



### **PREAMBLE**

Since it was founded in 1887, the Institut Pasteur has focused on developing basic and applied knowledge in the life sciences and working to improve human health. Aware of the challenges inherent in scientific progress, the Institut Pasteur promotes research that is both outstanding in its quality and responsible in its approach, incorporating the principles of universalism, humanitarianism and solidarity.

The aim of this Charter is to set out the broad principles and ethical values to which the Institut Pasteur is committed, which guide it as it carries out its four missions in the public interest: research, education, the health of individuals and populations, and developing and transferring technological innovation.

The Charter is also intended to raise awareness among the Institut Pasteur community<sup>1</sup> of the ethical challenges currently facing scientists and to encourage staff at the Institut Pasteur in Paris, working in France or abroad, to embrace these values.

The Charter also applies to OREX staff on the campus and to service providers working for the Institut Pasteur.

All these individuals are obliged to adhere to the Charter in the performance of their tasks.

The Ethics Charter applies in conjunction with other internal charters that have been approved by the Institut Pasteur's various governing bodies.

The Charter is published and implemented under the authority of the executive director of the institute.

<sup>&</sup>lt;sup>1</sup> The terms «Institut Pasteur community» and «scientist» refer to all the following individuals: anyone working at, within or for the Institut Pasteur in any capacity, exercising an activity on a temporary or permanent basis as an employee or in another role (board members, employees, staff of external research organizations (OREX), interns, temporary staff, contract workers, PhD students, consultants, experts, etc.).

### **OVERVIEW**

The Charter sets out four basic principles, which apply jointly.

The Institut Pasteur is committed to research integrity as a means of guaranteeing reliable results and research independence, thereby justifying the trust placed by society in the scientific community.

The Institut Pasteur ensures that it conducts research that is respectful of human dignity, in compliance with international ethical standards and legislation in force in the countries in which the research is being conducted. The Institut Pasteur systematically applies standards that are very stringent in terms of protecting research participants, including standards applicable in France even if the research is being conducted abroad.

The Institut Pasteur is committed to fair and equitable research, in other words research carried out in a way that is transparent, fair, neutral and in the interests of peace and which takes into account any situations of vulnerability in the context in which the research is conducted.

The Institut Pasteur promotes responsible research, exploring novel and increasingly innovative research fields with the aim of serving the public interest.

## I. Research integrity

Scientific integrity implies strict adherence to a number of principles and practices that guarantee reliable results and research independence. Research is carried out in accordance with methodological, ethical and professionally acceptable procedures. This approach underpins the trust placed by society in the scientific community.

- The principle of originality, transparency and reproducibility of results: Knowledge is a common good to which scientists contribute, together with their peers in the scientific community. They undertake to produce knowledge by means of a rigorous, transparent scientific approach and to ensure that this knowledge is disseminated in a responsible way, so as to guarantee the originality, validity and reproducibility of research results, independently of the source of funding.
- The principle of research independence and neutrality: The aim of research is to advance knowledge, and the scientific approach must be protected from the influence of external interests. Conflicts of interest may be harmful for research participants, for the reliability of results, for the Institut Pasteur's reputation and ultimately for society as a whole, for it is society that benefits from the knowledge that is acquired and developed. Any relationship or conflict of interest, whether actual, potential or apparent, must be declared before the research is implemented or as soon as it occurs if it emerges during the course of the research, so that suitable measures can be adopted to resolve the problem. Moreover, in line with the recommendations of its Ethics Committee, the Institut Pasteur refuses to associate its work with, or accept any funding from, private or public stakeholders whose products are medically recognized as being harmful for health.
- The principle of knowledge transfer: The Institut Pasteur is committed to transferring knowledge, especially to early career scientists, PhD students, interns and students of all backgrounds. This knowledge transfer, like research supervision, must be carried out in a supportive environment which promotes respectforindividuals and integrity of practices, based on a tradition of theoretical and practical teaching and training, in accordance with the Institut Pasteur's missions and values.

