



CODE OF ETHICS

BOARD OF DIRECTORS MEETING DATE

20 JULY 2023

FORMALISATION

CHAIRMAN PROT. DIREG 10/2023 DATED 25 JULY 2023



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This text - which replaces in its entirety the previous Prot. direg 6/2021 dated 8 September 2021 - has immediate effect and may be circulated by Bambino Gesù Children's Hospital for the uses permitted.



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PART ONE







PART ONE

The mission, purposes and recipients of the Code of Ethics

1.1 THE MISSION THAT UNDERLIES THE BAMBINO GESÙ CHILDREN'S HOSPITAL

The Bambino Gesù Children's Hospital (the 'Hospital' or 'OPBG') is an institution of the Holy See, reporting directly to it and submitting to its supervision and direction. It was established in the second half of the nineteenth century thanks to the generous initiative of the Dukes Scipione and Arabella Salviati. Its foundation dates back to 19 March 1869. Since 1985, it has been recognised as a Scientific Research and Healthcare Institute (IRCCS) in paediatrics. It is also accredited as an Academic Hospital by Joint Commission International (JCI).

Constantly referencing the Catholic values and the resulting principles that inspired its establishment and ensure its development, the Hospital pursues the best care together with the best translational research activity, which is clinically oriented. It strives for the true good of the patient, integrating the new gains made by biomedical research, all in a context of sustainability and continuity. This ensures increasingly effective hospitality and care for patients (chil-

dren, teenagers, adolescents and, more generally, all patients in the paediatric field) and their families, both local, from Italy, and from every country in the world.

The Hospital does not pursue a financial profit, and guarantees clinical and care activities in the paediatric field, focusing also on those for whom access to care is not always guaranteed, a factor that undermines human and spiritual dignity.

Clinical support and didactic, scientific and administrative activities are guided by the following principles:

- a central focus on the human person, who is entitled to the greatest dignity, understood as full recognition and respect for human beings, who must be served by every expression of care activity and scientific and technological research;
- striving towards new goals achievable by scientific and technological progress, un-



derstood as a projection into the future to keep pace with progress, within the framework of the Christian vision of existence and respect for the person, with the aim of humanising science and technology and making it a sign of Christ;

- excellence, understood as a continuous effort to reach the highest level in every situation and attitude, which must guide all research, technology, professionalism and behaviour.

All of this is undertaken in the context of the essential ethical principles of Catholic morality and, therefore, of the sacredness of life, with the awareness that it is always a blessing, with the purpose of both spiritual and material charity.

The above is the response to the broader mission that the Pope entrusted to the Hospital: support the poorest in building a world in which there is no longer an insurmountable gap between the haves and the have nots, between those who can afford healthcare and those who cannot.

In this way, Christ's teaching to care for and serve the sick, which is the mission representing the foundation for all the activities of the Bambino Gesù Children's Hospital, can be fully implemented.

1.2 PURPOSES AND RECIPIENTS OF THE CODE OF ETHICS

Within the context of the Hospital's mission, the Code of Ethics identifies the values, principles and rules of conduct that characterise all facets of the activity of the Bambino Gesù Children's Hospital, both internally and in its external relationships, within an overall framework that involves all stakeholders.

The Code of Ethics is thus an integral part of the internal control system and, as such, has significant strategic value in preventing illegal behaviour and in consolidating a culture that increasingly values ethics, fairness, observance of the rules and transparency.

Through the Code of Ethics, the Hospital also intends to consolidate its relationship of trust with all stakeholders, aware that it must uphold noble values due to its distinctive nature as an institution of the Holy See. The Hospital believes that legal rules are not sufficient if not supported by ethics, which contribute to guiding individual and collective behaviours and choices, so as to pursue the high interests that underpin the mission of the Bambino Gesù Children's Hospital.

It follows that the Code of Ethics is mandatory:

- for people who hold positions and responsibilities in the Hospital's governance and organisational struc-





ture, including the members of the Hospital's Supervisory Bodies and all those who perform work in the Hospital in any form or who act and work in any way in the name and on behalf of the Hospital (the 'Recipients'). By observing and complying with all the principles, values and rules of conduct contained in the Code of Ethics, the Recipients, each within their own responsibilities and powers, contribute to achieving the Hospital's mission and objectives. This is fundamental for the proper functioning, reliability, credibility and reputation of the Hospital. For all intents and purposes, compliance with the Code of Ethics should be considered an essential part of the contractual obligations assumed with the Hospital. All Recipients have a duty to be familiar with the Code of Ethics, to understand its meaning and to actively contribute to its implementation;

- For third parties who have relationships with the Bambino Gesù Children's Hospital (suppliers, contractors, consultants, partners, trainees, volunteers – 'Third Party Recipients'), the provisions of the Code of Ethics are applied as part of existing contractual relationships. The Hospital requires them to behave in a way that is in line with the values, principles and rules of conduct specified in the Code of Ethics. To this end, contracts will in-

clude clauses and/or the signing of declarations relating to ethical conduct and transparency aimed at obtaining the commitment of those individuals to act in the performance of their contracts in compliance with the regulations in force in a proper and transparent manner, avoiding – in the context of their relationships with the Hospital – behaviours, acts or omissions that could be construed as maladministration for illegal purposes and, more generally, that are in conflict with the principles, values and rules of ethical conduct such as to create liability for illegal acts on the part of OPBG or its staff.







PART TWO







PART TWO

Values

2.1 VALUE OF LIFE AND SPIRITUAL AND HUMAN DIGNITY OF EVERY PERSON

Inspired by a central focus on the human person, the Bambino Gesù Children's Hospital carries out its work by giving attention to the value of life and the personal dignity of every person. These are protected by the Hospital as a fundamental element of Christian ethics, physical and mental integrity, and respect for physical and psychological suffering.

The words of the *Evangelium Vitae* of St John Paul II are an inspiration: 'Life is always a good. This is an instinctive perception and a fact of experience, and man is called to grasp the profound reason why this is so.'. Based on this fundamental moral principle, the Hospital upholds and respects the dignity of the human person, created in the image and likeness of God, in every phase of its existence, from conception to death.

