



**Penta**

Child Health Research

## **Organization, Management and Control Model**

### **Special Part C**

#### **No. 1.**

#### **OFFENCES IN RELATIONS WITH THE PUBLIC ADMINISTRATION OR THE JUDICIAL AUTHORITY**

## 1. PREAMBLE

With Law no. 3 of 9 January 2019, which amended Legislative Decree 231/2001, the legislator introduced important changes regarding sanctions in relation to the offences referred to in Art. 25 (Offences of *Extortion, undue incitement to give or promise benefits and corruption*).

In particular, in Art. 25, para. 5, the legislator has envisaged different durations of the prohibitive measures depending on whether offences are committed in favour of the entity by Persons in senior positions or by Persons in subordinate positions. Specifically, the Decree envisages prohibitive measures for a minimum duration of 4 years and a maximum of 7 years in the event that it is a person in a senior position who engages in the conduct, while for a person in a subordinate position it envisages a minimum duration of 2 years and a maximum of 4 years.

The Decree was also amended by inserting the provision of more favourable sanctioning in the event of so-called active repentance. Art. 25, para. 5-*bis* provides that the prohibitive measures may have a minimum duration of 3 months and a maximum duration of 2 years, in the event that the entity, before the lower court's decision, has endeavoured to:

- avoid further consequences of the offence;
- secure the evidence with respect to the offences and identify those responsible;
- ensure the seizure of the sums or other benefits transferred;
- eliminate organizational shortcomings that led to the offence by adopting and implementing organizational models capable of preventing offences like the one that occurred.

## 2. DEFINITIONS

### 2.1 Public Administration

The Special Part considers the Offences that may be committed by the Recipients in the context of relations between the Foundation and the Public Administration, to the detriment of the State, Public Entities and/or the European Union.

For the purposes of the Decree, **Public Administration** (PA) means all those individuals and/or public bodies that perform a "public function" or a "public service", including the bodies of the European Union.

## 2.2 Public Function

A **public function** is defined as the activities, governed by rules of public law, related to:

- *legislative* functions (State, Regions, Provinces with special status, etc.);
- *administrative* functions (members of state and local administrations, police forces, members of supranational administrations (e.g. European Union), members of the Authorities (e.g. Antitrust, Data Protection Authority, Consob) or of the Chambers of Commerce, of Building Commissions, inspectors of public works, etc.);
- *judicial* functions (Judges, Judicial Officers, subsidiary bodies of the administration of justice such as receivers, liquidators in bankruptcy, administrators, commissioners, etc.).

## 2.3 Public Official

Art. 357 of the Criminal Code defines a “*public official*” as someone who “performs a public legislative, judicial or administrative function.”

A **public official** is the person who implements or helps to implement the will of the public entity or, in any case, represents it in dealings with third parties.

The qualification must therefore be given to persons, whether public or private employees, who can or must, within a power governed by public law, implement or help to implement the will of the Public Administration or exercise decision-making, authorization or certification powers (e.g. the employee of an Administration with powers of certification or attestation).

## 2.4 Public Servant

A **public servant** is a person who, in whatever capacity, provides a public service.

“*Public service*” is an activity governed by rules of public law but characterized by a lack of certification, authorization and decision-making powers in the public sector.

“*Public service*” can never be carrying out “*simple routine tasks*” or the “*provision of purely manual work*.”

With regard to activities that are carried out by private persons on the basis of a concession arrangement with a public entity, it is considered that the existence of an act authorizing the investiture of the public service is not sufficient to define the entire activity as a public service, rather it is necessary to ascertain whether the individual activities are themselves subject to rules of a public nature.

The case law has identified the category of public servants, emphasizing the instrumental and accessory nature of the activities compared to the public one in the strict sense.

In this way, the “indicators” of the public nature of an entity have been identified as:

- the State or other public bodies exert control and guidance for social purposes and have the power to appoint and dismiss directors;
- the presence of an arrangement and/or concession with the PA;
- the financial contribution from the State;
- the immanence of public interest in the economic activity.

The discriminating element, therefore, is not the legal nature of the person but the functions entrusted to them, which must consist in the care of public interests or in satisfying needs of general interest.

### **3. CRIMINAL OFFENCES**

The Offences considered herein may be committed within the At-Risk Areas that, directly or indirectly and during performance of normal working activities, have or may have, at all organizational levels, relations with the PA in the broad sense of the term, as considered by the Decree.

The following is a summary description of the Offences covered by the Decree in relation to the Foundation, which can be traced back to more general cases of:

- extortion and corruption;
- misappropriation and undue receipt of funds;
- fraud to the detriment of the PA.

With regard to the offences described below, reference is also made to the detailed information provided in the Introduction to the Special Part of the Foundation’s Organizational Model, in relation to “Sensitive Processes”, and in particular to the document Annex 2 cited therein.

