

# **STATUTE**

## **TEDDY – EUROPEAN NETWORK OF EXCELLENCE FOR PAEDIATRIC RESEARCH**

### **ART. 1 – (Name and Venue)**

It is set up, in compliance with the art.36 and the following of the Italian Civil Code, the association named:

<< TEDDY – EUROPEAN NETWORK OF EXCELLENCE FOR PAEDIATRIC RESEARCH >>  
located in Pavia (Italy), via Luigi Porta 14.

The moving of the legal venue does not require any statutory amendment, but the obligation of communication to the competent office.

### **ART. 2 – (Aim and Activities)**

The association cannot have profit and is aimed to perform activities of promotion and social utility.

The aim of the Association is to valorize the results and keep on the activities of TEDDY NoE, Task - force in Europe for the Drug Development for the Young – Network of Excellence, a project funded by the European Commission under the Sixth Framework Programme of the European Union, coordinated by Prof Adriana Ceci on behalf of CVBF (Consorzio per Valutazioni Biologiche e Farmacologiche, Pavia, Italy) and by Dr Carlo Giaquinto on behalf of PENTA Foundation (Padova, Italy).

The Association therefore has a European dimension.

In particular, it has the purpose to bring together subjects involved in paediatric drugs development processes, to share ideas about paediatric research, to contribute to the implementation of paediatric initiatives by

- a) raising and analysing children diseases specificities and unmet needs with a multidisciplinary approach
- b) promoting initiatives for innovative research methodologies including secondary use of paediatric data to accumulate clinical evidence
- c) identifying and taking part in initiatives on safe and cost-effective use of health products in children
- d) promoting integration of basic and developmental research with clinical research to accelerate the availability of paediatric medicines, devices and innovative therapies on the market
- e) addressing ethical, legal, social and regulatory issues of research, from the preclinical phase to clinical evaluations and medicines utilization, access policies and education
- f) engaging children and young patients in decisions related to clinical research and healthcare
- g) enhancing the awareness of the main stakeholders including authorities and public, on the still unmet needs and peculiarities of paediatric research.

The Association activities are addressed to national, European and international Authorities, public and private Institutions and Companies devoted to Research and Care, Pharmaceuticals Companies, Researchers, Professionals, Young Persons Advocacy/Advisory Groups and Patients' Associations.

The Association aims to promote informative actions and support activities for the development of drugs, medical devices and other products for human use, more effective and safer for the paediatric use.

The Association aims to perform the following activities:

- Development and application of new methodologies in paediatric research
- Preparation, participation, coordination and management of projects at national, European and international level
- Education, creation of tools for research and data banks
- Scientific and methodological advice as well as advice in ethical, legal, regulatory and social aspects linked to paediatric research
- Promotion and support to the creation and valorization of young persons advocacy/advisory groups and creation of age-tailored tools for research and education
- Organization and promotion of initiatives, debates, forums and conferences to engage the public and the main stakeholders in the themes relevant for paediatric research
- Development of innovative IT tools for distance learning and empowerment of children and families.

The Association will be able to perform, in accordance with the provisions of law, all the operations considered necessary or useful for the achievement of the association aim and activities, including the staff hiring and the purchase of various goods and services as well as instruments, facilities, software and cutting-edge technologies for innovation in paediatric research.

### **ART. 3 – (Associates)**

All legal and physical persons, sharing the same aims, presenting the request and accepting this statute and the internal regulation, are admitted to the Association. Legal entities already members of the TEDDY NoE and of the Network created at the end of the project with the denomination TEDDY – NETWORK OF EXCELLENCE FOR PAEDIATRIC CLINICAL RESEARCH (TEDDY Network) and their affiliated physical persons are recognized as being associated after a simple request, having already shared the purposes during previous years of collaboration.

The Association Body able to decide on the admission applications is the General Assembly. The denial must be motivated. In the application form, the applicant has to specify his / her personal information and attach a curriculum vitae from which the competences and reasons of interest to join the association can be traced, by committing to paying the membership fee.

Two categories of associates are foreseen:

Ordinary: the physical persons paying the registration fee, annually established by the Assembly.

Supporters: Legal entities contributing to the activities and paying extraordinary fees.