The value of life therefore requires the protection of the physical and moral integrity of patients and their families, their safety and their right to have adequate, competent and attentive care and assistance. It also requires protection of the integrity of all those who work within and in the interest of the Hospital, ensuring their working conditions

are respectful of individual dignity, offering safe and healthy working environments. The sacred concept of life, taught and defended by the Catholic Church, is the root of these fundamental principles: protection of physical life, the therapeutic principle, or the principle of wholeness or benefit (proportionality of care, prohibition of aggressive treatment), the principle of solidarity and subsidiarity.

Personal dignity includes equal social dignity and, therefore, also equality, impartiality and equal opportunities. The Hospital therefore firmly rejects any form of discrimination.

However, personal dignity is not only social. It is also closely related to the sacredness of life.

In this context, the Bambino Gesù Children's Hospital rejects any clinical care that causes the voluntary interruption of life, such as abortion or euthanasia. Every intervention is aimed at diagnostic, therapeutic and rehabilitative goals that reduce as much as possible any physical and psychological suffering.



2.2 LEGALITY

Compliance with current regulations, whether legislative or statutory, constitutes a further essential value on which the Bambino Gesù Children's Hospital's activities are based.

Within the scope of their respective responsibilities, the Recipients are therefore required to know and observe the laws and regulations applicable to their activities, to avoid any behaviour that could expose the Hospital to a risk of conduct in breach of the current legislation.

2.3 ETHICS OF SCIENTIFIC RESEARCH ACTIVITIES

The Bambino Gesù Children's Hospital carries out research guided by the principles of Catholic Doctrine, always giving particular attention to the central position of the person, the value of life and respect for human dignity in its physical, psychological and spiritual dimension, starting from the moment of conception.

Also taking into account its qualification as a Scientific Research and Healthcare Institute (IRCCS), the Bambino Gesù Children's Hospital ensures that all research is conducted according to rigorous scientific methods and in compliance with current legislation on biomedical research and health protection.

2.4 SOLIDARITY

The Bambino Gesù Children's Hospital recognises the great value of solidarity, striving to implement it with actions that bring the Hospital's services to the weakest and least fortunate patients, where applicable through cooperation at national and international level.

2.5 HEALTH AND SAFETY OF PERSONS

The Bambino Gesù Children's Hospital gives particular attention to creating environments that ensure conditions are respectful of human health, safety and well-being.

Health and safety are appropriately monitored through a number of core activities: identifying hazards and implementing the necessary preventive actions, constantly updating risk assessments, and consequently identifying corrective actions and monitoring their effectiveness in order to constantly improve health and safety protection levels. These activities are also supported by appropriate training and communication activities, as well as ongoing methodological and professional training.

The Bambino Gesù Children's Hospital is also aware that adopting an organisational system aimed at ensuring the achievement of health, safety and well-being goals can also promote efficiency, reducing the costs deriving from accidents, injuries and occupational diseases, and – by improving levels





of health, safety and well-being at work – create a peaceful working environment.

2.6 ENVIRONMENTAL PROTECTION

The Bambino Gesù Children's Hospital is committed to safeguarding and respecting the environment, and its activity is always geared towards environmental compatibility and sustainability.

The Hospital complies with regulations and is active in limiting the environmental impact of its activities. In particular, it undertakes to comply with the obligations, prohibitions and restrictions in this field, to properly dispose of waste and to carry out actions aimed at the continuous improvement of its environmental performance, at saving energy and water, at minimising waste production and at recovering resources.

The Recipients are required to comply scrupulously with the procedures adopted by the Hospital on environmental matters.

2.7 CONFIDENTIALITY

The Bambino Gesù Children's Hospital is committed to ensuring the protection and confidentiality of personal data and information in its possession in accordance with applicable data protection legislation.

The personal data of which the Bambino Gesù Children's Hospital

is the Data Controller (in particular, personal data of patients, their families and people who exercise parental responsibility or legal representation, as well as all those who have relationships with the Hospital, including people who provide their services for any reason) are processed in accordance with the provisions of the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016) and Italian Legislative Decree No 196/2003 (as amended), and, in this context, by the Organisational Privacy Model adopted by the Hospital, as well as by the related and further specific internal regulations. In any case, this processing ensures that – pursuant to the abovementioned legislation – data subjects can exercise their fundamental right to the protection of personal data and, therefore, self-determination in decision-making and control over the collection, use, dissemination and storage of the data.

The Recipients are required to act in all cases in compliance with the confidentiality obligations assumed by the Hospital. For this reason, they are prohibited from disclosing or using personal data and, more generally, all confidential information that they have become aware of while performing their work for any purpose unrelated to said work.







PART THREE







PART THREE

General rules of conduct

3.1 ORGANIZATIONAL PRINCIPLES

In carrying out its activities, the Bambino Gesù Children's Hospital undertakes to act with fairness, transparency, truthfulness and traceability, including in reporting the objectives achieved and the resources used.

The Recipients are therefore required to ensure the maximum truthfulness, transparency and completeness of the information, both verbal and documentary (paper and digital), produced by their work within their respective areas of responsibility.

All operations and transactions must be legitimate, consistent and appropriate, authorised, correctly recorded and verifiable. All actions and operations must be adequately recorded, where applicable to ensure that decision-making, authorisation and implementation processes can be verified. Every operation must be adequately documented so that checks can be carried out at any time to certify the characteristics and the reasons for the operation, and to identify who authorised, performed and recorded the operation.

All processes and procedures are structured so as to guarantee: (a) separation of duties and responsibilities; (b) independent analyses related to areas of responsibility and technical professional skills; (c) preliminary assessment of sustainability and legal adequacy of the initiatives; (d) preparation of specific documents proving the operations and the objective basis of the choices made; (e) recording, detection, reporting, traceability and documentability of data, information and controls; (f) formal assessment and authorisation of operations; (g) definition of the acts in accordance with the powers of representation and signature; (h) monitoring; and (i) filing.



