

ENTIS

EUROPEAN NETWORK OF TERATOLOGY INFORMATION SERVICES Constitution and Bylaws

1. Name

European Network of Teratology Information Services (ENTIS)

2. Domicile

ENTIS has taken domicile at the Netherlands, where the ENTIS Foundation is registered.

3. Characteristics

ENTIS is a voluntary, non-profit organisation.

4. Objectives and functions

- a) The main task of ENTIS is to recognize and to detect risk factors with the objective of preventing birth defects, fetotoxicity, neonatal problems and developmental disorders.
The purpose of ENTIS is to improve the efficiency, efficacy and quality of each Teratology Information Service (TIS) and to contribute to the primary prevention of birth defects and developmental disorders.
- b) ENTIS shall stimulate and facilitate the exchange of experience between the different TISs. The task of each TIS is to counsel individual cases of exposure to drugs, vaccines and/or other exogenous agents during pregnancy with respect to reproductive risks. Clients who request information are generally from medical and paramedical professions as well as the public.
- c) ENTIS shall promote the skills of counselling in risk assessment in pregnancy. Counselling is based on literature searches as well as the individual experience of previous cases of the TIS.
- d) ENTIS shall provide training in counselling. ENTIS shall help the individual service to obtain an overview of substantial scientific literature and to train new staff members by developing quality control guidelines, and by providing facilities for staff exchange.
- e) ENTIS shall provide support for risk assessments regarding exposures via breastfeeding for the TISs that also counsel on these exposures.
- f) ENTIS or its members communicate risk - or safety issues with the scientific community, regulatory authorities or public when required.

5. Membership

a) General

Full members or *TIS members* respectively are organisations or institutions engaged in counselling following exposures during pregnancy, evaluating and following up pregnancy outcome. Each TIS member designates a programme director or

representative to be its principal liaison with ENTIS. The representation of each TIS member during meetings of ENTIS will be through its programme director or representative.

Observers or *candidates* respectively are institutes planning to establish a TIS or TISs considering ENTIS membership.

In addition, individuals scientifically engaged in clinical teratology and/or drug risk assessment in pregnancy can be *associate members*. Individual members who are no longer officially associated with a TIS can become an *honorary member*.

b) Qualifications

The person in charge of a TIS (*full members*) should be a medical doctor, a pharmacist, or an individual with an equivalent academic degree and should have experience in clinical teratology. TISs can be affiliated to universities, hospitals, public or other health institutions. TISs should offer information and/or advice on a non-profit basis and should be free of charge¹.

The same applies to *observers* (candidates). Candidates for ENTIS membership can be any institute or TIS with practical experience in counselling. Experience in a pregnancy follow-up procedure or the willingness to establish a follow-up procedure is recommended. Candidates must submit a description of structure, means and activities of their institute (see further details at 5 e, Observers).

Individuals scientifically engaged in clinical teratology and/or drug risk assessment in pregnancy can be *associate members* (see further details at 5 f).

c) Admission procedures

The ENTIS Board reviews all applications. If an application meets all the requirements, the applicant *TIS member* or *associate member* is invited to present the service or themselves at the annual meeting. The Board will review any potential conflicts of interests. ENTIS members vote whether the applicant is eligible. A majority vote is required for admission.

Each TIS member has two votes. Associate members have one vote, with a maximum of one vote per department/organisation. Observers and honorary members have no vote.

¹ Free of charge means that a patient or HCP should not pay a (additional) fee for the counselling. If a patient shall pay, payment of the costs should be in the same way as other consultations and ideally covered by the person's health insurance.

d) Types of membership - Obligations

Full members

Full members should take part in the annual meeting as well as in other joint activities.

Full Members:

- are expected to respond within one-week (or before a deadline) to information requests and other personal or professional communications within ENTIS,
- must pay an annual membership fee. The amount is to be established by the Treasurer approved by the Board and presented at the annual meeting,
- get free access to Reprotox database,
- are entitled to two votes.

Observers

Representatives of institutes planning to establish a TIS or TISs considering ENTIS membership can apply for the status of observer (candidate). The Board decides about the admittance of non-members as observers and informs the ENTIS community in a suitable way. The Board must report at the annual meeting on its decision regarding observers.

Observers:

- can be invited to the annual meetings and collaborative activities of ENTIS,
- pay the same conference fees as full members,
- may attend business meetings only at the invitation of the Board,
- should introduce themselves and their institution at an ENTIS meeting,
- pay one third of the annual fee of ENTIS members,
- get free access to Reprotox database,
- have no vote.

The observer status is limited to a maximum of three years. After three years at the latest, ENTIS members vote on whether the applicant is eligible. The observer will be granted either full membership (after a majority vote has been declared) or observer status will be cancelled. After the observation period, there is no obligation for candidates to become ENTIS members.