#### **3.1 Corruption and Extortion**

- *Extortion* (Art. 317 of the Criminal Code) and *undue incitement to give or promise benefits* (Art. 319-*quater* of the Criminal Code)

Extortion occurs when a public official or a public servant, abusing their position or powers, compels someone to unduly give or promise them or a third party money or other benefits to which they are not entitled.

The offence is subject to mere residual application within the scope of the Decree.

The Offence of undue incitement to give or promise benefits is a “mitigated” form of extortion from which it differs in several aspects, including the element of “incitement” (and not “coercion”) and the fact that the active participant in the Offence may also be the public servant.

Extortion could occur if a person included in the Foundation’s organization chart participates in the offence committed by a public official who, taking advantage of their office, requests benefits they are not entitled to from third parties, if such conduct results in an advantage for the Foundation.

*- Corruption in the exercise of the office (Art. 318 of the Criminal Code)*

Corruption relating to the exercise of the office (so-called indirect corruption) occurs when a public official receives, for themselves or for others, money or other advantages to perform, omit, delay or issue acts (resulting in an advantage for the offeror) that are understood as being included in the official’s duties.

The public official’s activity can be either an act that is due (e.g. more rapid processing of paperwork falling within the official’s responsibility) or an unlawful act (e.g. a public official who, in order to ensure the award of a contract, accepts money or accepts a promise to receive a benefit, even without immediate material consideration).

Example: a director, a manager or other employee or consultant of the Foundation offers a sum of money or other benefit (e.g. gifts in kind, travel, etc.) to a public official in order to obtain the rapid issue of an administrative measure (e.g. authorizations, etc.) necessary for the Entity to conduct its business.

*- Corruption for an act contrary to the duties of office (Art. 319 of the Criminal Code)*

The offence of corruption for an act contrary to the duties of office is committed when the public official, in return for payment of money or other benefits, performs an act that is not due, even if it is apparently and formally valid and, therefore, contrary to the “principles of sound performance and impartiality of the Public Administration.”

This act, which is not due, can be traced back to a lawful or unlawful act or to an act carried out contrary to the duties incumbent on the public official.

Example: a director, an employee or consultant of the Foundation offers a sum of money or other benefit (e.g. gifts in kind, travel, etc.) to a public official in order to obtain the issue of an

unlawful administrative measure to the benefit of the Foundation (e.g. deny an authorization to a competitor).

- *Corruption of a public servant* (Art. 320 of the Criminal Code)

The provisions of Art. 318 of the Criminal Code (Corruption in the exercise of the office) and Art. 319 of the Criminal Code (Corruption for an act contrary to the duties of office) also apply to the public servant.

- *Incitement to corruption* (Art. 322 of the Criminal Code)

Incitement to corruption occurs when, in the face of conduct aimed at corruption, the public official rejects the offer unlawfully made to them. Therefore, the Offence takes the form of a simple promise of money or other benefit aimed at inciting the public official to perform an act of office and the refusal of the public official.

Example: a director, an employee or consultant of the Foundation promises a sum of money or other benefit (e.g. gifts in kind, discounts, etc.) in order to obtain more rapid issue of an administrative measure (e.g. concessions, licences, etc.) necessary for it to conduct its business to a public official who refuses.

- *Corruption in judicial proceedings* (Art. 319-ter of the Criminal Code)

The offence of corruption in judicial proceedings is a separate offence and occurs when a person is party to a judicial proceeding and, in order to obtain an advantage in the proceeding, bribes a public official (magistrate, clerk of the court or other official).

For example: a director, an employee or consultant of the Foundation pays a court clerk money to accept pleadings or documents, even though the term has elapsed, in violation of the terms imposed by the Civil Procedure Code, for the benefit of the Foundation's defence.

- *Penalties for the briber* (Art. 321 of the Criminal Code)

In application of Art. 321 of the Criminal Code, anyone who gives or promises money or other benefits to the public official or public servant (as referred to in the above cases) is also punished.

### **3.2 Trafficking in unlawful influence**

The offence of trafficking in unlawful influence is a so-called common offence which is committed when anyone who, by exploiting or boasting existing or alleged relations with a public official or a public servant (or members of international courts, bodies of the European Communities, international parliamentary assemblies, international organizations and functionaries of the European Communities), unduly **causes money or other benefits to be given or promised** to themselves or others:

- i) as the price of their unlawful mediation with a public official or public servant; or
- ii) to remunerate the public official or public servant for the performance of their duties or powers.

In this case there is a relationship of subsidiarity with respect to the offences of corruption (Art. 318, 319, 319-ter and 322-bis) and it occurs at the moment when the agreement between the private party and the intermediary is concluded.

The same penalty as for the intermediary also applies to the principal of the mediation, i.e. the person who gives or promises money or other benefits in exchange for the exercise of influence.

The penalty is increased in the event that:

- the mediator is a public official or a public servant;
- the act is committed in connection with the exercise of judicial activities;
- the act is committed in connection with the performance of an act contrary to their official duties or the omission or delay of an act that is part of their official duties.

