

CODE OF VALUE AND ETHICS

This document lists the principles and values that are the basis for the work of the Mario Negri Institute for Pharmacological Research (hereinafter IRFMN).

This document is divided into two parts:

- The Charter of Values
- The Code of Ethics

The Code of Ethics was adopted in relation to the provisions of the regulations on the administrative liability of legal persons for criminal offences (Legislative Decree 231/2001). The Charter of Values defines principles to be followed and behaviours to be avoided. The only potential, significant consequences of non-compliance are administrative sanctions (e.g. revocation of authorisations).

The IRFMN requires that the following persons respect the values outlined here:

- **All individuals who work at the IRFMN.**
- **All those who fund its research.**
- **All those who provide support services.**

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A brief history of the Mario Negri Institute for Pharmacological Research (IRFMN)

The IRFMN was founded thanks to a bequest left by the *Cavaliere del Lavoro* Mario Negri (1891-1960), based on an agreement with Prof. Silvio Garattini, who was appointed director of the institute in Negri's will. The *ente morale* (the name used at the time to describe foundations or non-profit institutions) that was to become the Mario Negri Institute was created on 5 May 1961 through a decree issued by the President of the Republic (D.P.R. 361/1961), which approved the by-laws of the institute.

Work on the building that housed the laboratories, offices and a meeting room began in September 1961. On 1 February 1963, the research staff (20 researchers from the Institute of Pharmacology of the University of Milan, who were part of Prof. Silvio Garattini's team) took possession of the building and began to conduct research there. As the years went by, the number of researchers increased thanks to the establishment of a training school for laboratory technicians and because the institute was licensed to issue a professional qualification in pharmacology (both of these are for graduates and post-graduate qualifications). The initial research areas were psychopharmacology, lipid metabolism and chemotherapy. Initially, the research was strictly experimental, but over time researchers developed an interest in clinical research.

As early as 1970, with researchers having gained expertise in the field of pharmacokinetics, the first clinical studies conducted at the institute began to establish relationships between the levels of drugs found in the bloodstream and their efficacy or toxicity in patients.

In the second half of the 1970, the institute began to conduct multicentre controlled clinical trials to establish the real efficacy of drugs. These trials involved numerous Italian hospitals, thus extending the principles of evidence-based medicine into clinical practice. In 1976, the spread of a toxic cloud at Seveso led the IRFMN to develop a strong interest in environmental issues, which continues to this day. The institute played a key role in identifying the toxic substance that was being spread through the cloud (dioxin), and in mapping the polluted area.

At the same time, the institute's interest in cardiovascular diseases grew, while epidemiological studies in the IRFMN's various fields of interest continued to develop, and the institute was enriched by the arrival of researchers with expertise in the field of haematology, particularly coagulation. At the beginning of the 1980s, in collaboration with the National Association of Hospital Cardiologists (ANMCO), the IRFMN was involved in the largest controlled clinical trial (GISSI) ever conducted in the world. It established the clinical efficacy of fibrinolytics in reducing mortality following a heart attack. The GISSI trials continue to provide therapeutically interesting results to this day.

Clinical trials have since been carried out in various fields of medicine: gynaecological cancers (GIVIO), dermatology (GISED), intensive care medicine (GI-VITI), and psychopharmacology (GISAS).

At this point, in the early 1980s, it was time to integrate pharmacology more directly with the clinic. The arrival of a group of young nephrologists made it possible to set up new offices and laboratories in Bergamo to conduct what is now called ‘translational research’, involving a continuous, reciprocal exchange of research between the IRFMN (Laboratori Negri Bergamo) and the Ospedali Riuniti (the local hospital) in Bergamo. The building that housed these new offices was called the Conventino, as it had formerly been a convent. The renovation of the convent was made possible by contributions from three Bergamo banks, and research there began in 1984. This research has made a decisive contribution to understanding and treating kidney diseases and problems related to organ transplants, particularly kidney transplants.

The experimental and clinical studies conducted at the Negri Bergamo have provided an enormous amount of information on the physiopathological mechanisms of the progression of chronic nephropathy, opening up new opportunities for developing therapeutic strategies to prevent these diseases. The results of these studies, in particular the REIN study, have demonstrated the effectiveness of a class of antihypertensive drugs – ACE inhibitors – in slowing the progression of kidney disease, thanks to their ability to reduce proteinuria.

Subsequently, an intensive protocol called the Remission Clinic, involving a combination of several antihypertensive drugs, the reduction of circulating lipid levels, cessation of cigarette smoking and strict glycaemic control, was found to halt progressive kidney disease in non-diabetic patients. Halting the progression of nephropathy in diabetic patients remains an important challenge.

In the 1980s researchers at the institute developed an interest in experimental and clinical research that focuses on ‘vulnerable’ populations: women accessing perinatal care, children, pregnant women, the elderly, patients with dementia and psychiatric patients. The IRFMN also began to work on promoting better communication in the scientific community and in the general public, contributing pharmacological and epidemiological research.

There has since been a strong focus on rare diseases – over 6,000 diseases, often of genetic origin, which have been neglected by industrial pharmacological research because of their intrinsic lack of remunerability. Since the end of the 1980s, the IRFMN has been working to raise awareness of these diseases in Europe and Italy. These diseases affect millions of families who, in most cases, are left without any hope of finding a cure after diagnosis.

This research is now carried out at the Aldo and Cele Daccò Clinical Research Centre for Rare Diseases, inaugurated in 1990, in Ranica (BG). Over time the Daccò Centre has acquired experience in conducting research into, diagnosing and treating a number of rare diseases. Through their dedication and commitment, different specialists have created a range of multidisciplinary projects, from basic to clinical research. The centre coordinates several Rare Disease Registries and offers patients nephrological and

genetic counselling (also in collaboration with the Italian National Health System) in order to improve diagnosis, prognosis and therapy. The centre carries out clinical trials with new drugs in its day hospital. The centre's researchers have coordinated several European projects dedicated to rare kidney diseases and have contributed to changing the natural history of at least three rare diseases.

The Daccò Centre is part of the Cluster Lombardo–Scienze della Vita. Since 2001 it has been recognised as the Coordination Centre of the regional network of rare diseases in Lombardy and it collaborates with the Istituto Superiore di Sanità (Italian National Institute of Health) in the National Centre for Rare Diseases.

In 2002, a laboratory for the experimental study of transplants was set up next to the Centre for Rare Diseases, called the C. Cucchi De Alessandri e G. Crespi Transplant Research Centre. Its aim is to help patients to achieve tolerance after kidney transplants in order to avoid the use of immunosuppressants, which are often toxic and increase the likelihood of patients developing infections and cancer.

In 2004, researchers at the Daccò Centre carried out a clinical study that changed the natural history of diabetic nephropathy. This study, called BENEDICT, showed that a relatively simple pharmacological treatment can prevent kidney damage in diabetic patients. The treatment, developed at the Daccò Centre with 1,200 diabetic patients, also limited cardiovascular events and reduced retinal changes that are typical in these patients.

