**Section 1: Details of Applicant(s)**

1. **Applicant Information:**

|  |  |
| --- | --- |
| Family Name …………………………………………….. | Title, position. Please select  Other ………………………….…………………….. |
| First Name …………………………………………….. | Department ………………………….…………………….. |
| Email …………………………………………….. | Specialization ………………………….…………………….. |
| Phone …………………………………………….. | UJ ID ………………………….…………………….. |
|  | University ………………………….…………………….. |

1. **Research Title:**

Short title of Project: “ Click or tap here to enter text.“

Full title of Project: “Click or tap here to enter text.“

1. **Co-PI (s)** *Note, to add more researchers press the “+” sign at the end of Co-Pi entry table*

|  |  |
| --- | --- |
| Name …………………………………………….. | Title, position. Please select  Other ………………………….…………………….. |
| Email …………………………………………….. | University ………………………….…………………….. |

1. **Authorship Order**

*[first Author, Second, ……,Last]*

**Section 2: Study Type/Funding**

1. **Approval Request:**

General Ethics Approval Bio-Ethics Approval

1. **Study will be carried out on:**

Human Animal Other: …………………….

1. **Study Design:**

Cross-sectional Case series  Case Report  Case Control

Cohort:(Prospective/ Retrospective) Correlational Experimental

Qualitative Other, explain….

1. **Funding Type:**
2. Funded applied for: Yes No
3. Funded secured: Yes No
4. Does the investigator(s) have any direct personal involvement?*(e.g. financial, share-holding, etc.) in the sponsoring organization?* Yes No
5. If Yes, in any of the above, please give details: …………………….
6. **Schedule:**

Proposed starting date: Click or tap to enter a date.

Proposed duration (in months): …………………….

1. **Where will the study take place and in what setting?**

*Click or tap here to enter text.*

1. **Does the study fall into any of the following categories:**

**Pilot** Yes No N/A

**Multi-center study** Yes No N/A

If multi-center, please name the center(s) …………………….

**Undergraduate Student Project** Yes No N/A

If yes, please name the institution(s): …………………….

please name the supervisor(s): …………………….

*For student(s), attach approval letter from your supervisor*

1. **Have any other Ethics Committees been approached, and what is the outcome to date?** *Name of Ethics Committee(s) and Outcome (please attach letter(s))*

*Click or tap here to enter text.*

**Section 3: Details of Project**

1. **Research Abstract:**

*[Briefly summarize your research within the count of 200 words.]*

*Click or tap here to enter text.*

1. **Aims and Objectives:**

*[Briefly describe the broad aims and objectives of this project. You can use bullet points]*

*Click or tap here to enter text.*

1. **Key Question(s):**

*[What question, or questions, does the project intend to examine? Where relevant, state the hypothesis to be tested. You can use points.]*

*Click or tap here to enter text.*

1. **Scientific Background:**

*[Provide a summary of background information and literature on the topic of this research study. What is the current state of research/knowledge in the area of the proposed research. Explain the significance of the proposed research in the context of this background. 500 words for both D and E.]*

*Click or tap here to enter text.*

1. **Significance of This Research:**

*[Explain the significance of the proposed research project in light of existing research, knowledge or understanding. How does your research help to fill a gap in the literature? within the word count limit. 500 words for both D and E.]*

*Click or tap here to enter text.*

1. **Research Design:**

*[Outline the research design/approach by emphasizing In the type(s) of participants, and type(s) of data collection. Provide details of your research design and your proposed methodology. Please List any additional items requiring additional approvals, for example children recruitment ]*

*Click or tap here to enter text.*

1. **Data/Material/Samples Collection Technique(s):**

*[What data/materials/samples will be collected? Where will the data be collected? List/describe all sites.] Sample size determination (Include power calculations or provide justification for their absence, e.g., pilot/feasibility study)]*

*Click or tap here to enter text.*

1. **Data Analysis:**

*[How will data/materials/samples be analyzed? What statistical methods?/techniques/theories will be used?]*

*Click or tap here to enter text.*

1. **References**

*[Please provide list of references that you used here]*

*Click or tap here to enter text.*

**Section 4: Recruitment of Participants and Control Groups**

1. **Participants (or Recruitment Targets, such as medical records):**

*[Explain who/what are the intended participants or recruitment segments with justification behind your choice. Include your eligibility criteria for example inclusion/exclusion conditions. Also, the demographics of your samples. If the project is dealing only with data rather than human interaction state that here.]*

*Click or tap here to enter text.*

1. **Recruitment:**

*[Describe how you are going to approach the targeted sample. Clarify how potential participants will be recognized, approached and by whom. In the event that you’ll be utilizing records or data. clarify how the records/data will be distinguished, collected and accessed. And if there is an adopted protocol, please state.]*

*Click or tap here to enter text.*

1. **Participant Incentives:**

*[Do you propose to reward and/or reimburse and/or compensate participants in any way? If yes, give details here.]*

