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| **Medical Education & Research Dept**  Medical Research Section | **إدارة التعلـــــــــــــيم الطـــــــــــــبي والأبـــــــــــــــحاث**  قسم البحـــــــــــــــــــــــوث الطبية |
| **Undertaking Letter to Conduct Human Subjects Research** | |
| **Facility Name:**  **DHA Health Facility License number:** | |
| 1. **Our facility/ facilities intend to conduct Human Subjects Research\*** | |
| 1. **Our facility/ facilities will apply and follow Research Ethics as mandated by DHA.** | |
| 1. **We certify that our Facility/Facilities will maintain the availability of scientifically qualified research team that fulfil the clinical trial purpose.** | |
| 1. **We certify that our facility/facilities will report to DHA, through periodic progress reports or upon DHA request, a clinical trial progress report.** | |
| 1. **We certify that our facility/facilities will immediately report to DHA the occurrence of any serious adverse event.** | |
| 1. **We certify that our facility/facilities will immediately report to DHA any serious breaches of approved research protocols or conditions or principles of Good Clinical Practice (ICH GCP).** | |
| 1. **We certify that our facility/facilities will immediately report to DHA any provision of false or misleading information in an application submitted for ethical approval.** | |
| 1. **We certify that our facility/facilities hold appropriate human subjects research indemnity insurance covering all adverse outcomes for individuals who are the subject of the research, all other potential liabilities of the Institution, and all potential liabilities of individual clinicians and researchers employed by, or contracted to, the Institution.** | |
| \*Human Subjects Research includes studies of physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or in patients or on Human Tissue, controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation, studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures, and/or studies concerning human health-related behavior in a variety of circumstances and environments. | |
| Agree  Disagree | |
| Name of Authorized Official:  Title: Phone: Email:  Signature & Stamp: | |
| *Official signature and agreement to this form means that you read and understand the contents and hereby abide by the mentioned points regarding the Department of Health Regulations.* | |