In 2005, after a preliminary clinical study, the IRFMN carried out the largest randomised controlled clinical trial in Italy, involving about 1,200 general practitioners, to assess the efficacy of omega-3 fatty acids in managing cardiovascular pathology in current clinical practice, and replicating the favourable results of previous research conducted in hospital. This trial demonstrated that it is possible to conduct rigorous studies that are relevant to clinical practice through the collaboration of local doctors. Research documenting the transferability of results from the hospital to everyday medicine is still very much lacking.

In February 2013, the IRFMN was recognised as an Institute for Research, Hospitalisation and Healthcare (IRCCS). This was subsequently confirmed in 2015, 2018, 2021 and August 2025.

The IRFMN has always been interested in issues concerning pain management, particularly the pain caused by cancer in terminal patients. The institute has been twinned with the Associazione Via di Natale – which has built a hospice in Aviano (Pordenone) – for over 20 years. This led, in 2005, to the creation of a centre for pain studies within the institute. The aim is to integrate experimental and clinical research, controlled clinical trials and epidemiology.

In 2002, as new biomedical technologies developed, a new building was planned in Milan to meet new research needs. This modern, 30,000-square metre facility was inaugurated in 2008, following a visit by the President of the Republic. New laboratories, covering 5,400 square metres, were also built in Bergamo and opened in 2010 in the Kilometro Rosso Science and Technology Park.

Currently, therefore, the IRFMN's work is spread over three locations in Milan, Bergamo and Ranica (BG), with about 700 employees who are working on new challenges in biomedical research. In today's high-tech environment, patients' needs must never be overlooked.

The IRFMN has also been active in drug information projects, raising awareness among health professionals and the public of the need for rigorous studies to establish the risk-benefit ratio of taking a variety of drugs. The IRFMN has contributed to the work of regulatory bodies and to creating drug policies where the needs of patients prevail over those of the pharmaceutical industry. Some significant milestones on this path include participating, since 1993, in restructuring the Prontuario Terapeutico Nazionale by eliminating unnecessary drugs, with savings of about € billion per year; being a part of the CPMP (Committee for Proprietary Medicinal Products) of the EMEA (European Medicines Agency) for over seven years; and a member of the Scientific-Technical Committee of AIFA (the Italian Medicines Agency) until 2009. Through its employees, the IRFMN has contributed to research and health policy in Italy by working with various committees, such as the Comitato di Medicina e Biologia del CNR (the Committee on Medicine and Biology of the National Research Council of Italy), the The Committee for experts in research politics, the Consiglio Sanitario Nazionale (National Health Council), the Consiglio Superiore di Sanità (advisory panel on Public Health of the Italian Ministry of Health), the Comitato Nazionale di Bioetica (Italian Committee of Bioethics) and the Board of Directors of the Istituto Superiore di Sanità (Italian National Institute of Health).

- Environmental Health Sciences
- Molecular Biochemistry and Pharmacology
- Biomedical Engineering
- Acute Brain and Cardiovascular Injury
- Medical Epidemiology
- Molecular Medicine
- Neuroscience
- Clinical Oncology
- Experimental Oncology
- Health Policy

The departments coordinate the work of several laboratories, to meet the demands of modern medicine, by integrating disciplines to facilitate continuous dialogue between experimental and clinical research. The Coordination Centre of the Regional Network for Rare Diseases and the Health Directorate of the Daccò Centre, in particular, take this approach.

The Aldo and Cele Daccò Clinical Research Centre for Rare Diseases in Ranica runs the Clinical Centre, which is composed of the Clinical Centre (with three Multi-

Speciality Units: Renal Diseases, Rare Diseases, and Regulatory, Ethics and Legal Affairs) and the Centre for Human Genetics.

In addition, the IRFMN, within the limits of its financial resources, facilitates the participation of researchers – fellows and employees – in national and international conferences and courses, as well as periodic consultation with international tutors by PhD candidates.

The work of the Mario Negri Institute

The primary aim of the IRFMN is to study issues related to pharmaceutical drugs from all angles, including discovering new targets with therapeutic uses, studying the mechanisms of action of new drugs at the molecular and cellular levels through *in vitro* and *in vivo* studies, drug kinetics in the body, clinical trials, epidemiology and pharmacoconomics. To achieve these objectives, the IRFMN focuses on three areas: research, training and information.

Researchers at the institute are committed to carrying out experimental or clinical research with great rigour, based on the state of knowledge, keeping meticulous records so that each stage of each experiment can always be replicated. All steps must be recorded in laboratory notebooks, including the date and justifications for any corrections.

The IRFMN has specific Standard Operating Procedures (SOPs) regarding the use of human material, the use of radioisotopes and toxic materials, and ethical rules for animal experimentation.

The Mario Negri Institute's values

For over 50 years, the IRFMN has based its research, training and educational initiatives on its core values: independence, loyalty to the scientific method and ethics. For these reasons it has worked towards using financial resources that are obtained independently. Each researcher, in line with their level of seniority, is responsible for obtaining the necessary funds to carry out their research and is committed to using these resources appropriately.

The IRFMN does not accept funds that are tied to promoting commercial products or supporting ideologies that are contrary to science or disrespectful of public and individual health. Fundamental conditions for accepting research projects are that the institute be able to conduct the studies independently, own the data until publication, and that third-party rights regarding patentability be respected.

The IRFMN accepts research funds without prejudice from public and private non-profit and for-profit sources, with the exception of bodies such as tobacco manufacturers, which sell products that are harmful to human health. The IRFMN does not accept funds from any single source that exceed 10% of its annual budget. This is to

maintain independence and freedom in choosing lines of research, with the exception of generous donations or bequests, and funds that the Board of Directors accepts for clear reasons.

The IRFMN expresses its gratitude to private donors by naming laboratories or meeting rooms after them or by thanking them in scientific publications unless the donations are anonymous. The IRFMN is especially grateful for funds for scholarships to train young researchers.

Within the limits of their qualifications and experience, members of the IRFMN are always available to patients to provide information and to endeavour to provide advice on doctors, treatment centres and the most appropriate treatments.

The IRFMN as a whole supports the adoption of the organisation's internal Gender Equality Plan (GEP). The GEP describes the actions taken by the institute to follow the guidelines of the European Institute for Gender Equality, with the goal of 'identifying and implementing innovative strategies for promoting cultural change and equal opportunities in Universities and Research Centres.'

The IRFMN does not view the GEP as an imposition but as a valuable opportunity to promote female researchers' development and careers in order to avoid wasting talent. In addition, the GEP aims to improve decision-making by addressing gender imbalances, addressing the issues of sex and gender in research, and raising awareness of gender-related issues.

IRFMN Code of Conduct

Clinical trials

Clinical trials must be authorised by an ethics committee. SOPs are available for clinical trials and to monitor participating clinical centres. Researchers who conduct a clinical trial may not consult for a company that is sponsoring the study. Relationships with patients in the Ranica (BG) facility are established according to specific SOPs.

Animal experimentation

An Ethics Committee has been established to conduct preliminary evaluations of experiments that require the use of animals. The use of animals must always be authorised by the Ministry of Health and justified by the impossibility of using other *in vitro* methodologies. Researchers must select animal species from the lowest ontological level that is consistent with the purposes of the study and must use anaesthesia if the animals are likely to suffer.

