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| **Medical Education & Research Dept**Medical Research SectionDubai Scientific Research Ethics Committee | **إدارة التعلـــــــــــــيم الطـــــــــــــبي والأبـــــــــــــــحاث**قسم البحـــــــــــــــــــــــوث الطبيةلجنة أخلاقيات البحث العلمي بدبي |

**DSREC Application Form**

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| 1. **Instructions**
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| **Fill in this application form, sign it electronically then send it to** **DSREC@dha.gov.ae** **considering the below**:* The application must be clearly legible
* Typing is a must. No handwritten form will be accepted
* The modification of the original content of the form is strictly prohibited.
* All sections of the application form must be completed
* Write “Not Applicable” wherever appropriate
 |
| 1. **Principle Investigator’s Details** (undergraduate students can’t be principle investigators on a clinical study)
 |
| **2.1 Name:** |  | **2.2 Staff ID:** (applicable for DHA staff) |  |
| **2.3 Designation:** |  | **2.4 Unit/Department:** |  |
| **2.5 Institution/Uni:** |  | **2.6 Email:** |  |
| **2.7 Contact no. Office:** |  | **2.8 Mobile:** |  |
| **2.9 Does the principle investigator or other key personnel have any conflict of interest in this study?**[ ]  **No** [ ]  **Yes, please specify**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Co-Investigators and Study Staff**
 |
| **3.1 Are co-investigators involved in this study?** | [ ]  Yes, please fill below table | [ ]  No, why?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Title | Name | Designation | DHA Staff ID | E-Mail/Contact | Unit/Dept | Role in the study |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| \*\* you may add more rows if required |
| 1. **Research/Study Details**
 |
| * 1. Title:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.2 Short Title (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.3 Proposed Study Start Date | dd/mm/yyyy | 4.4 Proposed Study End Date | dd/mm/yyyy |
| 4.5 Retrospective Study Period (From) *only if applicable:* | dd/mm/yyyy | 4.6 Retrospective Study Period (To) *only if applicable:* | dd/mm/yyyy |
| 4.7 Type:[ ]  Drug Study [ ]  Device Study [ ]  Chart/Records Review [ ]  Biomedical Research [ ]  Health Related Research [ ]  Community-Based [ ]  Social and Behavior Research [ ]  Research with Genetic Material [ ]  Genomics-Related Research[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.8 Summarize the background and hypothesis of the study:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.9 What are the primary and secondary objectives of the study?**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.10 Why is this research important? What contributions will it make?**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.11 Has this research proposal been approved by an Institutional Review Board (IRB) or Research Ethics Committee elsewhere? [ ]  Yes [ ]  NoIf ‘Yes’, please attach a copy of the approval and provide the following information:1. Name of institution that reviewed this research proposal \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Address of reviewing institution \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| 4.12 Has this study been done elsewhere? [ ]  Yes [ ]  NoIf ‘Yes’, how does this differ from the ones done earlier?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.13 Is this a multi-center trial? [ ]  Yes [ ]  NoIf yes, which are the other centers involved? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.14 List the research site(s) in UAE, where the study is to be conducted and the contact person details of each site (title, name, mobile, email, etc.):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.15 Will this study involve human subjects? [ ]  Yes [ ]  No [ ]  Not-applicableIf ‘Yes’, will you have direct contact or intervention with them? [ ]  Yes [ ]  No(e.g., as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) |
| 4.16 Research Population:1. **Research population and sample size calculation:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Expected total number of participants in the study**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Age range of participants**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **How will participants be included in the study?**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **If randomization is used, please explain how this will be done**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **How much time will a subject have to dedicate to the project beyond that needed for standard treatment?**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **If normal volunteers are involved, please explain how many will be selected and the method of selection employed?**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.17 This study will involve the following subject types (check mark the applicable subject type):[ ]  Normal Volunteers [ ]  Subjects Incapable of giving Consent [ ]  In Patients [ ]  Prisoners or Institutionalized Individuals [ ]  Out Patients [ ]  Fetuses[ ]  Patient Controls [ ]  Infants (0 -3 Y)[ ]  Students [ ]  Children (3-12Y) [ ]  Cognitively Disabled [ ]  Minors (Under Age 18)[ ]  Physically Disabled [ ]  Over Age 60 [ ]  Pregnant Women [ ]  Other Potentially Elevated Risk Populations |
| **4.18 What are the inclusion criteria?**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.19 What are the exclusion criteria?**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.20 Please specify any incentives, compensation or treatment the participants will receive through participation in this study:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.21 Does this project call for?** (Check mark all that applies):[ ]  Use of Voice, Video, Digital, or Image Recordings? [ ]  Advertising for subjects?[ ]  More than Minimal Risk?[ ]  More than Minimal Psychological Stress?[ ]  Extra Costs to the subjects (tests, hospitalization, etc.)? |
| **4.22 Are there any predictable risks to the subjects of physical or psychological pain or discomfort, or risk of injury of any kind?** [ ]  **Yes** [ ]  **No** [ ]  **Cannot Predict**If ‘Yes’ or ‘Cannot predict’, describe the possible areas of risk. Outline briefly any steps taken to minimize the possibility of pain, discomfort or injury and procedures for determining levels of discomfort at which you will terminate the participation by the subject in the research:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.23 This project involves the use of** (Check mark all that applies):[ ]  An Investigational New Drug (IND) or an approved drug for an unapproved indication. Drug name and company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  An Investigational Medical Device or an Approved Medical Device for An Unapproved Use Device name and manufacturer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Radiation or Radioisotopes[ ]  Blood, total amount of blood needed \_\_\_\_\_\_\_\_\_\_\_\_\_ over time period (days)\_\_\_\_\_\_\_\_\_[ ]  [rDNA or Biohazardous materials](http://www.purdue.edu/Research/ORA/rdna/rdna-main.html) [ ]  Human Tissue or Cell Lines |
| **4.24 If a drug or a device will be used for the study:****Is the drug or the device approved (registered) by DHA or MOH?** [ ]  **Yes** [ ]  **No**  **If No,**1. Is the drug or the device approved by any major International Organizations, e.g. FDA, EMEA?

