Regulation (EU) No 536/2014 – Part II
Model approved by the National Coordination Centre of Ethics Committees
Nov. 10th, 2022 - version n°2

"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

Approccio multimodale in pazienti con carcinoma prostatico metastatico ormono sensibile. Studio pragmatico randomizzato con Apalutamide e trattamento locale. (APPROACH Trial)

To be held at the Centre: Department of Urology, University of Foggia

Coordinator Centre: NO

I, the undersigned, prof. Giuseppe Carrieri

Affiliated to the structure Department of Urology, University of Foggia

Principal Investigator: YES

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:

[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.

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

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)	X			
B) Scientific Consultant ([3])	X			
C) Member of a collegial scientific body with advisory functions for the sponsor of the trial	X			
D) Principal *Investigator*	X			
E) *Investigator*	X			

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 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 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).

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

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	X			
I possess a patent on the investigated medicine or a related product	x			

(→ 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.

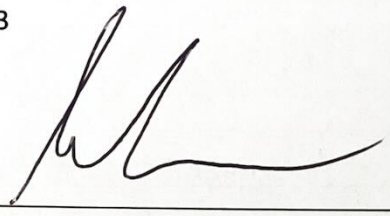
I declare that I have no other interests, activities and/or direct or indirect relationships in or with the pharmaceutical industry, economic interests, institutional affiliations, or personal interests that could influence my impartiality.

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: 27/03/2023

Signature:



"CURRICULUM VITAE PRINCIPAL INVESTIGATOR"

(EU REGULATION no. 536/2014, ART. 49, ANNEX I, SECTION M, PARAGRAPH 65)

Each Member State, for each clinical trial, will have to evaluate the aspects related to Part II of the Regulation among which there is the "**Curriculum vitae of the principal investigator**". This document must be prepared by the investigator, according to the model shown below, for the applicable parts, and is part of the application dossier. [1]

This model has been developed and approved by the National Coordination Centre of Ethics Committees, based on the model elaborated by the EU Clinical Trials Expert Group in compliance with Regulation (EU) no. 536/2014 on clinical trials on medical products for human use. However, this model is also relevant under Directive 2001/20/EC.

Personal Information

Name:	Giuseppe Carrieri
Title:	Professor
Profession:	Urologist
Current position:	Chairman Dept. of Urology University of Foggia, Italy President of the Italian Society of Urology

Professional Registration[i]

Registration number	N. 0000007973
Registration body:	Ordine dei medici e chirurghi di Bari
Membership expiry date (if applicable):	N/A
Registration state/province (if applicable):	Italy/Bari

([1]) Pursuant to the EU REGULATION n. 536/2014, ART. 2 par. 2 n° 15 and 16 an "investigator" is defined as: a person responsible for conducting a clinical trial at a clinical trial site; 'principal investigator' means an investigator who leads, as head, a team of investigators to conduct a clinical trial at a given site.

Education and qualifications[ii]

Institution name	Qualification	Year
University of Bari, Bari, Italy	Urology Resident	1985-1988
University of Barcelona	Clinical and Research Fellowship	1988-1989
University of Pittsburgh	Clinical and Research Fellowship	1989-1992

Current employment

Institution name:	University of Foggia
Department:	Urology
Institution address:	Via Luigi Pinto 1
Phone number:	+39 0881
E-mail address:	giuseppe.carrieri@unifg.it

Professional experience[iii]

Position:	Name of institution and department:	Start year	End year
Instructor of surgery	Department of Surgery University of Pittsburgh. Pittsburgh, U.S.A.	1991	1992
Assistant Professor of Urology	Department of Urology University of Bari	1992	1997
Associate Professor of Urology	Department of Urology University of Bari	2000	2003
Full Professor of Urology and Chairman	Department of Urology University of Foggia	2003	Present

Training

Research training (including GCP)	Institution name	Year of achievement
Clinical and Research Fellowship	*University of Barcelona*	1989
Clinical and Research Fellowship	*University of Pittsburgh*	1992

In compliance with the Reg. EU678/2016 (GDPR), I hereby authorize you to use and process my personal details contained in this document.

Date completed:
27.3.2023

Signature:

[i] As required by national legislation
[ii] Relevant to being an investigator
[iii] This should cover the preceding 10 years as a maximum