Associate Members

Individuals, scientifically engaged in clinical teratology and/or drug risk assessment in pregnancy, can apply for associate membership. The full application should be sent to the ENTIS Board and Scientific Committee. The Board decides about the eligibility for associate membership. ENTIS members will vote whether the applicant is eligible. A majority vote is required for admission.

Associate members:

- are welcome to the annual business meetings and collaborative activities of ENTIS,

- have an option to pay one third of the annual fee of ENTIS members which does not include access to Reprotox database or pay the full annual membership fee to receive access to Reprotox database,²
- receive all other obligations of ENTIS members,
- have one vote, with a maximum of one vote per department/organisation.

Honorary Members

Former employees of a TIS who are no longer officially associated with a TIS, or associate members who have given distinguished service to ENTIS, may be appointed honorary members by the Board. The Board shall announce its decision at the business meeting.

Honorary members:

- receive annual meeting registration fees by ENTIS,
- may participate in all meetings,
- are not required to pay membership fees,
- receive access to Reprotox database for life,
- are not eligible to serve on the Board but may be consulted as advisors,
- have no vote.

e) Cancellation of membership

Members, Observers and Associate Members must inform the Board, in writing, of their intention to leave the network. Membership will cease on December 31st of the year of cancellation.

The Board has the right to cancel membership if the fee is not paid in two successive years and/or if a member repeatedly violates basic rules of the constitution and/or if a member has not participated for three successive years in the annual meeting without written notice and has not actively participated in (scientific) correspondence.

f) OTIS

ENTIS and the Organisation of Teratology Information Specialists (OTIS) in North America are sister organisations, which promote clinical teratology and support mutual exchange of information and enhance international collaboration of TISs. Members with voting rights of OTIS have the same rights as an ENTIS observer.

All members of ENTIS including associate members have a corresponding nonvoting membership in OTIS and pay the same conference fee as OTIS members for their conferences. ENTIS members have the opportunity to join OTIS, as voting, dues-paying members.

² Only one associate member per department/organisation has to pay for Reprotox access.

6. Board

The Board of ENTIS consists of an odd number of ENTIS members, numbering at least three. The Board consists of a chairperson (President), a vice-chairperson (Secretary), a Treasurer and council members. The President must be a person who works at a TIS. Board members must be working in the field or at a TIS for at least one year. At most, one person of the Board may be an associate member.

One of the Board members will serve as liaison officer with other organisations engaged in clinical teratology, such as OTIS. The Board can also appoint a member outside the Board as a liaison officer.

The Board proposes new Board members, aiming to achieve diverse representation.

The procedure should be as follows:

- Before the annual meeting, the Board announces their proposed new Board member(s).
- Other candidates are eligible to apply for the election, by sending an e-mail to the Secretary.
- A Board candidate will need recommendations from two other ENTIS members.
- The Board will inform the ENTIS community regarding the election process and timeline.
- A majority vote is required.

A Board member is elected for three years; re-election for another two years is possible³. Membership starts on January 1st following the conference. However, there is a transition period, which lasts from the elections at the conference until 31 December. In this transition period, the current member has all duties and rights, and the newly elected member is encouraged to participate in the meetings/telephone conferences but does not yet have voting rights.

The Board can arrange standing or not-standing committees, e.g., membership committee, website committee, scientific advisory committee etc. Apart from the annual meeting, the Board can arrange additional meetings, workshops or working groups.

At least four Board meetings are to be held each year. If there is a face-to-face meeting, at least one Board meeting requires the **physical** presence of the majority of the Board members. The remaining meetings may be held virtually. It is expected that at least the President, Secretary and Treasurer attend the annual meeting. Board members should participate in the teleconferences of the Board. Each year, one fourth of the Board members rounded up to the nearest whole number shall retire by rotation in accordance with a schedule determined by the Board, as such that each member of the Board will retire after five years maximum.

³ This time limitation does not apply to the Treasurer's position (due to responsibility of the ENTIS bank account).

7. Scientific Committee

The Scientific Committee (SC) of ENTIS consists of an odd number of members, numbering at least three. The SC consists of a chairperson and council members.

SC members must be full members, associate, or honorary members (numbering no more than one) of ENTIS and should have a strong scientific background. They must be active researchers and/or clinicians and have good English language skills. The ENTIS President is automatically a member of the SC, but cannot be the Chair of the SC.

The governing period of SC members should be at least two years but no longer than three years. A second (2 or 3 year) period is possible by internal approval of the SC (two-thirds majority).

SC-membership can be recalled by the SC and the Board (combined two-third majority) when responsibilities are repeatedly neglected.

The Chair is elected among the SC members for a period of 3 years; this can be prolonged for another three years by internal approval of the SC (two-thirds majority).