3.2 DISSEMINATION AND CONSOLIDATION OF THE CULTURE OF TRANSPARENCY AND CONTROL

The Bambino Gesù Children's Hospital is committed to the dissemination and consolidation of a culture of transparency and control that values ethics, loyalty and good faith, correctness and compliance with the rules.

Conducting activities transparently, with an approach based on ethics, loyalty and good faith, correctness and respect for the rules and the implementation of an effective control system: all these elements contribute to a management system in line with these objectives, promoting informed decision-making and contributing to ensuring the protection of assets, the efficiency and effectiveness of processes, the reliability of financial information and compliance with both external and internal rules and regulations, including procedures, all appropriately based on the Vatican legislative and regulatory context of reference of the Hospital as an Institution of the Holy See.

3.3 ABSENCE OF CONFLICTS OF INTEREST

The Bambino Gesù Children's Hospital works to avoid creating conflicts of interest. It commits all Recipients to aligning their conduct with this principle, refraining from any situation or activity – even if only potential – that could pit a

personal interest against the interests of the Hospital, or that could interfere with the ability to make impartial and objective decisions in the Hospital's interest.

3.4 ASSETS AND FINANCIAL FLOWS

The Bambino Gesù Children's Hospital guarantees that the assets and the related financial flows that it receives are managed in a transparent, documented and traceable manner. These are intended solely for its research, hospitality and care activities, where the financial remuneration is aimed at sustainability rather than profit.

Therefore, no operating profits can be distributed or allocated for purposes other than those of hospitality, care and the related research in the paediatric health field.

3.5 SCIENTIFIC RESEARCH ACTIVITIES

The Bambino Gesù Children's Hospital guarantees that research activity – whether pre-clinical or clinical – is guided by principles based on methodological rigour, compliance with good research practices, and critical and non-prejudicial observation of the results, observing its responsibility for identification, communication and appropriate protection and exploitation of the results achieved through this research activity.





3.6 CLINICAL STUDIES AND RELATIONS WITH THE ETHICS COMMITTEE

In the constant pursuit of its objectives of excellence in healthcare services based on cutting-edge research and clinical activities, the Bambino Gesù Children's Hospital carries out clinical studies both individually and by joining network projects.

The management of clinical studies – supported by specific procedures in accordance with the values, principles and rules of conduct of the Code of Ethics – complies rigorously with the rules and guidelines of good clinical practice. This process gives particular focus to the protection of patients' rights, following a complete and objective evaluation of clinical scientific value, medical feasibility, economic sustainability and legal suitability.

The proper management of clinical studies requires the prior involvement of both the Ethics Committee, which expresses a binding opinion, and the competent authorities, which issue the relevant authorisations. This also requires the thorough monitoring of correct implementation and related reporting, which is also important for potential internal or external audits and any prompt corrective actions.

A similar independent assessment is carried out by the Ethics Committee for all the cases that require its involvement, in accordance with the provisions of the external

and internal regulations, including those relating to the specific duties of the Ethics Committee.

The independent assessments – of which the Ethics Committee and the competent authorities are guarantors – also assume an important role as fundamental vehicles of direction and further assurance. In this way, any cases submitted for these assessments are geared in all cases towards compliance with the ethical, scientific and methodological parameters protected by the current industry regulations and by the guidelines of good clinical practice.

3.7 PRE-CLINICAL STUDIES

Pre-clinical research activities that may include animal studies (in vivo) are carried out through the use of scientifically validated methodologies and techniques that minimise animal stress. Moreover, they comply rigorously with current legislation on this issue and with the developments that have occurred with the transposition in Italy of Directive 2010/63/EU.







PART FOUR







PART FOUR

Specific rules of conduct

4.1 RELATIONSHIPS WITH PATIENTS AND THEIR FAMILIES

4.1.1 CENTRAL POSITION OF PATIENTS AND THEIR FAMILIES. QUALITY OF HOSPITALITY, CARE AND RESEARCH

The Bambino Gesù Children's Hospital places patients and their families at the centre of its activities. The Hospital's activities and the continuous improvements in clinical and scientific research are dedicated to patients and their families, ensuring accessibility and appropriateness, equality and ethics of health services and clinical studies, and quality and safety of treatments and care activities.

With the central focus on patients and their families as a constant point of reference, the Hospital bases its interactions with them on respecting the condition of illness and vulnerability. It also aims to create an integrated environment among all the parties involved, building dialogue and trust while working towards the common goal of appropriate care based on good clinical practices and always striving for excellence.

The overall care path for each patient is always fully considered,

so that even in the case of serious pathologies, recovery is not the only possibility. The care path provides the best possible care, always ensuring dignity and the protection of life, if necessary through the support of the specific palliative care centre.

To this end, the Hospital favours a relational model that values the family and those who exercise parental responsibility, always taking into account the patient's primary interest and his or her right to self-determination.

It follows that in reference to the entire path of care and assistance, and, where applicable, to clinical studies and scientific research, the relationship that the Bambino Gesù Children's Hospital establishes with patients and their families requires:

- compliance with the waiting lists, focusing on reducing the related time frames;
- the implementation – to ensure conscious decision-making – of transparent, understandable (and therefore where necessary through the



use of languages other than Italian or interpreters with adequate linguistic skills) and thorough information that never uses deceptive or untruthful persuasive tools, aimed solely at ensuring that complete, adequate and accurate information is provided about the diagnosis, prognosis and clinical studies and research that concern each patient, as well as the prospects of the treatments and any diagnostic and therapeutic alternatives, and the risks and foreseeable consequences of the choices made. This is based on the awareness that communication must be commensurate with an ability to understand on a cultural, linguistic, psychological and emotional level, and highlighting, in the medical records, the right to request a second opinion;

- the obtaining of free, informed consent, with the most general prohibition on exercising any form of pressure or persuasion of a scientific or other nature towards patients and their families or guiding them towards private professional visits;
- absolute compliance with the ethical and impartiality principles also in prescribing drugs or therapeutic paths;
- the correct management of medical records and, more generally, of health documentation relating to the entire clinical care path, guaranteeing its completeness, truthfulness and clarity;

- protection of confidentiality;
- due consideration, through the relevant offices, of any complaints from users, providing adequate feedback on the outcome of the appropriate checks and implementing any corrective actions, where necessary; achieving the foregoing also through the use of specific, anonymous questionnaires – with content also accessible in multiple languages – to measure the quality of the care provided.

