

1. **Introduction**

Tel Aviv University (the “**University**” or the “**Institution**”) is committed to conducting scientific research that meets the highest scientific and ethical standards.

In this context, the University is committed to the advancement of science and human knowledge and to the protection of the rights and safety of the research participants, while weighing the implications for the populations represented by these participants, the research community and the public as a whole.

To this end, the University has chosen to establish an Ethical Review Board for any research in which humans participate or which is carried out on information or material of human origin, as stated below in this procedure.

The board described in this procedure draws inspiration from local and foreign legislation, including:

The Public Health Regulations (Clinical Experiments on Humans, 5741-1980¹ (hereinafter: “**Public Health Regulations**”) and the subsequent procedure of the Ministry of Health² (hereinafter: the “**Ministry of Health Procedure**”);

The Federal Policy for the Protection of Human Subjects or the “**Common Rule**” as in HHS Regulations, 45 CFR part 46;

The Canadian Tri-council policy statement on ethical conduct for research involving humans;

¹ <https://www.gov.il/he/departments/legalInfo/briut18>

² <https://www.gov.il/he/departments/guides/protocol-of-medical-research-involving-human-subjects>

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Guidelines for good clinical practice as published by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH);

The position paper of the Chairman of Association of University Heads - The examination of ethics in research using humans in academic institutions - is attached hereto as **Appendix A**.

This procedure is written in the masculine language but it refers equally to all sexes and genders.

2. **Definitions:**

- 2.1 “**Special Population**”: pregnant women, minors, those whose judgment is impaired due to their physical or mental condition, people who are disadvantaged economically or educationally, people in legal custody (such as prisoners) and people under supervision (such as soldiers and students).
- 2.2 “**Interaction**”: Mutual interaction that includes communication or interpersonal contact between the researcher and the participant (including online surveys), with the exception of interventional research.
- 2.3 “**Exploratory Procedures**”: Their purpose is to examine the feasibility of the research and/or to create a collaboration and/or to collect information that will enable planning of the research proposal.
- 2.4 “**Anonymization**”: A process that prevents, or at least significantly reduces, the risk of identifying the individual, and associating research conclusions with a specific person. “Coded Information” does not meet the definition of information that has undergone anonymization.

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- 2.5 “**Ethics Committee**” or the “**Committee**”: An institutional committee for examining the ethical implications of research involving human participants or material or information of human origin.
- 2.6 “**Researcher**”: Anyone involved in the research by collecting information, processing, analyzing and saving it, as well as anyone who has physical or verbal contact with participants during the research – with the exception of sub-suppliers.
- 2.7 “**Principal Investigator**”: Anyone from the University faculty who, in accordance with the rules, leads the research and is responsible for all the ethical, scientific and administrative aspects of the research. In the case where the principal investigator in the research is not a senior faculty member, he will be mentored by a senior faculty member.
- 2.8 “**Research**”: Systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable scientific knowledge.
- 2.9 “**Evaluation Process**” - A process aimed at evaluating programs or performance or improving processes, which is conducted for internal organizational needs at the University that is not intended for academic publication. The evaluation process does not require prior approval of the Ethics Committee, but it is appropriate that the principal investigator consult the Ethics Committee on bioethical questions. Use of the data collected in the evaluation process to conduct a retrospective research will require the approval of the Ethics Committee for the research according to this procedure as secondary research (as defined below).
- 2.10 “**Interventional Research**” (**Intervention**): Research that includes physical procedures in which data or samples are collected (for example, venipuncture) as well as manipulations of the subject or his environment that are performed for research purposes.

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- 2.11 “**Secondary Research**”: Research conducted on information or samples not collected for research purposes (for example: organizational records, medical records, information collected as part of an evaluation process), or that have been collected for other research purposes and subject to anonymization processes.
- 2.12 “**Non-Identifiable Genetic Information**”: Information resulting from genetic testing of a sample of a person’s DNA or RNA for characterization and comparison of sequences. Genetic information will be considered non-identifiable information if the following conditions are met: (a) the information does not include identifying details of the subject, and (b) the Ethics Committee instructs the researchers, and they undertake, not to identify the subject of the information based on an analysis of the genetic information.
- 2.13 “**Coded Information**”: Information or samples are considered coded when the identifying information that allows the researcher to easily identify the specific person to whom the private information or samples belong (such as name, National Insurance number, etc.), has been replaced (for example, by a number, letter or a symbol or a combination thereof), and a key is required to decipher the code in order to enable the link between the identifying information and the private information or the samples. Coded information is identifiable information. Coded information does not meet the definition of information that has undergone anonymization.
- 2.14 “**Identifiable Private Information**”: Individually identifiable information or samples; i.e., the identity of the person who provided the information, or to whom the information belongs, can be easily determined by the researcher, or who is associated with the information. This includes:
- 2.14.1 Information provided for research purposes;

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- 2.14.2 Information provided for specific purposes by a particular person, where that person can reasonably expect that this information will not be made public (for example, a medical record, school grades, or height and weight measurements);
- 2.14.3 Information about behavior that occurs in a context where a person can reasonably expect that observation or recording will not be made;
- 2.14.4 Examples of research studies that make use of private information: reviewing medical charts, performing laboratory tests on identified tissues and samples, using identifiable information from databases or tissues, using grades from schools, private interviews or surveys on opinions and attitudes.
- 2.14.5 Incidental information collected using technological platforms (such as I.P. addresses or geographical 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 an analysis of the information.
- 2.15 “**Human Subject/Participant**”: A person, with whose participation or on whom the principal investigator and other researchers conduct research in order to obtain data or personal information, through Intervention or interaction with the person.
- 2.16 “**Minimal Risk**”: Risk of injury or discomfort, the severity and probability of which are expected as part of the research, are not greater than those to what a reasonable person is exposed in his day-to-day conduct, or when performing routine psychological or physical tests or examinations.
- 2.17 “**Sub-Supplier**”: Any entity that provides services that are necessary for the implementation of the research protocol, and that is not organizationally

subordinate to the principal investigator (such as Google, a survey company, voice technicians, statistical services, etc.).

3. Ethics Committee

3.1 The rector of the University will appoint the members of the Ethics Committee. The appointment will be for a period of three years, and it may be extended, from time to time, for additional periods of up to three years each time. The appointment will be subject to the approval of the Central Committee and the Senate. In the event that the three-year term of office expires, from the date of appointment, and a new appointment is not made, the Committee member will continue to serve temporarily in his position until a new appointment is made.

3.2 The Ethics Committees in the various academic units do not have authority according to this procedure.

3.3 The plenary session of the Ethics Committee will convene at least once a year.

4. Composition of the Ethics Committee

4.1 The Ethics Committee will include at least 10 members, whose qualifications reflect the academic and professional disciplines that support the research submitted to that Committee.