*Click or tap here to enter text.*

1. **Participant Task(s):**

*[What will participants be asked to do? What is the approximate time commitment required of each participant? If using records or data only, state “N/A.”]*

*Click or tap here to enter text.*

1. **Control group:**

*[How will the control group (if used) be selected, approached, and recruited. What inclusion and exclusion criteria will be used?]*

*Click or tap here to enter text.*

**Section 5: Risks, Benefits and Monitoring Management**

1. **Potential Risks to vulnerable groups:**

*[Identify and recognize any risks to participants within your scope of research. This can be seen from the interview questions or the sensitivity of the obtained data behind the questions. Also, This could arise from not adopting the right behavior traditions/cultural norms. Potential risks, moreover may be related to the inquire about research setting (e.g. outside, timing, country, emotional, mental and the list goes on). In case you believe that these risks are minimal, please describe on the scope of your research.]*

**i. Please specify if the study involves the following groups:**

* Children under the age of 18: Yes No N/A
* Participant with learning difficulties: Yes No N/A
* Participant with psychological disorders,

Dementia, etc.)? Yes No N/A

* Participant with language barriers? Yes No N/A

**If yes, to any of the previous questions, please answer the following:**

1. **What arrangements have been made to deal with the issues of consent and assent, e.g. is parental or guardian consent to be obtained, and if so what form?**

*Click or tap here to enter text.*

**2. In what way, if any, can the proposed study be expected to benefit the individual / groups who participate? What is the expected benefit for the community of society?**

*Click or tap here to enter text.*

**ii. Potential risks or hazards to participants or patients:**

*[Please specify if the study involves the following]*

* Complications of study procedures: Yes No N/A
* Drug side effects and toxicities/device malfunctions: Yes No N/A
* Psychosocial (non-medical) risks, discomforts,

inconveniences: Yes No N/A

* Radiation exposure: Yes No N/A

**If yes, to any of the previous questions, please answer the following:**

1. **What precautions to be taken to minimize complications/risk**

*Click or tap here to enter text.*

1. **Was this made clear in the participant information sheet? If not, please give reasons?**

*[Please attach Participant Distress Protocol]*

*Click or tap here to enter text.*

1. **Will treatments provided during the study be available if needed at the end of the study? If not, please give reasons?**

*Click or tap here to enter text.*

1. **Risk Management Strategy:**

*[Based on the identified risks, define your strategy to counteract and control them. In some cases for sensitive data collection participants may feel stressed in regards of their data and privacy, how you are going to destress and deal with these situations. Attach or include a copy of any distress protocol or adverse event protocol which you have developed.]*

*Click or tap here to enter text.*

1. **Potential Risks to Non-Participant:**

*[Identify and recognize any risks to non- participants within your scope of research. This could arise from dealing with genetics research which would lead to family genetics, or by violating general privacy of others. If you believe that these risks are minimal to non-participants, please describe on the scope your research.]*

*Click or tap here to enter text.*

**Section 6: Monitoring and Management**

1. **Management**

*[define in top level executive summary how and by whom research tasks will be managed through the course of research process. Furthermore, state how you plan to maintain regulations control. Also, state if you intend to seek specific staff at certain phase of the research.]*

*Click or tap here to enter text.*

1. **Monitoring**

*[if your research involves distant work, please explain how this going to occur and how/whom going to handle this task. This may involve part of the research being conducted in different countries, which may require additional approvals depending on the nature of the research process. Another important point to describe is the strategy in supervising students involvement as part of their coursework, seminars or senior project. In addition add any relevant information.]*

*Click or tap here to enter text.*

1. **Independent Contractors**

*[If any independent contractors (i.e. persons not listed in the proposed application) will be executing any task (partially or fully) in the study, please elaborate here including their roles and justify their involvement. If no independent contractors will be involved, state “N/A”.]*

*Click or tap here to enter text.*

**Section 7: Consent and Dissemination**

1. **Obtaining Informed Consent**

*[Describe the consent process and how consent will be obtained and by whom. Pay attention and elaborate if the main researcher or any team member involved in relation with participants. Also, in case of a consent waiver request, ensure to justify the request. If you are not planning to obtain consent please elaborate why.]*

*Click or tap here to enter text.*

* **Is written consent to be obtained?** Yes No N/A

*If “yes”, please attach a copy of the Consent Form to be used*

If No, please justify …………………….

1. **Future Use of Data, Materials, or Tissues**

*[Describe how you intend to reuse these data, materials or tissues in the future. This includes the conditions that apply to the use of the reused item and how to identify them. Also, data that requires databank alteration and approval must be mentioned here. If there are no plans to reuse the data or you are following an approved protocol, simply state “N/A” here. And attach the approval form]*

*Click or tap here to enter text.*

1. **Conflict of Interest**

*[If YES, explain what the potential conflict of interest is and how it will be managed. If applicable, you may also need to include. If NO, state “N/A”.]*

*Click or tap here to enter text.*

1. **Information for Participants**

*[Describe how participant will be informed about the research. for example how you are explaining the informing session, method or letter. Identify lack of literacy skills, for example and how to manage this. This activity is related to medical research in general. Pay attention to risks that may occur. If you believe your research does not need such consent then state “N/A”.]*

*Click or tap here to enter text.*

* **Will the participant be given a written information sheet or letter?**

Yes No N/A

*If “Yes”, please attach a copy of the written sheet to this sheet application form*

If “No”, please justify …………………….

