Date: Ref:	**Application for Authorization to Conduct Human Subjects Research**	دائـــــرة الـصـــحـــة DEPARTMENT OF HEALTH

Institute Name:	**DoH Facility License #:**

1. **Our facilities/ facility intend to conduct Human Subjects Research**
   *(*Please see the definition of Human Subjects Research at the bottom of the page).*

2. **Our facilities/ facility have an established Research Ethics Committee (REC).**

3. **We Certify that our Facility/Facilities developed SOP for Research Ethics Committee (REC).**
(Attach it with the application upon submission))

4. **We certify that our facility/facilities will report to DoH, through periodic progress reports or upon DoH request, a summary of institutional REC activities on a form approved by DoH.**

5. **We certify that our facility/facilities will immediately report to DoH the occurrence of any serious adverse event.**

6. **We certify that our facility/facilities will immediately report to DoH any serious breaches of approved research protocols or conditions or principles of Good Clinical Practice (ICH GCP).**

7. **We certify that our facility/facilities will immediately report to DoH any provision of false or misleading information in an application submitted for ethical approval.**

8. **We certify that our facility/facilities holds 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 generalisable 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.
*SOP: Standard Operating Procedure

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.

Please return form and attachments to Department of Health Abu Dhabi, Medical Research Department, P.O.BOX 5674, UAE.
Email: medical.research@doh.gov.ae