4.2 The Chairman of the Committee will be a senior faculty member with the rank of associate professor or higher (including those who are retired) with significant experience and training in the field of ethics of human research.

4.3 The Ethics Committee will appoint a representative (preferably a lawyer or a philosopher), who is not a member of the University faculty and who is not a direct family member of anyone affiliated with the University (except as a student).

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- 4.4 The legal advisor or his representative will be appointed as a member of the Committee.
- 4.5 It is appropriate that adequate representation be given in the Ethics Committee to both sexes, and to as wide a cultural diversity as possible.
- 4.6 In interventional research, one of the members of the Ethics Committee will have appropriate expertise for examining the research, or the Committee will consult with a person who has the appropriate expertise in the relevant field.
- 4.7 Reviewing research that has potential for injury that exceeds minimal risk will require the involvement of a committee member that has the appropriate background or it will be in consultation with a person that has expertise in the relevant field (medical or psychological).
- 4.8 The Ethics Committee is authorized to invite and consult with experts in specific fields, who, in the Committee's opinion, are required as part of reviewing a particular research.

5. **Authority of the Ethics Committee**

- 5.1 Any research with **human participants and/or on material of human origin and/or on information of human origin** (hereinafter: "**Research on Humans**"), conducted by any of the Institution's staff, under its institutional affiliation (including research conducted as part of the studies for the various degrees³), will be submitted to the Ethics Committee for review **and will require its approval** before commencing with its implementation.

³ Except as stated in Section 5.8 regarding exceptions to the obligation to submit to the Committee.

It is hereby clarified that every researcher, including research students, are required to submit the research study for the approval of the Ethics Committee⁴. Such research may not be carried out without the approval of the Ethics Committee.

- 5.2 Research that is **not** conducted by a principal investigator of the Institution, but the subjects of the research are among the students of the Institution, as part of their normal academic activities, will require the approval of the academic secretariat only.
- 5.3 Research partners from another institution: When a request is submitted with co-researchers from another institution, the co-researchers require the approval of the corresponding committee at their institution.
- 5.4 Services provided by the University to researchers from other institutions, which include research involving human subjects, human material or human information (for example in the case of providing MRI scanning services to humans using the University's equipment for external researchers), will also require the **consent** of the Chairman of the Ethics Committee, and this in addition to the approval of the Ethics Committee/Helsinki Committee of the institution to which the external researcher belongs.
- 5.5 Research involving human subjects, human material, or human information may **also** require:
- 5.5.1 Approval by the Helsinki Committee of an Israeli medical institution⁵ ("**hospital**") according to the Public Health Regulations (Clinical Experiments on Humans, 5741-1980, for example: where there is cooperation with a medical institution, in which the material / information is received from patients who undergo medical treatment in a medical

⁴ Except as stated in Section 5.8 regarding exceptions to the obligation to submit to the Committee.

⁵ Or another medical body that has a Helsinki Committee; for example, a health insurance company.

institution; or, if the institutional committee deems it appropriate that due to the characteristics of the participants in the research and/or the procedures involved in the research protocol, close medical monitoring is required.

5.5.2 Compliance with additional regulatory requirements of an external body involved in the research or overseeing the research. For example: research involving children and teenagers which are conducted in educational institutions – in addition to the approval of the University Ethics Committee – will require the approval of the Chief Scientist of the Ministry of Education.

5.5.3 In secondary research, checking that collection of the materials or the primary information and sharing them were done subject to the rules of ethics.

5.5.4 Approval of the Supreme Committee for Clinical Trials on Humans for Research regulated by the Genetic Information Law, 5761-2000.

5.6 As a general rule, research involving a risk that is not higher than minimal risk, which includes one or more of the procedures listed in **Appendix B** and which is not done in collaboration with a hospital, does not require the approval of the hospital's Helsinki Committee and it will only require the approval of the Ethics Committee.

5.7 The Ethics Committee will be authorized:

5.7.1 To advise researchers on constructing the research, in a way that is applicable and consistent with the principles of research ethics.

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5.7.2 To examine the suitability of the research protocol to the rules of ethics that are relevant to research on humans and to the guidelines of this document; to confirm the existence of compliance with the rules of ethics in the appropriate cases and to give permission to conduct the research.

5.7.2.1 In qualitative research that uses an evolving protocol, the research will be examined based on an initial protocol, even if consciously imperfect, which will be gradually completed as the research progresses. Thus, among other things, in cases where final versions of a questionnaire or interview have not been developed at the time of the ethical review of the research, the researchers will submit a draft of sample questions, chapter headings or other outlines of the procedures to be performed during the collection of data. Final versions will be submitted for approval by the Committee as soon as they are available and before they are applied in the research.

5.7.2.2 A sample protocol is attached hereto as **Appendix C**.

5.7.3 To ensure proper implementation of institutional privacy protection and information security requirements within the scope of the research approval, including in research conducted in whole or in part through Sub-Suppliers. Below is a link to the Privacy Protection Procedure [Directive No. 01-014]:

https://www.tau.ac.il/sites/default/files/media_server/General/yoets/01-014B.pdf

5.7.4 To assist the research team in solving ethical dilemmas that may arise during the research and confirm the appropriateness of changes or

developments that are required with respect to the protocol during the Research.

- 5.7.5 To receive a report from the researchers on unexpected issues or events that occurred during the research which have the potential to increase the risk to the participants or that have other ethical implications, and to offer an appropriate response.

5.8 Exceptions to the obligation to submit to the Committee

- 5.8.1 Study exercises and research teaching that are not within the scope of research (as defined in Section 2.8) are not under the Committee's authority. This includes research method courses and research seminars. The responsibility for such exercises and courses, including the ethical aspects thereof, are under the authority of the faculties.
- 5.8.2 It is within the authority of the Ethics Committee to guide the researchers as to which investigative procedures may be carried out without the obligation to submit to the Committee and prior to ethical approval.

6. Training the Ethics Committee Members

Each member of the Ethics Committee will be required to undergo training in the ethics of research on humans, which is appropriate to his position, in accordance with the decision of the Chairman of the Ethics Committee.

7. Training and competence of the Researchers

- 7.1 It is within the authority of the Ethics Committee to define the nature of the training required of researchers, provided that every principal investigator and every researcher who comes into verbal or physical contact with research participants will be obliged to complete a course (online or frontal) that deals with the ethics of

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human research (such as: CITI, GCP, an academic course at a recognized institution or equivalent training) that has been approved by the Ethics Committee. A document attesting to the completion of a training course must be submitted to the Committee as an attachment to an ethical submission, being a condition for examination of the research by the Committee. It is within the authority of the institutional committee to decide on the scope of the training and the need for a periodic refresher.

7.2 The principal investigator must have the qualifications and expertise required for the good scientific planning and execution of the research, as well as for the protection of the research participants against the risks that may be involved with a particular Research.

