

ETHICS REGULATIONS IN RESEARCH WITH/ON HUMAN SUBJECTS

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Introduction

The aim of scientific research is to expand human knowledge and the understanding of processes in nature and in the world of humans.

The principle of academic freedom is fundamental to academic thinking. However, it is not an absolute principle. In cases of clashes with other basic principles, a balance between all the principles should be sought.

Scientific research that involves human beings is subject to moral constraints that are connected both to the manner in which the research is conducted and to its outcomes and implications.

The rights of people involved - directly or indirectly - in the research, their well-being and their dignity, should be respected by those engaged in scientific research. Concern for the person participating in the research as well as the wider implications of the research must always be taken into account when considering the scientific interest. Although the principles below are primarily concerned with the protection of the people directly involved in the research, the researcher must exercise due caution also with regard to the potential effects of the research on society.

All scientific research involving humans shall be subject to these principles.

1. Definitions

- 1.1 **“Special population”**: Pregnant women, minors, those whose judgement has been impaired due to their physical or mental condition, financially or educationally disadvantaged people, people who are in legal custody (such as prisoners) and people subject to authorities (such as soldiers and students).
- 1.2 **“Interaction”**: A mutual interaction that includes communication or inter-personal connection between the researcher and the participant (including online surveys), other than interventional research.
- 1.3 **“Exploratory Procedures”**: Their purpose is to examine the feasibility of the research or to create a collaboration or collect information that shall make designing the research proposal possible.
- 1.4 **“Anonymization”**: A process that prevents, or at least significantly reduces, the risk of identification of the individual and the association of research conclusions with a

specific person. “Encoded information” does not meet the definition of anonymized information.

- 1.5 **“Ethics Committee” or “the Committee”**: a university committee for examining the ethics of research in which human participants or material or information of human origin are involved.
- 1.6 **“Researcher”**: Any person involved during the research in the collection, processing, analysis and preservation of information, and any person who has physical or verbal contact with participants in the course of the research – other than a sub-contractor.
- 1.7 **“Principal Investigator”**: A member of the university faculty, in accordance with the rules of the University, who leads the research and is responsible for all the ethical, scientific and administrative aspects of the research.
- 1.8 **“Research”**: Systematic investigation, including development, testing and assessment, designed to develop or to contribute to generalizable scientific knowledge.
- 1.9 **“Evaluation research”**: a process aimed at evaluating programs or performance or improving processes which is conducted for internal organizational needs at the university, and which is not intended for academic publication. Evaluation research does not require advance approval of a research ethics committee. In the event of a retroactive intention to publish the results of the evaluation study, ethical approval as “secondary research” under these Regulations shall be required.
- 1.10 **“Intervention research”**: Research that includes physical processes in which data or samples (such as venipuncture) are collected, as well as manipulations of the participant or of their environment that are carried out for the purposes of the research.
- 1.11 **“Secondary research”**: Research done using information or samples collected for non-research purposes (for example: organizational records, medical records, information collected as part of an evaluation study), or which was collected for other research purposes, and subject to anonymization procedures.
- 1.12 **“Non-identifiable genetic information”**: Information derived from genetic testing of a DNA or RNA sample of a person for the purpose of characterization and comparison of sequences. Genetic information shall be deemed non-identifiable information if the following conditions are met: (a) the information does not include identifying details of the subject, and (b) an ethics committee instructed the researchers, and they undertook, not to make any deliberate effort to identify the subject of the information on the basis of an analysis of the genetic information.

- 1.13 **“Coded information”**: Information or samples are considered to be coded when the identifying information that allows the researcher to easily identify the specific person to whom the private information or the sample belongs (such as name, social security number, etc.) is replaced (for example, by a number, letter or symbol or a combination thereof), and a key is required to decode the code in order to enable the link to be made between the identifying information and the private information or samples. Coded information is information that can be identified, and does not meet the definition of anonymized information.
- 1.14 **“Identifiable private information”**: Individually identifiable information or samples – that is, the identity of the person who provided the information or to whom the information belongs, can be easily determined by the researcher, or is associated with the information, including:
- 1.14.1 Information supplied for the purpose of the research;
 - 1.14.2 Information provided for specific purposes by a particular individual, when that individual can reasonably expect that this information shall not be made public (for example, a medical record, school grades or height and weight measurements);
 - 1.14.3 Information about behavior occurring in a context in which a person can reasonably expect that there shall be no observation or recording;
 - 1.14.4 Incidental information collected using technological platforms (such as I.P. addresses or geographic landmarks), unless the ethics committee instructs the researchers, and they undertake not to make a deliberate effort to identify the subject of the information based on the analysis of the information.
 - 1.14.5 Examples of studies that use private information: review of medical charts; performance of laboratory tests on identified tissues and samples; use of identifiable information from databases or tissues, use of grades from schools, private interviews or surveys on opinions and attitudes.
- 1.15 **“Human subject/participant”**: A living person participating in the research, or upon whom the principal investigator and other researchers conduct research in order to obtain data or personal information, by means of intervention or interaction with that person. The participant may be a healthy person or a patient.
- 1.16 **“Minimal risk”**: The risk of harm or discomfort, the severity and probability of which, as anticipated in the framework of the study, are not greater than those to which a reasonable person is exposed in the course of their daily life, or during the performance of psychological tests or examinations or routine physicals.

1.17 **“Sub-contractor”**: Any entity that provides services that are necessary for the implementation of the research protocol, and which is not subordinate organizationally to the principal investigator (e.g. Google, a survey company, sound technician, statistical services etc.).

2. Ethics Committees

2.1 A University-wide Supreme Ethics Committee shall be established (hereinafter: the “Supreme Committee”) as well as committees of faculties or schools (hereinafter: “faculty committees”), all in accordance with the following provisions.

2.2 Appointment of the members of the Supreme Committee: The Standing Committee shall appoint the chairperson of the Supreme Committee and its members.

2.3 Deans and heads of schools shall appoint the chairpersons of the faculty committees and their members. In the case of a joint committee for several academic units, the appointment shall be made by agreement of the deans of the units, and in the absence of agreement shall be decided by the Rector.

