

**THE CONSTITUTION
OF THE
EUROPEAN HUNTINGTON'S DISEASE NETWORK**

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Constitution - Article 1

NAME, MISSION AND PRINCIPLES

1.1 **Name**

This network shall be known as the European Huntington's Disease Network and referred to in this Constitution as "EHDN".

1.2. **Mission**

EHDN aims to advance knowledge of Huntington's disease by promoting and supporting non-clinical and clinical efforts to develop and test therapeutic interventions that will improve the quality of life of people with Huntington's disease.

1.3. **Principles**

EHDN is committed to the principles of

- open and full scientific communication,
- broad sharing of scientific data,
- collaborative planning and implementation of both non-clinical and clinical projects,
- compliance with applicable good research and clinical practice in all non-clinical and clinical projects,
- peer review,
- prompt publication of all valid results of scientific enquiry,
- full and open disclosure of potential conflicts-of-interest,
- democratic governance of its organization and activities,
- working with other professional organizations, government and industry sponsors, and lay organizations,
- recognition and protection of the interests of people with Huntington's disease and their families, and
- working to advance its mission as quickly as possible consistent with the foregoing.

Constitution - Article 2

ORGANIZATION

2.1 Network

EHDN is an independent and not-for-profit network. EHDN serves as a platform for clinicians, scientists and people affected by Huntington's disease to collaborate in support of both non-clinical and clinical research on Huntington's disease.

2.2 Limitation

Nothing contained in this Constitution shall constitute or be deemed to constitute EHDN either a partnership between the members or a formal business organization or legal entity. Each member is acting as an independent person and not as the agent of any other member. Nothing contained in this Constitution shall be construed as entitling any member to share in the profits or losses arising out of the efforts of any other member.

Constitution - Article 3

MEMBERSHIP

3.1 Regular Members

Any individual actively contributing to Huntington's disease research in Europe is eligible to be a regular member of EHDN. Each regular member of EHDN shall have one vote on any matter submitted to the membership.

3.2 Associated Members

Any individual actively contributing to Huntington's disease research outside Europe is eligible to be an associated member of EHDN. Except as otherwise specifically provided in this Constitution associated members shall not have voting rights.

3.3 Other Rights Associated with Membership

All members have the right to take part in the activities of EHDN,

- the right to access the members-only areas of the EHDN web portal,
- the right to attend the Plenary Meetings of EHDN,
- the right to participate in EHDN working groups,
- the right to propose non-clinical and clinical projects for review and endorsement by the Scientific and Bioethics Advisory Committee, and
- the right to qualify as an EHDN investigator eligible to participate in clinical studies and trials endorsed by EHDN.

3.4. Adherence to Rules and Policies

All members of EHDN are expected to adhere to this Constitution and to the by-laws, rules and policies adopted by EHDN pursuant hereto.

3.5 Application for Membership

Any individual desiring to become a member of EHDN shall make application for membership in such form as may be prescribed by the Executive Committee. Questions of eligibility for membership shall be determined by the Executive Committee.

3.6 Membership List

The membership list of EHDN shall be public except that an individual who is a member solely by virtue of being a member of a family affected by Huntington's disease may designate that her or his membership be kept confidential.

3.7 Resignation

Any member may terminate membership in EHDN by written notice to the Executive Committee.

3.8 Removal of Member

The Executive Committee may terminate an individual's membership in EHDN for violation of this Constitution or the by-laws, rules and policies adopted by the EHDN pursuant hereto or other scientific, professional or individual misconduct that may be expected to bring the reputation of EHDN into disrepute.

3.9 Dues; Fees

The Executive Committee may propose annual dues or other fees payable by EHDN members in order to support EHDN activities. Any such proposal for dues or other fees will not come into effect until approved by a majority of votes cast by the regular members either at a Plenary Meeting or in a mail-in/online ballot distributed for that purpose.

Constitution - Article 4

EXECUTIVE COMMITTEE

4.1. Executive Committee

The activities of EHDN shall be coordinated by an Executive Committee consisting eleven voting members as follows:

- nine persons elected by the EHDN membership (the “Elected Members”),
- one person appointed by the European Huntington’s Disease Association, and
- one person appointed by CHDI Foundation, Inc.

The chairs of EHDN standing committees and the designated administrator of Central Coordination shall be ex officio members of the Executive Committee and shall not have voting rights for Executive Committee business.