7.3 In research involving more than minimal risk, the principal investigator must ensure the physical and mental well-being and safety of the participants by consulting with an expert in the field, and, where necessary, he must recruit an appropriate professional advisor (medical, paramedical, psychological, etc.).

7.4 Where a research activity requires training and/or licensing, it is the responsibility of the principal investigator to ensure that the activity is performed only by someone with the appropriate training.

8. The Review Procedure

8.1 Ethical review of human research (i.e., research with human participants and/or on material of human origin and/or on information of human origin) will be carried out according to the determination of the Chairman of the Committee, in accordance with what is stated below.

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- 8.2 Any research on humans will be reviewed by a reviewer from among the Committee members who are assigned by the Chairman of the Committee or by a member on his behalf, and thereafter it will be reviewed by the Chairman of the Committee.
- 8.3 In complex research, at the discretion of the Chairman of the Committee, it will be possible to refer the research for review by additional Committee members and even to bring it up for discussion before the plenary of the Committee.
- 8.4 In research conducted on data/materials that are provided to the researcher by an external party, the researcher must present the Ethics Committee with proof of the fact that the party collected the data/materials legally and that he is authorized to provide them for the purposes of the research.
- 8.5 The researcher must submit the research request in sufficient time before the planned date for the start of the research in order to allow it to be dealt with properly by the Committee.
- 8.6 In the event that, due to the urgent nature of the research, it is necessary to review it without delay, the said request can be submitted by e-mail: ethicsbe@post.tau.ac.il and the research will be reviewed in accordance with the decision of the Chairman of the Committee, either by the Chairman of the Committee or by another member assigned by him for this purpose.

9. **Criteria for research approval by the Ethics Committee**

In order to approve research, to which this procedure applies, the Ethics Committee must determine that the requirements listed in **Appendix D** have been met.

10. **Informed Consent**

Before recruiting a research participant, to whom this procedure applies, the researcher must obtain legally valid informed consent from the participant or his legal representative in accordance with the principles listed in Appendix E.

11. Validity of the Approval

11.1 The ethical approval will be valid for one year. The Committee is authorized to decide on the extension of the approval for a period of an additional year each time. In cases where the approval of another entity is required (such as the approval of the Helsinki Committee of a hospital, the Chief Scientist of the Ministry of Education, etc.), the validity of the approval given by the Committee will be the same as that given by the other entity. In any case, the validity of the approval shall not exceed one year from the date of its issuance.

11.2 The Ethics Committee is authorized to determine a shorter period during which the ethical approval will be valid, taking into account the requirements of external parties such as a funding party, a regulatory body involved in the supervision of the research, and so on.

11.3 The Ethics Committee is authorized to issue a “conditional approval” until final approval is presented from another party who is required to approve the research (for example, in cases where there is approval from the hospital’s Helsinki Committee but final approval from the hospital’s director has not yet been provided).

12. Regulation of cooperation in a contract and insurance

12.1 Regulation of cooperation in a contract.

12.1.1 In any case where the University, through its researchers, is involved in human research with another entity, consideration must be given to the

contractual-legal and insurance aspects arising from the very carrying out of the joint trial/research, for example with the medical institution.

- 12.1.2 Any cooperation to conduct research on humans should preferably be regulated in a contractual framework that defines the existence of the research and the cooperation of the parties, the different responsibilities assigned to each of the parties, including what is involved in fulfilling all the provisions of the relevant laws and procedures, as well as the degree of exposure of the University and its researchers to the risks arising from conducting the research, including the requirement to purchase insurance.

12.2 Insurance

- 12.2.1 Conducting research on humans can require the purchase of a dedicated insurance policy by the University.

This is about insuring the legal liability of the University and its staff and the researcher, arising from their involvement in conducting the research, against claims filed by the participants in the research who are injured and/or third party claims in connection with the research.

- 12.2.2 When submitting the research for the Committee's approval in the ERP system, the Researcher will be required to fill out a questionnaire in accordance with the attached **Appendix F**. Depending on the results of the questionnaire, the researcher will consult with the **person responsible for insurance at the University** at the email address: insurance@tauex.tau.ac.il, in order to examine the need to purchase dedicated insurance.

13. Administrative matters

13.1 Procedure and application documents:

The submission of research studies for the Committee's approval (including the forms required at the time of submission) will be done online through the ERP system, as specified in the tab "Instructions for submitting a research proposal" on the Committee's web page, at the link:

<https://acad-sec.tau.ac.il/senate/etics-en>

Questions about the Ethics Committee should be directed to the **secretary of the Committee**, by e-mail: ethicsbe@post.tau.ac.il

13.2 Documentation of the Committee's activities - The research documents, the research review procedures and the decisions of the Ethics Committee will be documented in a consistent, uniform and transparent manner, which will allow for examination when necessary. The documentation will be kept for a period of no less than seven years.

13.3 Confidentiality - The members of the Ethics Committee are committed to the confidentiality of the details of the research that they are exposed to, and the documentation of the review procedures will be carried out in a way that maintains this confidentiality as far as possible.

13.4 Keeping documents –

13.4.1 The Ethics Committee will keep the file of applications for at least 7 years after the date that the ethical approval expires.

13.4.2 A principal investigator will keep all application documents and all the information collected during the Research for at least 7 years from the end of the Research.

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13.5 Subordination - The Ethics Committee is subordinate to the rector of the University and it will report to the University senate once a year and upon request, with regard to its activities.

13.6 Transparency - The list of Committee members will be public and will be published on the Ethics Committee's web page at the link:

<https://acad-sec.tau.ac.il/senate/etics-en>

14. Conflict of interests

14.1 A member of the Ethics Committee will report to the Chairman of the Committee regarding a concern about a conflict of interests while performing his duties, and he will act according to the decision of the Chairman of the Committee after he has consulted with the legal advisor.

14.2 When applying to the Ethics Committee, a researcher will report a concern about a conflict of interests that could affect the planning or execution of the research, and he will act according to the decision of the Committee for Conflict of Interest in accordance with the Conflict of Interest Regulations in Research [Directive No: 10-024]. The link to the regulations is provided below:

https://www.tau.ac.il/sites/default/files/media_server/General/yoets/10-024B.pdf

15. Discipline

A violation of the provisions of the procedure constitutes a disciplinary offense.

In the event that it is brought to the attention of the Ethics Committee that the provisions of the procedure have been violated or a complaint has been filed in respect of a violation of the provisions of the procedure, the Chairman of the Committee or someone appointed by

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him will review the details of the case and forward recommendations to the rector of the University for his decision.

This version is an English translation of the Regulations published in Hebrew on the University's web-site. In the event of contradiction or inconsistency between this English version of the Regulations and the Hebrew version, the latter will prevail.

