POLICY ON THE HUMAN TECHNOPOLE RESEARCH ETHICS COMMITTEE

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POLICY ON THE HUMAN TECHNOPOLE RESEARCH ETHICS COMMITTEE

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1) Object

The present Policy institutes and defines the role, tasks, functioning and responsibilities of the institutional review board for research ethics and integrity of the Human Technopole Foundation, the «Research Ethics Committee» (henceforth also “REC” or “Committee”).

This Policy does not apply to any deliberative functions assigned to different regulatory bodies by the national or the European union legal system.

2) Abbreviations, terms, definitions

Research Ethics Committee (REC): independent body with a deliberative role on matters of research ethics, bioethics and biolaw. The REC is tasked with the release of institutional ethical clearances related to research projects involving HT as study promoter or investigator and its research personnel and funds. Furthermore, the REC also has an advisory role over ethical and juridical issues that fall within the scope of research integrity and scientific misconduct.

Ethics and Regulatory Support Office (ERSO): dedicated office within HT with the twofold aim of supporting the activities of the REC and providing ethical and regulatory support to HT research and management personnel.

Ethical clearance: an institutional ethics opinion released by the REC assessing whether a research project meets all the necessary regulations, norms, ethical principles, and requirements for approval.

Ethics consulting: counselling activity meant to provide support and guidance over ethical issues pertaining to research ethics and integrity issues.

Ethics mentoring: counselling activity carried out by an ethics expert meant to provide support and guidance over the compliance of various ethical and regulatory aspects and tasks related to a specific project.

Research ethics: a specialised subfield of applied ethics dealing with the theoretical, normative, and regulatory implications of scientific research.

Research integrity: the body of principles and ethical values, legal obligations and professional standards that form the basis of the responsible conduct of those who carry out, finance, or evaluate scientific research, as well as the institutions that promote and perform it.

Research misconduct: a violation of the ethical principles and values, as well as the ethical duties and professional standards, on which responsible and correct conduct is based by

those who carry out, finance, or evaluate scientific research and by the institutions that promote and perform such research.

3) Scope

The present Internal Rule applies to ethics and integrity, bioethics and biolaw matters related to Human Technopole research, funds and/or the use of its infrastructures.

4) Regulatory references

The present Policy is issued in compliance with the provisions contained in the following relevant sources, internal and external to the Human Technopole Foundation:

- HT Bylaws
- HT Policy for the Definition, Drafting and Approval of Policies, Internal Rules, Guidelines of the Human Technopole Foundation
- Current relevant Italian and European legislative and regulatory framework
- Recommendations for the Investigation of Research Misconduct by ENRIO – European Network of Research Integrity Offices (2019)
- Statement on the formulation of a code of conduct for research integrity for projects funded by the European Commission – EGE (European Group on Ethics of the European Commission)
- European Code of Conduct for Research Integrity 2017 – ALLEA (ALL European Academies)
- Singapore Statement on Research Integrity – WCRI (World Conference on Research Integrity, 2010)
- OECD Best Practices for Ensuring Research Integrity and Preventing Research Misconduct
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects] – World Medical Association

- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine – Council of Europe
- International Declaration on Human Genetic Data - UNESCO
- Guidelines for Research Integrity – CNR (Italian National Research Council)
- Opinions and motions of the CNB (Italian National Bioethics Committee)

5) The Research Ethics Committee (REC)

5.1 Role of the REC

The role of the REC is to evaluate scientific research projects and activities undertaken at the Human Technopole Foundation so that they are ethically reviewed, cleared and monitored in accordance with national and international ethical laws, norms, ethical principles, guidelines, standards and best practices regulating scientific research.

5.2 Tasks and Functions of the REC

The REC shall:

- Evaluate the ethical implications of proposed research projects and activities submitted to the REC, releasing institutional ethical clearances for such projects and activities if appropriate – not normally including projects conducted/promoted by external users of HT Facilities and not involving HT research personnel and funds
- Upon request, advise the HT President, Supervisory Board, Management Committee, Director and Heads of Research Centre on matters of research ethics and integrity related to HT activities
- Upon request, advise the HT President, Supervisory Board, Management Committee, Director and Heads of Research Centre on the management of alleged research misconduct cases involving HT research personnel and/or the use of HT funds and infrastructures
- Evaluate and provide opinions to the competent HT bodies on alleged cases of research misconduct involving HT personnel, other than those constituting disciplinary infringement or violations of HT's "Organisational, Management and Control Model Ex D. Lgs. n.231 from 8 June 2001"

- Define the relevant modalities, procedures, documentation and templates related to the submission of research project proposals for REC evaluation
- Contribute to the development of initiatives, documents, internal rules and guidelines aimed at implementing an “ethics by design” approach in the planning/drafting of research projects and across HT scientific activities
- Contribute to the development of initiatives, documents, internal rules and guidelines on research integrity
- Contribute to the development of initiatives, documents, internal rules, guidelines, and ethical toolkits on other ethically relevant issues pertaining to HT activities
- Promote, in collaboration with other HT structures, educational and training activities focused on research ethics and integrity for HT personnel
- Contribute to the definition of any necessary ethical requirements, documentation and template forms related to the use of HT infrastructure by external users of the HT National Facilities

The REC does not process ethical matters that do not relate to HT research, funds or the use of its infrastructures. Moreover, it cannot release binding opinions over ethical issues that fall under European or national laws regulating clinical trials with human participants and the use of animals in scientific research. It may, however, provide ethical counselling to HT personnel on these matters and liaise with other institutional bodies dealing with such ethical and regulatory issues, including Ethics Committees (ECs), Institute Review Boards (IRBs), and Committees for Animal Welfare (OPBAs, IACUCs, etc.).

