NOTIFICATIONS ON CHANGES FORM

1. **General Information on the Center:**

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

1. **Change**

|  |  |  |
| --- | --- | --- |
| **Scope of the Change** |  | **Reason** |
| Relocation of the center[[1]](#footnote-2) |  |  |
| Adding a new section |  |  |
| Closing of an existing section |  |  |
| Relocation of an existing section |  |  |
| Key personnel change |  |  |
| Change in organizational structure |  |  |
| Significant amendments in the contract[[2]](#footnote-3) |  |  |

1. **Authorization:**

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

**RELATED DOCUMENTS**

1. Organizational chart

* *Should be included in the amendments concerning key personnel or organization.*

1. Workflow chart

* *Should be included in the amendments concerning key personnel or organizational structure, when necessary.*

1. Key personnel list

* *Should be included in the amendments concerning key personnel or organization.*

1. Procedure list

* *Where necessary, a list of procedures that have been revised after changes (add, remove, move) in the organization and physical space should be presented.*

1. Layout plan

* *Layout plans should be submitted for changes made in the physical area (add, remove, move).*

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.

* *If natural entities, they should hold a degree in pharmacy, medicine or chemistry, be qualified to practice their profession in Türkiye, and also have training and expertise 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, the resume of the “authorized person”.
* *If legal entities, they should employ someone who has the qualifications listed in the preceding article and has knowledge and experience in clinical trials, as an "authorized person"*

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.*

**SIGNATURE OF THE APPLICANT**

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

Name and Surname :

Date :

Signature:

1. After a notification regarding the relocation of the center is submitted, a new inspection application should be made in accordance with the 2nd paragraph of Article 6.5 of the “Guidelines on Applications for Inspections of Good Clinical Practices”. [↑](#footnote-ref-2)
2. Changes in the contracts made between phase 1 clinical trial centers operating out of the hospital and tertiary healthcare institutions [↑](#footnote-ref-3)