APPENDIX A

POSITION PAPER OF THE COMMITTEE OF UNIVERSITY HEADS

(ATTACHED)

Pages 19-34 below

Position Paper of the Committee of University Heads

Examining ethics in research using humans at academic institution

Introduction

The Universities which are members of the Committee of University Heads (the “Universities”) are committed to conducting scientific research that meets the highest scientific as well as ethical standards.

In this context, the Universities are committed to the advancement of science and human knowledge, and to the protection of the rights and safety of the research participants, while considering the consequences for the populations represented by these participants, the research community and the public as a whole.

To this end, the Universities have chosen to establish an ethical review system for any research in which humans participate or which is carried out on information or material of human origin, all as set forth below:

The proposed system draws inspiration from local and foreign legislation, including:

The Public Health Regulations (Clinical Trials on Humans), 5741-1980 and the subsequent Ministry of Health procedure.

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The Federal Policy for the Protection of Human Subjects or the "Common Rule" as in HHS regulations, 45 CFR part 46;

The Canadian Tri-council policy statement on ethical conduct for research involving humans.

This position paper will be updated from time to time by a forum that will consist of representatives of the ethics committees and legal advisors of the institutions that are members of the Committee of University Heads.

This position paper is written in the masculine but it refers equally to all sexes and genders.

1. **Definitions:**

- 1.1 **“Special Population”**: pregnant women, minors, those whose judgment is impaired due to their physical or mental condition, people who are disadvantaged economically or educationally, people in legal custody (such as prisoners) and people under supervision (such as soldiers and students).
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- 1.7 “**Principal Investigator**”: Anyone from the University faculty who, in accordance with the rules, 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 evaluation designed to develop or contribute to generalizable scientific knowledge.
- 1.9 “**Evaluation Process**” - A process aimed at evaluating programs or performance or improving processes which is conducted for internal organizational needs (the institution) that is not intended for academic publication. The evaluation research does not require prior approval of an Ethics Committee for the research. It is appropriate that the academic institution establish mechanisms for relevant ethical control over this activity. If there is a retroactive intention to publish the results of the evaluation research, ethics approval will be required as a “secondary research” according to this procedure.
- 1.10 “**Interventional Research**” (**Intervention**): Research that includes physical procedures in which data or samples are collected (for example, venipuncture as well as manipulations of the subject or his environment that are performed for research purposes).
- 1.11 “**Secondary Research**”: Research conducted on information or samples collected not for research purposes (for example: organizational records, medical records,

information collected as part of an evaluation process), or that have been collected for other research purposes and subject to anonymization processes.

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1.14 **“Identifiable Private Information”**: Individually identifiable information or samples; i.e., 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. This includes:

1.14.1 Information provided for research purposes;

1.14.2 Information provided for specific purposes by a particular person, where that person can reasonably expect that this information will not be made

public (for example, medical records, school grades, or height and weight measurements);

1.14.3 Information about behavior that occurs in a context where a person can reasonably expect that observation or recording will not be made;

1.14.4 Examples of research studies that make use of private information: reviewing medical charts, performing laboratory tests on identified tissues and samples, using identifiable information from databases or tissues, using grades from schools, private interviews or surveys on opinions and attitudes.

1.14.5 Incidental information collected using technological platforms (such as I.P. addresses or geographical 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 an analysis of the information.

1.15 **“Human Subject/Participant”**: A living person, with whose participation or on whom the principal investigator and other researchers conduct research in order to obtain data or personal information, through intervention or interaction with the person. The participant can be a healthy person or a patient.

1.16 **“Minimal Risk”**: Risk of injury or discomfort, the severity and probability of which are expected as part of the research are not greater than those to which a reasonable person is exposed in his day-to-day conduct, or when performing routine psychological or physical tests or examinations.

1.17 **“Sub-Supplier”**: Any entity that provides services that are necessary for the implementation of the research protocol, and that is not organizationally

subordinate to the principal investigator (such as Google, a survey company, voice technicians, statistical services, etc.).

2. Ethics Committee

- 2.1 Every academic institution, at which research is conducted using human participants and/or on material of human origin and/or on information of human origin, will establish an Ethics Committee or a network of ethics committees, and it will allocate means to enable proper and efficient activity of the Ethics Committee(s).
- 2.2 According to the institution's decision, the Ethics Committees can be institutional, a faculty or multi-faculty, departmental or multi-departmental (in this document: "Ethics Committee").
- 2.3 It is appropriate for the Ethics Committee to serve a wide enough group of researchers so as to prevent judgmental biases. Therefore, it is appropriate that a departmental committee should only be allowed in exceptional cases, where the department is large enough and has a unique character in the institutional landscape.

3. Authority of the Ethics Committee

- 3.1 Any research with human participants and/or on material of human origin and/or on information of human origin, conducted by any of the institution's staff, under its institutional affiliation, will be submitted for review by the Ethics Committee before the start of its execution.
- 3.2 Research that is **not** conducted by a principal investigator of the institution, but the subjects of the research are among the students of the institution, as part of their normal academic activities, will require the approval of the academic secretariat only.

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- 3.3 Research involving human subjects, human material, or human information may also require:
- 3.3.1 Approval by the Helsinki Committee of an Israeli medical institution (“hospital”) according to the Public Health Regulations (Clinical Experiments on Humans, 5741-1980, for example: when there is cooperation with a medical institution, in which the material / information is received from patients who undergo medical treatment in a medical institution; or, if the institutional committee deems it appropriate that due to the characteristics of the participants in the research and/or the procedures involved in the research protocol, close medical monitoring is required.
 - 3.3.2 Compliance with additional regulatory requirements of an external body involved in the research or overseeing the research.
 - 3.3.3 In secondary research, checking that collection of the materials or the primary information and sharing them were done subject to the rules of ethics.
- 3.4 The Ethics Committee will be authorized:
- 3.4.1 To advise researchers on the constructing of the research, in a way that is applicable and consistent with the principles of research ethics.
 - 3.4.2 To examine the suitability of the research protocol to the rules of ethics that are relevant to human research and to the guidelines of this document; to confirm the existence of compliance with the rules of ethics in the appropriate cases and to give permission to conduct the research.

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- 3.4.2.1 In qualitative research that uses an evolving protocol, the research will be examined based on an initial protocol, even if consciously imperfect, which will be gradually completed as the research progresses. Thus, among other things, in cases where final versions of a questionnaire or interview have not been developed at the time of the ethical review of the research, the researchers will submit a draft of sample questions, chapter headings or other outlines of the procedures to be performed during the collection of data. Final versions will be submitted for approval by the Committee as soon as they are available and before they are applied in the research.
- 3.4.2.2 When the research protocol is performed in whole or in part through subcontractors, the entire protocol must comply with appropriate ethical rules.
- 3.4.2.3 A sample protocol is attached hereto as **Appendix 1**.
- 3.4.3 To ensure proper implementation of institutional privacy protection and information security requirements within the scope of the research approval, including in research conducted in whole or in part through sub-suppliers.
- 3.4.4 To assist the research team in solving ethical dilemmas that may arise during the research and confirm the appropriateness of changes or developments that are required to the protocol during the research.
- 3.4.5 To receive a report from the researchers on unexpected issues or events that occurred during the research which have the potential to increase the

risk to the participants or that have other ethical implications, and to offer an appropriate response.

