

French charter for the responsible development of neurotechnologies

Neurotechnologies offer therapeutic hope in the field of health and beyond, and will make it possible to effectively treat neurological and psychiatric diseases, which account for a third of health expenditures in Europe and are the cause of considerable suffering. Neurotechnologies also offer significant potential for economic growth.

Their ability to probe and interfere with an individual's brain activity call into question the notions of identity, physical and mental integrity as well as individual autonomy. As such, ethical questions and societal concerns must be taken into account when developing and validating neurotechnologies whether for or outside the healthcare sector.

This charter aims to promote the responsible development of neurotechnologies for medical and non-medical applications by strengthening the trust between all actors. It also aims to protect patients and consumers against potentially abusive and malicious uses leading to loss of cognitive freedom or a breach of confidentiality of the personal brain-data collected.

Companies, researchers from the public and the private sector, clinicians, patient and consumer associations, public authorities, investors and stakeholders in the field of scientific mediation are all potential signatories of this charter.

It responds to a moral commitment by France to implement the Organisation for Economic Cooperation and Development's (OECD) recommendation for the responsible development of innovation in neurotechnologies, which constitutes the first international standard in this field. An OECD recommendation is a non-binding legal instrument, but is considered as engaging.

This charter was jointly elaborated by all the stakeholders and its wording results from collegial exchanges between public and private actors. Its implementation remains voluntary but imposes a moral commitment on its members. Based entirely on a principle of free adhesion, it is a tool that is intended to be dynamic and open to review.



With the collaboration of Comité Consultatif National d'Éthique

Signatories of this charter, recognizing the right of proven or potential patients and users, to preserve their human identity, their freedom of thought, their autonomy, their cognitive liberty, their mental privacy, the right to oppose any non-consensual or abusive use of their personal brain data and to refuse any non-consensual or abusive manipulation of their brain, make the following short and long term commitments:

1 To protect personal Brain data, by committing to

- Provide patients and users with clear, accessible and rigorous information on the collection, processing and use of personal brain data as well as on the storage, dissemination and sharing of such data. Sharing needed to meet the requirements of open science will only occur with fully anonymized data and taking all reasonably practicable measures to prevent malicious re-identification.
- Recognize the patient's and the user's right to refuse the sharing of their personal brain data and reinforce the quality of information and the terms of consent, prior to data collection.
- Use all means available to delete or modify, upon request, the personal brain data collected, with the exception of data collected and already used for research purposes, and which has been anonymized and shared with the scientific community.

2 To ensure reliability, safety and security of medical and non-medical devices, by committing to

- Guarantee the use of all available means to protect the devices from external intrusion.
- Demonstrate, outside of clinical studies, the effectiveness of the devices, products and services for the proposed non-medical applications.
- Use all available means to ensure the reversibility of implantable devices and avoid adverse carryover effects.
- Seek and take into account feedbacks and comments from patients and users.

3 To develop an ethical and deontological communication, by committing to

- Make every effort to avoid raising unrealistic expectations or, conversely, unfounded fears concerning neurotechnologies.
- Provide users of commercial devices with scientific evidence of the expected risks and benefits.
- Ensure transparency about the use of algorithms, and even their content.

4 To prevent misuse, malicious applications and manipulation, by committing to

- Oppose applications that result in any intrusive surveillance and/or evaluation of a person without prior consent, in the abusive manipulation of the brain state or functioning, cognitive functions or behaviours of an individual, a patient and a user
- Desist from developing and implementing applications and uses of neurotechnologies if these are likely to harm the human person.
- Anticipate and block activities intended to influence the decision-making processes of individuals or groups by deliberately limiting freedom and self-determination.

5 To take into account societal expectations by committing to

- Question, in the design phase, the concept of reflectivity inviting to respond to the real needs of society, and the concept of inclusiveness which does not limit the stake of an activity solely to the simple producer-consumer relationship.
- Exercise special vigilance to detect applications leading to discrimination and communicate on the means implemented to prevent them
- Participate in societal dialogue as much as possible.
- Ensure that as many people as possible have access to the products and services developed
- Recognise, in the design phase, the need to anticipate potential abuses and apply *ethics by design* procedures as early as possible.
- Foster the development of neurotechnologies, particularly in the mental health area.

Definitions

The definitions used in this document are those of the OECD recommendation n°457 on the “responsible innovation in neurotechnologies” adopted by the OECD Council of Ministers on 11 December 2019.

Actors: public and private organisations, and individuals who play an active role in neurotechnology innovation, including research, development, uptake, and use.

Autonomy: the freedom to make one’s own choices.

Cognitive liberty: the right to mental self-determination.

Health: a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Personal brain data: data relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health, or mental states.

Neurotechnology: devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons.

Safety: an acceptable level of probable benefits and risks to health.

Stakeholders: all organisations and individuals involved in, or affected by, neurotechnology, directly or indirectly. Actors are a subset of stakeholders.