2.4 The composition of all committees shall be approved by the Vice President for Research and Development.

2.5 The Rector, in consultation with the heads of the relevant academic units and with the approval of the Standing Committee, may make changes to the structure of the committee set-up specified in section 2.6 below, including splitting committees, merging committees, etc.

2.6 These are the University committees:

Supreme Ethics Committee				
Joint Ethics Committee: Dept. of Psychology and ELSC	Joint Ethics Committee: School of Business Administration; School of Engineering and Computer Science; Faculty of Social Sciences (not incl. Dept. of Psychology)	Ethics Committee of the School of Social Work	Joint Ethics Committee: School of Education; Faculty of Law; Faculty of the Humanities	Joint Ethics Committee: Faculties and Schools of Medical Sciences; Faculty of Mathematics and Natural Sciences; Faculty of Agriculture, Nutrition and Environment

2.7 The composition of the ethics committee

- 2.7.1 Every ethics committee shall include at least 5 members, whose skills reflect the academic disciplines and the expertise that are relevant to the research activities submitted to that committee. The Supreme Committee shall include at least 7 members from the various faculties at the University.
- 2.7.2 Every ethics committee shall have at least one member who is not affiliated to the University and who is not directly related to those who are affiliated (other than as a student) to the University.
- 2.7.3 Every ethics committee shall have at least one member whose field of expertise is the law (including a representative of the Office of the Legal Adviser at the University), ethics or related fields.
- 2.7.4 A single member of a committee may serve both for the purpose of section 2.7.2 and for the purpose of section 2.7.3.
- 2.7.5 Every ethics committee shall have at least one member who is involved in research with humans, as it is defined in these Regulations.
- 2.7.6 On every ethics committee, adequate representation shall be given to all genders, and to as wide a cultural diversity as possible.
- 2.7.7 At least one member of the ethics committee who has appropriate expertise in the relevant research field shall participate in the examination of an application for the approval of interventional research; alternatively, the committee shall consult with a person with appropriate expertise in the relevant field.
- 2.7.8 No examination of research with a potential for harm that exceeds a minimal risk shall be carried out, without the involvement of a committee member with a suitable background or without consultation with an expert in the relevant (medical or mental) field.
- 2.8 An ethics committee is authorized to invite and to consult with experts in specific fields, as necessary in the committee's opinion in the framework of examining a certain research proposal.
- 2.9 When considering research on a community with unique characteristics, the ethics committee shall consider the need to consult with relevant parties from within the community.
- 2.10 If a committee frequently has occasion to deal with research involving vulnerable populations (such as: children, prisoners, the mentally disabled, pregnant women,

etc.), the committee ought to include a member who has expertise in the relevant field.

- 2.11 The chairperson of the Supreme Committee shall be a faculty member of the Hebrew University. The chairpersons of the other committees shall be faculty members of the relevant faculty or school.
- 2.12 Other than members of the committee who are not faculty members, all members of the committee shall be tenured or emeriti.
- 2.13 Every ethics committee shall have an administrative assistant whose role shall be, inter alia: to coordinate the applications; to check that they are in order; to ensure that the applications are reviewed in a timely fashion; to coordinate and document the committee's discussions; to answer applicants, and to ensure that reminders are sent for renewal or reporting as required.
- 2.14 Powers of the Supreme Committee
 - 2.14.1 Formulating policies and setting procedures on new issues;
 - 2.14.2 Advice to faculty committees;
 - 2.14.3 Discussion of appeals on decisions of the faculty committees;
 - 2.14.4 Handling complex research proposals that are referred to it by the faculty committees;
 - 2.14.5 Monitoring and controlling the operation of the faculty committees (see monitoring procedure, Appendix 5);
 - 2.14.6 Determining the training procedure for ethics committee members.
- 2.15 Powers of the Faculty Committee
 - 2.15.1 To approve research in accordance with the provisions of these Regulations.
 - 2.15.2 To advise researchers on constructing the research in an applicable manner, consistent with the rules of ethics in research.
 - 2.15.3 To examine the compliance of the research protocol with the relevant ethical rules for research on humans and with these Regulations.
 - 2.15.3.1 In qualitative studies that use an evolving protocol, the research shall be examined on the basis of a preliminary protocol, even if knowingly incomplete, which shall be gradually completed as the research

progresses. Thus, inter alia, in cases in which final versions of a questionnaire or interview have not yet been developed at the time of the ethics review of the study, the researchers shall submit drafts of sample questions, chapter outline, or other outlines of the procedures to be performed during data collection. Final versions shall be submitted for the committee's approval immediately upon becoming available and before their implementation in the research.

2.15.3.2 When the research protocol is carried out in whole or in part using sub-contractors, the entire protocol must comply with suitable ethical rules as determined by the committee.

2.15.3.3 Sample protocol in Appendix 1.

2.15.4 To ensure proper implementation of the university's requirements of privacy protection and information security within the framework of the research, including research carried out in whole or in part through sub-contractors, through approaching the relevant professional bodies at the university and receiving their response.

2.15.5 To assist the research team in solving ethical dilemmas that arise during the research and to approve the suitability of any changes or developments that may be required to the protocol during the course of the research.

2.15.6 To receive a report from the researchers on unforeseen issues or events that occurred during the research which may potentially increase the risk to the participants or which have other ethical implications, and to propose a fitting response.

2.15.7 To cancel a permit it has given in case of a breach of the research protocol or of the provisions of these Regulations; or upon the occurrence of unexpected events as aforesaid in section 2.15.6, provided the researcher was given an opportunity to be heard before the decision is made by the committee. In exceptional cases that the committee deems to be urgent, it may decide to suspend the approval of the research temporarily even before hearing the researcher's position, provided that the researcher is able to voice their position at the earliest possible date in the circumstances of the matter.

3. Submitting an Application for Approval of Research on Humans

3.1 All research with human participants, on material of human origin or on information of human origin, conducted by or under the guidance of a person from the University

faculty under their institutional affiliation, must be submitted for examination by the faculty ethics committee prior to the start of its execution.