3.5 Exceptions to the obligation to submit to the Committee

3.5.1 Study exercises and research teaching that are not within the scope of research (as defined in Section 1.2) are not under the Committee's authority. This includes research method courses and research seminars. It is appropriate that the academic institution establish mechanisms for relevant ethical control over this activity.

3.5.2 It is within the authority of the Ethics Committee to guide the researchers as to which investigative procedures may be carried out without the obligation to submit and prior to ethical approval.

4. Composition of the Ethics Committee

4.1 The Ethics Committee will include at least 5 members, whose qualifications reflect the academic and professional disciplines that support the research submitted to that Committee.

4.2 Every Ethics Committee will have at least one member who is not affiliated with the particular academic institution and who is not a direct family member of someone who is affiliated (except as a student) with that academic institution.

4.3 Every Ethics Committee will have one member whose field of expertise is not scientific (for example: a lawyer or a philosopher). There may be an overlap between the members defined in Sections 4.2 and 4.3.

4.4 It is appropriate that in every Ethics Committee adequate representation be given to both sexes, and to as wide a cultural diversity as possible.

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4.4.1 In interventional research, one of the members of the Ethics Committee will have appropriate expertise for examining the research, or the Committee will consult with a person who has the appropriate expertise in the relevant field.

4.4.2 Reviewing research that has potential for injury that exceeds minimal risk will require the involvement of a Committee member that has the appropriate background or it will be in consultation with a person that has expertise in the relevant field (medical or psychological).

4.5 The Ethics Committee is authorized to invite and consult with experts in specific fields, who, in the Committee's opinion, are required as part of reviewing a particular research.

4.6 When reviewing research on a community or organization with unique characteristics, the Ethics Committee will consider the need to consult with relevant parties from within the community.

5. **Training the Ethics Committee Members**

Each member of the Ethics Committee will be required to undergo training in the ethics of research on humans, which is appropriate to his position.

6. **Training and competence of the Researchers**

6.1 It is within the authority of the Ethics Committee to define the nature of the training required of researchers, provided that every principal investigator and every researcher who comes into verbal or physical contact with research participants, whether from within the approving institution or outside it, will be obliged to complete a course (online or face-to-face) that deals with the ethics of human research (such as: CITI, GCP, an academic course at a recognized institution or

equivalent training) that has been approved by the Ethics Committee. A document attesting to the completion of a training course must be submitted to the Committee as an attachment to an ethical submission, as a condition for examination of the research by the Committee. It is within the authority of the institutional committee to decide on the scope of the training and the need for a periodic refresher.

6.2 The principal investigator must have the qualification and expertise required for the good scientific planning and execution of the research, as well as for the protection of the research participants against the risks that may be involved with a particular research.

6.3 In research involving more than minimal risk, the principal investigator must ensure the physical and mental well-being and safety of the participants by consulting with an expert in the field, and, where necessary, recruiting an appropriate professional advisor (medical, paramedical, psychological, etc.).

6.4 When a research activity requires training and/or licensing, it is the responsibility of the principal investigator to ensure that the activity is performed only by someone with the appropriate training.

7. The Review Procedure

7.1 Ethical review of human research can be in one of three tracks: a full procedure, an abbreviated procedure or an expedited procedure.

7.2 Full procedure - Every research with human participants and/or on material of human origin and/or on information of human origin, with the exception of research studies listed in Sections 7.4 (Abbreviated Procedure) and 7.6 (Expedited Procedure) will be reviewed by the Committee with a composition of at least 2 members.

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- 7.3 In complex research studies, at the discretion of the Chairman of the Committee, the research will be discussed at a Committee meeting, in a forum of at least 5 (five) members, including a public representative and a member with the appropriate expertise in the relevant field.
- 7.4 Abbreviated Procedure - Any institution is entitled to establish an abbreviated review procedure, in which the research will be reviewed at least by the Chairman of the Committee or a person appointed by him.
- 7.5 The types of research studies that can be referred to an abbreviated procedure can include, according to the determination of the institution:
- 7.5.1 Research that has undergone a proper ethical review at another institution, including research that has been approved by the Helsinki Committee.
- 7.5.2 An anonymous survey of the general public.
- 7.5.3 Research in which information and samples are collected, provided that the participants are not from a special population.
- 7.5.4 Research carried out on databases and data that is legally accessible to the public and where there is no fear of invading the privacy of the data subjects.
- 7.5.5 Research in which identifiable information is collected – about a participant, whether through interaction or observation, provided that:
- 7.5.5.1 The participants are not from a special population; and
- 7.5.5.2 There is no potential for legal, occupational, economic or reputational risk to the participant;

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- 7.5.6 Research involving no higher than minimal risk that includes one or more of the procedures listed in **Appendix 2**.
- 7.5.7 If the research is interventional, the research will be reviewed by a Committee member who has appropriate expertise in the field of the research.
- 7.5.8 The procedures listed in Appendix 2 should not be considered to have "minimal risk" merely because they are included in the list. Inclusion in this list only means that the activity qualifies for review through the abbreviated review procedure when the specific circumstances of the proposed research actually involve at most “minimal risk” to human participants.
- 7.5.9 Secondary research, provided that the information and/or the samples on which the secondary research is carried out are not identifiable (i.e., that the identifying details have been separated in such a way that it is not in any way possible to return to the owner of the information as part of the secondary research) or that the informed consent of the participants has been given for such secondary use.
- 7.5.10 Observation without the collection of identifiable details, and without photography, in public places and websites (physical or virtual) where there is no restriction on exposure or entry beyond the payment of entrance fees (for example, parks, clubs, websites which are open to the public, virtual reality groups [for example, Facebook, WhatsApp] which are open to the public). An abbreviated procedure will not be used in circumstances where the observation is carried out in places where entry requires a process of identification, approval and association by the owners/operators of the place (for example, kindergartens, clubs operating on the basis of club membership, closed virtual reality groups).

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7.5.11 Minor changes to a research protocol, which has been approved in the full procedure, during the period for which the approval was given (as stated in Section 10 below), can be reviewed by the institutional committee using the abbreviated review procedure.

7.5.12 Extending the validity of a study that does not involve a request for protocol changes.

7.6 Expedited Procedure - Any institution may establish an expedited review procedure, to which requests requiring a quick review – due to the urgent nature of the research – will be directed.