The management of Clinical Risk is also fundamentally important as this is aimed towards guaranteeing effective and safe treatments. To this end, the management of Clinical Risk is based on and makes it possible to evaluate all sensitive areas (including care-related infections, surgery and medications) for the purpose of implementing and monitoring prevention measures.

The Bambino Gesù Children's Hospital commits all Recipients to ensuring that their conduct is in line with the above principles and guidelines, also ensuring that the competent internal structures provide the necessary training.

4.1.2 HOSPITALITY SERVICES

The Bambino Gesù Children's Hospital is aware that an effective patient care path cannot fail to consider all aspects related to hospitality, which can make the hospitalisation period less traumatic for the patient and his or her family,





recreating as much as possible the space, time and pace of life outside the Hospital.

The Bambino Gesù Children's Hospital guarantees the excellence that characterises its care for all the supplementary services of the treatment path as it is traditionally understood, from admission to the post-hospitalisation phase. This all-encompassing process of managing patients and their families takes into account their complex and delicate needs.

To make its commitment concrete, the Hospital carries out constant checks and controls aimed at preserving adequate hospitality services. It pays particular attention to developing all the roles involved in an organic way. This monitoring also ensures an overall hospitality path for patients and their families that is also adequately supported from an emotional, psychological and spiritual point of view.

4.1.3 COMMUNICATION

The Bambino Gesù Children's Hospital recognises and guarantees the right of patients and their families to receive clear and complete information. The communication must therefore be based on ensuring transparency and completeness, simplifying the methods for accessing the information as much as possible.

In accordance with the procedures and roles, the Hospital commits all Recipients to providing complete and understandable information, honouring the right to self-determination.



4.2 RELATIONS WITH STAFF

4.2.1 DEVELOPMENT AND PROTECTION OF STAFF

The staff (meaning anyone who works in any form in the Hospital) constitutes a fundamental resource for achieving the Hospital's objectives and mission.

Developing staff skills and expertise is of great strategic value. A high level of professionalism is a value that must be preserved and increased over time, because it affects the effectiveness of the outcomes of clinical care services and the quality of the results of scientific research.

The Bambino Gesù Children's Hospital recognises the central role of its staff and, therefore, protects and promotes their value, in order to improve and increase their professional skills.

In the context of the values that guide virtuous professional and relational action, staff management is based on respecting their rights and maximising their contribution, promoting their development and professional growth by refraining from any discriminatory and unfair behaviour.

The Hospital adopts criteria based on impartiality, merit, competence and professionalism for any decision regarding staff relations. Selections and recruitments are guided by the principles of fairness, transparency and impartiality, and no form of favouritism is permitted.

Staff are recruited in compliance with the labour laws and any other applicable provisions, on the basis of appropriate employment contracts, given the prohibition on any working relationship that does not comply with or aims to evade the current provisions.

In compliance with the contractual regulations, equal job opportunities and professional development are offered, on the basis of skills, potential and professional qualifications, without discrimination and/or favouritism, ensuring fair treatment based on individual skills and abilities.

Based on impartiality and respect for fair systems, all staff are granted the same opportunities for professional growth in their roles. Access to roles and positions of greater responsibility cannot however be unrelated to professional competence and experience, as well as the honesty and integrity of the individual.

Evaluations of activity are based on objective criteria, related to measurable parameters and minimising any areas of discretion and/or discrimination.

Interpersonal relationships, which underlie hierarchical relationships, are based on a fair and appropriate exercise of authority, avoiding any form of abuse and harm to a person's dignity, value and autonomy. The superior hierarchical position may not be a reason for prevarication over subordinates. Similarly, all forms of bullying or harassment, and





more generally any behaviour that could generate an intimidating, hostile or alienating work environment against individuals or groups of workers are prohibited.

The Bambino Gesù Children's Hospital guarantees the right to working conditions that respect everyone's dignity, protecting staff from acts of psychological violence and preventing any discriminatory or prejudicial attitudes or behaviours that could harm people and their convictions.

Confidential information concerning staff is processed in accordance with the applicable legislation in force, with methods that ensure maximum transparency for those directly involved and inaccessibility by third parties, except for justified and exclusive work-related reasons.

4.2.2 THE VALUES THAT MUST GUIDE STAFF ACTIONS

These are the values that must guide the professional and relational actions of the Hospital's staff in all activities carried out in the Hospital and for the Hospital:

Community

Understood as the ability to build relationships of esteem and trust through professional conduct supported by skills appropriate to the role and by authentic cooperative attitudes, aimed at the care of everyone's most precious and common asset: the patients and their families.

Transparency

Understood as a set of ethically correct behaviours (loyal, unambiguous, authentic, in line with the Hospital's identity), aimed at achieving clarity, truth and objectivity of information and respect for a system of shared values and rules that characterise the Hospital.

Innovation

Understood as the study and systematic introduction of solutions that create new value, in order to have a stable improvement in the outcomes of treatments, process efficiency and the satisfaction of patients and their families.

Leadership

Understood as the ability to inspire and help the group achieve shared goals and exploit the innate abilities of the group, through motivation for a path of continuous improvement.

4.2.3 PROACTIVE COOPERATION

Staff are required to cooperate proactively to achieve and maintain the objectives of excellence that characterise the Hospital in all its activities. They must do so with diligence and loyalty, reasonableness and objectivity, transparency, competence, professionalism, efficacy and efficiency, respect for the working environment and through constant commitment, ongoing professional training and appropriate behaviour. They must also act in accordance with any further internal provisions of the Hospital as well as, more general-



ly, with the values, principles and rules of conduct indicated in the Code of Ethics.

In the above context, there is also an obligation to actively cooperate in the Hospital's implementation of organisational plans and projects, with the understanding that they are the result of thorough analysis and careful evaluation by the appointed functions.

