"DECLARATION OF INTEREST"

(REGULATION 536/2014, ANNEX I, LETTER M, N. 66 AND ART. 6, PAR. 4, LEGISLATIVE DECREE 14 MAY 2019, N. 52, AS AMENDED BY ART. 11-BIS, PAR. 1, D.L. 19 MAY 2020, N. 34, CONVERTED INTO L. 77/2020)

Each Member State, for each clinical trial, will have to evaluate the aspects included in Part II of the Regulation including the "**Declaration of interest**" which must be completed by the investigator[1] and is part of the application dossier.

This model has been developed and approved by the Coordination Centre based upon the model drafted by the EU Clinical Trials Expert Group in compliance with Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. However, this model is also appropriate for trials conducted under Directive 2001/20/EC.

The following statement refers to the following clinical trial

[Please insert the full title and reference number]

To be held at the Centre [insert name Centre]

Coordinator Centre [YES] [NO]

I, the undersigned, prof./dr. [surname – name],

Affiliated to the structure [structure name]

Principal Investigator [YES] [NO]

in this trial,

DECLARE

that those indicated in the tables below constitute **all** interest, activities and/or relationship that I entertain with the Sponsor(s) of the trial and in general with the pharmaceutical/ biomedical industry:

Table 1.A Relevant activities carried out ([2])

[1]) Pursuant to Regulation (EU) no. 536/2014, ART. 2 par. 2 n° 15 and 16 an "investigator" is defined as: a person responsible for the realization of a clinical trial at a clinical trial site; 'Principal investigator': an investigator leading, as head, a team of investigators responsible for conducting a clinical trial at a certain site.

Role/position held in/for the Sponsor(s) of the trial and/or the pharmaceutical/biomedical industry in general in respect of a particular product/product group	**NO**	**Currently or during the past year**	**From 1 to 3 years**	**Over 3 years[2]**
A) Employee (clerk – middle management – manager)				
B) Scientific Consultant ([3])				
C) Member of a collegial scientific body with advisory functions for the sponsor of the trial				
D) Principal *Investigator*				
E) *Investigator*				

Table 1.B – identification of potential conflict areas

Type of activity (Table 1.A)	**Name of the company (SPONSOR OR NOT) for which you have carried out a relevant activity**	**Similar products to the one being tested**	
A) Employees B) Individual scientific advice C) member of collegiate bodies (e.g. Advisory Board, Steering Committee/Academy, ...) D) training activities (e.g. ECM, preceptorship) E) PI or Investigator F) Other			

[2]) By checking any box other than the "NO" column, it is required to provide information regarding the products concerned in Table 1B. Stating an interest in Table 1.A but not providing info in Table 1.B, results in the impossibility to submit the study to the Ethics Committee.

[3]For the purposes of this document, the definition covers any experienced professional who provides services to the Sponsor in a particular field, with or without compensation (personal and/or institutional).

(→ If necessary, use additional sheets)

2 - DECLARATION OF FINANCIAL, FAMILY OR OTHER INTERESTS

Table 2.A – Equity participations, funds/financing

	NO	**YES direct**	**YES Indirect** ([4])	**Company name**	**Indicate share in % or nature/amount of funds**
I hold a stake in the capital of a pharmaceutical/biomedical industry					
My department receives funds or other funding from pharmaceutical/biomedical industry (and I do not receive compensation)					
I am a recipient of funds or other financing from pharmaceutical/biomedical industries					

Table 2.B – Family relationships, patents

	NO	**YES**	**Company name and products**	**Description**
I have marital, cohabitation, kinship ties within the second degree with people linked to pharmaceutical/ biomedical industries by employment relationships or professional assignments				
I possess a patent on the investigational medicine or a related product				

(→ If necessary, use additional sheets)

Please specify below any other relevant interest:

.....

(→ *If necessary, use additional sheets*)

[4]) For the purposes of this document, the shareholding held by the spouse, the cohabiting partner or children, parents or siblings are considered indirect participation. By checking any box in the column "YES, indirect" you will have to provide in the following columns information regarding the company, the period of activity and the products concerned. Not providing the relevant information results in the study not being submitted to the Ethics Committee.

*** *** ***

I declare that I have no other interests, activities and/or direct or indirect relationships in or with the pharmaceutical/ biomedical industry, economic interests, institutional affiliations, or personal interests that could influence my impartiality.

I also certify, to the best of my knowledge and responsibility, that the information provided above is true and accurate.

I undertake to update them promptly, even after the start of the trial.

Date: Click or tap here to enter the text.