Each laboratory is managed by an individual who supervises the experimental work and must attend regular meetings for updates, which are organised by the team in charge of the animal facilities.

Any researcher who intends to carry out *in vivo* experiments must be adequately trained and up to date on the use of laboratory animals. They must attend courses accredited by the Ministry of Health that include both theoretical and practical training.

The institute has obtained an ISO 9001:2015 quality certification for animal breeding and experimentation services dedicated to biomedical research projects.

Scientific publications

The IRFMN does not restrict the publication of its work unless third-party interests are at stake. Researchers are obliged to report only objective data. They must respect the principles of objectivity and use their best judgement to avoid overstating the significance of results. Publications must be endorsed by the Director, or a person delegated for this purpose, before submission to scientific journals.

Patents

The IRFMN does not apply for patents, with the exception of the right of researchers to be recognised as the authors of an invention, so that all data obtained from this research can be made available in a timely manner for the benefit of the entire scientific community.

Training

The IRFMN is strongly committed to training young researchers and offering them the opportunity to attend training and qualification courses in the biomedical/experimental field that relate to clinical and statistical studies. The institute offers the following courses, for which it has the ISO 9001:2015 quality certification:

- Research Doctorate in Pharmacological Science recognised by the MUR (Ministry of University and Research) and equivalent to a PhD
- PhD course awarded by the Open University, UK
- Summer Student Course

In addition, the institute offers:

Doctorate in Clinical and Experimental Pharmacology, recognised by the MUR (Ministry of University and Research), which is equivalent to a research doctorate

And it participates in TECSBI, a doctorate course in Technologies Converging on Biomolecular Systems, alongside the University of Milan, Bicocca.

And other educational opportunities that differ from the above (such as the Clinical Monitor Course, the Test Your Idea Course and PhD courses in collaboration with

Maastricht University), as well as thesis opportunities with Italian and foreign universities, internships and Alternanza scuola lavoro (work experience) projects for secondary school students.

The same rules of conduct that apply to institute staff apply to those attending training and educational activities, and these are detailed in the documentation that each participant receives and must sign when they begin to work with the institute.

Dissemination

The IRFMN considers it its duty to communicate with the public and with peers about its fields of study. Information must, first of all, reach physicians through tools such as the organisation of Continuing Medical Education CME courses, and through the participation of IRFMN researchers in courses and conferences organised by public and private institutions.

Similar activities may also be aimed at nurses and auxiliary workers in the Italian National Health Service.

Finally, information must be shared with the public. This is done through press releases, the Newsletter, articles in newspapers, and participation in radio and television broadcasts and social media (Linkedin, YouTube, Facebook e Instagram). The public can access information about the IRFMN's work on the website at www.marionegri.it.

IRFMN researchers are committed to using plain language and not being a vehicle for pharmaceutical companies or other bodies with vested interests. Researchers' remuneration should be commensurate with the work they do and not grow excessive.

General communication principles:

- Avoid overstating the significance of results.
- Distinguish between findings that relate to advancing knowledge and those that have a direct bearing on patients' health.
- Manage patients' and their families' expectations.
- Defend positions backed by scientific knowledge even if they are unpopular.
- Do not hesitate to oppose politicians in the interests of patients.
- Do not subordinate research and the dissemination of knowledge to ideological, political or religious beliefs.

Ultimately, all IRFMN researchers must always put patients first, prioritising human health above financial interests.

Relationships with employees

Employees are employed on a fixed-term or permanent basis.

Scientific employees are researchers with a history of working with the IRFMN. With some exceptions - due to requirements specific to the vacancy that needs to be filled - the expected path is to have held a scholarship, to have obtained a research PhD or a PhD, and to have post-Doc experience abroad.

For administrative services, employees are selected based on competence, through advertisements on the IRFMN website. For technical services, the institute favours IRFMN researchers who want to change jobs within the institute. All employees share the ethical principles of IRFMN, and the clauses of the national contract for the tertiary sector and internal regulations apply to all employees.

Employees are classified according to the National Collective Labour Agreement for the Tertiary Sector and by an internal regulation that constitutes a supplementary company contract.

Other research staff

In addition to employees, research is carried out by grant holders, contract staff and consultants. Depending on the available funds, calls for applications are launched to recruit trainees for training courses. Applications are examined by a committee appointed by the Head of the Course and composed of members of the institute's scientific staff. Candidates who meet the requirements specified in the competition notice are called for a written examination and interview. Candidates are ranked based on the marks they have obtained in the written and oral tests.

Candidates are chosen based on merit, motivation and their CV. References are not taken into consideration. Recruitment is based on candidate ranking and the needs of the departments and laboratories.

Scholarship holders, contractors and consultants are selected according to the needs of specific research projects, and employed with Co.Co.Pro contracts. Contractors are required to collaborate with IRFMN members but do not have set working hours and are judged on the basis of their work. The Co.Co.Co. contract is used for those who already have a job that allows for other commitments, or for staff who have an old-age pension.

Consultants are contacted for specific projects and for varying lengths of time. They work on specific issues, on a part-time basis. Where it is relevant to the project, the person who is to carry out the task is explicitly mentioned in the project.

Fellows, contractors and consultants all share the IRFMN's ethical principles.

Research guidelines

For every ongoing experiment, each researcher has a protocol that describes how it was carried out. The results, and any other relevant details, are recorded in laboratory notebooks and signed by the experimenter. Pages are numbered and must be left in

place, even if corrections are made or entries erased. If a trial requires the use of animals, the SOPs drawn up by the Animal Care Unit are followed.

Scientific reports and papers must be written objectively, and must avoid reporting results that may be contrary to the thesis of the project. Scientific publications must be approved by management and must be accompanied by a statement from the individual responsible, attesting that the data obtained corresponds to that presented in the publication.

Drafting research projects

Research projects may be drawn up by individual laboratories, at the departmental or interdepartmental level. Each project must contain objectives, a breakdown of the research and a budget. All projects must be approved by the Director, or a person authorised by them, and a copy must be forwarded to the Office for Driving Innovation in Science and Technology, which files it for approval.

Following approval or rejection, the applicant must notify the Office for Driving Innovation in Science and Technology, which, in the event of approval, promptly informs the Chief Financial Officer as to the manner of invoicing, or of how any relevant grant funds will be allocated. At the end of the project, a final report is drawn up and the Chief Financial Officer is informed in order to make the financial arrangements.

Position vis-à-vis suppliers

Since the institute uses often highly specialised supplies, it may be difficult to obtain more than one bid for some supplies. Whenever possible, several should be obtained and evaluated based on quality and cost.

The IRFMMN undertakes not to purchase any material without an order, a delivery note and a regular invoice. There are procedures for tracing who placed an order, who authorised it and who made the purchase. The heads of laboratories and departments have access to an electronic database to keep track of orders and their costs. It is the responsibility of the head of department to ensure that the established expenditure ceiling is not exceeded, unless specifically authorised by management.

