(نموذج رقم 4) (Form No. 4)

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| **STATEMENT OF INVESTIGATOR** | | | | |
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| **NAME AND ADDRESS OF INVESTIGATOR** | | | | |
| Name of principal investigator | | | | |
| Address | | Saudi Commission for Health Specialties no. | | |
| City | Qualified area(s) of specialty | Telephone no. | E-mail | |
| EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(select* ***one****)*:  Curriculum vitae Other statement of qualifications | | | | |
| Does the investigator have GCP certification?  Yes No  If yes, attach your certification. | | | | |
|  | | | | |
| **NAME OF TRIAL SITE** | | | |  |
| Name of hospital or other research facility | | | | |
| Address | | City | | |
| Telephone no. |
|  | | | | |
| **NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY**  *(in case of central lab)* | | | |  |
| Name of clinical laboratory facility | | | | |
| Address | |  | | |
| City | Province/region | Country | | Postal code |
|  | | | | |
| **NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY/STUDIES** | | | |  |
| Name of IRB | | | | |
| Address | | Registration no. at NCBE | | |
| NAMES OF SUBINVESTIGATORS *(if not applicable, enter “none”)* | | | | |

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| **Details of Study**   |  |  | | --- | --- | | Study title | Protocol no. | | Version no. | SCTR no. | | |
| **COMMITMENTS**  I agree to conduct the study or studies in accordance with the relevant, current protocol(s) and will make changes in a protocol only after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.  I agree to personally conduct or supervise the described investigation(s).  I agree to inform any patients or any persons used as controls that the drugs are being used for investigational purposes, and I will ensure that the requirements related to obtaining informed consent and institutional review board (IRB) review and SFDA regulations are met.  I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with regulatory requirements. I have read and understand the information in the investigator’s brochure, including the drug’s potential risks and side effects.  I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study or studies are informed about their obligations in meeting the above commitments.  I agree to maintain adequate and accurate records in accordance with GCP E6 and to make those records available for inspection in accordance with GCP E6.  I will ensure that an IRB that complies with the requirements of the National Committee of Bioethics (NCBE) is responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval except where necessary to eliminate apparent and immediate hazards to human subjects.  I agree to comply with all other requirements regarding clinical investigators’ obligations and all other pertinent requirements in the Regulations and Requirements for Conducting Clinical Drug Trials. | |
| **NOTE**:  INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE SFDA. | |
| **DATE** *(mm/dd/yyyy)* | **SIGNATURE OF INVESTIGATOR** |