For the offence in question, it must be committed in the interest or to the advantage of the Entity.

Example: a director or employee of the Foundation, boasting of their relationship with a public official, causes money or other benefit to be given or promised by the Foundation, in order to obtain an administrative measure that is favourable to the Foundation itself.

### **3.3 Misappropriation and undue receipt of funds**

- *Misappropriation of funds to the detriment of the State or the European Union* (Art. 316-bis of the Criminal Code)

Misappropriation occurs when, after having received funding, grants or subsidies from the State, a public body or the European Union for the performance of works or activities, the sums obtained are not used for or allocated to the purposes for which they were intended.

Funding, grants and subsidies must be classified as non-repayable allocations or as having a lower onerousness than that resulting from the application of normal market conditions.

The Offence in question may also relate to funding obtained previously and not allocated to the purposes for which it was granted.

Example: a director, employee or consultant of the Foundation who has been entrusted with managing public funding (e.g. for the award of a tender by the European Union) uses the funds for purposes other than those for which the funding was granted.

- *Undue receipt of funds to the detriment of the State and the European Union* (Art. 316-ter of the Criminal Code)

Undue receipt of funds occurs when, through the use or submission of false statements or documents or through the omission of required information, grants, funding, subsidized loans or other disbursements of the same type granted or disbursed by the State, other public bodies or the European Union are obtained without being entitled to them.

In the offence in question, the use made of the funds is not relevant, since the criminal offence occurs at the moment the funds are obtained.

It should be noted that the offence in question has a residual nature with respect to that of fraud against the State.

Example: a director, an employee or consultant of the Foundation issues false documentation to obtain funding for the Foundation.

### **3.4 Cases of fraud**

- *Fraud against the State or other public body or the European Union* (Art. 640, para. 2(1) of the Criminal Code)

The offence occurs when, in order to make an unjust profit for oneself or for others, artifice or deception is used so as to mislead and cause damage to the State, to the public body or to the European Union.

Conduct may consist of any activity which is likely to mislead the person who is to pay out the funds.

Example: a director, an employee or consultant of the Foundation prepares untruthful documentation and submits it to the PA to ensure that the Foundation is awarded an EU tender.

- *Aggravated fraud to obtain public funds* (Art. 640-bis of the Criminal Code)

The offence occurs when the fraud is carried out in order to unduly obtain public funds. The qualifying element with respect to the previous offence (Art. 640 of the Criminal Code) is the material object of the fraud.

The criminal offence is committed when artifice or deception is used that could mislead the person providing the funds, such as, for example, in the case of submitting data that do not correspond to the truth or by preparing false documentation, with the intention of obtaining the fund.

Example: a director, an employee or consultant of the Foundation prepares untruthful documentation and submits it to the PA to ensure that the Foundation obtains public funding.

- *Computer fraud against the State or other public body* (Art. 640-ter of the Criminal Code)

The offence is committed when, by altering the functioning of a computer or communication system in any way or by manipulating the data contained therein, an unfair profit is obtained, causing damage to third parties.

The offence in question differs from fraud in that the object of the fraudulent activity is the computer system and not the person and may contribute to the offence of unauthorized access to a computer or communication system, referred to in Art. 615-ter of the Criminal Code.

The offence is aggravated if it is committed with theft or improper use of the digital identity to the detriment of one or more persons.

Example: once funding has been obtained, a director, an employee or consultant of the Foundation breaches the PA's computer system in order to enter a higher funding amount than the one legitimately obtained.

### **3.5 Incitement not to make statements or to make false statements to the judicial authorities (Art. 377-bis of the Criminal Code)**

The offence punishes the conduct of those who, by means of threats, violence, promises of money or benefits, incite a person called upon to make statements in the context of criminal proceedings (e.g. a witness) not to make statements or to make false or untrue statements.

### **3.6 Members of international courts, of bodies of the European Communities, of international parliamentary assemblies or of international organizations and functionaries of the European Communities**

Pursuant to Art. 322-bis of the Criminal Code, Embezzlement, extortion, undue incitement to give or promise benefits, corruption and incitement to corruption also apply to members of

international courts, of bodies of the European Communities, of international parliamentary assemblies, of international organizations and functionaries of the European Communities.

Following the introduction of Law no. 3 of 9 January 2019, the above cases also apply to:

- persons exercising functions or activities that correspond to those of public officials and public servants in international public organizations;
- members of international parliamentary assemblies or of an international or supranational organization as well as judges and officials of international courts;
- persons exercising functions or activities that correspond to those of public officials or public servants in other foreign States or international public organizations.