IRFMMN suppliers must sign an annual declaration concerning compliance with labour regulations, payment of taxes and social security contributions and anti-mafia certification.

The Procurement Department is obliged to report any anomalies or problems to the Director.

Continuing professional development

Research institutions must facilitate all their members' intrinsic need to stay up to date, made all the more urgent by the rapid and continuous progress of knowledge in their fields. The IRFMN provides all of its staff – regardless of role or level – with a monthly calendar of events that includes seminars and courses, as well as the *Club delle 2*, where researchers report the results of their research and their reflections on scientific and organisational topics.

CODE OF ETHICS

Article 1 - Fundamental principles

This Code of Ethics has been adopted in compliance with the Legislative Decree 231/2001 and is an integral part of the relevant body of documents, the overall purpose of which is to identify the risk profiles of the Istituto di Ricerche Farmacologiche Mario Negri IRCCS (IRFMN) with regard to sensitive activities. These are activities in relation to which conduct may occur that falls under the types of offence identified by the decree.

The IRFMN is a private foundation with legal status and was made a non-profit organisation by Presidential Decree 361/1961; it is listed at no. 227 in the register of legal entities held by the Government Territorial Office at the Prefecture of Milan.

The reference for the IRFMN's activities is Article 1 of its Statute, in which the Founder specified that the institute shall pursue its activities:

- a) by setting up specialised laboratories for technical and scientific research where Italian and foreign researchers can introduce young graduates and technicians to studying conditions that can favourably influence the course of diseases
- b) By setting up an internal school which, using IRFMN's results from the laboratories, will prepare young graduates and technicians, including visiting students from abroad, to spend periods studying at the institute. The school will be free of charge and open to young graduates with degrees in scientific subjects.
- c) By establishing a paper and digital scientific library, which will be at the disposal of students.
- d) By publishing its results and promoting conferences and refresher courses to disseminate basic and applied knowledge in the field of biomedicine.

The Organisational, Management and Control Model is approved by a resolution of the Board of Directors in accordance with the provisions of art. 6 of Legislative Decree 231/2001; the Board, Director, Departments, Laboratories and the various organisational units, employees, collaborators in any capacity, researchers, customers and commercial and financial partners of IRFMN, as recipients of the model, are formally committed to its observance and application in accordance with the general principles of this Code of Ethics.

This Code of Ethics and the Organisational, Management and Control Model are brought to the attention of all recipients and stakeholders in the most effective ways to ensure they are informed in a timely and appropriate manner.

In order to guarantee the full effectiveness of its Organisational Model, IRFMN ensures that it is constantly promoted, monitored and updated, especially as regards the identification and implementation of the most appropriate ways of preventing the offences covered/outlined/described in the legal regulations. The Code of Ethics and the Organisation, Management and Control Model are published on the IRFMN website.

Internal training aimed at disseminating knowledge of the Code of Ethics and the Organisational, Management and Control Model are differentiated in terms of content and delivery methods according to recipients' position in the organisational structure, and to the level of risk involved in their work.

Art. 2 - Legal framework

The main standards of reference, in addition to the aforementioned Legislative Decree 231/2001, are:

- Legislative Decree no. 81 of 9 April 2008 on the reform of existing rules on health and safety in the workplace and subsequent updates and additions.
- The CCNL for employees of tertiary and services companies and the supplementary company contract ('Internal Regulations').
- The ISO 9001:2015 procedures relating to quality processes regarding training and working in the animal facilities.
- Law 179/2017 on 'Provisions for the protection of the authors of reports of crimes or irregularities of which they have become aware in the context of a public or private employment relationship' ('Whistleblowing').
- Regulation (EU) 2016/679 (GDPR) of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to processing personal data and on the free movement of such data.

The Supervisory Board, composed of three members from outside the IRFMN, appointed by the Board of Directors and endowed with autonomous powers of initiative and control, verifies that the model is implemented effectively and updated as appropriate. The Supervisory Board also supervises the institute's conduct, manages any deviations, and supervises the work of the various operative units.

Art. 3 - Organisational structure

The organisational structure of the IRFMN is pictures in the organisational chart attached to this Code of Ethics.

In accordance with the Founder's Statute:

- It is the responsibility of the Board of Directors to deal with the ordinary and extraordinary management of the institution, nothing excluded.

- It is the responsibility of the Director to determine the scientific direction and work of the institute, to direct the research and teaching and to manage cultural relations according to the directives of the Board of Directors.

Pursuant to Articles 5 and 7 of Legislative Decree 231/2001, the following are considered to be senior figures:

- the President, and Chairman of the Boards
- the Director
- the Chief Financial Officer
- the Scientific Secretary
- the two Research Coordinators (for the Milan and Bergamo-Ranica sites)
- the IRCCS Process Coordinator
- the Heads of Departments/Centres/Multi-Speciality Units

Art. 4 – Definitions

The following definitions are used in this document:

Code of Ethics: statement regarding the values and principles that the IRFMN follows in its work.

Organisational Model: a document that defines the tools adopted by IRFMN to prevent the crimes described in Legislative Decree 231/2001, including the control methods, procedures and sanction profiles for any conduct aimed at committing and/or encouraging such crimes.

Recipients: all parties involved with the IRFMN, both internal and external. This includes internal stakeholders, top management, all employees at all levels, with any qualifications and duties, and all those who conduct research or work in any capacity at the IRFMN. External parties include all natural and legal persons who finance the IRFMN's work, who commission research or who are interested in the results achieved by the IRFMN.

Supervisory Board: a collegial body of the IRFMN, established pursuant to art. 6, paragraph 1, letter b) of Legislative Decree 231/2001, responsible for overseeing the effective application of the Organisational Model. The Supervisory Board has access to all IRFMN documents without exceptions and is independent with regard to all other bodies of the Institute. It can propose updates to the Organisational Model.

Departments, laboratories and units: units in the IRFMN's research structure.

Functions (Services and Offices): support structures for research.

Art. 5 - General Principles

The Supervisory Board supervises the functioning of the Organisational Model and compliance with it, as well as updating it. It has guaranteed autonomous powers of initiative and control.

The Supervisory Board has a collegial structure and is made up of three members from outside of the institute, who are appointed by the Board of Directors according to the following criteria:

- One member is chosen for their skills and experience in risk management.
- One member is chosen for their knowledge of the organisation of the institute and the manner in which biomedical scientific research is conducted.
- One member is chosen for their legal expertise.

The Supervisory Board remains in office for three years; the Board of Directors makes the appointments—Members of the Supervisory Board can be re-elected.

The Supervisory Board's main tasks are:

- to compare the behaviour actually adopted within the institute with the Code of Ethics, the Organisation, Management and Control Model and the operating procedures, by collecting, processing and storing all necessary information;
- to carry out periodic spot checks, also on a sample basis, with particular regard to the management of any sensitive processes identified in the model;
- to immediately inform the Director and/or the Board of Directors of any violations of the model, also in relation to behaviour relevant to any the offences set out in Legislative Decree 231/2001, in order for the above to adopt appropriate measures. In case of inaction, the Supervisory Board reports its findings to the Board of Auditors or to the Police Prefect;
- to assess the adequacy of the model, specifically with regard to how compatible it is with the IRFMN and in terms of its effectiveness in preventing the crimes referred to in Legislative Decree 231/2001;
- to propose updates to the model.

