# "DECLARATION OF INTERESTS"

**(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 interests**" 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 from the model elaborated 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 relevant 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** the interests, activities and/or relationships that I entertain with the Promoter(s) of the trial and in general with the pharmaceutical 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 a company in relation to 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 (PROMOTER OR NOT) for which you have carried out a relevant activity | Similar products to the one being tested | |
|---|---|---|---|
| A) Employees<br>B) Individual scientific advice<br>C) member of collegiate bodies (e.g. Advisory Board, Steering Committee/Academy, ...)<br>D) training activities (e.g. ECM, preceptorship)<br>E) PI or Investigator<br>F) Other | | | |

(→ If necessary, use additional sheets)

[2]) By checking any box outside 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 study not being submitted to the Ethics Committee.

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

**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 industry | | | | | |
| My department receives funds or other funding from a pharmaceutical industry (and I do not receive compensation) | | | | | |
| I am a recipient of funds or other financing from pharmaceutical industries | | | | | |

**Table 2.B – Family relationships, patents**

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

(→ If necessary, use additional sheets)

**Please specify below any other relevant interest:**

.....

(→ *If necessary, use additional sheets*)

*** *** ***

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

[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.

| |
|---|
| influence my impartiality.<br><br>I also certify, to the best of my knowledge and responsibility, that the information provided above is true and accurate.<br><br>I undertake to update them promptly, even after the start of the trial.<br><br>Date: Click or tap here to enter the text. |
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