4.2.4 ABSENCE OF CONFLICTS OF INTEREST

Staff must avoid any situation or activity – even if only potential – that could pit a personal interest against that of the Hospital or which may interfere with the ability to make impartial or objective decisions in the interest of the Hospital.

Staff must provide notification, in the manner defined by more detailed internal regulations, of the establishment of relationships or appointments with third parties, even if these are free of charge, that are not governed by agreements with the Hospital. This will allow the Hospital to determine the existence of any conflict of interest – even if only potential – or to monitor the occurrence of conflict situations, or to verify compliance with the obligation of loyalty. While respecting freedom of opinion, this reporting obligation also applies in regard to memberships of associations with areas of interest that could create the situations described above.

Without prejudice to the foregoing, staff must refrain – informing their Manager – from any initiative or action and related assessments that reflect on persons (physical, legal and non-profit) with whom the subject or his or her spouse, cohabiting partner, first- or second-degree relatives has (or has had in the previous two years) any interests, even if only potential. In such cases, the Manager provides the appropriate operational guidelines so that the initiative or action can be assessed and implemented objectively by a person other than the person with the conflict of interest. The foregoing applies, without prejudice to any internal regulatory provisions supplementing the obligations in question, taking into consideration the specific characteristics or nature of the individual initiatives.

Subject to the above, any person falling within the categories or holding roles or offices previously identified by the Chairman on the basis of the provisions laid down in the Apostolic Letter issued by His Holiness Pope Francis on 26 April 2021 in the form of a 'Motu Proprio' and any subsequent amendments or additions, will be required to sign, at the time when a relationship with the Hospital is established, a specific statement attesting to the situations provided for therein and in accordance with any further more detailed directions to this regard expressly indicated by the Chairman. The declaration must be renewed every two years.





4.2.5 GIFTS

The Bambino Gesù Children's Hospital prohibits Recipients from accepting or offering or in any case soliciting gifts – for themselves or for entities other than the Hospital, on account of or for the purposes of their office – and other forms of benefits or advantages, unless they are of such a nature and value as not to give rise, even potentially, to the suspicion of illegality or immorality or in any case of being connected with the acquisition or granting of undue advantages or with the impairment of integrity and independence of judgment.

The value of gifts, gratuities and other forms of benefits or advantages received or made may not exceed €40.00 (between the same persons, during the same year), and Recipients are required, if they receive gifts, gratuities and other forms of benefits or advantages of a higher value, to refuse such items, immediately notifying the Chairman of such situations.

4.2.6 CONFIDENTIALITY AND PROTECTION OF INTELLECTUAL PROPERTY

Staff must guarantee the maximum confidentiality of all personal data and all information that they have become aware of while performing their duties. Similarly, they may not exploit or mention the position held in the Hospital to gain undue advantages or benefits.

They may not engage in conduct that could constitute counter-

feiting, alteration and/or unlawful use of trademarks, patents, trade dress, designs, models and, more generally, intellectual property. The Bambino Gesù Children's Hospital expressly reaffirms this prohibition in consideration of the scientific value of research publications and the widespread use of computer programs to support clinical care activities.

4.2.7 APPROPRIATE USE OF THE HOSPITAL'S ASSETS AND RESOURCES

Staff must carefully and respectfully safeguard – avoiding waste and in a manner consistent with the correct exercise of the duties carried out in the Hospital – the Hospital assets assigned to or used by them, protecting their value. Staff must also refrain from any act that could compromise their functionality and must comply with the related internal provisions governing their use in more detail, also taking into consideration the underlying risks to be prevented, such as those relating to the security and protection of IT systems.

This also includes the use of IT and network resources, which must be for legitimate purposes related to the Hospital's activities and with the values, principles and rules of conduct by which it is characterised. Staff are therefore expressly forbidden from engaging in behaviour that could alter the functioning of information systems or manipulate the data they contain.



4.2.8 PROTECTION OF THE HOSPITAL'S IMAGE

Even outside their working activities, staff must act in a manner that demonstrates respect for the good name and reputation and, therefore, for the image of the Hospital, actively taking action to disseminate, share and observe the values, principles and rules of conduct specified in the Code of Ethics.

4.2.9 COMPLIANCE WITH HEALTH AND SAFETY PROTECTION MEASURES

In relation to their roles and duties, staff are required to comply strictly with the legislation on the protection of health and safety in the workplace and, in this context, with the measures specified in the Risk Assessment Documents prepared for each Hospital site and with any further directives and instructions given.

In order to contribute to the dissemination of a culture of safety, staff are required to participate in the training and information meetings organised by the Hospital and to scrupulously follow the procedures adopted by the Hospital in the field of safety.

4.2.10 BAN ON SMOKING AND THE USE OF ALCOHOLIC AND NARCOTIC SUBSTANCES

This is to be understood as an express ban on smoking and the use of alcoholic, narcotic and psycho-

tropic substances not intended for treatment, both in closed environments and in the open spaces inside the Hospital. The Bambino Gesù Children's Hospital expressly reaffirms this prohibition in consideration of the relevant values focused on the quality of hospitality and care and on the health and safety of persons.





4.3 RELATIONS WITH INSTITUTIONS AND REGULATORY BODIES

Research and care activities require an integrated relationship between Scientific Research and Healthcare Institutes, such as the Bambino Gesù Children's Hospital, and the institutions and regulatory bodies that issue authorisations, accreditations and recognitions, verifying that the requirements are maintained and carrying out supervisory activities and audits.

Being aware of the importance of this relationship, the Bambino Gesù Children's Hospital establishes – with the common goal of ensuring adequacy and excellence in research and care and through the appointed functions or duly authorised staff or consultants – a close network of relationships with institutional, ministerial and regional authorities, and with the appointed technical bodies as well as more generally with regulatory bodies, paying close attention to transparency, ethics, integrity and compliance with the rules.

In its relations with institutions and regulatory bodies, the Hospital commits all Recipients to forms of conduct based on maximum clarity, transparency and cooperation, in full compliance with the law and the highest professional and moral standards.