### **ART. 4 – (Rights and duties of the Associates)**

The admission of the associates is for an indefinite period, subject to the right of withdrawal and the continuation of the conditions of eligibility to the Association referred to in art. 3.

The associates have the right to elect the Association Bodies and be elected in the same ones.

They have the right to be informed about the activities of the Association and to be reimbursed for the expenses actually incurred in the performed activities.

The associates have to pay fees within the deadline and respect the statute and the internal regulation.

The associates will perform their activities in the Association mainly in a personal, voluntary and free manner, without any profit, even indirect, on account of their personal availability.

### **ART. 5 – (Withdrawal and exclusion of the Associates)**

The associates may withdraw from the Association by written communication to the Board of Directors.

The associates contravening duties established by the statute or the internal regulation may be excluded by the Association.

The Board of Directors may decide to exclude both ordinary members who are not in good standing with the payment of membership fees and supporter members who do not contribute to the extraordinary activities and needs of the association. However, it is admissible to appeal to the ordinary Court.

### **ART. 6 – (Bodies)**

The Association's Bodies are:

- General Assembly,
- Board of Directors,
- Chair,
- Young Persons Advisory Group.

### **ART. 7 – (General Assembly)**

The General Assembly is the sovereign body of the Association and consists of all the associates natural persons and legal representatives or their delegates of the associates legal persons.

It is convened at least once a year by the Chair of the Board of Directors by written notice to be sent by e-mail at least 10 days before the date set for the meeting and containing the agenda of the meeting.

The General Assembly is also convened at the request of at least one tenth of the associates or when the Board of Directors deems it is necessary.

The General Assembly may be ordinary or extraordinary. It is extraordinary when it is summoned for the amendment of the statute and the dissolution of the association. It is ordinary in all other cases.

#### **ART. 8 – (General Assembly responsibilities)**

The General Assembly must:

- approve the annual report on the activity of the Association, the annual economic and financial statement and the forecast statement;
- determine the programmatic guidelines of the association's activity;
- approve the internal regulation and the fees to be member of the Association;
- deliberate definitively on requests for new memberships and on the exclusion of members;
- elect the Association's Bodies;
- deliberate on what has been demanded by law or by statute, or by the Board of Directors.

#### **ART. 9 – (General Assembly constitution)**

The ordinary General Assembly is regularly constituted on first call if there is a majority of members with voting rights, and in second call whatever the number of members are present, in their own or represented by their delegates. It is possible to participate at a distance through audio or teleconference system that allow identifying the participants.

No more than three delegations are allowed for each member.

The Ordinary General Assembly resolutions are taken by a majority of the members participating or represented by delegation, and are expressed by a clear vote.

The Extraordinary General Assembly approves any changes of the statute with the presence of 2/3 of the members and by a decision deliberated with the majority of members participating or represented; it dissolves the association and transfers its assets after a favorable vote of 3/4 of the associates.

#### **ART. 10 (General Assembly verbalization)**

The General Assembly's discussions and deliberations are summarized in the minutes drawn up by the Chair and signed by the Secretary appointed by the attendants before the beginning of the meeting.

Every associate has the right to consult the minutes and to make a copy.

#### **ART. 11 (Boards of Directors)**

The Board of Directors is composed of a minimum of 3 and maximum 9 members elected by the Assembly among its components.

The Board of Directors is validly constituted when the majority of the members are present and valid decisions are taken by the majority of the members participating to the meeting. It is possible to participate remotely through audio or teleconference system that allow participants to be identified.

The Board of Directors performs all ordinary and extraordinary administration acts not expressly assigned to the Assembly; it prepares and presents to the Assembly the annual report on the activity of the Association, the annual economic and financial statement and the forecast statement.

The Board of Directors is in office for n. 2 years and its components can be re-elected for n.2 consecutive terms.

Members of the Board of Directors are selected between associates with scientific or managerial expertise, and are also in charge of strategic planning and scientific coordination.

Their specific duties is to establish relationships with relevant Institutions and stakeholders and to monitor all the scientific aspects of the Network, share knowledge and experience among the associates, monitor and review the progress of scientific activities, and ensure that relevant scientific objectives are achieved ensuring adherence to high quality standards and ethical principles.