8. **Criteria for research approval by the Institutional Committee**

In order to approve research, to which this procedure applies, the Ethics Committee must determine that the requirements listed in Appendix 3 have been met.

9. **Informed Consent**

Before recruiting a research participant, to whom this procedure applies, the researcher must obtain legally valid informed consent from the participant or his legal representative in accordance with the principles listed in Appendix 4.

10. **Validity of the Approval**

10.1 Every institution will determine the maximum period during which the ethical approval is valid. This validity will not exceed 4 years. The Committee is authorized to decide on an extension of the approval (of up to 4 years) each time.

10.2 In research in which a risk greater than the minimal risk is expected - the approval for its execution will be valid for one year and it will be renewed for another year each time, subject to a report on the (non-materialization of) actual risks.

- 10.3 The Ethics Committee is authorized to determine a shorter period during which the ethical approval will be valid, taking into account the requirements of external parties such as a funding party, a regulatory body involved in the supervision of the research, and so on.

11. Administrative matters

- 11.1 Resources - The Ethics Committee will be allocated the resources and manpower required to fulfill its duties according to this procedure.

- 11.2 Procedure and application documents: Every Ethics Committee will establish a clear and known application process in advance, which the researchers will use for the purpose of applying to the Committee, for preliminary review, for approval as well as for support in issues that arise during the course of the research.

- 11.3 Documentation of the Committee's activities - The research documents, the Research review procedures and the decisions of the Ethics Committee will be documented in a consistent, uniform and transparent manner, which will allow for review when necessary. The documentation will be kept for a period of no less than seven years.

- 11.4 Confidentiality - The members of the Ethics Committee are committed to the confidentiality of the details of the research that they are exposed to, and the documentation of the review procedures will be carried out in a way that maintains this confidentiality as far as possible.

- 11.5 Keeping documents –

- 11.5.1 The Ethics Committee will keep the file of applications for at least 15 years after the date that the ethical approval expires.

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11.5.2 A principal investigator will keep all the application documents and all the information collected during the research for at least 15 years from the end of the research.

11.6 Subordination - Every institution will define the institutional body responsible for the Committee, to which it will be subordinate and to which it will report.

11.7 Transparency - The list of Committee members will be published in a public record at the institution.

12. Conflict of interests

12.1 A member of the Ethics Committee will report to the Chairman of the Committee about a concern of a conflict of interest while performing his duties, and he will act according to the decision of the institutional body authorized to hear this matter (the Ethics Committee or another body)..

12.2 When applying to the Ethics Committee, a researcher will report a concern about a conflict of interests that could affect the planning or execution of the research, and he will act according to the decision of the institutional body authorized to hear this matter (the Ethics Committee or another body).

[The appendices to the Position Paper have intentionally not been attached]

APPENDIX B (SECTION 5.6 OF THE BODY OF THE DOCUMENT)

1. This appendix is based on the NIH rules, as they appear in the framework known as the [Common Rule](#).
2. The activities listed below should not be considered “minimal risk” merely because they are included in this list.
3. Interventional research using drugs/medical devices, only when the following conditions are met:
 - 3.1 The drug/medical device has been tested/approved for marketing by the relevant governmental authority; and
 - 3.2 The use/application of the drug/medical device according to the tested/approved label poses minimal risk at most.
4. Collection of blood samples by pricking the finger, heel, ear, or drawing venous blood, from healthy adults who are not pregnant, and who weigh at least 50 kg (110 pounds). The amount taken will not exceed 550 ml over a period of 8 weeks, and the collection will not occur more often than twice a week.
5. Prospective collection of biological samples for research purposes by non-invasive means.

Examples:

- 5.1 Cutting hair and nails in an acceptable manner;
- 5.2 Milk teeth when they fall out or if routine treatment of the patient indicates the need for extraction;
- 5.3 Permanent teeth if routine treatment of the patient indicates the need for extraction;

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- 5.4 Secretions (including sweat);
 - 5.5 Uncannulated saliva collected without stimulation or with stimulation by chewing gum base or wax, or by applying a diluted citric solution to the tongue;
 - 5.6 Plaque and calculus above and below the gums, provided that the collection procedure is not more invasive than routine cleaning of the teeth for preventive purposes, and the procedure is done in accordance with accepted prevention methods;
 - 5.7 Mucosa and skin cells collected by scraping or using an oral swab, skin swab, or mouthwash;
 - 5.8 Sputum collected after saline mist nebulization;
6. Data collection through non-invasive procedures (that do not involve general anesthesia or sedation) which are routinely performed in medical practice, except for procedures involving X-rays or microwaves. When medical devices are used, they must be tested/approved for marketing.

Examples:

- 6.1 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 invasion of the subject's privacy;
- 6.2 Weighing or testing sensory acuity;
- 6.3 Electrocardiography, electroencephalography, magnetoencephalography, thermography, detection of natural radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow test, and echocardiography; moderate physical activity, testing muscle strength, body composition assessment

and flexibility tests, taking into account the age, weight and health of the specific person.

Note: According to NIH rules, this category also includes MRI research. However, the university requires the approval of the Helsinki Committees to conduct this type of research, as a condition of the Ministry of Health for licensing the MRI device.

7. Research involving materials (information, documents, records or samples) collected, or to be collected, solely for non-research purposes (such as medical treatment or diagnosis or samples from the blood bank).
8. Collection of data from voice recordings, video, digital recordings or photos made for research purposes.
9. 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 surveys, interviews, oral history, focus groups, program evaluation, evaluation of human factors or quality assurance methodologies.

APPENDIX C

SAMPLE PROTOCOL

1. Title of the research
2. Details of the principal investigator and the other researchers
3. The goals of the research and the source of research funding
4. Details of the research methods
5. Description of the research participants and their total number
6. How the participants are recruited
7. Type of research
8. Additional information (risks, treatment of risks, benefits, confidentiality, how findings of clinical importance that may be discovered in the research are treated)
9. The place of the research (will the research be carried out at a specific institution, such as a school, hospital, community center, factory, etc.?)
10. Does the research deal with participants defined as disadvantaged or vulnerable populations
11. Informed consent or waiver therefrom
12. Protection of privacy
13. List of attached documents and notes
14. Declaration by the researchers and a non-disclosure agreement

APPENDIX D

Criteria for Research Approval by the Ethics Committee (Section 9 of the Body of the Document)

In order to approve research to which this procedure applies, the Ethics Committee is required to determine that all the requirements listed below have been met:

1. The risks for the participants have been minimized as much as possible:
 - 1.1 Through procedures that are consistent with appropriate 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 using procedures already performed on the participants for diagnostic, or treatment, or other purposes.
 - 1.3 The research activities are carried out by a researcher with specific training in the field of the research, in the procedures carried out in it, and who is qualified to deal with the risks inherent in it.
2. The risks to the participants are reasonable in relation to the expected benefit, if any, to the participants, or in relation to the importance of the knowledge that can reasonably be expected to be derived from the research. In evaluating risk versus benefit, the Ethics Committee is required to consider only those risks and benefits that can arise from the research itself (as distinguished from the risks and benefits of treatments that the participants would have received even if they had not participated in the research).
3. Selection of participants is done fairly, without unjustified discrimination based on characteristics such as language, religion, race, disability, sexual orientation, age or sex, and, to the extent possible, in the pursuit of gender and social equality, in accordance with the structure of the research. When making this assessment, the Ethics Committee is required to

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take into account the goals 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 involving Special Populations as defined in this procedure.