- The principle of protecting and disseminating the outputs of knowledge and innovation: Knowledge is disseminated in such a way that the innovations generated at the Institut Pasteur are protected effectively, so as to guarantee appropriate use of research and fair access to research applications.
- The principle of fair recognition of the scientific contributions and achievements of each individual: The publication process helps ensure the originality and reproducibility of results via a peer review system. This process is also bound by internationally recognized publication rules that take into account the contribution made by each author to the research.
- The principle of the relationship and interdependence between science and society: As a private foundation with recognized charitable status, the Institut Pasteur interacts with multiple research bodies, institutions in the public and private sphere and citizens' organizations. The Institut Pasteur is committed to addressing priorities and challenges in the field of health; it pays particular attention to the needs and issues of patient associations and more broadly those of civilians in general. The Institut Pasteur is aware of the role that scientists may be called on to play in social debates; it insists that no information provided about scientific discoveries should give rise to false or inflated hopes, especially among associations, patients and their families.

## II. Research that respects human integrity

Research conducted at the Institut Pasteur in Paris must comply with French and European law and with international ethical standards, such as those laid down in the Universal Declaration of Human Rights, the Declaration of Helsinki, the CIOMS guidelines, the Oviedo Convention and its additional protocols, the UNESCO Universal Declaration on Bioethics and Human Rights, and the Convention on Biological Diversity and its Nagoya Protocol. These texts promote research that respects human dignity and demonstrates fairness, integrity and responsibility. If the national legislation in the country in which the research is being conducted is not aligned with international texts or French legislation, the Institut Pasteur will always opt for the principles that are most respectful of human rights.

- · Priority given to the health, safety and well-being of participants: Any research including human subjects prioritizes the health, safety and well-being of these individuals above the aims and interests of the research. A rigorous assessment of the short-, mediumand long-term benefits and risks is carried out in advance of any research for all categories of participants. Risks are only acceptable if they are reduced as much as possible and are constantly monitored throughout the research process. The health needs of participants, especially the most vulnerable, must be taken into account so that they can be given access to high quality care throughout the study and, if necessary, to continuing care after the study, whenever possible.
- Respect for data and consent: Anyone included in a research study is informed in advance, in a clear and honest way, of the aims, risks and benefits of the research, as well as their right not to participate or to withdraw at any point. Secondary use of data, the potential sharing of data and samples with third parties, and more generally any information that may influence consent must be brought to the participants' attention. The way in which participants are informed must be appropriate to their age, cultural background, needs and potential vulnerability.
- The principle of non-discrimination and non-stigmatization: Research must not encourage discrimination or stigmatization of either an individual or a group. Any research must be preceded by a process of reflection on the selection criteria for participants, so that no categories of the population that could benefit are excluded a priori and without justification. When participants considered to be «vulnerable» are included in a study,

- particular attention should be paid to them to make sure that the results of the research are of benefit to them or to the group to which they belong or which they represent.
- Privacy and confidentiality: In a context characterized by the digitization and mass production of data and the proliferation of interactions and sharing, any personal information gathered for research purposes or produced during research must be treated in such a way as to respect the rights of the individuals concerned and in accordance national and European with standards confidentiality, safety and on privacy.
- The principle of non-ownership of the human body: Any research that involves obtaining and/or using human biological samples, whether or not they are placed in a collection, must be carried out independently of any economic considerations. It may not give rise to financial transactions exceeding the standard fee for conserving and preparing samples or any other processing that may give them added value for research purposes. If third parties are authorized to request access to the samples, any requests are evaluated and granted on the basis of a strict, regulated procedure, in accordance practices governance with good taking public health priorities into account.

## III. Fair and equitable research

The Institut Pasteur contributes to biomedical research in several countries, including among vulnerable populations, facing major health challenges in economically unfavorable contexts. The Institut Pasteur believes that it has a particular responsibility when members of its staff are involved in such projects and ensures that wherever the research is taking place, it is conducted in a transparent, fair, neutral and peaceful way.