- 3.2 In the case of research that is not conducted by a principal investigator from the University, but the subjects of the study are University faculty or students, in the framework of their routine academic activities, an application for approval of the research shall be submitted to the chairperson of the Supreme Ethics Committee who may approve it after ascertaining that the research received ethical approval from the parent institution of the research initiator, or he may hold a hearing on the request in one of the committees.
- 3.3 Research involving human subjects, human material, or human information may also require:
 - 3.3.1 Approval by the Helsinki Committee (Hospital Ethics Committee) of an Israeli medical institution ("hospital") in accordance with the Public Health (Medical Experiments on Humans) Regulations 1980, for example: when there is a collaboration with a medical institution, in the framework of which the material or information is received from patients who are undergoing medical treatment in a medical institution; or, if the committee deemed it appropriate that due to the characteristics of the participants in the study or the procedures involved in the research protocol, close medical monitoring is required. In cases in which there is a doubt as to whether the approval of the Helsinki Committee is required, the opinion of the Office of the Legal Adviser is to be sought.
 - 3.3.2 Compliance with additional regulatory requirements of an external body involved in the research or of the supervisor of the research.
 - 3.3.3 In secondary research, a check that the collection of the primary materials or information and their sharing conformed to the ethical rules.
 - 3.3.4 Research in which use is made of human DNA samples for the purpose of characterization and comparison of DNA sequences shall be carried out in accordance with the provisions of the Genetic Information Act, 2000.
- 3.4 As a rule, principal investigators shall submit a request for research approval to the faculty committee according to their academic affiliation. In cases of collaboration between researchers from different faculties or schools, the researchers shall decide on the committee to which the request will be submitted according to the type of research, so that the request is submitted to the committee that has the necessary expertise. The chairperson of the committee to which the application is submitted may transfer the request for discussion by a parallel committee in which, in their

opinion, the necessary expertise exists. A principal investigator who is the chairperson of a faculty committee shall submit a request relating to his research to a parallel faculty committee in the same field of knowledge or to the Supreme Committee, in consultation with the chairperson of the Supreme Committee. A request for research approval from a committee member may be discussed by the committee on which they serve, provided that they do not participate in the deliberations on approval of the request.

- 3.5 The application shall be submitted using the [online form on the website](#) and shall include, as appropriate, the text of the consent form, and the tools that shall be used in the research (such as questionnaires).
- 3.6 Ethical examination of a research may be conducted on one of three tracks: full procedure, shortened procedure or accelerated procedure.
- 3.7 Full procedure for approval
 - 3.7.1 All research with human participants, on material of human origin or on information of human origin, with the exception of research listed in sections 3.9 (shortened procedure) and 3.10 (accelerated procedure) shall be examined by a committee composed of at least 3 members, including the chairperson of the committee, provided that the specified requirements for the composition of ethics committees (section 2.7 above) are met.
 - 3.7.2 In complex research, at the discretion of the chairperson of the committee, the research shall be discussed at a committee meeting in a forum of at least five (5) members, provided that those present meet the specified requirements for the composition of ethics committees (section 2.7 above).
 - 3.7.3 The faculty committee shall meet at least once a month, on dates to be announced in due time, to discuss applications. The committee may also convene using electronic means (virtual meetings, etc.), and discussions may also be held through email correspondence.
 - 3.7.4 The committee's decision shall be given within a maximum of 4 weeks from the date of receipt of the request, including any required documents and additional information if requested from the researcher by the committee.
- 3.8 Shortened procedure for approval
 - 3.8.1 Research that meets the conditions specified in section 3.9 of these Regulations may be approved in a shortened procedure as described below.

- 3.8.2 The principal investigator submitting the request must indicate in the request that the research is suitable to a shortened procedure, and provide the reason therefor.
 - 3.8.3 The chairperson of the committee is authorized to decide on a shortened or full procedure for approval.
 - 3.8.4 A shortened procedure request shall be submitted in the same way as a full procedure request.
 - 3.8.5 Approval in a shortened procedure shall be given by the chairperson of the committee or by at least one member of the committee, to be appointed by the chairperson of the committee for this purpose, and they shall have all the powers of the committee, including asking for corrections, with the exception of final rejection of the proposal.
 - 3.8.6 The decision of the committee in a shortened procedure shall be given within 14 days at most from the date of receipt of the request, including all required documents and additional information if requested from the researcher by the committee.
 - 3.8.7 If the responsible committee member finds that the proposal should be rejected, it shall be brought before the committee's plenary session for discussion. It shall be brought for full discussion also in any case that the responsible committee member finds that the nature of the research is not suitable for a shortened procedure.
 - 3.8.8 Requests in a shortened procedure shall be discussed on an ongoing basis. Any member of the committee may review the list of research proposals that were approved in a shortened procedure and ask for a discussion of a particular request in the committee's plenary if he thinks this is justified, within two working days from the date of approval of that request.
- 3.9 Below are the types of studies that can be referred to a shortened procedure:
- 3.9.1 Research that has undergone a suitable ethical review at another institution, including research that has been approved by a Helsinki Committee.
 - 3.9.2 Anonymous survey among the general public.
 - 3.9.3 Research in which anonymized information and samples are collected, provided that the participants are not from a special population.

