APPLICATION FORM TO IMPORT INVESTIGATIONAL PRODUCTS FOR CLINICAL TRIAL USE

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A. APPLICATION TYPE		
First application ☐	Renewal ☐	Amendment ☐

B. INFORMATION ABOUT INVESTIGATION	
Please specify the full name of the investigation	
Protocol code/number	
Please specify the number/code attained by the Institution	

C. SPONSOR/LEGAL REPRESENTATIVE INFORMATION	
Sponsor name	
Sponsor address information	
Name and surname of the contact person of sponsor	
e-mail information of the contact person of sponsor	
Phone number of the contact person of sponsor	

(If present) Please specify the name and contact information of legal representative of sponsor	
Legal representative of sponsor address information	
Name and surname of the contact person of legal representative of sponsor	
e-mail information of the contact person of legal representative of sponsor	
Phone number of the contact person of legal representative of sponsor	

D. INFORMATION RELATED TO INVESTIGATION	
Please specify the initiation and termination date and duration (those in our country, if it is an international investigation) of the investigation	

Please specify the termination date of volunteer acquisition according to investigation protocol		
Please specify the number of volunteers in our country, which is approved the institution		
Please specify the number of volunteers included in our country so far in the investigation		
Please specify the number of volunteers currently active in our country in the investigation		
According to protocol, please specify the maximum treatment duration that can be applied to the volunteers		
According to protocol, please specify the maximum allowed dosage (daily or total dose; as unit and application route)		
Is the investigational product a blood product?	Yes ☐	No ☒

E. INFORMATION ABOUT THE AMOUNT OF REQUIRED INVESTIGATIONAL PRODUCT

Regarding the amount specified in this section, the accounting process performed in the direction of data such as number of volunteers, duration of investigation, dose, etc. has to be clearly shown.

F. INFORMATION RELATED TO DELIVERY OF INVESTIGATIONAL PRODUCTS

☐	**The distribution of the investigational product will be directly to the centers.**	
☐	**The investigational product will be stored in an approved store by the Institution.**	
	Please specify the name of the place where the investigational product will be stored	
	Address	

G. DISTRIBUTION OF INVESTIGATIONAL PRODUCTS TO BE USED IN THE INVESTIGATION

This section will be filled in for the applications that have been previously applied for import and granted import permission.

Amount of investigational product approved for import by the MoH	
Amount of imported investigational product	
Amount of the investigational product to be imported with the validated proforma invoice	
Stock of investigational product remaining in warehouse and research center	
Amount of investigational product used	
Loss of research product (including expired investigational products)	

H. PREPARATIONS CONTAINING CONTROLLED SUBSTANCE (DRUG OR PSYCHOTROPE SUBSTANCE)

In case of using preparations containing controlled substance (drug or psychotrope substance) in clinical investigations, importation permission should be obtained from the Risk Management Department.

I. RELATED DOCUMENTS

Documents specified in this section should be added to the application file, respectively. Applications containing missing information and documents will not be evaluated.

1. License of authorization *(*an original license of authorization for the first application to import, *copy* of license of authorization *for other applications)*
2. Proforma invoice for the investigational product (Approved by the company who issued the invoice or approved by the company who made application to import, wet signed, in two copies, with proforma date/number and page numbers)
3. In case of the use of products obtained from blood in drug clinical investigations, an "apostilled" original document that will be given by the manufacturer company regarding Creutzfeld Jacob (CJ) disease, including that they are safe in terms of disease or suspicion of disease and that no CJ disease is present among donors

J. DOCUMENTS TO BE PROVIDED PHYSICALLY

This section is only for applications to Turkey Pharmaceuticals and Medical Devices Agency.

All relevant users who are users of the Institution's Electronic Application System must make their applications through the system. Documents that do not need to be presented physically are only must be submitted through the Electronic Application System

The original document that must be submitted physically to the document unit of the Institution, the scanned version of them need to be submitted through the Electronic Application System firstly.

All documents must be physically submitted for applications made by natural person who is not user of the Institution's Electronic Application System.

1. If available, an original license of authorization for the first application to import
2. Proforma invoice for the investigational product
3. In case of the use of products obtained from blood in drug clinical investigations, an "apostilled" original document that will be given by the manufacturer company regarding Creutzfeld Jacob (CJ) disease, including that they are safe in terms of disease or suspicion of disease and that no CJ disease is present among donors

K. SIGNATURE OF THE APPLICANT

This application form must be signed electronically.

With this application form;

- All documents presented in the application are the same as the original,
- The information provided on the application is correct,
- The investigation / study will be carried out in accordance with the protocol, the relevant legislation and the principles of good clinical practice,
- The imported research products will be distributed to the centers approved by MoH where the research is being carried out, which is suitable for the conduct of the study,
- I undertake that the investigational products are produced in accordance with good manufacturing practices (GMP) and that they will be stored / distributed under appropriate conditions.

Name Surname	
Phone number	
E-mail	
Date (day/month/year)	
Signature:	