INSPECTION APPLICATION FORM FOR PHASE 1 CLINICAL TRIAL CENTERS

1. **GENERAL CONSIDERATIONS**
2. **General Information on the Center:**

|  |  |  |
| --- | --- | --- |
| Will the inspection be conducted at multiple addresses? | Yes | No |

|  |  |
| --- | --- |
| Name of the Center |  |
| Full address and contact information |  |
| Contact person |  |
| Phone number |  |
| e-mail: |  |

* *This part shall be replicated to receive the pertinent center information in case the inspection is to be conducted in more than one address.*

1. **Personnel:**

|  |  |
| --- | --- |
| The number of personnel working in the center (The number of administrative personnel, auxiliary personnel, healthcare personnel shall be specified separately) |  |

1. **Authorization:**

|  |  |
| --- | --- |
| Name of the authorized natural/legal person |  |
| Full address |  |
| Contact person |  |
| Phone number |  |
| e-mail: |  |

1. **RELATED DOCUMENTS**
2. Organizational chart

* *Organizational charts for the clinical department, administrative and technical units, as well as general organizational charts should be included in the application file.*

1. Workflow chart

* *Should be included in the application file for administrative and technical units and clinical department.*

1. Key personnel list

* *Should be included in the application file for administrative and technical units and clinical department.*

1. Procedure (SOP) list

* *The application file should include a list of the administrative, technical, and clinical departments' standard operating procedures.*

1. Previous inspections/examinations

* *Inspections/Examinations conducted by other health authorities (US FDA, EMA, etc.) or by the sponsor should be listed.*

1. Layout plan

* *Layout plans for Administrative and Technical Unit, Clinical Department should be submitted.*

1. Equipment List

* *The application file should include a list of the equipment used in the Technical Unit and the Clinical Department.*

1. In case natural or legal entities are authorized for the application:
   1. In case the applicant is a natural entity, a notarized copy of their diploma and the resume showing that they exercise one of the professions specified in Article 6 of the GCP Inspection Application Guidelines.

* *Natural persons must be graduated from one of the schools providing education in the fields of pharmacy, medicine or chemistry, have the authority to practice their profession in Turkey, and also have knowledge and experience in clinical trials.*
  1. In case the applicant is a legal entity, the original or copy of the trade registry gazette stating the purpose of establishment of the company, the partners and the duties and titles of the responsible persons, and the resume of the “authorized person”.
* *Legal entities must employ as an "authorized person" a person who has the qualifications listed in the previous article and the knowledge and experience in clinical trials.*

1. Approved documentation proving that the applicant is authorized to submit the application.

* *In case natural or legal entities are authorized to submit the application, the relevant authorization document should be included in the application file.*

*i. The documents specified in this section should be added to the application file in appropriate order.*

*ii. The application file should be submitted in two parts under the headings I-Administrative and technical unit, II-Clinical Department.*

1. **SIGNATURE OF THE APPLICANT**

Hereby I undertake that the information on this application form is accurate.

Name and Surname :

Date :

Signature: