

## **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.