4.2. Elected Members – Qualification; Classes

The Elected Members of the Executive Committee must be regular members of EHDN and shall be divided into two, as nearly equal as possible, classes. Each Elected Member shall serve for a four-year term ending on the date of the second Plenary Meeting following the Plenary Meeting at which such Elected Member was elected, provided, that the term of each Elected Member shall be subject to the election of her or his successor and to the earlier vacancy in her or his office as further described in this Constitution, and, provided further, that terms of each class of Elected Members shall be staggered so that one class is elected at each Plenary Meeting. An Elected Member is not eligible to serve for more than two consecutive terms.

4.3. Chair and Co-chair

Following the election of new Elected Members of the Executive Committee, the members of the Executive Committee shall meet and select from among their number a person to be the Chair and a person to be the Co-chair. The Chair and Co-chair shall serve until their successors are selected in accordance with this Constitution. The Chair and the Co-chair may separately be removed by majority vote of the Executive Committee. The Chair shall preside at all meetings of the Executive Committee except that in the absence of the Chair the Co-chair shall preside.

4.4. Vacancies; Replacements

In the event of the death, resignation or vacancy of the Chair, the Co-chair shall succeed the chair for the balance of his or her elected term. In the event of the death, resignation or vacancy of the Co-chair (including as a result of her or his succession to the Chair as described above), the Executive Committee shall appoint a replacement from among the other members of the Executive Committee. Such replacement shall be approved by majority vote of the voting members of the Executive Committee. In the event of the death, resignation or vacancy of an Elected Member of the Executive Committee, the position shall remain vacant until the next Plenary Meeting, at which time the voting membership of the EHDN shall elect a replacement to complete the remaining term of the departing member. In the event of the death, resignation or vacancy of an appointed member of the Executive Committee, a replacement member may be appointed by the organization that appointed the departing member.

4.5. Meetings

The Executive Committee shall meet at least quarterly. Members of the Executive Committee may attend such meetings through conference calls or other means of communication by which all persons participating in the meeting are able to hear each other. Any act of six or more voting members of the Executive Committee present at a meeting shall be the act of the Executive Committee unless a greater number is required by this Constitution. The Executive Committee may act without a meeting if, prior to or subsequent to the action, each member of the Executive Committee consents to the action.

4.6. Responsibilities

The EHDN Executive Committee shall

- oversee the activities of EHDN, including Central Coordination and Language Area Coordination,
- oversee the development and maintenance of the infrastructure of EHDN,
- ensure continued funding of the infrastructure of EHDN including proposing and overseeing potential dues, fees or surcharges for EHDN,
- evaluate and, if appropriate, endorse non-clinical and clinical projects and as set forth in Article 8,
- evaluate and, if appropriate, grant access to data or biomaterials or both as set forth in Article 9,
- convene Plenary Meetings and report to the members thereof, and
- adopt such by-laws, rules and policies not inconsistent with this Constitution as considered necessary or useful to further the mission of EHDN.

Constitution - Article 5

EHDN COMMITTEES

5.1 Committees

The EHDN shall have a standing Scientific and Bioethics Advisory Committee. From time-to-time the Executive Committee may appoint such other committees and task forces to assist it with the oversight of the activities of EHDN with such mandates and responsibilities as the Executive Committee may determine.

5.2 Scientific and Bioethics Advisory Committee.

5.2.1 Responsibilities

The Scientific and Bioethics Advisory Committee shall facilitate Huntington's disease research in Europe by acting as a source of scientific and bioethical knowledge and advice to members of the EHDN network. As such the Scientific and Bioethics Advisory Committee may consider and provide recommendations to members and the Executive Committee concerning:

- 5.2.1.1 applications for access to EHDN resources including data or biomaterials,
- 5.2.1.2 applications for EHDN endorsement of non-clinical or clinical projects, and
- 5.2.1.3 such other scientific questions as members may raise.

5.2.2 Members; Election

The Scientific and Bioethics Advisory Committee shall consist of twelve elected regular and associated members intended to reflect both basic scientists and clinicians and to include a broad representation of the research interests of EHDN. The members of the Scientific and Bioethics Advisory Committee shall be divided into four, as nearly equal as possible, classes numbered 1, 2 3 and 4. Members of classes 1 and 2 shall be elected together, and members of classes 3 and 4 shall be elected together at alternating Plenary Meetings. Members of classes 1 and 3 shall begin their terms immediately upon election at a Plenary meeting and members of classes 2 and 4 shall begin their terms upon the first anniversary of the Plenary Meeting at which they were elected. The provisions of sections 4.2 and 4.4 shall apply, mutatis mutandi, to their election to the Scientific and Bioethics Advisory Committee. Members of the Scientific and Bioethics Advisory Committee may not be re-elected for consecutive terms, but may be re-elected if the terms are not consecutive.