1. **Providing Results to Participants**

*[Describe how participants will be given access to the results of the research. if just initially set of data are utilized, for example you are accessing public data about participants then state “N/A”. Also, if no informed consent required, state “N/A”.]*

*Click or tap here to enter text.*

1. **Report Project Outcome**

*[Describe the format and means by which you intend to make the project’s results public. This might be through journal pulcation, conference or any other form]*

*Click or tap here to enter text.*

**Section 8: Data Management and Other issues**

1. **Privacy and Confidentiality**

*[Define the adopted protocol to protect the privacy and confidentiality of the participant. This includes the format in which you plan to save the data. Show how data for each participant is distinguished to prevent matching by any researchers if this is not addressed earlier. Elaborate if the date is identifiable or not.]*

*Click or tap here to enter text.*

1. **Security and Storage of Data**

*[Define whose is responsible for storing the data and who will have access and how. Also, what actions are in place to prevent or restrict access to these data. Note that this section is devoted for digital data. If you are planning to generate hardcopies or use non-digital data format, elaborate here.]*

*Click or tap here to enter text.*

1. **Retention**

*[For how long will you keep the data generated by this research? how will you evaluate the retention process?. Also, how you dispose the data and how to ensure a complete deletion of the data.]*

*Click or tap here to enter text.*

**D) Other Issues**

*[Please mention any other ethical issues which are not covered through this application, if no state “N/A.”]*

*Click or tap here to enter text.*

**Declaration on Accuracy of Information**

With my signature, I declare to the best of my knowledge that the information in this application is accurate. I acknowledge that providing misleading or untrue information may lead to my application being rejected.

**Applicant:**

Click or tap to enter a date. Click or tap here to enter text.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Print Name and Signature

**Declaration by the Researcher**

I have read and agreed upon the current bio-ethics committee guidelines of University of Jeddah. I accept responsibility for conduct of the procedures set out in the attached application in accordance with: those guidelines, with the University’s Research Criteria, with the national law of ethics of research on living things by Bureau of Experts at the Saudi Council of ministries and national committee of bioethics at King Abdulaziz City of Science and Technology. I certify that the research team has the appropriate qualification and experience to conduct the proposed research in compliance with these regulation.

If approval is granted, the research project will be undertaken strictly with the approved research protocol by Bioethics Committee of Scientific and Medical Research at university of Jeddah.

**Applicant:**

Click or tap to enter a date. Click or tap here to enter text. 

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Date Print Name and Signature

*After finishing and reviewing your application, please attach the following documents to this application and send via email to* [*DSRD@UJ.EDU.SA*](mailto:DSRD@UJ.EDU.SA) *:*

* *CV for principle investigator and Co-PI(s) to be grouped in one single file (word or PDF) Name file according to the following nomenclature ( applicant last name\_CV) e.g. Ghamdi\_CV*
* *Application form filled and signed*
* *Signed declaration forms (embedded to this application)*
* *Review the check list table below, and attach a copy accordingly. Following the same approach, please name the file according to this format (applicant last name\_TYPE of ATTACHMENT) e.g. Ghamdi\_Data module.*

|  |  |
| --- | --- |
| **Attachments Checklist** | |
| Review your answers above to determine which attachments (if any) are required for your application**.** Attach a copy of the items you have selected. | |
|  | **If you are student, Approval from supervisor is required** |
|  | **Consent Form for Participants** |
|  | **Additional Consent Form(s)** (e.g. for parents, teachers, schools; or assent forms for children) |
|  | **Recruitment Materials** (e.g. advertisement(s), posters, letter(s) or email(s) of invitation) |
|  | **Questionnaire(s)** |
|  | **Measure(s) – Procedures(s)** |
|  | **List of Interview Questions** |
|  | **Participant Distress Protocol** |
|  | **Adverse Event Protocol** |
|  | **Debriefing Statement** |
|  | **Approval(s) of research within University of Jeddah or** |
|  | **Other External Approval(s)** |
|  | **Full Protocol** (for Medical Research) |
|  | **Privacy and Databanks Module** |
|  | **Body Tissue and Genetic Research Module** |
|  | **Ionising Radiation Module** |
|  | **Interventions, Therapies and Trials Module** |
|  | **Reference Letter** |
|  | **Participant Information Sheet** |
|  | **Other Documents** (e.g. contracts, agreements) – specify which: |
| Click or tap here to enter text. |