Staff are therefore forbidden from undertaking any action that could improperly influence the decisions of the institutions or bodies with which they interact for the purpose of obtaining undue advan-

tages, or performing actions that do not comply with or are contrary to the duties of the office, in particular by offering or promising independently or by inducement, directly or indirectly, gifts, money, favours or benefits of any kind, or by conduct tending to mislead.

The Hospital ensures full transparency, thoroughness and completeness of information in preparing communications, statements and notices intended for the above institutions and bodies, strictly refraining from submitting false and/or altered documents, or from removing and/or omitting to show, where required, documents, information or data of any kind. With particular reference to discussions with the judicial authorities and in any case with all the institutions and bodies that carry out supervisory and control activities, the Bambino Gesù Children's Hospital guarantees broad cooperation in full respect of their role, autonomy and power of initiative and also reiterates the absolute prohibition on inducing any person not to make statements or to make false statements.

All services provided on behalf of the National Health Service must be legitimate, appropriate and adequately documented, so that they can be checked at any time (i) to verify their characteristics and motivations and (ii) to identify the parties who authorised, performed, recorded and verified the service.



4.4 RELATIONS WITH UNIVERSITIES, BODIES AND SCIENTIFIC SOCIETIES

The Bambino Gesù Children's Hospital is aware that striving for new goals made possible by scientific and technological progress and excellence requires effective cooperation with universities and other permanent and specialist education institutions. Forms of cooperation with bodies, institutions, industries and other entities in the private sector, Italian and foreign research laboratories, and other international bodies also enable coordinated programmes, helping to share common projects associated with research and care protocols, promoting the circulation and dissemination of knowledge.

In this context, the Hospital strives to ensure that the establishment and management of these relationships, including those with trainees, is also carried out with an assurance of transparency, ethics, integrity and respect for the rules.

4.5 RELATIONS WITH THE LOCAL AND INTERNATIONAL COMMUNITY

Inspired by the value of solidarity, the Bambino Gesù Children's Hospital is the driver of international cooperation initiatives.

The operating and governance model adopted by the Hospital in this regard is oriented towards an organic implementation of these initiatives, with the involvement of institutional bodies, based on specific agreements. These are aimed at fulfilling the primary need for medical and scientific training (both directly on site and at the Hospital sites), as well as offering local communities the highly qualified or complex services that characterise the Hospital. All of this takes place in the context of a complete, organic and systematic assessment that can enable appropriate clinical and administrative coordination, as well as compatibility with the ordinary operational continuity of the Hospital's overall activities.

The model also dedicates particular importance to coordinating the care of patients of foreign origin, covering aspects of care as well as logistics, and more generally the associated organisational and administrative aspects.

By means of specific assessments, significant attention is also given to all emergency humanitarian interventions involving the Hospital.





4.6 RELATIONS WITH VOLUNTEERS AND ASSOCIATIONS

Volunteer associations are an active part of a cooperative network intended to ensure the continuous improvement of the hospitality and care services provided by the Bambino Gesù Children's Hospital to patients and their families.

In this context – and with the understanding that these associations are not entities within the Hospital even though they carry out significant activities for its benefit – their operations are governed by specific contractual relationships supported by the prior identification of the necessary accreditation criteria.

4.7 RELATIONS WITH FINANCING PARTIES AND BENEFACTORS AND RELATED FINANCIAL FLOWS

The Bambino Gesù Children's Hospital does not seek to achieve a profit and relies for its sustainability on funding from public and private entities that support its scientific research and care activities.

The Hospital is therefore aware of the significance of this funding and of the resulting need to guarantee transparent management of the financial flows, which remain solely intended for its health-care, support and research activities.

In this context, all financial flows, including those not related to the National Health Service, are supported by specific legal documents and by appropriate procedures governing the management of the sensitive processes to which they relate.

Specific reporting is required for all financial flows intended for clinical studies and scientific research, including the use of the Hospital's '5 per 1000' contributions, which are allocated to support specific projects on the basis of an annual distribution plan.



4.8 RELATIONS WITH SUPPLIERS, CONTRACTORS, CONSULTANTS AND PARTNERS

The Bambino Gesù Children's Hospital bases its relations with suppliers, contractors, consultants and partners on legality, transparency, loyalty, integrity and the additional values expressed in the Code of Ethics. It demands the same conduct from all those it interacts with, where applicable through specific contractual provisions.

The selection and assessment process for suppliers, contractors and consultants is supported by the establishment of a register of suppliers and is carried out according to criteria that guarantee the rotation, as far as possible, of invitations to bid, while avoiding any situation that could generate undue disadvantage for some compared to others. It is based on cost-effectiveness of goods and services, sustainability, quality of service, safeguarding of safety and the environment, legal suitability and regulatory compliance, integrity and transparency, as well as monitoring. All of these activities are carried out in compliance with the additional specific control safeguards defined in the procedures applied in the relevant Vatican context.

The Hospital complies with all applicable regulatory provisions in matters of competition, refraining from engaging with suppliers, contractors, consultants and partners in general in deceptive or collusive conduct and, more generally, any behaviour that could

engender any form of unfair competition.

4.9 COMMUNICATIONS AND MEDIA RELATIONS

The Bambino Gesù Children's Hospital is particularly attentive to communications with all of its stakeholders, anchored in a relationship and dialogue based on providing access to news and on the quality and transparency of institutional information. It thus aims to ensure clarity, truthfulness and objectivity of information, where applicable to protect the image of the Hospital.

The Hospital is guided by an integrated communication model, which is also characterised by comprehensive annual institutional reporting.

In this context – and with the awareness of the media's importance as a fundamental vehicle for external communication – relations with the press and other mass media are the exclusive responsibility of the Hospital's Chairman or his representatives and of the appointed communication departments, where necessary in compliance with the fundamental confidentiality requirements that internal information may impose.

Any information regarding the Hospital's objectives, results and points of view is provided by the Chairman or his representative.