[ ]  Yes [ ]  No1. Is the documentation on the provision of the unregistered drug or the device to the site submitted?

[ ]  Yes [ ]  No (If no please provide the explanation1. Is the MOH UAE declaration for the entry of the unregistered drug or the device submitted?

[ ]  Yes [ ]  No (If no please provide the explanation) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Provide details of any known side effects, which may result from the investigational drug or device.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **If it is a drug, what phase of research the drug has reached to date?**

[ ]  Phase 1 [ ]  Phase 2 [ ]  Phase 3 [ ]  Post marketing studyFor clinical trials please complete the Clinical Trial Undertaking Letter.  |
| **4.25 Is this a double-blinded study?** [ ]  **Yes** [ ]  **No** **If yes,** 1. Is the code for unblinding in case of emergency available at both the investigator (e.g. hospital) and sponsor sites?

[ ]  Yes [ ]  No, justify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. Format in which code breaks for clinical trials are supplied

[ ]  Sealed envelopes[ ]  Scratch cards[ ]  Tear off label on the drug container which will be removed when dispensing the trial drug and place on the drug accountability form[ ]  Interactive voice response system – user identity and password are required to access such system[ ]  24-hour telephone number provided by the sponsor |
| **4.26 Does the project require special data collection (e.g., interview, questionnaire, case record forms)?**[ ]  **Yes** [ ]  **No** If Yes, please attach a copy |
| **4.27 What special training or qualifications are required for data gatherers? Who will provide training?***\*As per DSREC SOP, it is mandatory to submit the certificate for Clinical trial with certificate validity of two years.*

|  |  |
| --- | --- |
| **Training name** | **Certified** |
| ICH GCP | [ ]  Yes [ ]  No |
| NIH | [ ]  Yes [ ]  No |
| Other (Specify): | [ ]  Yes [ ]  No |

 |
| **4.28 Data handling:**1. **Who will have access to the data?**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Will all personally identifying data be held confidential?** [ ]  **Yes** [ ]  **No**
2. **Does the project require the linkage of project data on available subjects with other individually identifying data from outside the facility or division?** [ ]  **Yes** [ ]  **No**

*If yes, describe the other data sources and types of data used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*1. **What steps are being taken or will be taken to ensure that no information that may identify an individual be released?**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **How will the subjects’ rights to privacy and safety be protected? Describe measures that will be taken to protect the confidentiality of data containing patient-identifying information:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Will any patient identifiable information be provided to an external study sponsor?**

[ ]  Yes [ ]  No [ ]  Not-Applicable, there is no external study sponsor |
| **4.29 Anonymity and Confidentiality:**1. **Will the anonymity (*protection of the identity of participants*) of participants be protected?**

[ ]  **Yes (completely)** [ ]  **Yes (partially)** [ ]  **No**If ‘Yes’, how will anonymity be protected and how will this be explained in the consent process?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_If ‘No’, justify why loss of anonymity is required and explain how this will be explained in the consent process: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Will you provide confidentiality *(protection, access, control and security of the data and personal information*) to the participants and their data?** [ ]  **Yes** [ ]  **No**

If ‘Yes’, how will confidentiality be protected and how will this be explained in the consent process?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_If ‘No’, justify the lack of confidentiality and explain how this will be explained in the consent process.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.30 Informed Consent. It is DSREC’s requirement to have written consent for all projects involving human participants.** *Please ensure that information sheet and Consent Form includes all the essential elements as per the DSREC Information sheet and consent form template. Submit the same with its Arabic translation. The text description should be the same in both English and Arabic documents.***Other languages to be provided if needed.** |
| **4.31 If a signed written consent will not be obtained, explain what you will do instead and why?** Additionally, Provide a request for “Waiver of written Consent with a justification for the same”\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.32 What are the provisions made to obtain informed consents in case the participants were of minors or adults incapable of giving consent for themselves?**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.33 Do** **you expect this research to be used for commercial purposes?** [ ]  **Yes** [ ]  **No** If ‘Yes’, explain how will this information be declared and explained to the participants in the consent process and to the DSREC:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.34 Is this study funded?** [ ]  **Yes** [ ]  **No** If ‘Yes’:1. What is the nature of the fund? [ ]  Grant [ ]  Contract/Agreement [ ]  Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Full name of sponsor / funding source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Contract/agreement/grant (attach a copy)
 |
| 1. **Principle Investigator**
 |
| **Your signature indicates that you agree to abide by all policies, procedures, regulations and laws governing the ethical conduct of research involving humans.****Signature of the Principle Investigator** (print name)  (signature)  (date) |
| 1. **Head of Department of Study Site**
 |
| I have read this application and believe it to be scientifically and ethically sound. I approve the research design. I give my consent for the application to be forwarded to the Office of Dubai Scientific Research Ethics Committee with my recommendation that it be approved.**Signature of Head of the Department of the study site:**(print name)(signature)(date)**AND/OR****Signature of the Center’s CEO** (print name)(signature)(date) |
| 1. **If this is a supervised work** (applies to medical residents/students):
 |
| **Supervisor’s Title/ Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Position/Depart: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Contact Nos.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Supervisor’s signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***Your signature indicates that you have reviewed and approved the proposal, assisted the medical resident or student in the preparation of this application and agrees to be responsible for the ethical aspects of the project.* |