4. The research respects its participants, and ensures their voluntary participation, without any pressure or dependency, by requesting informed consent from each potential participant or his legal representative, in accordance with the rules and exceptions listed in Appendix E.
5. Where necessary, adequate instructions for monitoring the data collected will be provided in the research plan, in order to ensure the safety of the participants.
6. There are proper instructions in the research plan for protecting the privacy of the participants and maintaining the confidentiality of the information.

APPENDIX E

Informed Consent to Participate in Research (Section 10 of the Body of the Document)

For the purpose of this appendix, “participant” means - a potential research participant or the legal representative of a participant with diminished capacity to consent.

1. General

- 1.1 Before recruiting a participant for research to which this procedure applies, the researcher must obtain informed consent from the participant.
- 1.2 Consent will be sought in circumstances that provide the participant with enough time to consider whether or not to participate in the research, and that minimize 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 about whether to participate in the research and an opportunity to discuss this information. It is appropriate to start by providing basic and comprehensible information and after that to present sufficient details of the research, edited and presented in a way that not only provides details of a list of facts, but which helps the participant to understand the reasons for agreeing or refusing to participate in the research.
- 1.4 The information provided to the participant will be in a language the participant understands.
- 1.5 The process of informed consent will not include a waiver by the participant of his legal rights against the researcher, the sponsor, the institution, or any other entity.
- 1.6 Research involving minors

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- 1.6.1 In research where there is minimal risk, the consent of a single legal representative will suffice.
- 1.6.2 In research involving more than minimal risk, the consent of all the legal representatives of the minor will be required.
- 1.6.3 A minor's assent to the research will be required, in addition to the consent of his legal representative, if the researcher assesses his ability to take part in the consent process for his participation in the research, while providing an explanation in a language adapted to his age and developing skills.
- 1.6.4 A participant who turns 18 during the research will be required to give his informed consent for his continued participation in the research.

2. Information that must be provided as part of an informed consent process

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

- 2.1 An explanation of the complete research protocol, of all its participation groups, the goals of the research and the expected duration of the participant's participation, a description of the procedures that will be performed, and identification of each experimental procedures.
- 2.2 A description of the risks or discomfort to the participant, which can be reasonably anticipated.
- 2.3 A description of the benefit to the participant or others that will result from the research and which can reasonably be expected.

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- 2.4 Disclosure of alternative procedures or treatment methods that may be preferable to the participant.
- 2.5 Information describing the extent, if any, to which the confidentiality of the records identifying the participant will be maintained. This includes that consideration should be given to and details provided, *inter alia*, if relevant, of:
- 2.5.1 The removal or separation of identifying information;
- 2.5.2 Using an encryption key;
- 2.5.3 Information security;
- 2.5.4 If and when and the research documents will be destroyed.
- 2.6 In research that involves more than minimal risk, an explanation of possible compensation and treatment available in case of injury, and where to obtain further information on the matter.
- 2.7 Instructions about who to contact regarding answers to questions concerning the research and the rights of the participants, and who to contact in case of injury to the participant resulting from the research. In addition, available contact telephone numbers should be listed.
- 2.8 An explanation of the fact that participation is voluntary, and that refusal to participate does not involve any sanction.
- 2.9 An explanation that the participant may stop participating in the research at any time without sanction or loss of benefits to which the participant is entitled. Reference to the fate of the data collected before withdrawing. In the appropriate cases, it can be determined that upon commencement of the data analysis phase by the researchers, it will not be possible to delete personal information from the

research or to prevent further processing of information. Therefore, samples and information collected during participation in the research will remain part of the research database even if a subject withdraws from the research. This is to protect the integrity of the research and its scientific integrity.

- 2.10 Explaining about and obtaining specific consent on possible future use of the information or samples that are collected as part of the current research, for the purpose of secondary research, while removing its identifying data.
- 2.11 An explanation that the researcher is entitled to terminate the participant's participation in the research on his own initiative.

3. **Additional information required**

If relevant to the particular research, each participant must be given an explanation regarding the following details:

- 3.1 Whether the specific treatment or procedure may involve a risk to the participant (or to the fetus, if the participant is pregnant or may become pregnant) that cannot be observed today;
- 3.2 Foreseeable circumstances in which the researcher can terminate the participant's participation regardless of his consent;
- 3.3 The participant may incur additional costs from his participation in the research;
- 3.4 Consequences of a participant's decision to withdraw from the research, and the procedures for an orderly termination of the participant's participation;
- 3.5 That any new information discovered during the research, and which has significance regarding the participant's consent to take part in the research, will be reported to the participant, so that he can reconsider his participation.

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- 3.6 The estimated number of participants in the research, if it can be estimated.
- 3.7 That the participant’s information or samples (even if the identifying information is removed from them) can be used for commercial benefit and whether or not the participant will benefit from such income;
- 3.8 Whether the results with consequences for the participant (expected as well as incidental), including personal results, will be communicated to the participants 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 compensation for the participant and the conditions for receiving it;
- 3.11 Sources of research funding;
- 3.12 Full disclosure regarding the principal investigator’s financial interests.
- 4. Broad consent for storage, maintenance and secondary research using identifiable personal information or identifiable samples**
- 4.1 In this chapter – “information” means identifiable private information or identifiable samples.
- 4.2 Broad consent to the storage, maintenance and secondary research of information (which is collected for research purposes other than the proposed research, or not for research purposes), is allowed as an alternative to the requirements of informed consent, as stated in Sections 2 and 3 above.
- 4.3 Notwithstanding the foregoing, in order to obtain broad consent, the participant must be given the information listed below:

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- 4.3.1 With regard to risks and discomfort (§ 2.2 above); benefit (2.3); confidentiality of records (2.5); details of the contact person for obtaining additional information and protection of rights (2.7); the right to refuse to participate and withdraw (2.8); potential use for commercial benefit (3.7); giving/not giving results to the participant (3.8); the 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; whether sharing of the information will be allowed, and the types of institutions or researchers that will use the information.
- 4.3.4 A description of the period of time during which the information will be held, stored and used for the research (the aforementioned period of time can be unlimited).