#### **4. GENERAL PRINCIPLES OF CONDUCT**

While carrying out their work activity or professional and/or contractual service, the Recipients of the Model must comply with the general principles of conduct set out below. In particular, Recipients **are required** to:

- *observe* all the rules and principles contained in the Organizational Model, the Code of Ethics, laws, regulations and protocols governing the Foundation's operations, particularly with regard to activities involving contacts and relations with the Public Administration;
- establish and manage any *relationship* with the Public Administration based on criteria of maximum fairness and transparency;
- *refrain* from engaging in, cooperating with or contributing to conduct that may, in whole or in part, directly or indirectly constitute the offences examined above or simply facilitate their commission.

In particular, during performance of normal working activities, and in compliance with the principles of the Model and the Code of Ethics, it is **forbidden to** engage in the following conduct:

- submit *untrue or incomplete* documentation and/or statements to national or foreign public bodies (for example, in order to obtain grants, subsidies or funding, or to obtain the issue/renewal of authorizations, licences, concessions or any certificates and/or documentation required in order for the Foundation to conduct its business);
- *allocate* the sums received from these bodies to purposes other than those for which they were granted;
- certify possession of non-existent requirements, required by law or by administrative acts, in order to participate in tenders or similar or in order to win;
- engage in any conduct likely to mislead national or foreign public bodies;

- give Partners, consultants or external Contractors *compensation* (whether economic or services) that is not adequately justified in relation to the type of task to be performed and current local practices;
- make cash *donations* to Italian and foreign public officials or public servants;
- deliver, distribute, promise or guarantee gifts, any form of gratuity, discount, benefit and/or any other advantage to public officials in order to obtain preferential treatment. For example, it is forbidden to give gifts to inspectors or any other representative of the PA (e.g. functionaries of the European Union and employees of other public facilities (e.g. hospitals), representatives of the Labour Inspectorate, the Revenue Agency, the Customs Agency, etc.), or their families, with consumer goods and/or any other benefit;
- grant, promise or offer the possibility of obtaining other advantages of any kind to the representatives of the Public Administration that may affect independence of judgement or induce them to ensure any advantage for the Foundation;
- *hire*, promise to hire or offer the possibility of employing Italian or foreign persons in violation of internal protocols, in a way that could affect the independence of judgement of the Public Administration, or induce it to ensure advantages for the Foundation;
- *exploit* own relationship (existing or alleged) with a public official and conduct intermediation activities in favour of the Foundation in order to obtain a favourable administrative measure for the latter;
- donate, without specific authorization, money or other benefits for charitable/cultural initiatives or sponsorship. Any initiative of this type must be approved by the relevant corporate bodies or functions and documented to enable the necessary checks by the Supervisory Body;
- use violence, threats or any other form of coercion, or deliver, distribute, promise or guarantee money, advantage or benefit to third parties so that (i) they make fraudulent, incorrect or false statements, or (ii) they refrain from making statements before the Judicial Authorities in a proceeding.

## 5. OPERATING PRINCIPLES

In the performance of the Foundation's activities, relations with representatives of the Public Administration are mainly managed, directly or indirectly, by the following company Functions/Areas:

- Chairman;
- Secretary General;
- Chief Operating Officer;
- Finance Area;
- Administration Area;
- Project Management Area;

- Grant Office Area;
- Finance Manager.

The Foundation's Functions/Areas (even if not expressly mentioned above) which, in the performance of their activities, have relations with the Public Administration, must observe the operating principles described below.

### 5.1 Direct relations with the PA

Any person who represents and can bind the Foundation in its relations with the PA must have been **expressly delegated** to do so with a formal delegation of the relative power of representation.

Delegations to this effect must be arranged:

- with a resolution of the Board of Directors, for the Foundation's top management;
- with a specific power of attorney, for Employees;
- with a specific provision in the relevant consulting or partnership contract, for Consultants and Partners.

Persons who *have*, on behalf of the Foundation, relations with the PA, including a series of repetitive activities (e.g. Employees who deal with the necessary formalities to issue, obtain or renew licences, concessions, authorizations or certificates or upload administrative data to the European Union portal) must be identified and receive a **specific appointment** (on the basis of an assignment to a specific job/function, as described in the documentation relating to the assignment of tasks prepared by the Foundation - e.g. Job Description).

Hierarchical checks are carried out on the division of duties and tasks, including control activities, among the functions involved in carrying out the relevant activities for this Special Part.

The Supervisory Body must be informed, by any Recipient, without delay and in writing, of any significant issues that may arise with regard to the relationship with the PA.

### 5.2 Access, inspections and checks

**Access, inspections and checks** by representatives of the Public Administration are mainly managed, directly or indirectly, by the following company Functions/Offices:

- Finance Area;
- Administration Area;
- Legal Counsel;
- Chief Operating Officer.

Any contact with the Public Administration (particularly with reference to access by EU officials for checks) during access, inspections and/or checks must be carried out in the presence of at least **two employees** of the Foundation.

The manager of the Function involved in the access, inspections and/or checks shall, in each instance, provide information on the manner of contact with Public Officials, identifying the names of the Employees (or persons in charge) who must interact with said Public Officials and investing them with the specific delegation of powers.