The work of the Supervisory Board must be documented; this documentation is the responsibility of the Supervisory Board itself and must be archived in compliance with regulations regarding personal and sensitive data.

Art. 6 - Incompatibility, revocation and termination

Members of the Supervisory Board must never find themselves in a situation that could constitute a conflict of interest while appointed to the board, and for the duration of the assignment. Relationships up to the fourth degree of kinship and stable cohabitation with members of the IRFMN are to be considered a conflict of interest. This rule also

applies to senior management and to those who have commercial, consultancy or employment relationships with the institute. It is the duty of the members of the Supervisory Board to declare such situations.

Any act modifying or interrupting the IRFMN's relationship with the Supervisory Board or one of its members is subject to the prior justified approval of the Board of Directors.

Art. 7 - Supervisory Board rules

The Supervisory Board has at its disposal a suitable room for meetings, hearings and any other requirements. Special archives with locks are available for safekeeping documents or materials. Secretarial support to the Supervisory Board is provided by the institute's Quality Systems Management Secretariat.

The rules for the operation of the Supervisory Board, include, but are not limited to, the rules for convening meetings, the frequency of meetings and majorities for decisions. These are established by the Supervisory Board itself, according to the law.

The Supervisory Board must draw up minutes of its activities.

Art. 8 - Relationships with Institute bodies

The SB reports to the senior management of the IRFMN, i.e., the Board of Directors, the President and the Director, according to their respective responsibilities and the assessment made by the Supervisory Board itself. The Supervisory Board guarantees constant monitoring of this Organisational Model and proposes any updates deemed necessary to adapt to the changing circumstances of the institute. The Supervisory Board draws up an annual report that is submitted to the Board of Directors.

The Supervisory Board may be convened to examine specific topics or may be entrusted with examining specific situations, at the request of the following bodies:

- the Board of Directors
- the President
- the Director

The Board of Statutory Auditors and an auditing firm may submit specific requests to the Supervisory Board for clarification or further investigation.

Art. 9 – Crime prevention tools

The Supervisory Board acts *ex officio*, through appropriate inspections and checks. The Supervisory Board may act in response to communications received in any form. IRFMN employees, researchers, collaborators, consultants, lenders and suppliers are guaranteed the right to send reports and communications confidentially. Reports of conduct that may facilitate or constitute a crime under Legislative Decree 231/2001 are promptly examined by the Supervisory Board.

For this purpose, the institute, in accordance with the provisions of Law 179/2017 on 'Whistleblowing', provides two alternative channels (email address and postal address) for reports. First, the Supervisory Board can be reached through the email address *odv@marionegri.it*, to which only members of the Supervisory Board have access. Secondly, reports can be submitted by ordinary post, addressed to: Organismo di Vigilanza dell'Istituto di Ricerche Farmacologiche Mario Negri, Via Mario Negri 2, 20156 Milano (MI).

The Supervisory Board conducts any necessary internal investigations, assessing cases based on them meeting a criterion of prudent reasonableness. The aim is to maximise the effectiveness of the crime prevention model. Once an investigation has been completed, the Supervisory Board makes its decision, including reporting the relevant measures to the institute officials.

As part of its supervisory powers, the Supervisory Board has access to all IRFMN information, including direct hearings and the acquisition of documents.

Art. 10 - Relationship with the Institute's other control systems

As part of its work, the Supervisory Board coordinates with the following bodies of the institute:

- Board of Auditors
- Auditing company
- ISO 9001:2015 Quality System Management Manager
- Prevention and Safety Office Manager
- Data Protection Officer (DPO)
- Whistleblowing Case Manager

To guarantee the integration of the control systems, it is the duty of these bodies to report to the Supervisory Board any facts or situations that may constitute offences under Legislative Decree 231/2001 or factors that may lead to them.

Art. 11 – Hypothetical offences

IRFMN's liability for offences committed that are in its interest or to its advantage is limited to the cases expressly indicated in Legislative Decree 231/2001, which are listed below (the articles cited below refer to this decree, except where otherwise indicated; offences that are not considered particularly important in relation to IRFMN's activities are in square brackets).

Offences committed in relations with the Public Administration (art. 24)

- Misappropriation to the detriment of the State or other public entity
- Aggravated fraud to obtain public funds
- Misappropriation of public funds

- Fraud
- Computer fraud to the detriment of the State or other public entity
- Fraud in public supply
- [Fraud in agriculture]
- Bid-rigging
- Interference with the freedom of the tendering procedure

Offences committed in relations with the Public Administration (art. 25)

- [Bribery]
- Bribery for the exercise of office
- Bribery for an act contrary to the duties of office
- Bribery in judicial acts
- Undue inducement to give or promise benefits
- Corruption of a person in charge of a public service
- Penalties for the corruptor
- Incitement to corruption
- Embezzlement, extortion, undue inducement to give or promise benefits, bribery and incitement to bribery of members of bodies of the European Communities and officials of the European Communities and foreign states
- Illicit trafficking in influence
- Embezzlement (in cases of complicity)
- Embezzlement through profiting from the error of others (in cases of complicity)
- Misappropriation of money or movable property

Computer crimes and unlawful data processing (art. 24-bis)

- Unauthorised access to a computer or telecommunications system
- Illegal interception, impediment or interruption of computer or telematic communications
- Installation of equipment designed to intercept, impede or interrupt computer or telematic communications
- Damage to information, data and computer programs
- Damage to information, data and computer programs used by the State or other public body or in any case of public utility
- Damage to computer or telematic systems of public utility
- Unauthorised possession and dissemination of access codes to computer or telematic systems
- Dissemination of equipment, devices or computer programs intended to damage or interrupt a computer or telecommunications system
- Computer extortion
- Computer documents
- [Computer fraud of the electronic signature certifier]

- [Article 1, paragraph 11, of Decree-Law. 105/2019 Whoever, for the purpose of hindering or conditioning the execution of the procedures referred to in paragraph 2, letter b), or paragraph 6, letter a), or of the inspection and supervision activities provided for in paragraph 6, letter c), provides information, data or factual elements that are not true, relevant for the preparation or updating of the lists referred to in paragraph 2, paragraph 2, letter b), or for the purposes of the communications referred to in paragraph 6, letter a), or for carrying out the inspection and supervisory activities referred to in paragraph 6, letter c), or fails to communicate the aforesaid data, information or factual elements within the prescribed time limits, shall be punished by imprisonment for between one and three years].