5. **Waiver of the consent requirement or parts thereof**

5.1 Waiver of the Consent Process:

- 5.1.1 An Ethics Committee can waive the informed consent requirements, as detailed above, in secondary research, which makes use of unidentifiable private information, or if the conditions stipulated in Section 5.3 below are met:
- 5.1.2 Notwithstanding the foregoing, if a participant is asked to give broad consent as stated in Section 4 of this appendix, and refuses, the Ethics Committee is not entitled to waive the informed consent requirement for

the storage, maintenance and secondary use of identifiable private information.

- 5.1.3 In addition, if a person refuses to participate in specific research, in which identifiable private information is collected, the Ethics Committee will not be entitled to waive the consent requirement for participation in that research, through the secondary use of non-identifiable information that exists about him.

5.2 Changing the consent requirements:

- 5.2.1 An Ethics Committee can approve a consent process that omits or changes all or part of the requirements listed in Sections 2 and 3 above, provided the conditions in Section 5.3 below are met.

- 5.2.2 Notwithstanding the foregoing, the Ethics Committee is not entitled to omit or change the general consent requirements (Section 1 above).

- 5.2.3 In addition, if broad consent is used, the Ethics Committee is not entitled to omit or change the requirements relating to broad consent (Section 4 above).

5.3 Conditions for waiver or change of informed consent requirements

- 5.3.1 There are cases in which compliance with (any) “informed consent” requirements may thwart the research. Examples of this: emergency research, and research in which providing information to the participant in advance, regarding the goals of the research, will skew its results. In order for an Ethics Committee to approve a waiver or change of the informed consent requirements, it must verify and document that all of the following conditions have been met:

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- 5.3.2 The research involves no more than minimal risk to the participants. In emergency research only – which may involve a higher than minimal risk to the participants – the expected benefit from the research for the participants, or the group they represent, must be greater than the risk;
- 5.3.3 The research will not be able to be carried out without a waiver or changing the requirements; and there is sufficient data to assume that the research could help its participants.
- 5.3.4 The waiver or change will not adversely affect the participants' rights or their well-being;
- 5.3.5 All the information that can be given without affecting research goals will be given to the participant in advance. Apart from in exceptional cases, information will be given to the participant afterwards – and the participant will be allowed to advise of his refusal to take part in the research, while removing the data collected in this context.

5.4 Recruitment of participants incapable of giving consent

Recruiting participants who are unable to consent, temporarily or permanently, will only be allowed if the following conditions have been met:

- 5.4.1 The researcher involves the participant, as fully as possible, in the consent process (for example by obtaining assent to participate).
- 5.4.2 The consent of the participant's legal representative will be obtained, while protecting the participant's interests.
- 5.4.3 The participant's legal representative is not a member of the research team.

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- 5.4.4 The research is to be carried out for the purpose of (a) promoting the direct benefit to the participant or (b) promoting the specific benefit of the group of people to which the participant belongs, and it involves only minimal risk.
- 5.4.5 The research question cannot be answered without the participation of participants from the relevant characterization group.
- 5.4.6 If the participant regains decision-making capacity during the research - his consent will be required from this stage onwards, as a condition for his continued participation.

6. Documentation of informed consent

- 6.1 The consent of the potential participant will be given after receiving an exhaustive explanation and documented in writing in a consent form which incorporates the elements of informed consent required in this appendix.
- 6.2 The consent form for the particular research must be approved by the Ethics Committee, and only the approved version will be used during the research.
- 6.3 The authority to propose a template for a consent form, which meets the principles appearing in this appendix, rests with the Ethics Committee.
- 6.4 The researcher will give the potential participant adequate opportunity to read the document thoroughly before signing.
- 6.5 The document must be signed by the participant or by his authorized representative.
- 6.6 A copy of the form will be given to the person signing it.

7. Exceptions to the obligation to obtain informed consent in writing

- 7.1 The Ethics Committee is entitled to exempt a researcher from the need to obtain informed consent in writing in one of the following cases:
- 7.1.1 The research does not involve the collection of identifiable private information (anonymous research).
 - 7.1.2 A suitable alternative has been implemented to document the participant's informed consent (for example – a video or audio recording or ticking an acceptance box on internet).
 - 7.1.3 The consent form is the only document that identifies the participant in the research, and the main risk for the participant lies in the infringement of his right to confidentiality.
 - 7.1.4 The research cannot be carried out if a form is required to be signed, provided that the research involves a risk that does not exceed a minimal risk for the participant.
- 7.2 In cases where an exemption from signing a consent form is granted, the Committee has the authority to require the researcher to provide the participant with an information sheet about the research that will include the information contained in the consent form, apart from the signature, accompanied by a concluding sentence acknowledging the participant's consent to participate in the research. (Example: filling out this questionnaire constitutes your consent to participate in the research).

APPENDIX F

RISK ASSESSMENT QUESTIONNAIRE

(SECTION 12.2.2 OF THE BODY OF THE DOCUMENT)

The questions listed below aim to examine research risks that require contacting the insurance supervisor at the University for consultation regarding the need to purchase dedicated insurance for research.

In the event that the answer to one or more questions is positive - you must contact the insurance officer for a consultation, at the same time as the approval process for the research by the Committee.

The questions are as follows:

1. Is the research an interventional research (as defined in the procedure in Section 2.10 below)?

2.10 “**Interventional Research**”: Research that includes physical procedures in which data or samples are collected (for example, taking venous blood (venipuncture) as well as manipulations on the subject or his environment which are performed for research purposes).

2. Does the research involve a higher than minimal risk (as defined in the procedure in Section 2.16 below)?

2.16 “**Minimal Risk**”: A risk of injury or discomfort, the severity and probability of which – expected within the scope of the research – are not greater than those to what a reasonable person is exposed in his day-to-day conduct, or during the performance of routine psychological or physical tests or examinations.

3. As part of the research, will humans be tested using the University’s equipment such as an MRI machine/medical equipment/paramedical equipment?

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4. Do the research participants (“Participant” as defined in Section 2.15 of the Procedure) belong to the following groups - people who are not healthy, pregnant women, minors, those whose judgment is impaired due to their physical or mental condition, or economically or educationally disadvantaged people?
5. Could the participants in the research (“Participant”, as defined in Section 2.15 of the Procedure) suffer physical or mental harm due to their participation in the study?
6. Do the results of the research have any effect on the physical or mental health of the participant in the study (“Participant”, as defined in Section 2.15 of the Procedure) and will the results of the research be provided to the participants in the study or to a third party that relies on these results in providing treatment to the participants in the research or in the development of a drug/medical device?

In any case of doubt, you should contact the insurance officer at the following email address:

insurance@tauex.tau.ac.il.