If, for reasons of appropriateness/confidentiality, the meeting must be conducted separately, this will be done by the Manager of the relevant Function.

In any case, at the end of the meeting/access a summary **report** must be drawn up. In cases of particular importance, the report will be sent to the Supervisory Body.

### **5.3 Obtaining authorizations, licences and concessions in order to conduct business**

Activities for obtaining **authorizations, licenses and concessions in order for the Foundation to conduct its business** are mainly managed, directly or indirectly, by the following Functions/Areas of the Foundation:

- Finance Area;
- Administration Area;
- Legal Counsel;
- Chief Operating Officer.

In order to obtain authorizations, licenses and concessions (or other acts) to conduct its business, the Foundation defines the roles and responsibilities of the persons involved by observing the following operating principles:

- definition of the responsibilities of the persons involved in the application for authorizations, licences and concessions (or other acts) in compliance with the principle of the **segregation** of duties. In particular, the persons involved in the following distinct stages are identified:
  - a) identification of the measure needed to conduct business;
  - b) contact with the relevant public body or authority;
  - c) collection and/or preparation of the documentation necessary for the application;
  - d) verification of the final documentation;
  - e) signing of the documentation by the person with signatory powers;
  - f) sending the documentation, including electronically;

- the statements, documentation and any other act provided to public authorities or bodies (national or foreign) for the purpose of obtaining authorizations, licenses and concessions (or acts) in order to conduct business activities must be:
  - a) truthful and not contain false or altered elements;
  - b) complete and not omit any required information;
- absolute confidentiality over the application for authorizations, licences and concessions (or acts) and over the related process;
- formalization of the stage for checking possession of the necessary requisites for obtaining such authorizations, licences and concessions (or acts);
- clear identification of the person responsible for checking that the documentation to be sent to the public body or authority is complete and correct;
- evidence that the documentation has been approved;
- correct and systematic archiving of all the above documentation.

Any direct contact with the Public Administration to obtain authorizations, licences and concessions (or other acts) for the Foundation to conduct its business must be formalized in accordance with section 6 below.

In the event that the Foundation makes use of **external contractors**/agents to carry out some of the activities relating to obtaining authorizations, licences and concessions for the company to conduct business, relations with such persons must be formalized and contain the safeguard clause set out in Annex 5.

#### **5.4 Participation in tenders promoted by the European Union**

Participation in **tenders promoted by the European Union (EU)** is mainly managed, directly or indirectly, through the various stages - from the award of the grant to project execution and, at the end, to reporting - by the following Functions/Areas of the Foundation:

- Chairman;
- Chief Operating Officer;
- Finance Area;
- Administration Area;
- Finance Manager;
- Data Area;
- Project Management Area;
- Communications Area;
- Grant Office Area.

In order to avoid the commission of Offences connected with the award of tenders and obtaining funding from the European Union, and without prejudice to the application of internal procedures and SOPs in use, the following **operating principles** are generally respected:

- the decision regarding participation in an EU tender must be taken by the Chairman with the participation of the administrative body and must be formalized in writing (e.g. with minutes prepared by the Chairman);
- the statements and documentation provided to the bodies of the European Union for the purpose of obtaining funding must be:
  - a) truthful and not contain false or altered elements;
  - b) complete and not omit any required information.
- any use of funds obtained other than that envisaged in the tender is prohibited, also in compliance with the provisions on expenses relating to EU projects eligible for reporting (as provided for in the European Union Reporting Guidelines);
- the involvement of different operators in the various stages/activities of the process of participation, award and management of the tender promoted by the EU should be envisaged as far as possible;
- the persons who, for various reasons, have relations with European Union bodies/officials must be formally identified in relation to each operation relating to the process of participation, award and management of the tender promoted by the EU;
- the persons exclusively authorized to access the platform set up by the EU for managing applications must be formally identified.

In compliance with these general principles, for participation in EU-funded projects, the Foundation implements the following control systems.

**A) Project coordination (Foundation as Coordinator):**

**a) Project submission to the EU**

1. Drafting and preparing the documentation to be submitted to the EU bodies, as well as the identification of the various Partners for the execution of the project, is managed by the following Functions/Positions:
  - Chairman;
  - Chief Scientific Officer;
  - Finance Planning Analysis & Reporting Officer;
  - Grant Office Area;
  - Project Management Area.
2. Preparation of the necessary documentation for participation in the tender is divided into:
  - i)* documentation relating to the **scientific project** being funded, under the responsibility of the Chief Scientific Officer and the Project Management Area; *ii)* documentation relating to **administrative** requirements (in particular, administrative and tax data relating to the

Foundation and other partners - entered in the EU portal by the Grant Office Area - and financial information relating to the budget, under the responsibility of the Financial Planning Analysis & Reporting Officer);

3. The **entry of data** and information in the portal of the European Union (e.g. data relating to the scientific project, work packages, etc.) is handled by the Grant Office Area, the Project Management Area and the Financial Planning Analysis & Reporting Officer;
4. The final **check** on the correctness and truthfulness of the documentation submitted for participation in the EU tender is carried out by the Chairman and the head of the Grant Office Area.