Organised crime offences (art 24-ter)

- [Conspiracy]
- [Mafia-type association]
- [Political-mafia electoral exchange]
- [Kidnapping for the purpose of robbery or extortion]
- [Association for the purpose of illegal trafficking in drugs or psychotropic substances]
- [Illegal manufacture, introduction into the State, sale, transfer, possession and carrying in a public place or a place open to the public of weapons of war or warlike weapons or parts thereof, explosives, clandestine weapons as well as more common firearms]

Forgery of money, public credit cards, revenue stamps and means of identification or signs (art. 25-bis)

- [Counterfeiting of money, spending and introduction into the State, in concert, of counterfeit money]
- [Alteration of currency]
- [Spending and introduction into the State, without concert, of counterfeit money]
- [Spending of counterfeit money received in good faith]
- [Counterfeiting of revenue stamps, introduction into the State, purchase, possession or circulation of counterfeit revenue stamps]
- [Counterfeiting watermarked paper in use for the manufacture of public credit cards or stamps]
- [Manufacture or possession of watermarks or instruments intended for the counterfeiting of currency, revenue stamps, or watermarked paper]
- [Use of counterfeit or altered revenue stamps]
- [Counterfeiting, alteration or use of distinctive signs of intellectual works or industrial products]
- [Introduction into the State and trading in counterfeit products]

Crimes against industry and trade (art. 25-bis.1)

- [Disruption of industry or commerce]
- [Fraud in the exercise of trade]

- [Sale of non-genuine foodstuffs as genuine]
- [Sale of industrial products with mendacious signs]
- [Manufacture and commerce of goods made by usurping industrial property rights]
- [Counterfeiting of geographical indications or designations of origin of agro-food products]
- [Unlawful competition with threats or violence]
- [Fraud against national industries]

Corporate crimes (art. 25-ter)

- False corporate communications
- Misdemeanours
- [False corporate communications of listed companies]
- Obstruction of checks
- [Unlawful restitution of contributions]
- [Illegal distribution of profits and reserves]
- [Illegal transactions involving shares or quotas of the company or its parent company]
- Transactions to the detriment of creditors
- Failure to disclose a conflict of interest
- Fictitious capital formation
- [Unlawful distribution of company assets by liquidators]
- Corruption among private individuals
- Incitement to corruption among private individuals
- Unlawful influence on shareholders' meetings
- [Agiotage]
- Obstructing the exercise of the functions of public supervisory authorities
- False or omitted statements for the issuance of the preliminary certificate.

Crimes for the purpose of terrorism or subversion of the democratic order (art. 25-quater)

- [Subversive associations]
- [Associations with the purpose of terrorism, including international terrorism, or subversion of the democratic order]
- [Assistance to members]
- [Recruitment for the purpose of terrorism, including international terrorism]
- [Organization of transfers for the purpose of terrorism]
- [Training in activities for the purpose of terrorism, including international terrorism]
- [Financing of conduct for the purpose of terrorism]
- [Seizure or misappropriation of property or money under seizure]
- [Possession of material for the purpose of terrorism]
- [Conduct for the purpose of terrorism]
- [Attack for terrorist or subversive purposes]
- [Act of terrorism using deadly or explosive devices]

- [Kidnapping for the purpose of terrorism or subversion]
- [Kidnapping for coercion purposes]
- [Incitement to commit any of the crimes provided in Chapters One and Two]
- [Political conspiracy by agreement]
- [Political conspiracy by association]
- [Armed gang: formation and participation]
- [Assistance to participants in conspiracy or armed gangs]
- [Seizure, hijacking, and destruction of an aircraft]
- [Damage to ground installations]

Practices of female genital mutilation (art. 25-quater.1)

- [Practices of female genital mutilation]

Crimes against the individual (art. 25-quinquies)

- [Reducing or keeping persons in slavery or servitude]
- [Child prostitution]
- [Child pornography]
- [Possession of pornographic material]
- [Virtual pornography]
- [Tourism initiatives to exploit child prostitution]
- [Trafficking in persons]
- [Purchase and alienation of slaves]
- [Illicit intermediation and exploitation of labour]
- [Solicitation of minors]

Market abuse (Article 25-sexies)

- [Insider trading]
- [Market manipulation]

Manslaughter and grievous or very grievous bodily harm, committed in violation of health and safety at work regulations (art. 25-septies)

- Manslaughter
- Negligent bodily injury

Receiving stolen goods, money laundering and use of money, goods or benefits of unlawful origin, as well as self-laundering (art. 25-octies)

- Receiving stolen goods
- Money Laundering
- Use of money, goods or benefits of illicit origins
- Self-laundering

Crimes related to non-cash means of payment (Article 25-octies.1)

- Misuse and forgery of non-cash means of payment
- Possession and dissemination of computer equipment, devices or programmes aimed at committing crimes regarding non-cash means of payment
- Computer fraud
- Fraudulent transfer of assets

Copyright infringement offences (Article 25-novies)

- Making available to the public, through a telematic network system, by any type of connection, a protected work or part thereof (Art. 171, Law No. 633/1941, paragraph 1, letter a-bis).
- Offenses referred to in the previous point committed on works not intended for publication when the honor or reputation of others is harmed (Art. 171, Law No. 633/1941, paragraph 3).
- Unauthorized duplication of computer programs for profit; import, distribution, sale, or possession for commercial or business purposes, or rental of programs contained in media not marked by SIAE; preparation of tools to remove or circumvent protection devices of computer programs (Art. 171-bis, Law No. 633/1941, paragraph 1).
- Reproduction, transfer to another medium, distribution, communication, public presentation or demonstration of the content of a database; extraction or reuse of the database; distribution, sale, or rental of databases (Art. 171-bis, Law No. 633/1941, paragraph 2).
- Unauthorized duplication, reproduction, transmission, or public dissemination by any means, in whole or in part, of works intended for television, cinema, sale or rental of discs, tapes, or similar media, or any other medium containing phonograms or videograms of musical, cinematographic, or audiovisual works or sequences of moving images; literary, dramatic, scientific, or educational works; musical or dramatic-musical works; multimedia works, even if included in collective or composite works or databases; unauthorized reproduction, duplication, transmission, or dissemination; sale or trade; transfer under any title; or unlawful import of more than fifty copies or specimens of works protected by copyright and related rights; making available on a telematic network system, through any type of connection, a protected work or part thereof (Art. 171-ter, Law No. 633/1941) [amended by Law No. 93/2023].
- Failure to communicate to SIAE the identification data of media not subject to marking, or false declaration (Art. 171-septies, Law No. 633/1941).
- Fraudulent production, sale, import, promotion, installation, modification, or use for public or private purposes of devices or parts of devices intended for decoding audiovisual transmissions with conditional access via terrestrial, satellite, or cable systems, in either analog or digital form (Art. 171-octies, Law No. 633/1941).