- 3.9.4 Research carried out on databases and data that is legally accessible to the public, and the conduct of which raises no risk of harm to the privacy of the data subjects.
- 3.9.5 Research in which identifiable information is collected about a participant either through interaction or through observation, or research that includes one or more of the procedures listed in Appendix 2, whether or not identifiable information is collected, provided that:
 - 3.9.5.1 The participants are not from a special population, and -
 - 3.9.5.2 There is no potential for legal, occupational, financial or reputational risk to the participant;
 - 3.9.5.3 The research involves a risk that is at most minimal. The procedures listed in Appendix 2 are not to be regarded as posing “minimal risk” merely because they are included in the list. Inclusion in this list means only that the activity is eligible for examination using the shortened procedure when the specific circumstances of the proposed research actually involve at most “minimal risk” to the human participants.
- 3.9.6 Secondary research, provided that the information or samples on which the secondary research is conducted are not identifiable (that is, the identifying details have been separated in such a way that it is not possible in any way to attribute them back to their owner as part of the secondary research) or that the informed consent of the participants for such secondary use has been given.
- 3.9.7 Observation without the collection of identifiable details, and without photographs, in public places and sites (physical or virtual), in which there is no limitation on exposure or entry apart from payment of entrance fees (for example parks, clubs, internet sites open to the public, online groups [e.g. Facebook, WhatsApp] that are open to the public). A shortened procedure shall not be used when the observation is carried out in places where entry requires a process of identification, approval, and affiliation by the owners or operators of the place (e.g., kindergartens, clubs that operate on the basis of club membership, closed online groups).
- 3.9.8 Minor changes in a research protocol that was approved in the full procedure, during the period for which the approval was given (as specified in section 10 below), can be examined by the committee in a shortened examination procedure.

- 3.9.9 Extension of the period of a research that does not involve a request for protocol changes.
- 3.10 Accelerated procedure for approval
 - 3.10.1.1 In cases involving exceptional urgency, the chairperson of the committee shall convene the committee in the required composition at the earliest opportunity, at most within a week, to discuss the request.
 - 3.10.1.2 Special urgency may exist when uncontrollable circumstances arise, such as a natural disaster, a pandemic, or a war, for which research is required. Deadlines for submitting applications for funding are not a reason, per se, for accelerated approval.
- 3.11 Exploratory Research
 - 3.11.1 Exploratory research is research that precedes principal research, and its role is to test certain aspects of the research, including technical aspects and experimental parameters that will improve the chances that the research will produce meaningful results. Exploratory research is carried out on a small number of subjects and is not intended for publication (except when describing the main research).
 - 3.11.2 By their nature, at the time of the exploratory research the exact conditions of the main research have not yet been determined. Nevertheless, all ethical aspects relevant to research on humans apply to exploratory studies.
 - 3.11.3 Exploratory research shall be submitted for approval by the ethics committees and may be approved in a shortened approval procedure. The description of the research shall include the range of parameters and methods that are likely to be tested in the course of the research. When a decision is made regarding the exact characteristics of the research (i.e., with the move from exploratory research to principal research), a request to update the research protocol may be submitted for the approval of the committee.
- 3.12 Exceptions to the obligation to submit a request to the committee
 - 3.12.1 Educational tutorials and research teaching that are not in the framework of research as defined in section 1.8 are not within the competence of the committee. This includes courses in research methodology and research seminars. It is the responsibility of the dean or head of the schools to establish mechanisms for the ethical monitoring of such activities.

4. Criteria for Research Approval by the Committee

- 4.1 To approve research to which these Regulations apply, the Ethics Committee must determine that the requirements specified in Appendix 3 have been met.

5. Duration of Effectiveness of the Approval

- 5.1 For research in which the risk is anticipated to be above minimal – approval for its execution shall be in effect for one year and shall be renewed each time for another year, subject to reporting on the (non)realization of risks in practice.
- 5.2 In cases in which the committee believes that the risk is minimal, it may grant a permit that remains in effect for a period of up to 4 years at most, subject to an annual reporting obligation on the part of the researcher which shall include: the number of participants in the study, unusual events, participants whose participation was terminated and the reason for this.
- 5.3 An ethics committee may fix a shorter period during which the ethical approval shall remain in effect, taking into consideration the requirements of external parties such as a funding body, a regulatory body involved in the oversight of the research and the like, as well as in light of the special risks anticipated in the research, and in any other case in which the committee deems it appropriate that there be frequent monitoring of the research.

6. Appeal

- 6.1 A researcher may appeal the decision of a faculty ethics committee not to approve research or to subject it to conditions. The appeal is submitted to the Supreme Committee.
- 6.2 Appeals must be lodged in writing within 14 days from the date of receipt of the committee's decision.
- 6.3 The Supreme Committee may ask the researcher to complete details at its discretion.
- 6.4 As a rule, a decision on an appeal shall be given without the presence of the appellant researcher, unless the researcher requests that an oral hearing be held in his presence.
- 6.5 A decision on the appeal shall be made within 30 days from the date on which the appeal was lodged or from the date on which the details were completed or from the date of the oral hearing on the appeal, whichever is later.

7. Training of Ethics Committee Members

- 7.1 Every member of an ethics committee is required to receive training in the ethics of human research appropriate to their duties, as determined by the Supreme Committee from time to time.

8. Training and Competence of the Researchers

- 8.1 Every principal investigator and every researcher involved in the research, whether from within the University or outside of it, shall be required to complete a course (online or in-person), dealing with the ethics of human research (such as: CITI, GCP, an academic course at a recognized institution, or equivalent training) approved by the ethics committee, and also to undergo information security training as determined by the Supreme Committee. A document attesting to completion of a training course shall be submitted to the committee together with the request for ethical approval, as a condition for examination of the research by the committee. The Supreme Committee shall determine the scope of the training and the need for periodic refresher training.
- 8.2 The principal investigator must have the training and expertise required for the planning and good scientific execution of the research, as well as for the protection of the participants in the research against the possible risks a research may involve.
- 8.3 In research involving more than minimal risk, the principal investigator must ensure the safety of the participants by consulting with an expert in the field, and, when necessary, enlisting suitable professional accompaniment (medical, paramedical, psychological, etc.).
- 8.4 When an activity in the research requires training or licensing, it is the responsibility of the principal investigator to ensure that the activity is performed only by a person with appropriate training.

9. Administrative Issues

- 9.1 Application process and documents: The Supreme Ethics Committee shall define a process, including documents and forms for submissions to committees, for preliminary examination, approval and control as well as for support in issues that arise in the course of conducting the study.
- 9.2 Documentation of the procedures of the committee's activity: The research documents, the examination procedures of each research project and decisions of the ethics committee shall be documented in a consistent, uniform and transparent manner that allows for examination when necessary.
- 9.3 Confidentiality: The members of the ethics committee are bound by the confidentiality of the research details to which they are exposed, and documentation

of the examination procedures shall be carried out in a manner that preserves this confidentiality insofar as possible.