#### **ART.12 – (Chair)**

The Chair, elected by the Assembly, is the legal representative of the Association. He/She is a member and convenes the General Assembly of Associates and the Board of Directors.

#### **ART. 13 – (Young Persons Advisory Group)**

The Young Persons Advisory Group (which may also be briefly referred to as "TEDDY Kids") is composed of at least 5 individuals, both patients and non-patients, recruited by the associates and selected on the basis on their motivation and interest in paediatric research. Associates who are

promoters of existing KIDS groups, will have the right to express at least one representative in the Young Persons Advisory Group TEDDY Kids. TEDDY Kids has the following aims: promotion and coordination between different young persons advocacy/advisory groups established all over Europe and outside; peer support and information for children, young patients and participants in pediatric studies; training and engagement of children on issues linked to research; increase in public awareness.

One member from TEDDY Kids elected within the group participates in the Board of Directors.

#### **ART. 14 – (Working Groups)**

Thematic working groups are set up within the Association. The constitution of these thematic working groups, in compliance with the aim and activities of the association, is authorized by the Board of Directors. They are initiated on a written and justified request by one or more associates.

#### **ART. 15 – (Foreground e Background)**

All the scientific results obtained through the activities carried out by the Associates will be the shared property of those who participated, except for the results coming exclusively from the activities of a single Associate, who in this case remains the owner of that result.

The Associates will use the results or will ensure their use. The expected use of results will be communicated to the Board of Directors.

The Associates share the property of the background arising from the TEDDY NoE project and the TEDDY Network.

The Associates agree that any background not produced within the TEDDY NoE project and the TEDDY Network should be explicitly excluded from the access rights. The associates agree, however, to negotiate in good faith supplements to the common background if one or more associates request it.

Foreground and background must only be used for the purposes for which the access rights have been granted.

The access rights are granted on a non-exclusive basis, unless otherwise agreed in writing by the involved associates.

The granting of the access rights may be subject to the acceptance of specific conditions to ensure that such rights are used only for the purpose envisaged and that the in-force confidentiality obligations are adequate.

The associates must inform each other as soon as possible of any restrictions on the granting of the access rights to the background or any other restrictions that may substantially affect the granting of the access rights.

#### **ART. 16 - (Economic resources)**

The economic resources of the association consist of:

- a) Fees and contributions of the Associates
- b) Contributions from third parties
- c) Inheritance, donations and bonds
- d) Any other incomes compatible with the relevant legislation, like those coming from participation in research projects.

The association is not allowed to distribute, even indirectly, retained earnings and surpluses, as well as funds, reserves or capital during the life of the entity, in favor of directors, associates, participants, employees and in general of third parties, unless the destination or the distribution is made by law, or is carried out in favor of entities that by law, statute or regulation are part of the same and unified structure and carry out the same activity or other institutional activities directly and specifically provided by current legislation.

The association has the obligation to reinvest any earnings and retained earnings exclusively for the development of functional activities in pursuit of the institutional purpose of promoting social utility.

#### **ART. 17 – (Economic and financial statement)**

The economic and financial statement of the association is annual and starts from January 1st of each year. The final account contains all the incomes and expenses incurred for the year elapsed. The forecast statement contains the previsions of the expenses and the revenues for the following year. The economic and financial statement is prepared by the Board of Directors and approved by the Ordinary General Assembly with the majorities provided by this Statute, is filed at the headquarter of the Association at least 20 days before the assembly and can be consulted by each Associates upon

simple request. The balance account must be approved by April 30 of the year following the financial year.

**ART.18 – (Dissolution and Devolution of Heritage)**

The eventual dissolution of the Association will be decided only by the General Assembly in accordance with the provisions of Art. 9.

The Association, in the event of its dissolution for whatever cause, is obliged to transfer its assets to another non-commercial entity that carries out activities for similar purposes or for purposes of public utility, except for a different destination set by law, consulted the body of control referred to in Article 3, paragraph 190 of the Law of 23 December 1996, no. 662.

**ART. 19 – (Final provisions)**

For all that is not expressly provided by this Statute, the provisions of the Italian Civil Code and the applicable Italian laws and relevant European regulations shall be applied.