**Proposal Application for studies involving Human Subjects**

**Form # PSAU- BERC**

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| **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** | | **Phone No.** | | **Department/College** | |  |  | |  | |  | |  |  | |  | |  | |  |  | |  | |  | | **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**

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

**SECTION III: CONFLICT OF INTEREST**

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| 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:**

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| 1. **Drugs/ Device Use** | | | |
| * A SFDA approved drug or medical device | **□** Yes | | **□** No |
| * Chemical, Natural Products or biological products | **□** Yes | | **□** No |
| Specify:  Signe the Pledge for SFDA approval. | | | |
| 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 |
| If “Yes”  Provide full details about the Country, Institution and personnel responsible  How the samples will be preserved during shipping?  What will happen to sample after the study is over? |  | |  |
| 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).**

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

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1. **Provide the exact Sample size**

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1. **Short literature Review**

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**SECTION VI: Safety measures**

1. **Qualified personnel needed other than research team for emergency.**

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1. **Facilities required for emergency intervention.**

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1. **Safety measures for infections prevention if applicable.**

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1. **Health Institution where the project will be performed (Full Details).**

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**SECTION VII: Qualification of the Research Team**

1. **Attach The C.V. of all members of the research team.**

**SECTION VIII: Pledges**

1. **تعهد بالمحافظة على سرية المعلومات**

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| اتعهد انا الباحث الرئيس وكافة اعضاء الفريق البحثي بان نلتزم بسرية المعلومات وحفظها حسب الانظمة المعمول بها محليا لفترة قانونية لا تقل عن خمس سنوات مع ضمان سرية المعلومات وعدم اطلاع أحد عليها مالم يكن مشمولا حسب الانظمة. كما نتعهد بعدم الافصاح عن اي معلومات تؤدي الى الكشف عن شخصية المشترك بالبحث مالم يكن ذلك ملزما كأمر قضائي او جهة رقابية مع الالتزام بتطبيق انظمة الدولة. كما نلتزم بعدم مشاركة البيانات في اغراض او ابحاث خلاف التي تم الموافقة عليه الا بعد الحصول على الاذونات اللازمة من اللجنة.  Yes **□** No **□** |

1. **تعهد بالحصول على موافقة المشارك**

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| اتعهد انا الباحث الرئيس وكافة اعضاء الفريق البحثي بالحصول على اذن موافقة ساري المفعول والموقعة من الشخص المشارك او وكيله أو الأوصياء الشرعيين وفقا للشروط المنصوص عليها في القانون والنظام، شريطة أن يتم إعلامهم بمستوى المخاطر والاحتمالات، وبما فيها الشخص المعني. كما نتعهد بإعلام المشارك او وكيله أو الأوصياء الشرعيين بالحق في ايقاف المشاركة في أي مرحلة من مراحل اجراء الدراسة. كما نتعهد بإرفاق صورة الموافقة السارية في سجل المريض. ولا يتم اجراء الدراسة في حال انقضاء اجل الموافقة.  Yes **□** No **□** |

1. **تعهد بارفاق نموذج طلب موافقة المشارك**

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| اتعهد انا الباحث الرئيس وكافة اعضاء الفريق البحثي بارفاق النموذج المعد من قبل الفريق البحثى للحصول على موافقة المشارك مع الطلب المقدم للجنة للحصول على موافقة اجراء البحث.  Yes **□** No **□** |

1. **تعهد بالحصول على موافقة جهة اجراء الدراسة**

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| اتعهد انا الباحث الرئيس وكافة اعضاء الفريق البحثي بالحصول على الموافقة الادارية من الجهة التي سوف يتم اجراء الدراسة بها ومتابعة المريض حتى انقضاء مدة مشاركته في الدراسة. كما نتعهد بتغطية تكاليف أي مضاعفات تنتج عن الدراسة مالم تكن مكفولة بالتامين الطبي الخاص بالمريض.  كما نتعهد بان تكون الدراسة خاضعة لجميع الانظمة والقوانين واللوائح المعمول بها في الجامعات ذات الصلة. وفى حال عدم الحصول على موافقة جهة اجراء البحث تعتبر موافقة لجنة اخلاقيات البحوث الحيوية منعدمة الاثر.  Yes **□** No **□** |

1. **تعهد بالتعامل مع المخلفات الناتجة من البحث**

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| اتعهد انا الباحث الرئيس وكافة اعضاء الفريق البحثي باتباع الاجراءات المطبقة في جهة اجراء البحث للتخلص من المخلفات الناتجة عن البحث بالطرقة الآمنة التى تحافظ على سلامة العاملين البيئة.  Yes **□** No **□** |

**SECTION VIII: PRINCIPAL INVESTIGATOR CERTIFICATION**

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| **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. 9. Signe all the required Pledges for the study. |

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