- 9.4 Convening the committee: Both the Supreme Committee and faculty committees shall meet at least once a year in an in-person meeting (which may also be held as a virtual meeting).
- 9.5 Saving documents
 - 9.5.1 The ethics committee shall retain the application file for at least 7 years from the expiration date of the ethical approval.
 - 9.5.2 A principal investigator shall retain all application documents and all documents collected during the research for at least 7 years after the research has ended.
- 9.6 Transparency: A list of committee members shall be published on the University's website, which is open to the general public.

10. Conflict of Interest

- 10.1 A member of the ethics committee shall not be involved in examining a research proposal in any case in which there is a real concern about of a conflict of interest or bias, and they shall report this to the chairperson of the committee.
- 10.2 When making a submission to the ethics committee, a researcher shall report a concern about a conflict of interest that may affect the planning or the execution of the research, and act in accordance with the decision of the ethics committee, which shall consult on this matter as necessary with the legal advisor.

APPENDIX 1

Sample Protocol

1. Title of the study
2. The expected number of participants
3. The number of research branches
4. Scientific abstract
5. Information collection methods
6. Criteria for including or rejecting participants
7. The principal investigator
8. The other researchers in the study
9. A researcher who will provide an immediate response to participants and a mobile phone
10. Participating researchers and the nature of the ethical training they received
11. Risk assessment (minimal or otherwise)
12. Assessing the suitability of the research for shortened procedure for approval
13. Whether the research has been approved by an external ethical committee such as Helsinki (Hospital Ethics Committee)
14. Whether the research deals with participants defined as disadvantaged or vulnerable populations
15. The information security plan
16. Full disclosure of conflicting interests – institutional or of the researchers in the experiment, including full disclosure of financing sources
17. Checklist for publication of the research
18. Checklist for the structure of an informed consent form

APPENDIX 2

Research Eligible for Shortened Examination (section 3.9 of the Regulations)

1. This Appendix is based on the NIH rules, as they appear in the framework known as [Common Rule](#).
2. The types of research listed below are eligible for shortened examination provided that they do not involve more than a minimal risk.
3. The activities listed below should not be considered “minimal risk” merely because they are included in this list. Inclusion in this list means that the activity is eligible for examination using the shortened procedure when the specific circumstances of the proposed research actually pose at most a minimal risk to the participants.
4. Interventional research through use of drugs or medical devices, only when the following conditions are met:
 - 4.1 The drug or medical device has been tested and approved for marketing by the relevant governmental authority; and -
 - 4.2 The use or application of the drug or medical device according to the tested and approved indication poses at most a minimal risk.
5. Collection of blood samples by pricking the finger, heel, ear, or taking venous blood, from healthy adults who are not pregnant, weighing at least 50 kg. The amount taken shall not exceed 550 ml in a period of 8 weeks, the collection shall not occur more frequently than twice a week and shall be done by a person trained for this in accordance with the regulations of the Ministry of Health.
6. Prospective collection of biological samples for research purposes by non-invasive means.
Examples:
 - 6.1 Cutting hair and nails in a normal manner;
 - 6.2 Baby teeth when they fall out or if routine treatment of the patient indicates the need for extraction;
 - 6.3 Permanent teeth if routine treatment of the patient indicates the need for extraction;
 - 6.4 Secretions (including sweat);
 - 6.5 Uncannulated saliva collected without stimulation or with stimulation by chewing a gum base or wax, or by applying a diluted citric solution to the tongue;

- 6.6 Plaque and calculus above and below the gums, provided that the collection procedure is not more invasive than routine cleaning of plaque from the teeth for preventive purposes, and the procedure is done according to the normal preventative methods;
 - 6.7 Mucosa and skin cells collected by scraping or using an oral swab, skin swab, or mouth washes;
 - 6.8 Sputum collected after saline mist nebulization.
7. Data collection through non-invasive procedures (that do not involve general anesthesia or sedation) that are routinely performed in medical practice, other than procedures involving X-rays or microwaves. When medical devices are used, they must be tested and approved for marketing. Examples:
- 7.1 Physical sensors that are placed on the body or at a distance from it and which do not involve the absorption of a significant amount of energy by the subject or an invasion of the subject's privacy;
 - 7.2 Weighing or testing sensory acuity;
 - 7.3 Electrocardiography, electroencephalography, magnetoencephalography, thermography, identification of natural radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow test, echocardiography, MRI (magnetic resonance test), moderate physical activity, muscle strength test, assessment of body composition and flexibility tests, taking into account age and weight and the health of the specific person.
Note: The approval of a Helsinki Committee to conduct MRI research may be required, as a condition set by the Ministry of Health for licensing the MRI machine.
8. Research involving materials (information, documents, records or samples) that have been collected, or shall be collected exclusively for a non-research purpose (such as medical treatment or diagnosis or samples from the blood bank).
9. Collection of data from sound recordings, video, digital recordings or photos made for research purposes.
10. Research on individual or group characteristics or behaviors (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research that includes a survey, interview, oral history, focus group, program evaluation, evaluation of human factors or quality assurance methodologies.

