

Code of Ethics and Procedures for Research in Humans

The Procedure of the Ethics Committee Reichman University (IDC) Herzliya

1. Introduction; Definitions

- (a) Conducting researches is meant to advance human knowledge and to achieve further important goals. The principles of ethics are meant to describe the practical ideals of how researchers are to behave in conducting their profession activities, and they are inseparable from the scientific and methodological components of any study. The goals of the ethical principles are not intended to make the research unnecessarily difficult or to prevent a research from taking place, but rather to strengthen the principals of the research itself, so that it will take place while preserving ethical principles and protecting the physical and mental health of all people involved.

- (b) In this Procedure:

“RU” - Reichman University (IDC) Herzliya

“Procedure” - this Ethical Code of RU which refers to conducting researches in humans, taking place at RU.

“Institutional Committee” or the **“Committee”** - the ethical committee of RU.

“Research” - a project that sets defined scientific goals, such as: understanding of physiological, psychological, or social phenomenon, or evaluating treatments that aim to diagnose, prevent or treat disorders. The procedures involved in the research may include watching and observation, conducting changes in the day to day routine or in the living environment, systematic manipulations in the research lab, distributing questionnaires or performing psychological assessments and exams, checking personal files or other already collected data, etc. The term “research” also includes the ways of preserving and publishing any such collected data.

“Researcher” - Any person who performs research and is associated with the RU as an employee, faculty member or student.

“Participant” - any person who has agreed to assist in a Research by participating therein, and about whom the Researcher obtained or collecting information by performing any procedure for the purpose of the Research.

2. Purpose of the Procedure

- (a) This Procedure is intended to regulate the activities of the Institutional Committee and the main ethical principles that are required to guide Researchers in the various schools and in the various units of Reichman University, on the basis of which the Institutional Committee operates. It shall be clarified that the Committee will not evaluate nor approve Researches that require the approval of the Helsinki Committee.
- (b) The The Ethics Committee is required to examine the ethical aspects that are included in Researchers involving human beings and/or that include materials collected from human

sources and/or that are based on information from a human sources, and are conducted by any of RU staff and/or associated with RU.

- (c) Approval of the Institutional Committee as required under this Procedure is required to be obtained prior to the commencement of the Research and as a condition for its commencement.

(d) An application for a research approval by the Institutional Committee will be made upon the following events:

- (i) In the event that is no specific ethics committee exists at the applicable school/ educational unit/research unit at RU, in the framework of which the research is intended to take place. Insofar as such a school ethics committee exists, applications for Research approvals should be directed to it and not to the Institutional Committee.
- (ii) Researches funded by an external source, and that under their condition there is a requirement to obtain the Institutional Committee's approval.

(ee) This Procedure is intended to add to (and not to derogate from) any provision of law as well as any provision, directive, regulation and/or other existing procedures applicable to the proper conduct of a Research or any other matter relevant to the conduct of a Research, such as aspects of conflicts of interest or others. This Procedure does not derogate from the need to obtain such additional permits or confirmations, by virtue of law or another procedure, to the extent that such are required in order to carry out the relevant Research.

(ff) In this Procedure, a masculine pronoun also refers to a feminine pronoun, and a singular pronoun also refers to a plural pronoun, and vice versa.

3. Basic Principles

(a) Truth

The Researchers are interested in expanding human knowledge about the world, in deepening human understanding of its aspects, and in improving human ability to use such knowledge to achieve vital human goals or worthy social goals. The Researchers serve these goals while they operate according to the methods of the relevant scientific subject of the Research and according to behavioral rules of the scientific community as a whole.

(b) Freedom

The Researchers will carry out their study with a maximum amount of independence from foreign influences, and will respect the life of human-beings and their dignity and liberty. The Researchers must disclose in advance any issue that could create or could be regarded as a potential conflict of interest, whether it is related to personal, professional, commercial, or financial matters, and to follow the instructions of RU in that respect. In the event of a

funded Research, the Researchers must make sure that the funding is used for the purpose of which it was designated and only for that purpose.

(c) Moral responsibility

The Researchers shall bear full responsible for any scientific research and experiment they perform, especially for the direct influences thereof on people's lives, physical and mental health, wellbeing, dignity and liberty. The Researchers shall bear full responsible especially for the direct influence of the study on the participants. The Researchers should pay specific attention to the reasons for the need to perform their planned study on actual human subjects, and to consider the lives and wellbeing of the Participants, and in particular, to minimize any suffering that may be incurred during or after the study. While doing so, the Researchers should further consider, *inter alia*, the possibility that the results of their scientific research might be a tool for different purposes, including wither desirable goals for the benefit of human kind but also could be used for criminal purposes.