The procedure for electing members onto the Scientific Committee is as follows:

- The chairperson of the SC invites ENTIS members (including the Board and SC) to make proposals for future SC members. Members proposed should have given prior confirmation of their candidacy. The call should preferably be made at least two months before the ENTIS conference.
- New members are selected from the proposed candidates by the sitting SC based on formal qualifications aiming to achieve a diverse representation.
- A new SC member must be supported by two-thirds of the sitting SC. The outgoing member(s) do not have a vote.
- The new members will be announced via mail after their nomination and at the next ENTIS-meeting.

8. Meetings

It is obligatory for ENTIS to organise at least one meeting annually.

The procedures and guidelines for organising an ENTIS meeting are as follows:

- A meeting must be prepared by the Board and/or by the local host.
- The SC in conjunction with the Board and the local host organises the scientific program of the ENTIS-meeting.
- All ENTIS members must be invited at least three months in advance of the meeting.
- ENTIS meetings are open to all interested parties. Interested parties may be charged a higher conference fee than ENTIS members.
- Commercial advertising of any kind is prohibited.
- Participation of the business meeting is restricted to ENTIS members (full membership, associate members, and honorary members). However, the Board has the right to invite observers or guests to attend all or part of the business meeting. Minutes of the business meeting are to be distributed within two months after the conference.

- Applications for extra meetings, workshops and working groups can be made by each member. They must be submitted to the Board in time, preferably before the agenda has been finalised.

9. Resources and accounting

An ENTIS foundation was established in 1991. The Board of this foundation shall consist of the ENTIS Treasurer and at least two other members of the Board of ENTIS. The Board of the foundation can decide to give financial support for organising annual meetings, workshops, or other activities. The Treasurer must prepare an annual budget for approval at the annual meeting. The Board undertakes commitments and makes disbursements in accordance with the budget approved by the annual meeting of ENTIS members. Details of financial support to members or projects must be circulated in a written form by the Board to all members.

10. Independence

a) General

Each TIS is autonomous and responsible for its own scientific and financial organisation. However, ENTIS members are expected to work in line with the code of ethics of ENTIS. These specify that information given to clients about the safety and risks of medicines and other exposures, should conform with the highest standards of scientific and medical integrity and objectivity. Statements should be free from any conflicts of interest. Recommendations and guidelines made (under contract) by an ENTIS member should not be influenced by specific interests of the requesting party (e.g. pharmaceutical industry).

Case reports collected by a TIS are the property of that TIS and must not be sold to pharmaceutical industry. The TIS has the responsibility for independent evaluation of these data. To prevent misinterpretation and misuse of the case data, these should not be shared with institutions or persons not experienced in evaluating clinical teratology data.

In any collaboration with pharmaceutical, or other relevant industries, care must be taken to preserve the final rights relating to interpretation and publication of the results. This applies to work undertaken by individual TISs as well as ENTIS collaborative studies.

The TIS should be aware of (inter)national regulations regarding privacy and confidentiality of data related to their users or clients.

b) Research

- Objectives of research must be defined by the ENTIS members willing to collaborate in a study. Design, outcome parameters, methodology of a study, interpretation and publication of results are exclusively decided by the collaborating ENTIS centres.
- Research priorities in ENTIS should consider the primary goal of ENTIS to prevent damage to the offspring AND optimise treatment of the pregnant mother.

- Research projects should normally focus on drugs that are already frequently used by women of reproductive age and/or belong to evidence-based medicines or good therapeutic practice or follow established therapy guidelines.
- If a pharmaceutical company asks ENTIS (members) to investigate their products (i.e., contract research), such a project should only be performed when in accordance with the research ethics of ENTIS.
- The ENTIS mission of independent research must be published on the ENTIS website. Every publication of an ENTIS study should refer to this mission statement.
- Collaborative ENTIS studies should be approved by the ENTIS Scientific Committee if three or more ENTIS centres collaborate.
- In case of research grants (from industry) for collaborative ENTIS studies the TIS that receives the grant must provide transparency and account of received grants and supported studies.
- ENTIS members should primarily apply for other financial sources (than industry) for research projects, e.g. grants from health ministries, universities, European Union sources, insurance companies, other research organisations and foundations.

11. Official language

The official language of ENTIS is English.

12. Adoption of Bylaws

These bylaws originally accepted by the majority of votes cast after the fifth annual meeting of ENTIS in Crete, Greece in March 1994, were modified during and after the 18th annual meeting in Helsinki, Finland June 2007. These modifications of the bylaws were accepted by the majority of ENTIS members (16 of 20 of the valid poll) during the 19th annual meeting in Edinburgh, Scotland in September 2008.

The modifications on membership were accepted by the majority of ENTIS members during the 24th annual meeting in Amsterdam, Netherlands, April 2013.

The modifications on the whole document and the accompanying documents were accepted by the majority of ENTIS members during the annual meeting in Bergamo, Italy in September 2022.