APPENDIX 3

Criteria for Ethics Committee's Approval of Research (section 4 of the Regulations)

To approve research to which these Regulations apply, the ethics committee must determine that all the requirements specified below have been met:

1. The risks to the participants have been minimized insofar as possible:
 - 1.1 By using procedures that are consistent with suitable research design, and that do not expose the participants to unnecessary risk, and in addition:
 - 1.2 Where possible, depending on the nature of the research, by utilizing procedures that the participants have already undergone for diagnostic, or treatment, or other purposes.
 - 1.3 The research activities are carried out by a researcher with training appropriate to the field of research, in procedures that are carried out within its framework and who is trained to handle the risks inherent in it.
2. The risks to the participants are reasonable in relation to the anticipated benefit, if any, to the participants, or in relation to the importance of the knowledge that may reasonably be expected to result from the research. In assessing risk versus benefit, the ethics committee must consider only those risks and benefits that may result from the research itself (as distinct from the risks and benefits of treatments that the participants would have received even had they not participated in the study).
3. The selection of participants is done fairly, without unjustified discrimination based on characteristics such as language, religion, race, disability, sexual orientation, age or gender, and striving for gender and sectorial equality insofar as possible, in accordance with the research structure. In carrying out this assessment, the ethics committee must take into account the aims of the research, its scope, and the environment in which the research is to be carried out, and it must pay special attention to the problems unique to research that involves special populations as defined in these Regulations.
4. The research respects its participants, and ensures that their participation is voluntary, without pressure or contingency, by seeking informed consent from each potential participant or their legal representative, in accordance with the rules and exceptions specified in Appendix 4. The above does not prevent a requirement of participation of students as subjects in research as part of fulfilling an academic obligation, provided that the student is allowed to choose the study in which they participate.
5. If necessary, the research plan will provide appropriate instructions for monitoring the collected data, to ensure the safety of the participants.

6. In the research plan, there are appropriate instructions for protecting the privacy of the participants and maintaining the confidentiality of the information.
7. The remuneration to the participant, if such exists, is reasonable in the circumstances of the matter.

APPENDIX 4

Informed Consent to Participate in the Research (section 4 of Appendix 3)

For the purpose of this Appendix, “participant” means – a potential participant in the research or the legal representative of a participant lacking legal capacity.

1. General

- 1.1 Before recruiting a participant for research to which these Regulations apply, the researcher must obtain the participant’s informed consent and document it.
- 1.2 Consent shall be sought in a way that provides the participant with enough time to consider whether to participate in the research, and that minimizes the possibility of coercion or undue influence.
- 1.3 The participant must be provided with information that a reasonable person would want to receive in order to make an informed decision whether to participate in the research and an opportunity to consider this information. The proper way to start is to provide basic and understandable information followed by a satisfactory description of the research, drawn up and presented in a way that does not merely list a set of facts, but helps the participant understand the reasons for agreeing to participate in the research, or refusing to do so. The information shall include the name of the researcher and the academic institution in which the research shall be conducted.
- 1.4 The information that is provided to the participant shall be in a language and a linguistic register that he understands.
- 1.5 The informed consent process shall not include a participant’s waiver of legal rights vis-à-vis the researcher, the sponsor, the institution, or any other entity.
- 1.6 Research involving minors
 - 1.6.1 In research involving minimal risk, the consent of a single legal representative shall suffice.
 - 1.6.2 In research in which the risk is more than minimal, the consent of all the legal representatives of the minor shall be required.
 - 1.6.3 The assent of the minor to the research shall be required, in addition to the consent of their legal representative, if the researcher assesses that the minor has the ability to take part in the consent process for their participation in the research, having provided an explanation in a language that is appropriate for their age and developing skills.

1.6.4 A participant who turned 18 years old during the research shall be asked for their informed consent to continue participating in the study.

2. Information to be Provided as Part of an Informed Consent Process

In the informed consent process, the following information shall be provided to each participant, if relevant to the particular research:

- 2.1 An explanation of the complete research protocol, all its branches (participation groups), the research goals and the anticipated duration of the participant's participation, a description of the procedures to be performed, as well as identification of each experimental procedure.
- 2.2 A description of the risks or discomfort to the participant that can be reasonably anticipated.
- 2.3 A description of the benefit to the participant or others, that can reasonably be expected to result from the research.
- 2.4 Disclosure of alternative procedures or treatment methods that may be preferable for the participant.
- 2.5 Information describing the extent, if any, to which records identifying the participant will be kept confidential. This includes taking into account and specifying, inter alia, if relevant:
 - 2.5.1 Removal or separation of identification information;
 - 2.5.2 Use of a coding key;
 - 2.5.3 Information security;
 - 2.5.4 Whether and when the research documents are to be destroyed.
- 2.6 In research involving more than minimal risk, an explanation of treatment available in case harm occurs, and where additional information on this is available.
- 2.7 An explanation of whom to contact regarding answers to questions about the research and the rights of the participants, and whom to contact in case of harm to the participant which is related to the research.
- 2.8 An explanation of the fact that participation is voluntary, and that refusal to participate does not involve any sanctions.

- 2.9 An explanation of the fact that the participant may discontinue their participation in the research at any time without sanction or loss of benefits to which they are entitled according to the stage at which they discontinued participating in the research. Reference to the fate of the data collected before the termination of participation in the study. In the appropriate cases, it is possible to determine, and inform the participant via the consent form, that at the beginning of the data analysis phase by the researchers, it will not be possible to delete personal information from the research or prevent further processing of information. Therefore, samples and information collected during participation in the research will remain part of the database even if the subject discontinues their participation in the research: this is designed to ensure the completeness of the research and its scientific integrity.
- 2.10 Explanation and obtaining specific consent for possible future use of the information or samples collected during the current research, for the purpose of secondary research, having removed its identifying data.
- 2.11 An explanation that the researcher may terminate the participant's participation in the study on their own initiative.
- 2.12 The funding sources of the research, other than in special cases to be approved by the ethics committee.
- 2.13 Conflict of interest – insofar as such is declared by the researcher and insofar as the committee issued instructions to include in the informed consent form a declaration concerning the existence of a conflict of interest (section 10.2).