#### **b) Grant preparation stage and award**

1. Relations with EU bodies during the **grant preparation stage** (e.g. for budget review and any changes to work packages) are managed by the Grant Office Area, the Project Management Area and the Financial Planning Analysis & Reporting Officer;
2. The appointment, through the procedures provided for by the portal, of the individuals identified by the Foundation to access the portal and manage certain processes relating to management of the project (e.g. *participant contact, project legal signatory, project financial signatory*, etc.) is managed by the Grant Office Area;
3. In the event of award, the Grant Office Area is responsible for **signing the contracts** relating to the project (e.g. *Declaration of Honour, Grant Agreement, Consortium Agreement*).

#### **c) Project execution (progress) stage**

1. Depending on the type of activity, the following Positions/Areas of the Foundation may be involved in the execution of the project:
  - Chairman;
  - Data Area;
  - Regulatory & Clinical Area;
  - Project Management Area;
  - Communications Area;
2. Coordination and control activities regarding the work of Partners, as well as the progress of the activity envisaged under the project, are carried out by the Project Management Area through: *i)* the organization of **periodic meetings**; *ii)* verification of the **reports** (financial and scientific) submitted periodically by each Partner to the Coordinator;
3. In the event of **clinical studies (observational or interventional)** conducted in connection with the project, the Project Management Area, in collaboration with the Chairman and the Chief Scientific Officer, as well as the Protocol Writing Group, is responsible for managing all the obligations, including those of a legal nature, related to the study (e.g. preparation of the Protocol - based on the SOP **CLI -03 - Drafting and Review of the Protocol for Clinical**

**Studies** - acquisition and preservation of the Study Master File, protection of data collected during the study, etc.).

**d) Project reporting and scientific dissemination stage**

The **reporting** of expenses attributable to activities carried out within the project is managed by the Finance Area, with the support of the Project Manager, in compliance with the provisions on invoicing and recording of expenses in the Introduction to the Special Part.

The **dissemination** of the research results is handled by the Data Area and the Regulatory and Clinical Area.

**B) Participation in a project (Foundation as Partner):**

1. In cases where Penta **acts as a Partner** in EU projects subject to the coordination of third parties, the persons in charge of the following are identified:
  - entering data, statements and documents on the EU portal;
  - managing relations with the Project Coordinator;
  - managing the project activities;
  - completing the reporting activities for expenses attributable to the project.
2. In any case, the general and special operating principles set out above shall be respected.

\*

In all cases of participation in projects funded by the European Union, the Foundation undertakes to use all the sums received - either directly from the European Commission, if the Foundation acts as Coordinator, or indirectly from the Project Coordinator, if the Foundation participates as Partner - in accordance with the principles of loyalty, fairness and truthfulness as regards the stage for reporting expenses incurred in the execution of the project.

**5.5 Participation in tenders organized by public service providers**

The operations connected with the participation in tenders organized by public service providers (public, private or semi-public entities) are mainly managed, directly or indirectly, by the following Functions:

- Chairman;
- Chief Operating Officer.

For participation in tenders organized by public entities or semi-public entities, the Foundation, without prejudice to the application of the rules set out in section 5.4 on participation in tenders promoted by the European Union, clearly defines roles and responsibilities based on the following operational principles:

- definition of the responsibilities of the persons involved in the management of tenders in compliance with the principle of the **segregation** of duties. In particular, the persons involved in the following distinct stages are identified:
  - a) identification of tenders of interest;
  - b) decision to participate in the tender;
  - c) collection and/or preparation of the documentation necessary for formulating the bid;
  - d) verification of the final documentation;
  - e) signing of the documentation by the legal representative/person with signatory powers;
  - f) sending of the documentation;
  - g) participation in the award stage.
- where appropriate and applicable, the obligation of absolute **confidentiality** regarding participation in the tender and the related procedure;
- formalization of the stage for checking possession of the requirements indicated in the tender;
- clear identification of the person responsible for checking that the documentation to be sent for participation in the tender is complete and correct;
- evidence that the documentation has been approved;
- formal identification of the persons authorized to access the information system used to manage the tenders. Authorized persons must have limited authorization in order to avoid manipulation/alteration of the data to be transmitted;
- formal check that the conditions and terms of the award decision conform with what was envisaged during the tender approval stage;
- correct and systematic archiving of all the above documentation.

In the event that the Foundation makes use **external contractors**/agents to carry out some of the activities relating to the management of tenders (e.g. preparation of the tender bid), relations with such persons must be formalized and contain the safeguard clause set out in Annex 5.