Inducement not to make statements or to make false statements to judicial authorities (art. 25-decies)

- Inducement not to make statements or to make false statements to the judicial authorities

Environmental crimes (art. 25-undecies)

- Environmental pollution
- [Environmental disaster]
- Culpable crimes against the environment
- Trafficking and abandonment of highly radioactive material
- Aggravating circumstances
- [Killing, destroying, capturing, taking, or possessing specimens of protected wild animal or plant species]
- [Destruction or deterioration of habitat within a protected site]
- Discharge of industrial wastewater containing hazardous substances
- Discharges to soil, subsoil, and groundwater
- [Discharge into the sea of prohibited substances or materials from ships or aircraft]
- Collection, transport, recovery, disposal, trade and intermediation of waste in the absence of the prescribed authorisation, registration or communication
- Construction or operation of an unauthorised landfill
- Mixing of hazardous waste
- Temporary storage at the place of production of hazardous medical waste
- Pollution of soil, subsoil, surface water or groundwater with the exceeding of risk threshold concentrations
- Pollution, caused by hazardous substances of soil, subsoil, surface water or groundwater with the exceeding of risk threshold concentrations.
- Violation of reporting requirements, the keeping of obligatory registers and forms
- [Illegal waste trafficking: shipment of waste constituting illegal trafficking]
- Organised activities for the illegal trafficking of waste
- Organised activities for the illegal trafficking of highly radioactive waste
- False information on the nature, composition and chemical-physical characteristics of waste or inclusion of a false certificate in the data to be provided for waste traceability purposes
- Use of a waste analysis certificate containing false information on the nature, composition and chemical-physical characteristics of the waste transported
- Fraudulent alteration of a hard copy of the SISTRI - AREA MOVEMENT form by the transporter
- Exceeding, in the running of an establishment, emission limit values that also result in exceeding air quality limit values
- [Import, export or re-export of specimens belonging to endangered animal and plant species]
- Falsification or alteration of certificates, permits, import notifications, declarations, communication of information for the purpose of acquiring a permit or certificate, use of false or altered certificates or permits]

- Possession of live specimens of wild mammals and reptiles and live specimens of mammals and reptiles from captive breeding
- Use of ozone-depleting substances
- [Intentional dumping of pollutants at sea or spills of pollutants from ships]

Transnational Crimes [art. 10 L. 146/2006]

- [Conspiracy]
- [Mafia-type association]
- [Association for the purpose of illicit trafficking in narcotic drugs or psychotropic substances]
- [Criminal association for the purpose of smuggling foreign-processed tobacco products]
- [Inducement not to make statements or to make false statements to judicial authorities]
- [Aiding and abetting]
- [Provisions against clandestine immigration]

Employment of citizens from third world countries whose stay is irregular (art. 25-duodecies)

- Provisions against illegal migration
- Fixed-term and open-ended subordinate employment

Racism and Xenophobia (art. 25-terdecies)

- [Ratifying and enforcing the International Convention on the Elimination of All Forms of Racial Discrimination, opened for signature in New York on 7 March, 1966]

Fraud in Sports Competitions, Illegal Gaming or Betting and Gambling by Prohibited Devices (art. 25-quaterdecies)

- [Fraud in sports competitions]
- [Abusive exercise of gaming or betting activities]

Tax offences (art. 25-quinquiesdecies)

- Fraudulent declaration through the use of invoices or other documents of non-existent transactions (art. 2 Lgs. Decree 74/2000)
- Fraudulent declaration through the use of invoices or other documents of non-existent transactions (art. 3 Lgs. D. 74/2000)
- Issuing invoices or other documents for non-existent transactions (art. 8 Lgs. D. 74/2000)
- Concealment or destruction of accounting documents (art. 10 Lgs. D. 74/2000)
- Fraudulent withholding of taxes (art. 11 Lgs. Decree 74/2000)
- [Untrue declaration (in case of serious cross-border VAT fraud) (art. 4 L.D. 74/2000)]
- [Failure to make a declaration (in case of serious cross-border VAT fraud) (art. 5 L.D. 74/2000)]

- [Undue compensation (in case of serious cross-border VAT fraud) (art. 10-quater L.D. 74/2000)]

Contraband (art. 25-sexiesdecies)

- Ecco la traduzione in inglese del tuo elenco, mantenendo un registro tecnico-legale:
- [Customs duties and border duties]
- [Smuggling due to failure to declare]
- [Smuggling due to false declaration]
- [Smuggling in the movement of goods by sea, air, and border lakes]
- [Smuggling through improper use of imported goods with total or partial duty reduction]
- [Smuggling in the export of goods eligible for duty refund]
- [Smuggling in temporary export and in special use and processing regimes]
- [Smuggling of manufactured tobacco]
- [Criminal association aimed at smuggling manufactured tobacco]
- [Evasion of assessment or payment of excise on energy products]
- [Evasion of assessment or payment of excise on manufactured tobacco]
- [Sale of manufactured tobacco without authorization or purchase from unauthorized sellers]
- [Illegal production of alcohol and alcoholic beverages]
- [Association for the purpose of illegal production of alcohol and alcoholic beverages]
- [Evasion of assessment or payment of excise on alcohol and alcoholic beverages]
- [Tampering with devices, stamps, and marks]
- [Deficiencies and surpluses in the storage and circulation of excise goods]
- [Irregularities in circulation]

Crimes against the Cultural Heritage (art. 25-septiesdecies e 25-duodevicies)

- Violations in the area of disposal of cultural property;
- Misappropriation of cultural property;
- [Illicit importation of cultural property];
- [Unlawful removal or export of cultural property];
- Destruction, dispersal, deterioration, defacement, defilement, and illegal use of cultural or scenic property;
- [Counterfeiting of works of art];
- [Theft of cultural property];
- Receiving stolen cultural property;
- Forgery in private writing relating to cultural property;
- Laundering of cultural property;
- [Pillaging and looting of cultural and scenic property].

Crimes against animals (Art. 25-undevicies)

- Killing or harming animals belonging to others

- [Prohibition of animal fights]
- [Prohibited shows or events]
- Animal mistreatment
- Killing of animals

Transnational Crimes [Art. 10 L. 146/2006]

- [Criminal Association];
- [Mafia-type association];
- [Association for the purpose of illegal trafficking in narcotic or psychotropic substances];
- [Conspiracy aimed at smuggling foreign tobacco products];
- [Inducement not to make statements or to make false statements to judicial authorities];
- [Aiding and abetting];
- [Provisions against illegal immigration].

Art. 12 - Processes

In the context of the work that the IRFMN carries out, the processes within which the offences referred to in the previous article may be committed are highlighted. For each of these processes, the sensitive phases are described.

The processes that must be monitored are:

- a) Management of relations with the Public Administration and Supervisory Authorities
- b) Research work
- c) Administrative and financial management
- d) Management of personnel
- e) Management of information systems
- f) Management of obligations relating to health and safety in the workplace
- g) Management of environmental obligations
- h) Management of animal experimental activities

Art. 13 - Management of relations with the Public Administration and Supervisory Authorities

Relations with the Public Administration and the Supervisory Authorities include the following activities:

- management of communications, fulfilments, authorisations, accreditations and requests for information;
- management of relations with public officials during inspection visits;
- management of relations with public officials during meetings/conventions.

Monitoring the management of communications, fulfilments, authorisations, accreditations and requests for information must include an analysis of the

completeness, correctness and accuracy of the data and information prepared for the Public Administration. The checks carried out must be adequately traceable.

Monitoring relations with public officials during inspections must involve the persons formally granted the power to interact with these officials, the way in which inspections are carried out, minutes and the traceability of their findings.

Monitoring relations with public officials in the context of meetings and/or conferences must have regard for authorisation to attend such events and communications these participants send.