3. Required Additional Information

If relevant to the particular study, each participant must be provided with an explanation regarding the following:

- 3.1 Whether the specific treatment or procedure may involve a risk to the participant (or the fetus, if a participant is pregnant or may become pregnant) which cannot be anticipated based on the existing information, such as through use of innovative equipment;
- 3.2 Foreseeable circumstances in which the researcher may terminate the participant's participation without notice irrespective of their consent;
- 3.3 Additional costs to the participant that may arise from their participation in the study;
- 3.4 Consequences of a participant's decision to discontinue their participation in the study, and the procedures for an orderly termination of the participant's participation;

- 3.5 The fact that the participant shall be informed of any new information that is discovered during the research, and that impacts their consent to take part in the research, to allow them to reconsider their participation.
- 3.6 The estimated number of participants in the research, if this can be estimated.
- 3.7 That the participant's information or samples (even if the identifying information is removed from them) may be used for commercial profit, and whether or not the participant shall benefit from said commercial profit;
- 3.8 Whether results that have consequences for the participant (anticipated as well as incidental), including personal results, shall be conveyed to them and if so, under what conditions;
- 3.9 In research that includes samples, whether the research is expected or likely to include genetic sequencing.
- 3.10 Possible remuneration for the participant and the conditions for receiving it.
- 3.11 Full disclosure regarding the principal investigator's financial interests.

4. Broad Consent for Storage, Maintenance and Secondary Research regarding Personally Identifiable Information or Identifiable Samples

- 4.1 In this chapter – “information” – identifiable private information or identifiable samples.
- 4.2 Broad consent for storage, maintenance and secondary research regarding information (as defined in section 1.11 of the Regulations), is permitted as an alternative to the informed consent requirements, as mentioned in sections 2 and 3 above.
- 4.3 Despite the aforementioned, the participant must be provided with the information specified below in order to obtain broad consent:
 - 4.3.1 Regarding risks and inconvenience (section 2.2 above); benefit (2.3); confidentiality of the records (2.5); the details of the source for obtaining additional information and protection of rights (2.7); the right to refuse to participate and to discontinue participation (2.8); potential use for commercial gain (3.7); conveying or not conveying results to the participant (3.8); possibility of performing genetic sequencing (3.9).
 - 4.3.2 A general description of the types of research that may be carried out using the information.

- 4.3.3 A description of the information that may be used in the research, will sharing the information be possible, and the types of institutions or researchers that might use the information.
- 4.3.4 Description of the time period over which the information shall be held, stored and used for research (time period as stated may be unlimited).

5. Waiver of Consent Requirement or Parts Thereof

5.1 Waiver of consent process:

- 5.1.1 An ethics committee may waive the requirements of informed consent, as specified above, in secondary research that uses unidentifiable private information, or if the conditions specified in section 5.3 below are met.
- 5.1.2 Notwithstanding the above, if a participant was asked to give broad consent as specified in section 4 to this Appendix, and refused, the ethics committee is not permitted to waive the requirement of informed consent for the storage, maintenance and secondary use of identifiable private information.
- 5.1.3 In addition, if a person refuses to participate in a specific study in which private identifiable information is collected, the ethics committee is not permitted to waive the consent requirement for participation in that research by means of secondary use of non-identifiable information that exists regarding this person.

5.2 Changes in consent requirements:

- 5.2.1 An ethics committee may approve a consent procedure that omits or changes all or part of the requirements specified in sections 2 and 3 above, provided the conditions in section 5.3 below are met.
- 5.2.2 Notwithstanding the above, the ethics committee may not omit or change the general requirements regarding consent (section 1 above).
- 5.2.3 In addition, if broad consent is invoked, the ethics committee may not omit or change the requirements concerning broad consent (section 4 above).

5.3 Conditions for waiver or modification of informed consent requirements

- 5.3.1 There are cases in which compliance with (all) “informed consent” requirements is likely to obstruct the conduct of the research. Examples of this are: emergency research, and research in which providing advance information to the participant regarding the goals of the research shall skew its results. For the ethics committee to

approve a waiver or modification of the informed consent requirements, it must verify and document that all the following conditions have been met:

- 5.3.2 The research involves no more than minimal risk to the participants; in emergency research only, that is likely to involve a greater than minimal risk to the participants – the anticipated benefit from the research to the participants or for the group that they represent shall outweigh the risk;
 - 5.3.3 It shall not be possible to conduct the research, or the goals of the research shall be adversely affected without a waiver or modification of the requirements;
 - 5.3.4 The waiver or modification shall not adversely affect the participants' rights and well-being;
 - 5.3.5 All the information that can be given without adversely affecting research goals shall be given to the participant in advance. Other than in exceptional cases, information shall be given to the participant after the fact; the participant shall be able to declare their refusal to take part in the study, and the data collected concerning them shall be erased.
- 5.4 Recruitment of participants incapable of consent

The recruitment of participants who are unable to consent, temporarily or permanently, shall only be possible if all the following conditions are met:

- 5.4.1 The researcher involves the participant, in as complete a manner as possible, in the consent process, and does everything possible under the circumstances to obtain their consent (for example by securing assent for participation).
- 5.4.2 The consent of the participant's legal representative is obtained, with the participant's interests being protected.
- 5.4.3 The participant's legal representative is not a member of the research team.
- 5.4.4 The research is likely to contribute to (a) promoting the direct welfare of the participant or (b) promoting the welfare of humankind, including that of the group of people with which the participant is associated, and involves minimal risk only.
- 5.4.5 The research question cannot be answered or the research goals will be compromised without the participation of participants from the relevant characterization group.
- 5.4.6 In the event that the ability of the participant to make decisions is restored to him in the course of the research, their consent shall be sought at that stage as a condition for their continued participation.

6. Documentation of Informed Consent

- 6.1 The consent of the potential participant shall be given after they have received a comprehensive explanation and it shall be documented in writing on the consent form, which integrates the elements of informed consent required in this Appendix.
- 6.2 The consent form for the particular research shall be approved by the ethics committee, and use shall be made of the approved version only.
- 6.3 The ethics committee has the authority to propose a template for a consent form that satisfies the principles appearing in this Appendix.
- 6.4 The researcher shall give the potential participant sufficient opportunity for an in-depth reading before signing.
- 6.5 The document shall be signed by the participant.
- 6.6 A copy of the form shall be given to the signatory.