- Public health priorities: TAny research carried out in a country with limited resources is done so in response to the public health needs of local populations and in accordance with priorities determined by local and international health authorities. It takes into account the cultural, philosophical and social contexts encountered. It is conducted in cooperation with the other partners involved (WHO, funding agencies, laboratories and health networks, NGOs, etc.). The research conducted must never excessively divert, for scientific purposes, resources earmarked address the humanitarian, sanitary and medical needs of the population, nor must it delay the implementation of responses to health crises or epidemics.
- The principle of double ethical review: Any research study led by the Institut Pasteur involving human subjects must be examined in advance by one or more appropriate research ethics committees and is subject to the approval of the relevant authorities, in accordance with legal requirements. If research is conducted in another country under the responsibility of the Institut Pasteur, the Institut Pasteur ensures that before the research begins, the research protocol is submitted for a double ethical review, carried out by both an appropriate committee in France such as the Institut Pasteur's Institutional Review Board (IRB) and by an appropriate committee in the country where the research will be taking place.
- Sharing the benefits and advantages associated with research: Research produces knowledge and contributes to the creation of various benefits and advantages. Research is only fair and equitable if these benefits and advantages are shared fairly. With regard to local research teams, training or technology transfer may be offered to strengthen capabilities and offer lasting support for the development of local

- expertise. With regard to participants and those who have contributed to the research, privileged access to products resulting from scientific discoveries will be encouraged. Furthermore, if a research study is based on biological resources belonging to another country, bilateral agreements are drawn up, in accordance with the Nagoya Protocol, to guarantee that the advantages associated with the use of these resources are shared fairly.
- The principle of return of results to participants and the wider community: All research may generate results and information that are of interest for the health of participants if they are seeking a diagnosis or receiving therapeutic or prophylactic treatment. The procedure for the individual return of research results must be prepared collectively before the research begins. The participants can decide whether or not they wish to receive these results and their choice will be respected. Individual results must be reported by clinical investigators or any other qualified healthcare professional. Similarly, there is an obligation to report general research results to participants and public health authorities. In a health crisis or epidemic, general research results must be reported as soon as possible to WHO and to the relevant national and international authorities, if necessary prior to publication (before the peer review process).

## IV. Responsible research

The Institut Pasteur is at the forefront of scientific and technological research in its efforts to tackle the ongoing challenges facing health and society; it aims for excellence, exploring novel and increasingly innovative research fields in order to serve the general interest. New disciplines, methods and approaches are emerging and are used by scientists to improve their understanding of the living world. But this scientific progress must be governed by a framework that fosters responsible research.

- Research on animals and animal welfare: Animal testing has a unique and continuing vital role to play among the methodological approaches of biological and medical research, especially prior to research on human subjects. It raises legitimate questions among the general public regarding the need to use animals, the conditions they are exposed to during testing and the measures taken to avoid any suffering. All research must comply with the «3R» rule (replacement, reduction and refinement of procedures) and must be fully justified in a research proposal that has been submitted for prior ethical review and granted authorization. The Institut Pasteur is concerned with animal welfare; it is committed to promoting the development of experimental methods that avoid the use of animals where possible and to ensuring the well-being and comfort of the animals used by its staff, in strict compliance with ethical and regulatory provisions.
- The principle of vigilance and risk prevention: The Institut Pasteur recognizes the legitimacy of carrying out research, in line with its missions, involving the handling of infectious agents and chemical or biological products that represent a risk. This research is conducted with due vigilance, in strict compliance with safety and security regulations for staff, the community and the environment. The potential risk of generating results that may give rise to improper or malicious use must be taken into account. The Institut Pasteur is committed to training and guiding members of staff in identifying, appraising, managing and preventing risks of all kinds associated with their research. In return, members of staff have a duty to contact the relevant departments institution whenever necessary.