(d) Scientific integrity

The Researchers will perform every scientific action in accordance with all requirements of the applicable scientific method, and in the highest standards. The Researchers will conduct researches and analyze data, whether their own or others, in the strictest manner and with the necessary depth and accuracy. The Researchers must present the Research and its findings as is and in a complete, accurate, honest, and fair manner, subject to any law.

(e) Partnership

The Researchers should act in the framework of scientific collaboration by upholding an open atmosphere, mutual trust and a willingness to help one another. The Researchers must mention the relative contribution of the material people involved in the study, to refer to previous works, if any, and to act according to the rules for referencing and citing other researches and other researchers' intellectual property, if applicable. The Researchers must act in open communication and with the goal of contributing to the public knowledge and to the scientific community by publishing their results, subject to any law.

(f) Professional standards

The Researchers will carry out their scientific work in a distinctly professional manner, using their expertise wisely and constantly. The Researchers should make sure to update their knowledge in their area of expertise and in any other relevant subject which is relevant to their work. The Researchers must be committed to the originality of the Research and their writing, under the prohibition of copying or stealing words of others or findings of others and presenting them as if they were their own.

(g) Respect for those who participate, their benefits and protection

The basis for human research is the understanding that the purpose of advancing human knowledge is to advance the well-being of human-beings in general, and of the Participants in particular, and to protect them from unwanted and unnecessary harm. According to basic human rights principles, the Research cannot discriminate (such as on the basis of religion, sex, age, ethnicity, socio-economic status, etc.), unless methodological considerations so require. The Researchers should also ensure that the methods of conducting the Research and its implementation are done with the utmost care and respect for the dignity of the Participants and other related parties (including family, friends, colleagues, etc.), their privacy and their broader rights. The Research should be conducted in such a way that it does not create physical and mental risks for the Participants and other relevant parties. The Research must be conducted while maintaining the privacy of the Participants and meet the full requirements set forth in this matter by law, including within the framework of requirements for information security and confidentiality.

4. Applying Ethics Principles

(a) Prevention and minimization of potential risks and damages

The Researchers must perform an assessment of the expected risks associated with the Research, including risks of physical harm, mental harm, damage to reputation and good name or self-esteem or other potential damages to Participants or any other material damages that may result from the Research. Researchers must avoid, as far as possible, these potential risks and damages, and this is a necessary precondition for conducting a Research. In the event that unforeseen risks arise while conducting the Research, the Researches should act to eliminate or minimize them immediately, and if necessary to discontinue the Research. In any case, the Researchers must ensure that the risk and damage expected from the Research are significantly lower than the benefit expected from the Research, and to inform the relevant parties accordingly.

(b) Informed Consent

Informed consent is one of the basic principles of any research that includes human beings. It ensures that the Participants have the ability and the understanding to agree to participate in the Research, out of true freedom of choice, without open or covert coercion, and full knowledge of the essence of the consent. In this process, the Researchers are required to inform the Participants about all relevant aspects of the Research, in a clear and specific manner, and are required to make sure that the Participants fully understood the information, and that the Participants' consent is given in a fully voluntary manner without pressure or manipulation. In the event that the Research involves disclosing the name of the Participant, prior specific written approval must also be obtained from the Participant for this detail as well.

With regard to minors, people under parents and the helpless - in the event that the Participant does not have the ability to agree or to exercise discretion, prior written consent must be obtained from the Participant's legal guardian. If such Participants are able to understand what is happening to them, their consent must also be obtained.

The Researchers must make clear to the Participants their right not to participate and/or their right to withdraw their original consent for any reason, and that such disagreement or retirement will not harm them in any way.

Researchers must keep records of all consent received by Participants' and/or on their behalf.

Participants will not be materially, professionally-disciplinary or emotionally dependent on the Researchers. Participation will not be a condition for receiving benefits or rights or from denying rights from a third party. In cases in which there is a methodological requirement not disclose the true purpose of the study (e.g. in field studies), the Researchers may (subject to the approval of the Institutional Committee), postpone the explanation of the goals of the Research until the end of the study.

(c) Benefits and Protection for Participants

A Research that jeopardizes the Participants and that may cause them physical or mental harm will not take place, even if the Participants received or will receive for such participation monetary consideration or any other consideration. Researches should not be conducted in the event that they risk causing humiliation or mental harm to Participants, even if they gave prior consent thereof. Researchers must ensure that the Participants' anonymity is maintained, and that no personal data will be disclosed in any way that could harm them in the future. Researchers are strictly prohibited from using information about Participants' private interests for purposes that are not directly related to the study. Researchers must ensure the confidentiality of the identity and privacy of the Participants. Researches performed on minors or other people who are not legally independent should preferably be done in the direct or indirect presence of their guardians or adults with a suitable position.