5.2.3 Chair; Procedures

Each year upon new members commencing service on the Scientific and Bioethics Advisory Committee, the members of the committee shall select from among their number a person to be the chair. The members of the Scientific and Bioethics Advisory Committee may, from time-to-time, adopt such procedures for the holding of meetings and the conduct of its activities as they consider useful or necessary.

Constitution - Article 6

ADMINISTRATION

6.1 Central Coordination

Central Coordination shall be managed by an administrator designated by the Executive Committee.

6.2 Responsibilities of Central Coordination

Central Coordination shall manage the day-to-day activities of EHDN including,

- the coordination of the development of the information technology tools available to EHDN as directed by the Executive Committee,
- the coordination and the instruction of the work of the Language Area Coordinators of EHDN who shall be native speakers ensuring the fast dissemination and prompt implementation of the EHDN endorsed scientific projects and studies,
- accounting for the budget of EHDN.

6.3 Language Area Coordination

Language area coordinators shall be located in Language Area Coordination Centers as appropriate and shall organize, assist and conduct the practical aspects of EHDN within their area of language coordination; the language area coordinators are accountable to Central Coordination of EHDN.

6.3.1 Responsibilities

The tasks of language area coordination include but are not limited to

- translating written materials of EHDN into the respective languages,
- identifying sites interested and capable in participating in EHDN,
- visiting sites on a regular basis,
- organizing a yearly meeting of the EHDN sites in their respective area of language coordination
- assisting sites in Ethical Review Board applications and in conducting clinical studies in agreement with ICH GCP guidelines, and
- providing on site monitoring for EHDN endorsed clinical projects according to the guidelines of Central Coordination in agreement with ICH GCP guidelines.

6.4 Finances

Any income or property provided for EHDN shall be applied solely towards the promotion of the mission of EHDN as set forth in Article I, and no portion shall be paid or transferred to any officer, member or employee of EHDN, except for reasonable and proper remuneration, including repayment of out-of-pocket expenses, for any services rendered to EHDN. All income and expenses of EHDN shall be recorded and transacted in a discrete, designated account for which there are minimal administrative or overhead charges. An auditable accounting shall be kept of all income and expenses of EHDN and presented to EHDN membership.

6.5 Policies, Practices and Procedures

The Executive Committee is authorized to adopt such policies, practices and procedures not inconsistent with this Constitution as they consider necessary or useful for the administration of EHDN. Any policies, practices or procedures so adopted will be reduced to writing and incorporated in the minutes of the Executive Committee meeting at which they were adopted.

Constitution - Article 7

MEETINGS OF EHDN

7.1 Plenary Meetings

EHDN shall hold a Plenary Meeting not less frequently than every second year to provide an opportunity for meetings of EHDN members generally, executive and standing committees, steering committees of EHDN endorsed clinical projects. The Plenary Meeting may also include scientific presentations, reviews and other sessions related to Huntington's disease. At the Plenary Meeting there shall be a meeting of the EHDN membership for the purpose of

- receiving the report of the Executive Committee,
- holding elections,
- if necessary, amending this Constitution, and
- conducting such other business that may properly come before the meeting.

7.2 Nominations; Voting Procedures

The Executive Committee may determine procedures for the nomination to committees, and holding of elections and other votes of regular members as required by this Constitution, which procedures may include oral, written or electronic balloting. Any election or other vote taking place both at a Plenary Meeting and via written or electronic balloting, during the not more than two month period immediately prior thereto may be deemed by the Executive Committee to constitute a single election or vote for all purposes of this Constitution.

7.3 Required Vote

The act of a majority of regular members voting in an election or other vote shall be the act of the members of the EHDN unless a greater number is required by this Constitution.

7.4 Working Groups; Meetings

Members of EHDN are invited to organize peer groups to address particular topics of relevance to the mission of the EHDN (e.g. to improve assessment tools available, to discuss observational studies and interventional trials and to prepare proposals for future EHDN endorsed non-clinical and clinical projects). Such working groups may apply to the Executive Committee for sponsorship of their meetings and other activities.