The principle of sustainable development:
The Institut Pasteur's activities are carried

out in line with a sustainable development strategy based on individual and collective responsibility, in recognition of the crucial importance of this issue for our society. In the context of environmental protection, staff members are encouraged to conduct their work on and off campus in a way that makes rational use of resources and with a continuous effort to prevent any pollution or other negative impact. Any research making use of natural biological resources, in France or elsewhere in the world, must be conducted in such a way as to protect and encourage biodiversity. Finally, the Institut Pasteur is committed to promoting any initiatives that help reduce the impact of its activities on the environment and to informing all individuals of their responsibility with regard to sustainable development.

# V. Implementation of the charter

This Charter is distributed to all Institut Pasteur staff. It is also given to all new members of the Institut Pasteur, regardless of their status or role or the length of their service in the organization. It is accessible via the Institut Pasteur intranet and extranet.

The Institut Pasteur actively promotes the principles set out in the Charter and is committed to encouraging staff to accept and adhere to the Charter via a specific program.

The Institut Pasteur will monitor application of the Charter by conducting regular awareness-raising initiatives among members of staff and offering guidance for its effective implementation. The Charter will be updated whenever necessary.

Appendix: list of committees with ethics, professional conduct and/or integrity among their responsibilities.

## **Appendix 1: Ethics committees at the Institut Pasteur – an overview**

#### Institutional committees

#### Institut Pasteur Ethics Committee (CEIP)

The Institut Pasteur Ethics Committee reports directly to the executive director. It is an advisory body with the task of assisting institutional decision-making on matters with an ethical dimension, stimulating debate and fostering a culture of ethics and responsibility within the institution. It is responsible for ensuring compliance with the Ethics Charter.

Presidence: Margaret Buckingham

Contact: CEIPadm@pasteur.fr

#### Scientific Integrity and Conciliation Committee (CISC)

The Scientific Integrity and Conciliation Committee reports directly to the executive director. It is an advisory body for fraud control and the resolution of disputes on matters related to scientific integrity. It delivers opinions and recommendations to the President on allegations involving breaches in scientific integrity and proposes solutions for interpersonal conflicts, opting for conciliation where possible. It is responsible for ensuring compliance with the Code of Scientific Ethics.

Presidence: Alain Fischer Contact: CISC@pasteur.fr

#### Ethics and Compliance Committee (CDC)

The Ethics and Compliance Committee reports to the executive director and the Board of Governors. It is an advisory body that assists the President and the Board of Governors in developing policies for the prevention and management of situations of conflict of interest by issuing recommendations and opinions. It is responsible for ensuring compliance with the Charter for the Prevention and Management of Conflicts of Interest.

Presidence: Luc Derepas

**Contact:** Matters are referred directly to the CDC by the Board of Governors or the senior management team.

#### Research review committees

#### Institutional Review Board (IRB)

This independent ethics committee is responsible for reviewing and authorizing the ethical aspects of clinical research protocols involving human subjects in cases where the Institut Pasteur is the sponsor of research conducted in a foreign country, when the funding body requires an ethical review by an IRB or there is no other appropriate ethics committee.

Presidence: Gilles Raguin Contact: irb@pasteur.fr

#### Committee for Ethics in Animal Experimentation (CETEA)

In accordance with the decree issued on February 1, 2013, and in conjunction with the French Ministry of Higher Education, Research and Innovation, which issues relevant authorizations, this ethics committee reviews the ethical dimension of projects that make use of animals for scientific purposes before they are implemented in one of the Institut Pasteur's animal facilities or in an animal facility affiliated with the Institut Pasteur, such as those at the Hearing Institute or the Institut Pasteur de la Guyane.

Presidence: Benoît Robert Contact: cetea@pasteur.fr

#### Research Practices Review Committee

#### Research Volunteers Committee (COVOL)

COVOL is a consultative body established to foster Institut Pasteur's links with the people who voluntarily participate in research, and to take into account their opinions and experiences regarding participation in research. COVOL is competent to give an advisory opinion on any aspect related to research involving the human being carried out at the Institut Pasteur. COVOL participates by right in the Ethics Committee of the Institut Pasteur (within college C – civil society), through a representative.

Coordination: Fanny Momboisse, Rémy Artus

Contact: covol@pasteur.fr



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