Art. 14 - Research

Conducting research involves the following steps:

- fundraising
- conducting research and reporting costs
- disseminating results

Monitoring the fundraising phase should include analysing the source of the funds raised, the presence of any undue demands or restrictions imposed by the study sponsor, and the absence of any illegal conduct in the fundraising process.

Monitoring should also check how the funds collected are used, and that the research respects all relevant regulations, for example those relating to workplace safety, copyright infringement and computer-related crime.

Monitoring in the dissemination phase must verify that no false or altered results are disseminated and that no results are concealed in order to commit or facilitate the offence of market manipulation.

Art. 15 - Administrative and financial management

Administrative and financial management involves the following activities:

- Preparing financial statements
- Managing tax obligations
- Managing financial resources
- Managing the procurement of goods and services
- Managing consultants
- Managing relations with Statutory Auditors and Auditors
- Managing extraordinary operations
- Managing expense reimbursements

As part of managing accounts, financial statements and taxation, managing the supply of goods and services, consultants, relations with Statutory Auditors and Auditors and

extraordinary transactions, it is necessary to monitor activities that may lead to corporate offences, such as false corporate communications, obstruction of the exercise of the functions of public supervisory authorities, obstruction of control or bribery among private individuals, as well as tax offences, such as fraudulent declaration by means of invoices or other documents for non-existent transactions, concealment or destruction of accounting documents, or fraudulent evasion of tax payments.

Monitoring the management of financial resources must involve ensuring the correct management of receipts, payments and IRFMN funds, in order to avoid corruption or other illegal behaviour towards the Public Administration or private counterparts, as well as laundering. The tracking of financial flows must also ensure that there is no illicit use of the institute's money.

Monitoring expense reimbursement management must involve verifying the authorisation for travel and reimbursements and related administrative inspections of requests and justifications.

Art. 16 - Personnel Management

Personnel Management involves the following:

- Selecting, recruiting and managing staff (scientific and non-scientific)
- Selecting, recruiting and managing fellows

Monitoring the selection, recruitment and management of personnel and scholarship holders must involve ensuring compliance with the rules of selection and management of personnel in order to prevent crimes of corruption and bribery among private individuals and the employment of third-country nationals who are not legally entitled to stay in Italy.

Art. 17 - Information Systems Management

Monitoring this work should focus on ensuring that data and systems access, backups, software, equipment, devices or computer programs, network security and physical security are properly managed.

Art. 18 - Management of obligations relating to health and safety in the workplace

Monitoring this work involves ensuring compliance with the requirements of Legislative Decree 81/2008 and its updates, with particular regard to studies conducted in the laboratory.

Art. 19 - Management of environmental obligations

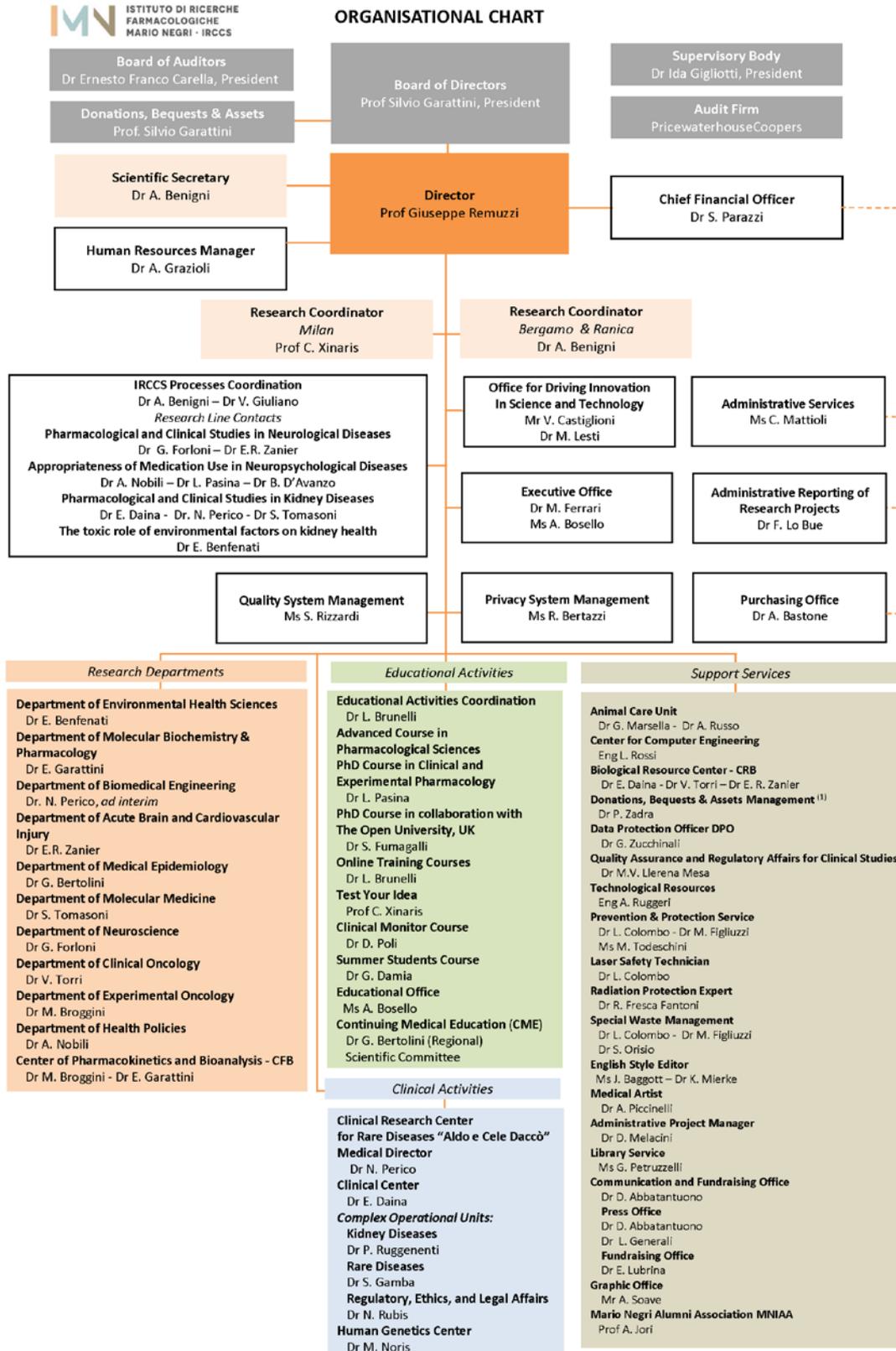
Monitoring this work involves ensuring compliance with regulatory requirements on waste management, water discharge management, preventing the contamination of soil, subsoil, surface water and groundwater and managing equipment containing fluorinated greenhouse gases.

Art. 20 – Management of Animal Experimentation Activities

Monitoring this work involves verifying compliance with the provisions of the special legislation on animal experimentation, in order to mitigate the risk of committing crimes against animals, such as, by way of example and not limitation, the offense of animal mistreatment.


Prof. Giuseppe Remuzzi
Director

Milan, December 9, 2025



February 10, 2026

⁽¹⁾ The activity is overseen by Prof. Garattini