nature of materials |
|  |
| 1. **Will food and water be provided *ad libitum*?**
 |
| **□** Yes **□** NoIf **No** Explain and Justify. |
|  |
| 1. **Is it likely that animals will experience Pain or Distress?**
 |
| **□** Yes **□** NoIf **Yes** Explain, Justify and how to Minimize pain or distress |
|  |
| 1. **A. Biological fluids will be collected from the animals?**
 |
| **□** Yes **□** NoIf **Yes** complete the table below. |
| **Fluid** | **Volume** | **Collection frequency** | **Collection site** | **Anesthetic** | **Dose** |
|  |  |  |  |  |  |
|  **B.Will animals survive the fluid collection procedure? □** Yes **□** No **□** N/A  |
| **6. Disposal of the dead animals?** |
| **□ Freeze** **□ Refrigeration**  **□ Institutional protocol** **□ Others** (Explain)  |
|  |

**SECTION VII: 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 Price Sattam Bin Abdulaziz University Bioethical Research Committee (PSAU- BERC)****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 **PSAU- BERC** before amending the research protocol.
3. Report to the **PSAU- BERC** in accordance with **PSAU- BERC** policy, any adverse event(s) and/or unanticipated problem(s) involving risks to animals.
4. Submit a progress report both annually and whenever requested by the **PSAU- BERC**.
5. Submit the Re-Approval form/Completion Form as needed
6. Include the **PSAU- BERC** approval no. in any published paper coming out of this study
7. Abide to the items and conditions listed in the attached files, including but not limited to the study proposal.
8. Abide timely with all the requested reports or forms, as failure to do so will entitle the **PSAU- BERC** to terminate the approval already granted to the study under progress.
 |

|  |  |  |
| --- | --- | --- |
| **Principle Investigator (PI) Name****---------------------------------------------** | **PI Signature****----------------------------------------** | **Date****--------------------------------** |