7. Exceptions to the Obligation to Obtain Written Informed Consent

- 7.1 The ethics committee may exempt a researcher from the requirement to obtain written informed consent in any of the following cases:
 - 7.1.1 The research does not involve the collection of identifiable private information (anonymous research).
 - 7.1.2 A sufficient alternative for documenting the informed consent of the participant (for example – video or audio recording) was implemented.
 - 7.1.3 The consent form is the only document that identifies the research participant, and the main risk to the participant lies in the breach of their right to confidentiality.
 - 7.1.4 It will not be possible to carry out the research if signing on a form is required, provided that the research involves no more than minimal risk for the participant.
- 7.2 In cases in which an exemption from signing a consent form is granted, the committee has the authority to demand that the researcher give the participant an information sheet about the research that includes the information contained in the consent form, other than the signature, and together with a concluding sentence acknowledging the participant's consent to participate in the research (e.g., "Filling out this questionnaire constitutes your consent to participate in the research").

APPENDIX 5

Regulations for Supervision and Control of Research on Human Subjects following Approval of the Research

Introduction:

Supervision and control are a means of ensuring the safety, well-being, dignity and rights of the participants in research. Supervision and control are a direct continuation of the initial approval process of research.

The ethics committees shall maintain contact with the researchers to address the needs that arise during the research and during unusual events. Emphasis shall be placed on education and cooperation with researchers.

It is the responsibility of the Supreme Ethics Committee to supervise and control the approved research. The committee shall determine the way the monitoring is carried out. Control shall be carried out as a continuation of the ongoing process of approving research as well as through sampling of the research being carried out (from the date of its submission until the end of the retention period).

In the event that it emerges from the monitoring that participants were included or information was collected in an experiment that does not have valid approval or that was found to deviate significantly from the protocol, the Supreme Ethics Committee may disallow the use of this information as part of the trial results, or suspend or not renew the research approval.

A periodic examination of the conduct of the ethics committees themselves shall be carried out by the University comptroller.

Types of Monitoring:

1. Post Approval Monitoring
 - a. Periodic monitoring: At the end of one year after approval of the research, the researcher shall submit a periodic report to the committee that approved the research. The periodic report documents shall be reviewed by the committee for the purpose of control and approval of the continuation of the study.
 - b. Ongoing monitoring: About 3-5% of approved studies shall be sampled by the Supreme Committee for the purpose of monitoring and testing. Monitoring may include the following elements: informed consent procedure, research procedures, various research documents.
2. Special monitoring:

Special monitoring shall be carried out when a suspicion of improper conduct in a particular research project arises with respect to research procedures, execution of the research in accordance with the approvals of the ethics committee, and the safety, well-being or rights of the participants in the research.

3. Monitoring initiated by the researcher:

Examination of the research at the request of the researcher.

Procedures:

Periodic monitoring (to be carried out by the ethics committees, using a dedicated computerized system)

1. The principal investigator is obliged to submit periodic reports to the ethics committee that approved the research at least once a year (interim report). The committee is authorized to demand more frequent reports as applicable.
2. A periodic report shall include information about the subjects who participated in the research, the number of participants in the research whose participation was terminated and the reasons therefor, a declaration regarding the conduct of the research in accordance with the approved research protocol and a description of unusual events that occurred during the research.
3. In cases in which the research has not yet been completed, failure to fulfill the obligation to submit the report on time shall obligate the researcher to submit an application to renew the study as a new application.
4. At the end of the research, the principal investigator shall report the completion of the research, i.e., the completion of all the procedures specified in the research protocol in relation to all research participants.
5. The committee shall review the reports that are received and review the manner in which the research was conducted in accordance with these Regulations. An ethics committee that discovers that the researcher did not submit the specified documents properly or within the set time frame shall demand an explanation from the investigator and conduct an inquiry.

Ongoing Monitoring (to be carried out by the Supreme Committee):

1. From the list of active research, the Supreme Ethics Committee shall select a sample of approximately 3-5% of the total studies approved in a certain academic year, which shall be selected for sampling according to the following criteria:
 - Research with a high level of risk for the participants

- Research involving drugs, materials or experimental devices
 - Research in which participants from special or vulnerable populations are tested
 - Research that incorporates “fraud” (deliberate delivery of incorrect or incomplete information as part of the research protocol) or with a higher risk of compromising the confidentiality or privacy of the research participants
 - Randomly sampled studies
2. The committee shall contact the researcher to explain the nature of the monitoring, to receive the required materials, and to coordinate execution of the monitoring over a period not to exceed one month.
3. The monitoring shall include a review of various materials (according to the ethics committee’s decision), such as:
- Correspondence with the ethics committee
 - Participation consent forms (signed by the participants)
 - Documents relating to the recruitment process of the subjects
 - Other documents given to subjects during the study
 - The data files
 - Research funding documents
 - Publications from the research
 - Reports of unusual events
 - Manner of storing data and research documents
 - Documentation of payment to subjects
 - Documentation of training of the research assistants

The researcher shall ensure that the research materials are kept in such a way that they can be checked at any time.

4. The conclusions of the monitoring process shall be forwarded to the principal investigator and documented in writing. The conclusions may be as follows:
- a. There is no need to take any action.

- b. Minor corrections of the defects that were found are necessary.
 - c. Significant corrections are needed.
 - d. There is a significant deviation which requires that the research be stopped, and disciplinary measures taken. In this event, the head of the committee shall report the case to the Rector and the Head of the Academic Administration.
5. If the committee's conclusions include the need to make changes, the researcher shall be given a set period in view of the circumstances to make the corrections and submit a report summarizing the changes introduced into the research.
6. If necessary, additional monitoring shall be arranged to monitor the implementation of the changes.

Special monitoring:

- 1. This monitoring is carried out at the request of the chairperson of the Supreme Ethics Committee following a complaint or information received, about the possibility of harm to the safety or rights of research participants or suspicion of damaging the credibility of the research.
- 2. Upon receipt of the complaint or the information, the committee shall institute without delay the procedures for investigating the complaint or the information received with all the relevant factors.
- 3. The committee is authorized to conduct the monitoring procedure in this case in a manner similar to the ongoing monitoring procedure above.