Any public speeches and announcements (also through the





media), any participation as speakers in conferences, seminars, congresses, university training events and the like, as well as the personal and editorial drafting of articles and essays on matters of direct or indirect impact on the Hospital are authorised within the scope of the provisions of specific agreements governing these events. If there are no standing agreements because they are specific or personal events, or they are not related to conventional relationships, they are authorised by the Chairman or his representative in accordance with more detailed internal regulations and after the texts and reports have been shared with the relevant Manager, if this is required by the topics covered.

Staff participating in such events are prohibited from accepting compensation, money or other benefits from the organising body or from any sponsors, with the exception of reimbursement of travel expenses, if provided for other participants. This reimbursement is subject to specific authorisation by the Chairman or his representative, in consideration of the absence of conflicts of interest with the Hospital in relation to the specific case or the absence of any prejudicial risks to sound operational governance, after a compliance and transparency check has been carried out.







PART FIVE







PART FIVE

Control system

5.1 ADOPTION OF THE CODE OF ETHICS

The Code of Ethics is sponsored by the Chairman of the Board of Directors and is adopted and approved by the Board of Directors.

5.2 IMPLEMENTATION AND DISSEMINATION OF THE CODE OF ETHICS

By observing and complying with all the principles, values and rules of conduct contained in the Code of Ethics, the Recipients, each within his or her own responsibilities and powers, contribute to achieving the Hospital's mission and objectives. This is fundamental for the proper functioning, reliability, credibility and reputation of the Hospital.

All Recipients have a duty to be familiar with the Code of Ethics, to understand its meaning and to actively contribute to its implementation.

All Recipients must refrain from any conduct that is contrary to the Code of Ethics. Depending on their duties, they must appropriately inform third parties about the commitments and obligations set out in the Code of Ethics and must re-

quire that they comply with the obligations that directly concern their activities.

The Bambino Gesù Children's Hospital actively works to ensure the dissemination and knowledge of the Code of Ethics, by distributing the document through a dedicated section of the internal online platform, posting it in a place accessible to all, publishing it on the Hospital's website, and promoting and planning periodic training initiatives on the content of the Code of Ethics.

In particular:

- the people who hold positions and responsibilities within the Hospital governance and organisational structure, including the members of the Hospital's supervisory bodies and all those who work in the Hospital for any reason or who act in any way in the name and on behalf of the Hospital (Recipients) must sign a specific declaration indicating full acknowledgement and acceptance of the Code of Ethics, committing to comply with the values, principles and rules of conduct contained in that code in carrying out their duties;



- with regard to suppliers, contractors, consultants, partners, trainees and volunteers (Third Party Recipients), evidence is provided – in the contracts concluded with such Third Party Recipients – of the availability of the text of the Code of Ethics on the Hospital’s institutional website. In this regard, contracts will include clauses and/or the signing of declarations relating to ethical conduct and transparency aimed at obtaining the commitment of those individuals to act in the performance of their contracts in compliance with the regulations in force in a proper and transparent manner, avoiding – in the context of their relationships with the Hospital – behaviours, acts or omissions that could be construed as maladministration for illegal purposes and, more generally, that are in conflict with the principles, values and rules of ethical conduct such as to create liability for illegal acts on the part of OPBG or its staff.

5.3 REPORTS

Compliance with the provisions of the Code of Ethics is entrusted to the prudent, reasonable and careful supervision of each of the Recipients.

All persons entitled under the applicable legislation – including all Recipients and Third Party Recipients, and in any case all stake-

holders, including patients’ families – are invited to report facts and circumstances (or in any case situations for which there are well-founded reasons for considering them to be such and therefore true) – and consequently conduct consisting of behaviours, acts or omissions – that constitute violations of the values, principles and rules of conduct stated in the Code of Ethics and therefore also violations of national or European Union regulations and more generally unlawful acts (i) of which they have become aware in the context of their work and (ii) that constitute maladministration for illegal purposes or (iii) that are in any case such as to harm the interests or institutional purposes of the Hospital or the integrity of values or administration and therefore also the assets of OPBG and more generally the public interest (‘Reports’ or ‘Report’ in the singular).

As long as they are not attributable to conduct in breach of the prohibitions laid down in the specific rules of conduct for the development and protection of personnel referred to in paragraph 4.2.1 above, with particular but not exclusive reference to the prohibition of any form of mobbing or harassment or, in any case, of discriminatory or unfair conduct or conduct detrimental to a person and his or her convictions, situations related to disputes, claims or requests linked to an interest of a personal nature that relate exclusively to individual employment relationships or are associated with employment relationships with hierarchically superior figures do not



constitute the object of a Report, insofar as they are protected elsewhere and without prejudice to the reference in this context to the applicable legislation.

Reports must be made promptly and must contain the following elements: a precise and complete description of the facts and circumstances that are the subject of the Report, any other persons who may report on the facts, documents and/or information corroborating the Report.

Reports are handled by the Board of Statutory Auditors with the support of specifically authorised staff from the Internal Audit Department.

The Hospital provides its own internal reporting channels that are only accessible to the members of the Board of Statutory Auditors and the abovementioned staff of the Internal Audit Department. These channels guarantee, where necessary through the use of encryption tools, the confidentiality of the identity of the person making the Report, the person involved and the person mentioned in the Report, as well as the content of the Report and the related documentation.

Specifically, Reports may be made in written or verbal form, at the option of the Reporting Party.

If in written form, Reports are made using a choice of one of the following methods:

- by email, to segnalazioni.codiceetico@opbg.net. Mes-

sages sent to this address can only be viewed by members of the Board of Statutory Auditors and authorised staff of the Internal Audit Department. Messages can be accessed through authentication with network credentials protected by an alphanumeric password created individually autonomously and in secrecy, and regularly changed, to which an additional authentication factor is added (Multi-Factor Authentication mechanism activated);

- by means of a software application that guarantees the encryption of the data of the Reporting Party and of the Report and that is made available by the Hospital on its website within the dedicated page. This application can only be accessed by the members of the Board of Statutory Auditors and by the authorised staff of the Internal Audit Department;
- by registered letter: (i) in an envelope sealed so that its contents cannot be read from the outside; (ii) marked 'confidential'; (iii) sent to the 'Collegio dei Revisori dei Conti presso Responsabile Funzione Internal Audit dell'Ospedale Pediatrico Bambino Gesù, Piazza S. Onofrio n. 4, 00165 Roma'. The envelope must not contain any reference on the outside to the sender's name or other elements enabling traceability.