The same principles, insofar as they are compatible and with any appropriate adjustments, must also be scrupulously observed:

- a) in the case of participation in “tenders” organized by private entities;
- b) in the case of participation in private negotiations with public bodies (e.g. invitation to bid).

In any case, the Foundation undertakes to use all the sums received from the public service providers for the execution of the project or activity that is the subject of the tender, in compliance with the principles of loyalty, fairness and truthfulness as regards the stage for reporting expenses incurred in the execution of the project or activity.

## **5.6 Public funding and subsidies**

In order to avoid the commission of Offences connected with the request for public funding (e.g. for the realization of research or projects or funded training), and without prejudice to the application of any internal protocols adopted and the rules referred to in section 4.4 on participation in tenders promoted by the European Union, the following additional operating principles are observed:

- any statements, documentation and any other act provided to public authorities or bodies (national or foreign) for the purpose of obtaining grants and/or funding, loans and any other subsidies must:
  - a) be truthful and not contain false or altered elements;
  - b) be complete and not omit any required information;
  - c) contain the Foundation's commitment, if it obtains the benefits, to actually using the funds obtained, in accordance with the purposes envisaged by the specific reference legislation;
- the involvement of different operators in the following process stages/activities should be envisaged as far as possible:
  - a) preparation and submission of the application for the grant, subsidy or funding by the relevant Public Administration;
  - b) checking the correctness and truthfulness of the documentation submitted;
  - c) management of resources for the execution of the stated initiative;
  - d) execution of the activity for which funding is provided;
  - e) preparation of the reports relating to management of the funding obtained;
  - f) control of the actual use of the funds, in relation to the declared objectives.
- the person (or persons) appointed to deal with the Public Administration in relation to each operation to apply for and manage public funds must be formally identified;
- in the case of training programmes funded or co-funded by public bodies, recourse to third parties who, formally or informally, carry out intermediation activities with the Public Administration or assist in the implementation of training programmes, other than in cases of absolute necessity, must be limited. This is in order to reduce the risk of intermediaries who, even if they work in concert with persons within the Entity, may illegally take advantage of the implementation of training programmes, for example by obtaining grants for activities already funded or which do not require funding.

The control systems described, in as far as they are compatible and with any appropriate adjustment, must also be applied:

- a) in processes relating to obtaining of loans in the form of tax credits and/or tax or social security benefits of various kinds;
- b) if the Foundation uses external contractors/agents to apply for public funding (or subsidies). In this case, relations with such persons must be formalized and contain the safeguard clause set out in Annex 5.

## **5.7 Debt collection activities**

Debt collection is mainly managed, directly or indirectly, by the following Functions:

- Chairman;
- Legal Counsel.

In order to avoid the commission of Offences in relations with the Judicial Authorities, and without prejudice to the application of any internal protocols adopted, the following control systems are implemented on a preliminary basis:

- definition of the responsibilities of the persons involved in relations with the Judicial Authorities in compliance with the principle of segregation of duties;
- clear identification of the person in charge of the relationship with the Judicial Authorities;
- evidence that the documentation has been approved;
- correct and systematic archiving of all documentation.

In the event that the Foundation makes use **external contractors**/agents to carry out some of the activities relating to debt collection, relations with such persons must be formalized and contain the safeguard clause set out in Annex 5.

The decision to use external contractors is taken by the Chairman and the Administrative Body.

Any decisions regarding settlements are taken by the Chairman, who signs any settlement agreements.

## **5.8 In-house training**

Training activities for Recipients operating in At-Risk Areas are carried out by the Administration Function. The relative training content is aimed at:

- highlighting the problems underlying the activities involving relations with the PA;
- identifying and explaining the criminal issues connected with relations with the PA;

- making employees with roles in At-Risk Activities explicitly aware of their responsibilities with an illustration of the procedural and ethical measures adopted by the Foundation on the subject (internal protocols, Organizational Model, Code of Ethics).

## 6. PROTOCOLS FOR ENSURING EVIDENCE OF THE DECISION-MAKING PROCESS

For each operation falling within the scope of the At-Risk Areas envisaged in this Chapter, which involves (i) the submission, including electronically, of applications, requests or appeals to the national and/or foreign PA (e.g. participation in tenders) or which, in any case, relates to procedures for (ii) obtaining licences, authorizations, funding or the like, it is necessary to:

- adopt procedures for managing the relationship with the PA, where necessary;
- identify a person to be in charge, in order to guarantee unitary management of the activity and who reports on the operation carried out;
- give due evidence of the operation by archiving the relative documentation;
- provide mechanisms for reporting to the Supervisory Body any disputes originating from the PA and/or third parties that may arise in relation to the risk of commission of the Offences.

In particular, a process owner who is involved in the operation (e.g. project) to be carried out/implemented will be identified, who is the “internal manager” of the operation falling within the At-Risk Area and who, in this capacity, is the contact person for this operation and has the task of managing it.

