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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 |

**Investigational Medical Device Form**

**Instructions:**

* If you are planning to use Investigational medical device/s in human subjects’ research, you must complete this form. This form must be included with DSREC application submission documents.
* If you answered yes to “Device study” under Section 4.7 of DSREC application form you need to complete this form.
* If you answer yes to “An Investigational Medical Device or an Approved Medical Device for An Unapproved Use: under Section 4.23 of DSREC application form you need to complete this form.
* Make sure to complete this form for each new Investigational device/s separately.
* Attach any other supporting document available for the device along with this form.

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| 1. Protocol Title and number:
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| 1. Investigational medical device name and Device manufacturer:
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| 1. Is an Investigational medical device/s approved (registered) by DHA or MOH?

[ ]  Yes [ ]  No  If No,1. Is the Investigational medical device/s approved by any major International Organizations, e.g. FDA, EMEA?

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

 [ ]  Yes [ ]  No (If no please provide the explanation) ­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. 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. Describe the Investigational medical device/s:
2. Anatomical site where the device/s will be used, if applicable:
3. Provide an intended use of the Investigational medical device/s:
4. Structure and dimensions of device/s:
5. Provide any additional information/ images available for the device (brochures and usage manuals etc.)
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| 1. Provide Safety and efficacy data available from the previous phases, if applicable
 |
| 1. 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
2. If ‘Yes’ or ‘Cannot predict’, describe the possible areas of risk:
3. 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:
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| 1. Provide details of any known side effects, which may result from the investigational medical device/s:

*An unanticipated adverse device effects (UADEs) must be reported by filling DHA’s (Serious Adverse Events Reporting form) by the Principal Investigator within 48 hours (Initial Report) of Investigator’s awareness. Follow up Report, if any, should be completed and submitted within 14 days.* |
| 1. Describe the handling of the Investigational medical device/s information (such as transportation/ storage/dispensing etc..):
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| 1. What special training or qualifications are required to use this Investigational medical device/s? Who will provide these training?
 |
| 1. Does the device have the capability to capture/process/store/communicate healthcare data and outcomes?

[ ]  Yes [ ]  No [ ]  Not applicableIf yes, describe how the device will be capturing/processing/storing/communicate healthcare data and outcomes: |
| 1. Is there any future plan of importing and marketing an Investigational medical device/s in UAE?
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