If in oral form, Reports are made using a recorded voice messaging



system through the number (+39) 06 6859 7321. The recording can only be accessed by the above-mentioned members of the Board of Statutory Auditors and authorised personnel of the Internal Audit Department using the credentials indicated above.

The Reporting Party may also make a Report through a face-to-face meeting to be requested from the Head of the Internal Audit Department, who will promptly inform the members of the Board of Statutory Auditors.

The use of the abovementioned internal reporting channels by persons entitled to report constitutes an obligation, without prejudice to the provisions of the applicable legislation on the Reporting Party's right to use external channels if the necessary conditions are met.

Any Reports mistakenly forwarded by the Reporting Party to addresses other than those indicated above will be promptly – and in any case within seven days – forwarded by the recipient to the Head of the Internal Audit Department, it being understood that the recipient is also under an obligation to ensure absolute confidentiality. Evidence of such erroneous receipt of the Report and of its re-submission to the management entities will be provided at the same time to the Reporting Party by the recipient.

The Board of Statutory Auditors will adopt a set of rules for the handling of Reports, which guar-

antees absolute confidentiality, including as regards the identity of the persons, in compliance with the applicable legislation and, in this respect, with reference both to the Reporting Parties and to those who may have assisted them in the Reporting process and to the persons involved in the Report and those mentioned in any way.

Within the above framework, the Board of Statutory Auditors is entitled, directly or through the Internal Audit Department, to hear the Reporting Party, the person mentioned in the Report and any other persons involved.

If the Report concerns conduct relating to the members of the Board of Statutory Auditors or staff of the Internal Audit Department, it must be sent to the Board of Directors by registered letter containing the same information as described above and addressed to the 'Presidente dell'Ospedale Pediatrico Bambino Gesù, Piazza S. Onofrio 4, 00165 Roma'.

The Board of Directors – and, on its behalf, the Chairman, where necessary through his duly authorised representative – will implement all appropriate measures to ensure absolute confidentiality in the management of the Report, in the same way as described above. In compliance with confidentiality obligations, it may also hear the Reporting Party, the person mentioned in the report and any other persons involved.

The Report and its documentation are kept for as long as necessary to





enable processing of the Report and, in any case, no longer than five years from the date of notification of the final outcome of the Report procedure, in compliance with the confidentiality obligations provided for by the applicable legislation.

The Hospital guarantees the absolute protection provided by the applicable legislation on the prohibition of retaliation related to legitimate Reports.

The Hospital also guarantees absolute confidentiality for the Reporting Parties, within the framework of any disciplinary proceedings that may ensue for the persons involved in the Report, without prejudice to the limitations provided for by the applicable legislation in respect of protecting their right to defence.

Within the overall framework described above, the Hospital considers a breach of confidentiality rights and of the prohibition of retaliation referred to in this paragraph as a serious breach, along with conduct obstructing a legitimate Report, and such breaches are sanctioned as such in accordance with the broader penalties regime set out in the following paragraph on 'Penalties'. This system of penalties also applies with reference to Reports that are not legitimate under the applicable legislation on the protection of persons who report violations, with particular reference to situations of slander or defamation, as well as, more generally, with reference to the violation of further binding provi-

sions laid down by that legislation, including the incorrect adoption of the procedures for the management of Reports or the failure to verify and analyse Reports.

5.4 PENALTIES

The violation of the values, principles and rules of conduct contained in the Code of Ethics compromises the relationship of trust between the Bambino Gesù Children's Hospital and the Recipients. Any violations will be prosecuted vigorously, promptly and immediately, through appropriate and proportionate disciplinary measures, regardless of the possible criminal relevance of such behaviour and the initiation of criminal proceedings in cases where they constitute an offence.

Failure to comply with the Code of Ethics and therefore violation of the values, principles and rules of conduct contained therein may result in disciplinary penalties against the employees, proportionate to the seriousness and/or repeated nature of the violation and/or to the degree of fault, in compliance with the applicable provisions of the law and/or of the Hospital's individual and/or collective agreements.

These penalties – insofar as it may need to be specified – also apply with reference to any breach of the applicable legislation on the protection of persons who report breaches, also taking into account the more detailed provisions set out in the section on 'Reports'



above. This will apply without prejudice to further binding provisions, where applicable in terms of penalties that may be imposed as laid down in the applicable legislation.

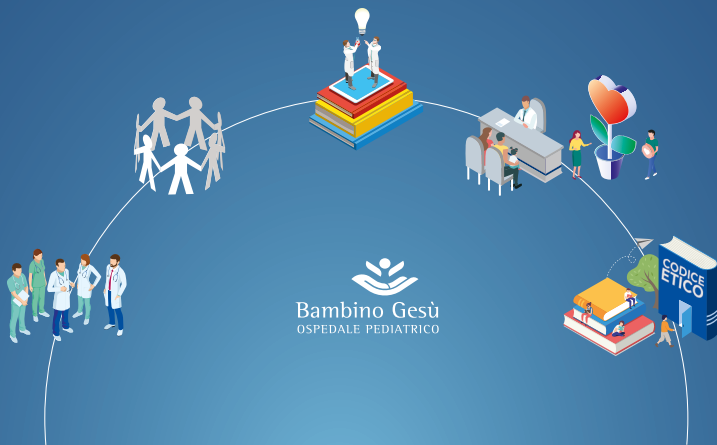
Any behaviour of suppliers, contractors, consultants, employees, partners, trainees and volunteers violating ethical and transparent conduct may result in the termination of the contract, in accordance with the clauses of the relevant contracts.

Without prejudice to the scenarios described above and if the conditions exist, the Hospital has the right to take action to obtain compensation for damages.



The Chairman
Tiziano Onesti

25 July 2023




Bambino Gesù
OSPEDALE PEDIATRICO