In any case, the person in charge, especially with reference to particularly complex operations, is allowed to identify and appoint in writing one or more sub-managers for each individual operation. In the event of such a (possible) sub-delegation, the manager will in any case continue to be responsible for the activity carried out and to be its contact person.

## 7. INFORMATION FORM

For operations of particular importance falling within the scope of the At-Risk Areas envisaged for this Chapter, and in particular for: **1)** each operation relating to the award of European tenders; **2)** accesses/checks by EU officials, a specific "*information sheet*", containing the essential details of the operation according to the template in Annex 6, which can be adapted on a case-by-case basis, must be **completed and kept by the Project Manager** or the person in charge of the area involved in the review (Finance and/or Administration Area).

The purpose of this form is to enable the internal manager, the Management Body and the Supervisory Body to carry out, at any time, checks on the operation carried out, identifying its characteristics, rationale and the persons who worked on behalf of the Foundation.

Therefore, this form must be accompanied by documentation relating to the operation (or express reference to it, with easy access to a copy) and must be updated as the procedure progresses.

The Information Form and the enclosed documentation must contain the following elements:

- a description of the operation, including the subject matter, the expected value and other relevant information;
- the Public Administration that is competent and/or involved, even if only during a preparatory stage of the operation itself (e.g. the entity that issued the call for tenders, or the PA that issued statements or certificates required for the submission of applications, etc.);
- the main formalities carried out in relation to the operation (e.g. handling of money, obtaining certificates, submission of applications, production of documentation and environmental analysis);
- the internal person responsible for the operation, indicating their position within the Foundation's organization (e.g. Function Manager);
- any persons sub-delegated by the person responsible for executing the operation, indicating their position within the Foundation's organization;
- any external contractors who may be appointed to assist the Foundation in the execution of the operation. In particular, the following must be provided:
  - a) evidence of the reasons that led to the appointment of such contractors and of the agreed fee;
  - b) a copy of the contract concluded with the contractors (containing the contractual clause in Annex 5) must be attached.

The Information Form also contains a section reserved for the Supervisory Body, so that it can indicate further elements and documentation relating to the operation and provide evidence of any inspections carried out.

In accordance with the rules for keeping the Information Form and related documentation, the person responsible for the operation must:

- make the documentation relating to the operation available to the Supervisory Body, together with any annexes;
- ensure the documentation itself is kept up to date.

## 8. COMMUNICATIONS TO THE SUPERVISORY BODY

The Recipients of the Model - employees and members of the Administrative Body - are obliged to report to the Supervisory Body, within the scope of their respective areas, the commission of Offences, conduct and/or practices that are not in line with the rules of conduct contained in the Organizational Model and the Code of Ethics.

On this point, in addition to that already highlighted in this Special Part C No. 1, reference should be made to the Introduction to Special Part C, section 6, as well as the provisions on whistleblowing in the General Part of the Model, Chapter 4.

## 9. DOCUMENTATION

Reference is made to the Introduction to Special Part C, Chapter 7.

## 10. DISCIPLINARY SYSTEM

Violation of the rules of conduct and/or principles set out in this Special Part, and of the Model and the Code of Ethics in general, may be the subject of disciplinary proceedings in accordance with Chapter 7 of the General Part of the Model, to which reference is made.

## 11. SUMMARY OF ACTIVITIES

 <b>ACTIVITIES THAT INVOLVE GREATER RISK</b>	<ul style="list-style-type: none"><li>• Access, inspections and checks (section 5.2)</li></ul>
	<ul style="list-style-type: none"><li>• Participation in tenders promoted by the European Union (section 5.4)</li></ul>
 <b>PERSONS INVOLVED</b>	<ul style="list-style-type: none"><li>• Finance Area;</li><li>• Administration Area;</li><li>• Legal Counsel;</li><li>• Chief Operating Officer.</li><li>• Chairman;</li><li>• Finance Manager;</li><li>• Data Area;</li><li>• Project Management Area;</li><li>• Communications Area;</li><li>• Grant Office Area.</li></ul>

 <p><b>CONTROL POINTS</b></p>	<ul style="list-style-type: none"> <li>➤ Any access, inspections and/or checks take place in the presence of at least two employees of the Foundation.</li> <li>➤ The manager of the Area concerned draws up a report on the access, inspection and/or check.</li> <li>➤ Intervention of various Positions/Areas in the award, execution and reporting stages of the project promoted by the European Union.</li> <li>➤ Compilation of the "<i>Information Sheet</i>" (Annex 6) by the relevant Project Manager for each operation relating to the award of projects promoted by the European Union.</li> <li>➤ Training activities, including specific training.</li> </ul>
 <p><b>INFORMATION TO BE SENT TO THE SUPERVISORY BODY</b></p>	<ul style="list-style-type: none"> <li>• Transmission of reports relating to access, inspections or checks by representatives of the PA.</li> <li>• Transmission of the "<i>Information Form</i>" (Annex 6).</li> <li>• Communication that the training has been carried out.</li> </ul>