7.5 Science and Education Meetings

EHDN may organize and sponsor scientific and educational meetings as directed by the Executive Committee.

Constitution - Article 8

EHDN ENDORSEMENT OF PROJECTS

8.1 Principles

EHDN is committed to enabling Huntington's disease research by endorsing non-clinical and clinical projects which meet its standards of scientific rigour and ethical conduct. Members conducting non-clinical and clinical projects endorsed by EHDN are expected to comply with the provisions of this Constitution and to the policies and procedures adopted by EHDN pursuant hereto including the provisions relating to Publication and Authorship and Ethics and Conflicts-of Interest.

8.2 Application for Endorsement

Any person may make application to EHDN for endorsement of a non-clinical or clinical project related to Huntington's disease by submitting such information as the Executive Committee may, by policy and procedure, prescribe.

8.3 Science; Bioethics Recommendation

The Scientific and Bioethics Advisory Committee shall review each application for endorsement of a non-clinical or clinical project and submit a report thereon to the Executive Committee, including such conditions for endorsement as the Scientific and Bioethics Advisory Committee deems appropriate in the circumstances. In deciding whether to recommend endorsement of a non-clinical or clinical project, the Scientific and Bioethics Advisory Committee may consider the aims, objectives, scientific and clinical adequacy of the protocol, the qualifications and capabilities of the investigators, the mechanism for funding, the sponsorship of the proposed project, ethical issues and any other factors it deems appropriate in the circumstances.

8.4 Endorsement Criteria

In deciding whether to endorse a non-clinical or clinical project the Executive Committee shall consider the report of the Scientific and Bioethics Advisory Committee and may consider any other factors it deems appropriate in the circumstances.

8.5 Conduct

All EHDN endorsed non-clinical and clinical projects shall be conducted in accordance with this Constitution, the policies and procedures adopted by EHDN pursuant hereto and all applicable laws and regulations.

8.6 Policies and Procedures

The Executive Committee may adopt policies and procedures to give effect to these endorsement principles, including specification of the information to be included in an application for EHDN endorsement of a non-clinical or clinical project.

Constitution - Article 9

ACCESS TO EHDN DATA AND BIOMATERIALS

9.1 Principles

9.1.1 Ownership of Clinical Data and Biomaterials

Clinical data and biomaterials remain the personal property of the research participant providing them. Such data and biomaterials may only be used by investigators for research upon and subject to the terms of the informed consent of the research participant providing them.

9.1.2 Sharing Data and Materials

EHDN is committed to enabling well-powered, conclusive studies of Huntington's disease by making data and biomaterials provided by patients and collected through the efforts of contributing sites available to competent scientific investigators who propose ethically sound projects. In exchange for receiving the data and biomaterials, members using biomaterials obtained from EHDN are expected to submit promptly all sample-level data derived in the course of the project back to EHDN to further annotate the biomaterials used.

9.1.3 Other Compliance

Members conducting non-clinical or clinical projects using data or biomaterials obtained from EHDN are also expected to comply with the provisions of this Constitution and to the policies and procedures adopted by EHDN pursuant hereto including the provisions relating to Publication and Authorship and Ethics and Conflict-of Interest.

9.1.4 Site Access

Subject to the informed consent pursuant to which such clinical data and biomaterials were provided each site investigator shall have the right to access to all clinical data and biomaterials of all patients under the care of her/his study site; the use of these data by the site investigator does not require approval of EHDN, although it is recommended that the investigator keep EHDN informed of major ongoing scientific projects.

9.1.5 Sponsor Access

Subject to the informed consent pursuant to which such clinical data and biomaterials were provided each study sponsor of an EHDN-endorsed clinical study or trial shall have the right to access to all clinical data and biomaterials of all research participants participating in the sponsor's study; the use of these data and biomaterials by the sponsor does not require approval of EHDN, although it is recommended that the sponsor keep EHDN informed of major ongoing scientific projects.

9.2 Application for Access to EHDN Resources

Any member of EHDN may make application to EHDN for access to EHDN data or biomaterials or both by submitting such information as the Executive Committee may, by policy and procedure, prescribe and by providing such other information as the Scientific and Bioethics Advisory Committee or the Executive Committee may request.