(d) Use of deception or concealing information from participants

Research that in its very nature requires a lack of knowledge from the Participants and that are dependent on the element of surprise, secrecy or deception requires an approval of the Institutional Committee for that matter as well. In addition to such approval, the Researchers should strive to minimize concealment and deception as much as possible, and consider whether the potential Research conclusions require and justify deceiving the Participants and justifying that. The Researchers must reveal and explain to the Participants about any such deception or concealment that was an integral part of the study as soon as possible, and not later than at the end of the data collection period, and will allow

Participants to withdraw from the Research after they have received such information regarding the deception or misleading.

5. Submitting an Application for Research Approval

- (a) Submission of an application to the Institutional Committee will be made by filling out an application form for the approval of the Ethics Committee, in the form attached hereof as Appendix A, and sending it by electronic mail to the Institutional Committee, at the following address: _____.
- (b) It is emphasized, for the avoidance of any doubt, that the approval of the Institutional Committee under this Procedure:
 - (i) Does not stipulate that the Research is conducted in accordance with the provisions of any law, procedure, approval, contract or order of a competent authority (including, without limitation, the provisions of any privacy protection laws or the laws of other countries, including the laws of European countries or of the United States); and/or that the Research complies with or meets the requirements of such provisions.
 - (ii) Does not derogate from the Researchers any responsibility for the proper performance of the Research or from its results and all other related aspects, including the responsibility to follow the requirements of this Procedure and/or any law, procedure, approval, contract or order of a competent authority, as applicable and as the case may be.
 - (iii) Does not impose any responsibility on the Institutional Committee and/or the relevant school and/or RU, and/or anyone on their behalf and their representatives, in relation to the Research conducted and/or in relation to any aspect concerning it and/or the manner of its implementation and/or for the interpretation of this Procedure or of the provisions of any other relevant law or order, all - with respect to the Researchers, the Participants or any third party.
- (c) The Institutional Committee has four main goals:
 - (i) To promote the education and awareness of ethical principles in RU.
 - (ii) To review research applications and to consider if they meet the ethical research standards, as well as to propose amendments and to require any additional information that may enhance the ethics of the Research.
 - (iii) To approve research applications that meet the most updated requirements for ethical researchers on human subjects.
 - (iv) To address ethical issues that arise during the conduct of a Research or study, including matters of complaints from participants.

- (d) The Committee's approval is valid for the Research period or for any other period, as stated in the approval. An application for renewal of the approval may be filed upon the termination of such period. Researchers must keep record of the original approval to carry out the Research for the entire period of the Research and up to seven years after its completion, in order to enable reviews to be made by RU, state authorities and/or other competent bodies or in for the purpose of legal proceedings, etc.
- (e) In the event that material changes occur in a Research, including in relation to how it is conducted and implemented or in relation to the composition of the principal Researchers, such changes must be submitted for re-approval by the Committee, prior to their implementation.
- (f) In any event of possible threats to ethics during the course of the Research (such as injury to Participants, complaints, etc.), Researchers must file a report thereof to the Committee as soon as possible.
- (g) The responsibility for protecting the rights of the Participants lies with the Researchers conducting the Research, and they must act in accordance with the provisions of this Procedure, the provisions of other relevant procedures of RU and in accordance with any law, including (without limitation) any privacy protection provisions. It is the responsibility of the Researchers to check that beyond the principles of ethics, the Research is conducted within the framework of the law and within the framework of common sense.

6. The Institutional Committee

- (a) The Institutional Committee will include four members, as follows: Director of the Research Authority, and three representatives of the academic staff. The members of the Committee will be appointed by the Rector, who will also determine which of them will serve as the Committee's chairman.
- (b) The Committee will convene for discussions and/or approvals of applications and other request submitted to it, as shall be necessary. The manner and schedule of the convention of the Committee will be in accordance with the availability and accessibility of its members, while giving reasonable notice in advance.
- (c) The chairman of the Committee (who may be assisted by additional staff) will supervise administratively the manner in which the Committee conducts its affairs and convenes, and the manner in which the decisions are made in accordance with the provisions of this Procedure.

7. Documentation; Miscellaneous

- (a) The Committee and/or whoever it authorizes for this matter, will keep record of all applications and request submitted to it, of its operation and of the approvals provided by it.
- (b) This Procedure and/or any material change or amendment in it will be discussed in the Dean's Forum of RU.
- (c) Failure to enforce a provision of this Procedure or a delay in its enforcement will not constitute a waiver or impediment on behalf of RU regarding the enforcement of the provision and will not constitute any consent to its violation and will not be learnt as an equal ruling regarding other events or provisions.

* * *