5.3 Composition and Functioning of the REC

- The REC shall be composed of an odd number of members and consist of at least 5 and a maximum of 11 members.
- The Committee members shall be appointed by the Management Committee, in compliance with HT regulations.
- The majority of the REC members shall be external to HT.
- The Committee members shall possess a recognised expertise in ethics or other knowledge domains relevant to the mission of HT and the tasks of the REC.
- The names of all the Committee members shall be made public by online publication.
- Committee members may serve two four-year terms, with the possibility of being reappointed after a four-year lapse. Very rare exceptions to this rule can be made for members by virtue of their unique expertise or role in the organisation. In the first two

four-year periods, term lengths can be altered by agreement of the Committee members with the HT Director, to prevent all members turning over simultaneously.

- Committee members may resign at any time by presenting their resignation request to the Chair of the Ethics Committee (see section 5.4 of the present Policy). A replacement member will be appointed within 6 months.
- If a Committee member does not attend more than one-third of the meetings within a 12-month period, her/his appointment will expire and a new member shall be appointed until the end of the term. This period, if less than two years, does not count toward the maximum limit of appointment of two consecutive terms.
- Committee members external to HT receive an attendance fee for their participation in the plenary meetings of the REC; this fee is increased for the Committee member serving as the Chair of the REC and may also be increased for other members nominated for specific tasks (see section 5.3.1 of the present Policy). The amount of such fees shall be defined in line with national regulations and current practices of other research ethics committees, including those of Universities, research hospitals (IRCCS) and other research institutions and included in a dedicated guideline.

5.3.1 Appointment and Role of the Chair

The Chair of the Research Ethics Committee (henceforth also “Chair of the Committee” or “Chair”) shall be appointed by the Committee members during the first plenary meeting of each term and shall serve until the end of that term.

The Chair shall:

- Establish the agenda of the plenary meetings;
- Convene the plenary meetings according to the agenda and, if necessary, invite additional experts in non-represented domains required for a specific project discussion to participate in the meetings, after discussion with, and with the agreement of, the REC members;
- Receive reports on alleged research misconduct cases for evaluation by the REC
- Supervise the activity of the Ethics and Regulatory Support Office staff serving as the Scientific Secretariat of the REC (see section 5.5 of the present Policy), in particular for the release of ethical clearances;
- Supervise and approve the drafting, approval, publication and dissemination of the official documents released by the REC;

- Promote and advise, whenever appropriate or necessary, outreach and dissemination activities covering issues that fall under the roles and tasks of the REC.

5.3.2 Appointment and Role of the Vice-Chair

The REC shall appoint a Vice-chair (henceforth “Vice-chair of the Committee” or “Vice-chair") through a majority vote during the first plenary meeting of each term. The Vice-chair shall serve until the end of the term.

The Vice-chair substitutes the Chair in case she/he is unavailable.

5.4 Meetings and Deliberations

The REC shall meet at least twice a year. More plenary meetings may be scheduled each year, that the Chair will decide whether or not to convene based on need (i.e. issues or projects to be discussed). In addition, the Chair may convene extraordinary meetings to discuss and consider urgent matters. The dates and times of the plenary meetings shall be proposed by the Chair in discussion with the REC members and made public at the beginning of each year on the HT website. The plenary meetings shall occur only if more than half of the REC members, including either the Chair or the Vice-chair, can participate. The plenary meetings may occur in presence or through online tools and platforms. The plenary meetings of the REC are not public.

REC deliberations regarding the ethical clearance of submitted projects are binding for HT.

All decisions shall be made by a majority vote of the Committee members who are attending either in person or remotely. All votes are open, there are no secret votes. Each member has one vote. In the event of a tie, the Chair’s vote shall be decisive.

The members of the REC are required to abstain from voting and not to express assessments and opinions on issues for which there may be a direct or indirect conflict of interest.

During each plenary meeting the Scientific Secretariat of the REC (see section 5.5 of the present Policy) drafts a synthetic report. The meeting report is then submitted for official approval by the Committee at the following plenary meeting. If required, parts of the report may be approved during the plenary session in which the relevant topics are discussed. The final deliberations (e.g., ethical clearances) of the REC are returned to the applicants within two weeks from the date of the plenary session in which the projects are discussed. The synthetic reports and, more generally, all the documents related to the workings and activities of the Committee, are archived and preserved by the ERSO and shall be made available for

consulting only for internal purposes to the REC members. A summary report of the REC activities shall be provided to the Management Committee and Consiglio di Sorveglianza on an annual basis.

All the Committee members are bound by a strict duty of confidentiality over the opinions, facts, discussions and deliberations expressed during the plenary meetings of the Committee.

5.5 The ERSO as the Secretariat of the REC

The function of Secretariat of the REC (henceforth “the Secretariat”) is covered by the ERSO. The Secretariat shall:

- Make available, on a dedicated HT webpage, the required forms and templates to submit a request for obtaining official ethical clearance by the Committee
- Provide instructions, aid and guidance to HT researchers who wish to submit a request for official ethical clearance by the Committee, or to any member of HT personnel on cases of alleged research misconduct
- Receive the requests for ethical clearance by the Committee, verify the submitted documents in accordance with the relevant procedures, and transmit all the documents to the Chair of the Committee
- Help the Chair organise the meetings of the Committee
- Draft the synthetic reports of the REC plenary meetings and contribute to the drafting of other relevant REC documents and reports
- Return to the applicants the final deliberations of the REC concerning the ethical clearance of submitted projects
- Archive the documents in accordance with the policies and internal rules regulating the internal management of data and privacy within HT
- Liaise with other institutions and internal HT structures and departments as needed

The Secretariat does not vote and does not count for the quorum needed to approve research projects and other deliberations of the REC.