9.3 Science; Bioethics Recommendation

The Scientific and Bioethics Advisory Committee shall review each application for access to EHDN data or biomaterials and submit a report thereon to the Executive Committee, including such conditions for granting access as the Science and Bioethics Advisory Committee deems appropriate in the circumstances. In deciding whether to recommend giving access to data or biomaterials or both, the Scientific and Bioethics Advisory Committee may consider the aims, objectives, scientific and clinical adequacy of the scientific project or clinical study, the availability or scarcity of the biomaterials sought, the qualifications and capabilities of the investigators, the mechanism for funding, the sponsorship of the proposed study, ethical issues and any other factors it deems appropriate in the circumstances.

9.4 Access Criteria

In deciding whether to grant access to data or biomaterials or both, the Executive Committee shall consider the report of the Science and Bioethics Advisory Committee and may consider any other factors it deems appropriate in the circumstances.

9.5 Conduct

All EHDN data and biomaterials shall be used in accordance with this Constitution, the policies and procedures adopted by EHDN pursuant hereto and all applicable laws and regulations.

9.6 Policies and Procedures

The Executive Committee may adopt policies and procedures to give effect to these data and biomaterial access principles, including specification of the information to be included in an application for access to EHDN data and biomaterials.

Constitution - Article 10

PUBLICATION AND AUTHORSHIP

10.1 Principles

EHDN is committed to

- prompt publication of all valid results of scientific enquiries,
- fairness to all contributors including giving opportunities for authorship and proper acknowledgement of all investigators contributing data or materials,
- recognition of sponsor support for EHDN and EHDN endorsed non-clinical and clinical projects.

10.2 Policies and Procedures

The Executive Committee may adopt policies and procedures to give effect to these publication and authorship principles, including pre-publication review of any publication of results from an EHDN endorsed non-clinical or clinical project.

Constitution - Article 11

ETHICS AND CONFLICTS-OF-INTEREST

11.1 Principles

Members of EHDN should

- maintain the highest personal and professional standards in conducting non-clinical and clinical projects. Real and perceived conflicts-of-interest should be avoided,
- fully disclose their research support and any significant financial interest with manufacturer(s) of commercial products related to the topic of any presentation for education events in which they participate, and insist on full and meaningful disclosure of financial support for educational events to which they are invited to participate.
- not in any way or manner benefit financially from the information obtained as a result of their participation or knowledge of EHDN non-clinical or clinical projects. In particular:
 - not own or trade in the equity of a company whose drugs or products are being investigated by EHDN (an “involved company”) or inform or influence relatives, friends or others in financial transactions regarding an involved company.
 - not serve as paid consultants to an involved company in relation to the study drug or related drugs or products of an involved company during the period of the clinical project, except as requested by the involved company as an activity or consultation under the auspices of EHDN.

11.2 Education; Confidential Information

EHDN members have an obligation to act in the public interest and should be willing to educate the scientific and lay communities so long as doing so does not disclose confidential information or jeopardize the successful outcome of any non-clinical or clinical project which is in progress.

11.3 Policies and Procedures

The Executive Committee may adopt policies and procedures to give effect to these ethical and conflict-of-interest principles, including the timing of the application of these principles to clinical projects, permitted activities and the annual disclosure of certain relationships.

Constitution - Article 12

AMENDMENTS; DISSOLUTION; EFFECTIVE DATE

12.1 Amendments

Amendments to this Constitution may be proposed by any regular member, must be made in writing, must be signed by six other regular members, and must be submitted to the Executive Committee at least two months prior to a meeting of the Executive Committee, at which time the proposed amendment will be considered and voted upon. If the proposed amendment is approved by the Executive Committee, it will be submitted to a vote of the regular members of EHDN. Affirmation by at least two-thirds of the votes cast shall be required for the amendment to be adopted.

12.2 Ibid

At the request of the proposer, amendments not approved by the Executive Committee may be placed on the agenda at least one month prior to a Plenary Meeting of EHDN where the proposal may be enacted by an affirmative vote by at least two-thirds of votes cast by voting members at the meeting.

12.3 Dissolution

The dissolution of EHDN shall be decided by the affirmative vote of at least three-fourths of votes of cast. The procedure for proposing the dissolution of EHDN shall follow that outlined for proposing amendments in section 12.1.

12.4 Effective Date

This amended Constitution is effective as of September 15, 2012.